

TERCICA INC  
Form 10-K  
March 24, 2005  
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, 2004

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

26-0042539

Edgar Filing: TERCICA INC - Form 10-K

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer  
Identification Number)

**651 Gateway Boulevard, Suite 950**

**South San Francisco, CA 94080**

**(650) 624-4900**

(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: None**

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

**Common Stock, \$0.001 par value**

(Title of class)

---

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 an accelerated filer (as defined in Exchange Act Rule 12b-2). 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, 2004 was \$48,023,492 (based upon the closing sales price of such stock as reported in the Nasdaq National Market on such date). Excludes an aggregate of 18,688,906 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, 2004. 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 March 11, 2005, there were 31,578,517 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 2005 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, 2004**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	1
Item 2. <u>Properties</u>	47
Item 3. <u>Legal Proceedings</u>	47
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	48
<b><u>PART II</u></b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	49
Item 6. <u>Selected Financial Data</u>	50
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	51
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	62
Item 8. <u>Financial Statements and Supplementary Data</u>	63
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	94
Item 9A. <u>Controls and Procedures</u>	94
Item 9B. <u>Other Information</u>	94
<b><u>PART III</u></b>	
Item 10. <u>Directors and Executive Officers of the Registrant</u>	95
Item 11. <u>Executive Compensation</u>	95
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	95
Item 13. <u>Certain Relationships and Related Transactions</u>	95
Item 14. <u>Principal Accountant Fees and Services</u>	95
<b><u>PART IV</u></b>	
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 below, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.*

**Item 1. Business.**

We are focused on the development and commercialization of new therapeutics for the treatment of short stature and other related metabolic disorders. Our current product candidate is Increlex, (mecasermin [rDNA origin] injection), a DNA-derived recombinant human insulin-like growth factor-1, or rhIGF-1. We licensed the rights of Genentech to develop, manufacture and commercialize rhIGF-1 products for a broad range of indications, including short stature, worldwide. Our initial focus is on developing Increlex as a replacement therapy for primary IGF-1 deficiency, or Primary IGFD. We define the indication Primary IGFD to mean a child who has a height standard deviation score, or Height SDS, and an IGF-1 standard deviation score, or IGF-1 SDS, of less than minus two, and the indication Severe Primary IGFD to mean a child who has a Height SDS and IGF-1 SDS of minus three or less, in each case in the presence of normal or elevated levels of growth hormone. We submitted a New Drug Application, or NDA, seeking approval of long-term rhIGF-1 replacement therapy for Severe Primary IGFD to the U.S. Food and Drug Administration, or FDA, in February 2005, based on Phase III clinical trial data.

The endocrine system regulates metabolism through the use of hormones, including IGF-1. IGF-1 is a naturally occurring hormone that is necessary for normal human growth and metabolism. A deficiency of IGF-1 can result in short stature, which is characterized by children being shorter than approximately 97.5% of normal children, 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.

## **Table of Contents**

The cellular production of IGF-1 is regulated by growth hormone. Growth hormone deficiency, or GHD, leads to inadequate IGF-1 production, which results in short stature in children. Growth hormone replacement therapy, which increases IGF-1 levels, can be used to successfully treat GHD. 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 have Primary IGFD and are candidates for rhIGF-1 replacement therapy. Increlex is identical to naturally occurring human IGF-1, and we believe it performs the same functions in the body.

Our Phase III clinical trial results reflect the treatment of 71 children with Severe Primary IGFD with rhIGF-1 replacement therapy for an average of 3.9 years, with some patients being treated for up to 11.5 years. None of the 71 patients discontinued rhIGF-1 treatment due to safety concerns. Of these children, 61 completed at least one year of rhIGF-1 replacement therapy, which is the generally accepted minimum 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 in these patients ( $p < 0.0001$ ). 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 approved growth hormone treatments. Statistically significant increases in Height SDS were also observed during each of the first eight years of rhIGF-1 treatment ( $p < 0.001$ ).

We are also developing Increlex for use in the broad population of children with Primary IGFD. In late 2004, we initiated a 160-patient Phase III clinical trial of Increlex in children with Primary IGFD, which includes children with a less severe form of IGFD. We plan to initiate in mid-2005 another Phase III study of Increlex in Primary IGFD, in which we will investigate once-daily dosing of Increlex. We are assessing our Increlex development strategy for other indications.

Approximately one million children in the United States have short stature, and we believe that there are an equal number of children with short stature in Western Europe. Of the approximately 380,000 children in the United States referred to pediatric endocrinologists for evaluation of possible short stature, we believe that approximately 30,000 in the United States and an equal number in Western Europe, for a total of 60,000 children, have Primary IGFD and may be treated with Increlex. We believe that this represents an approximate \$1.0 billion annual market opportunity. We believe that Severe Primary IGFD constitutes approximately 20%, or 12,000, of the total population with Primary IGFD and represents an approximate \$200 million annual market opportunity in the United States and Western Europe.

We have completed the transfer of Genentech's proprietary manufacturing technology to our contract manufacturers and have established the process for high yield, commercial scale manufacturing of Increlex. We have manufactured Increlex on a full-scale production basis according to current good manufacturing practices, or cGMP, and completed the manufacturing of the conformance lots in our process validation

## **Table of Contents**

campaign. Based on extensive testing, we currently believe that Increlex is comparable to the rhIGF-1 previously manufactured by Genentech, and we are using this material in our Phase III clinical study.

## **Scientific Background**

### ***Role of IGF-1 in Growth and Metabolism***

The endocrine system regulates metabolism through the use of hormones, including IGF-1. IGF-1 is a naturally occurring hormone that is necessary for normal human growth and metabolism. A deficiency of IGF-1 can result in short stature, which is characterized by children being shorter than approximately 97.5% of normal children, 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. The cellular production of IGF-1 is regulated by growth hormone. Growth hormone deficiency, or GHD, leads to inadequate IGF-1 production, which results in short stature in children. Growth hormone replacement therapy, which increases IGF-1 levels, can often be used to successfully treat GHD. 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 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. Our product candidate, Increlex, is identical to naturally occurring human IGF-1, and we believe it performs the same functions in the body.

IGF-1 is a 70 amino acid protein that must be present in tissues for normal growth and metabolism in humans. 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, that produces IGF-1. IGF-1 is released into the blood, and in the tissues stimulates cartilage and bone growth.

Certain endocrine system disorders, including the failure of the pituitary gland to produce growth hormone, defective or nonexistent cell receptors that do not bind with growth hormone, or defects in the cell's growth hormone intracellular signaling, may inhibit the production of IGF-1. Insufficient blood levels of either IGF-1 or growth hormone in childhood result in short stature. Since the 1950s, children with low levels of growth hormone and resulting short stature have been given replacement growth hormone therapy, resulting in IGF-1 production and subsequent growth. However, there are children with short stature who, despite normal levels of growth hormone, have low levels of IGF-1. These children are IGF-1 deficient usually because of abnormalities in either their growth hormone receptors or in their growth hormone signaling pathways.

As children with IGFD become adults, they continue to suffer from the effects of IGF-1 deficiency. Since the growth plates in the long bones fuse and additional cartilage and bone growth can no longer occur after puberty, rhIGF-1 replacement therapy does

**Table of Contents**

not cause growth in adults. However, low levels of IGF-1 are also frequently associated with other metabolic disorders, including lipid abnormalities, decreased bone density, obesity, insulin resistance, decreased cardiac performance and decreased muscle mass. These disorders typically become increasingly apparent after a prolonged period of IGF-1 deficiency, as occurs in adulthood. We refer to this disorder as Adult IGF-1 Deficiency (IGFD).

***Role of IGF-1 in Glucose Metabolism***

IGF-1 and insulin receptors have similar intracellular signaling pathways and overlapping metabolic effects. The clinical trial data we acquired from Genentech demonstrate that the use of rhIGF-1 significantly improved blood glucose control and insulin sensitivity in type 2 diabetic patients. We believe that rhIGF-1 may be useful in treating diabetic patients who are resistant to the effects of insulin.

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



**Table of Contents**

**Table of Contents****Indications**

<b>Increlex Indication</b>	<b>Development Status</b>	<b>Commercialization Rights</b>
Severe Primary IGFD	Phase III completed and NDA submitted in February 2005	Worldwide
Primary IGFD	Phase IIIb trial initiated late 2004	Worldwide
Primary IGFD	Once-daily dosing trial planned for mid-2005	Worldwide
Adult IGFD	Assessing potential development strategy	Worldwide
Diabetes	Assessing potential development strategy	U.S.

**Short Stature**

Approximately one million children in the United States have short stature, and we believe that there are an equal number of children with short stature in Western Europe. 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 97.5% 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.

Approximately 380,000 children in the United States are currently referred to pediatric endocrinologists for evaluation of possible short stature. Of these children, we believe that approximately 30,000 in the United States and an equal number in Western Europe, for a total of 60,000 children, suffer from Primary IGFD and may be treated with Increlex. We believe that this represents an approximate \$1.0 billion annual market opportunity.

*Severe Primary IGFD.* We define the indication 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 or respond poorly to growth hormone therapy. There is no other treatment approved for this indication. As a result, we believe rhIGF-1 may qualify for the FDA's priority review. 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 4'9/2" for girls. We estimate that a total of 12,000 children in the United States and Western Europe have

## **Table of Contents**

Severe Primary IGFD. We believe that Severe Primary IGFD represents up to an approximate \$200 million annual market opportunity in the United States and Western Europe.

We have Phase III results from the treatment of 71 children with Severe Primary IGFD with rhIGF-1 replacement therapy for an average of 3.9 years, with some patients being treated for up to 11.5 years. Long-term Phase III clinical growth trials are generally not placebo-controlled due to ethical considerations. None of the 71 patients discontinued rhIGF-1 treatment due to safety concerns. Some patients experienced hypoglycemia, or low blood glucose levels. Enlargement of the tonsils or minor temporary hearing deficits were also noted in some patients.

Of these children, 61 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 in these patients ( $p < 0.0001$ ). 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 were also observed during each of the first eight years of rhIGF-1 treatment ( $p < 0.001$ ).

We have had discussions with the FDA regarding the use of Increlex in Severe Primary IGFD. We believe that our clinical data support the approval of an NDA for long-term rhIGF-1 replacement therapy in this indication. We submitted our NDA in February 2005. If our NDA is accepted for filing and we receive marketing approval, we expect to launch Increlex with our own sales force in the United States. In addition, we are currently assessing our regulatory strategy regarding submission of a Marketing Authorization Application with the European Medicines Evaluation Agency for Severe Primary IGFD.

*Primary IGFD.* We define the indication Primary IGFD to mean a child who has a Height SDS and IGF-1 SDS of less than minus two, in the presence of normal or elevated growth hormone. Although our first indication is for Severe Primary IGFD, we intend to evaluate the use of Increlex for the treatment of all 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 48,000 children in the United States and Western Europe suffer from Primary IGFD, representing a market potential of approximately \$800 million annually.

We recently initiated a 160-patient 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

## **Table of Contents**

conducting this study in the United States. 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 addition, we plan to initiate in mid-2005 another Phase III study in Primary IGFD, which will investigate once-daily dosing of Increlex.

*Adult IGFD.* Children with Primary IGFD who attain adulthood are considered to have Adult IGFD. Adult IGFD patients may have decreased cardiac performance, impaired exercise performance, decreased muscle mass, decreased bone density, obesity and abnormalities of carbohydrate and lipid metabolism. Replacement therapy with Increlex may have beneficial effects with respect to these metabolic abnormalities. We believe that at least a total of 120,000 people in the United States and Western Europe suffer from Adult IGFD. This market does not include adults who become IGF-1 deficient as a result of other disorders, including anorexia nervosa, malabsorption and liver disease, which could represent additional opportunities that we may study in the future. We currently are assessing our development strategy and timing for the use of Increlex in Adult IGFD.

### ***Diabetes***

Genentech originally developed rhIGF-1 as a potential treatment for people with a broad range of type 1 and type 2 diabetes. In four Phase II clinical trials using rhIGF-1 in over 700 type 2 diabetic patients, long-term glucose control was improved, as indicated by statistically significant improvements of approximately 1% to 2% in glycated hemoglobin, which is an indicator of an individual's average blood glucose concentrations over a three to four month period. Improvements of approximately 0.5% in glycated hemoglobin are frequently considered clinically significant. However, during the course of these clinical trials, potential concerns were raised that long term use of rhIGF-1 in diabetic patients might lead to an increased incidence and/or severity of diabetic retinopathy. As a result of the scope and extended timeframe of the clinical trials necessary to address this concern, Genentech discontinued development of rhIGF-1 for treatment of type 1 and type 2 diabetes.

We are currently assessing our development and regulatory strategies and timing for the use of Increlex in diabetes. We have developed an integrated database of the results from the diabetes studies conducted by Genentech. We are analyzing these data to determine a diabetes patient population that may benefit from treatment with Increlex while minimizing the side effects observed in prior studies. This patient population may include diabetes patients with low IGF-1 levels or those in orphan diabetes indications.

### **Strategy**

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

***Seek FDA approval of rhIGF-1 replacement treatment for Severe Primary IGFD.*** We submitted our NDA to the FDA in February 2005. Since there is currently no approved drug product in the United States for the treatment of Severe Primary IGFD, we believe our submission will qualify for the FDA's priority review.

## **Table of Contents**

***Expand the Severe Primary IGFD indication to Primary IGFD.*** Our goal is capitalize on the opportunities presented by Increlex for the treatment of short stature. If we receive FDA approval for Severe Primary IGFD, we intend to submit a supplemental NDA to expand the use of Increlex to encompass children with Primary IGFD. This will allow us to leverage our existing preclinical, clinical and manufacturing data from our NDA for Severe Primary IGFD. We believe this will expand the market for Increlex from the approximately 12,000 children with Severe Primary IGFD to encompass approximately 60,000 children with Primary IGFD, including Severe IGFD, in the United States and Western Europe. To support the supplemental NDA, in late 2004 we initiated a Phase IIIb clinical trial of Increlex in children with Primary IGFD.

***Establish a U.S. sales and marketing organization.*** We intend to develop a sales and marketing force to target the approximately 400 active U.S.-based pediatric endocrinologists who treat children with short stature. Because these pediatric endocrinologists are primarily hospital-based and concentrated in major metropolitan areas, we believe that a focused marketing organization and specialized sales force can effectively serve them. In addition, we intend to conduct medical education programs, medical symposia, and regional speaker programs aimed at establishing awareness of Increlex in the physician community. We also intend to conduct post-marketing studies and establish a patient registry to provide further data on the safety and efficacy of Increlex. We acquired certain international rights to rhIGF-1 from Genentech and are evaluating our international commercialization strategy.

***Develop Increlex for additional indications.*** We intend to develop Increlex for those indications where preclinical or clinical data show significant promise as a potential treatment. These indications may include Adult IGFD and diabetes. We anticipate that the risks and time required to obtain FDA approval of Increlex for new disease indications may be reduced once Increlex is approved for our initial indication.

***Broaden endocrinology portfolio based on our expertise.*** We intend to pursue the development and commercialization of additional products for the treatment of significant unmet medical needs, principally endocrine disorders. We have an opportunistic approach to in-licensing products and product candidates. We are seeking to in-license products that may benefit from our expertise. We believe our scientific expertise in endocrinology may make us an attractive licensee. We actively maintain ongoing discussions with academic research institutions and other companies regarding preclinical and clinical development projects in the endocrinology area.

## **Genentech Relationship**

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. 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 IGFBP3, for a broad range of

**Table of Contents**

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. and International License and Collaboration Agreements with Genentech, Genentech agreed to transfer to us its preclinical 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 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 United States License and Collaboration Agreement. We paid Genentech \$1.7 million upon execution of the International License and Collaboration Agreement. We paid Genentech \$1.3 million related to rights related to the license to Genentech's rights to IGF-1 combined with IGFBP-3. 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. In addition to the amounts already paid to Genentech, if we achieve all of the additional milestones for rhIGF-1 under the U.S. and International License and Collaboration Agreements, we will owe Genentech up to an aggregate of approximately \$34 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. If we achieve all of these milestone events for both rhIGF-1 and for rhIGF-1 in combination with IGFBP3, we would owe Genentech an aggregate of approximately \$66.5 million in milestone payments. Both agreements require us to fulfill certain obligations to maintain our licenses. These obligations include a requirement to use reasonable business efforts to develop and obtain approval for the products we have been licensed, and in particular, require us to use reasonable business efforts to file for regulatory approval with the FDA by December 31, 2005, which we have accomplished, and an equivalent authority in either the European Union or Japan, by December 31, 2007 in each case, for growth hormone insensitivity syndrome, which we believe is substantially equivalent to Severe Primary IGF1D. In the United States, we also are required to use the same efforts to file for regulatory approval with the FDA for diabetes or a substitute indication, subject to Genentech's consent, by December 31, 2006. If we fail to use reasonable business efforts to meet our obligations under either agreement, Genentech may terminate that agreement and we would have no further rights to utilize the technology and intellectual property covered by that agreement to develop, manufacture and commercialize rhIGF-1 for any indications. This may prevent us from continuing our business.

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, which we refer to as the Opt-In Right, to elect, within a limited

**Table of Contents**

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, which would have a one-time positive impact on our operating results. 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 be Genentech, under the terms of the current agreement, must have a potential market greater than \$250 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 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 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. or 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

## **Table of Contents**

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.

### **Manufacturing**

We have a manufacturing and services agreement with Cambrex Bio Science Baltimore, Inc., or Cambrex Baltimore, for the manufacture and supply of bulk rhIGF-1. This agreement terminates in December 2008. Under this agreement, Cambrex Baltimore is obligated to provide us with up to 24 kilograms of rhIGF-1 per year, subject to the establishment and validation of the manufacturing process for rhIGF-1. We currently believe that this quantity will be sufficient to supply our expected requirements through at least 2008. We executed a Quality Agreement with Cambrex Baltimore in order to ensure that we maintain product quality, compliance with cGMP and oversight over all critical aspects of rhIGF-1 production, testing and release.

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.

We have completed the transfer of Genentech's proprietary manufacturing technology to our contract manufacturers and have established the process for high yield, commercial scale manufacturing. We have manufactured rhIGF-1 on a full-scale production basis according to cGMP and completed our manufacturing process validation conformance campaign.

In order to obtain FDA approval of our Increlex, we are required to conduct a comprehensive assessment program to demonstrate structural and functional comparability between the Genentech and Tercica rhIGF-1 products. In November 2003, we submitted a comparability plan for discussion with the FDA. We executed this plan in 2004 during the manufacturing and testing of full-scale production runs of rhIGF-1. The FDA accepted this plan for demonstration of product comparability as part of our NDA at our pre-NDA meeting, and we have submitted these results as part of our NDA. Based on extensive testing, we currently believe that our rhIGF-1 is comparable to the rhIGF-1 previously manufactured by Genentech and are using this material in our current Phase III studies. If we fail to convince the FDA that we have established comparability of rhIGF-1, FDA approval will be delayed while we conduct additional testing.

We believe that there is an increasing acceptance by the FDA and European Medicines Evaluation Agency of a comparability-based assessment without the need to repeat clinical studies, if appropriate analytical methods are available to fully characterize the product. There can be no assurance, however, that such regulatory bodies will permit us to proceed with our marketing applications based solely on comparability-based laboratory assessments. There are a number of regulatory agency guidelines



## **Table of Contents**

providing guidance to the industry on the demonstration of comparability for human therapeutic products. Specific FDA guidances enable manufacturers to assess changes to manufacturing processes based on the potential impact on final product safety and efficacy, to develop a comparability assessment program appropriate to the molecule, and to verify the impact of the changes.

## **Sales and Marketing**

Our sales and marketing efforts will initially be focused on the market for endocrine growth disorders, targeting the approximately 400 pediatric endocrinologists practicing in the United States. Pediatric endocrinologists are the physicians who generally treat children with Severe Primary IGFD or Primary IGFD, our first two planned indications. Because these pediatric endocrinologists are primarily hospital-based and concentrated in major metropolitan areas, we believe that a focused marketing organization and specialized sales force can effectively serve them. We plan to conduct a variety of programs aimed at establishing awareness of Increlex in the physician community, in particular as a treatment for Severe Primary IGFD and Primary IGFD. These programs will include medical education programs, symposiums, and regional speaker programs. In addition if Increlex is approved by the FDA, we plan to conduct post-marketing studies and establish a patient registry in order to provide further data on the safety and efficacy. We are evaluating our international commercialization strategy. As we develop Increlex for indications other than Severe Primary IGFD and Primary IGFD, we will evaluate expanding our sales and marketing efforts as appropriate.

## **Research and Development**

Our capabilities are principally in developing and commercializing late-stage product candidates. We do not conduct any of our own preclinical laboratory research. However, we actively maintain ongoing discussions with academic research institutions and other companies regarding both IGF-1 and non-IGF-1 related projects in endocrinology. Our current product candidate, Increlex, is a late-stage product, and we intend to develop other potential indications for rhIGF-1. We will be conducting advanced Phase II and Phase III clinical trials, for which we may contract with third parties for support. Our research and development expenses were \$27.9 million for the year ended December 31, 2004, \$19.2 million for the year ended December 31, 2003 and \$2.0 million for the year ended December 31, 2002.

## **Patents and Proprietary Rights**

Our policy is to enforce our licensed patents to the extent Genentech has granted us such rights, and 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

## **Table of Contents**

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 their intellectual property rights, including patent rights and preclinical 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.

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.

For example, we initiated patent infringement proceedings against Avecia Limited and Insmmed in the United Kingdom and against Insmmed in the United States to enforce

## **Table of Contents**

patent rights we licensed from Genentech. The United States action, among other things, alleges infringement of United States Patent No. 6,331,414 B1. We cannot predict the outcome of such litigation. Either or both of those actions could require a substantial diversion of financial and personnel resources in support of such actions and expose us to liability for costs or other awards of damages. If the court finds any of the patents at issue in those litigations, including United States Patent No. 6,331,414 B1, to be invalid or unenforceable, we would be prevented from enforcing such patents against third parties in the future, thus preventing us from using the affected patents to exclude others from competing with us. Declaratory judgments of invalidity against the patents asserted in 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**

We are engaged in an industry that 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 and expertise in developing and commercializing products.

We cannot predict the relative competitive position of Increlex if it is approved for use. However, we expect that the following factors will determine our ability to compete effectively: safety and efficacy; product price; ease of administration; and marketing and sales capability.

There is no drug in the United States or Europe approved as replacement therapy for the treatment of Severe Primary IGFD, Primary IGFD or Adult IGFD. We believe that rhIGF-1 is the only treatment that has been specifically shown to be useful in treating children with Severe Primary IGFD on a long-term basis. However, Inmed recently announced that it has submitted an NDA for a product containing rhIGF-1 in patients with GHIS. In addition, we are aware that Chiron 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 rhIGF-1.

## **Table of Contents**

Growth hormone may also be a competitive product for the treatment of some patients with Primary IGFD or Adult IGFD. Although patients with Primary IGFD and Adult IGFD are resistant to growth hormone, higher doses of growth hormone may be effective in these patients. The major suppliers of commercially available growth hormone are Genentech, Eli Lilly and Company, Novo Nordisk A/S, Pfizer Inc. and Serono A.S. In 2003, Eli Lilly and Company received FDA approval for its growth hormone, Humatrope, for the treatment of children with idiopathic short stature, or ISS. Children with Primary IGFD may be diagnosed as having ISS, which may cause growth hormone to be competitive with rhIGF-1. We believe that Novo Nordisk is conducting or has completed clinical trials for the use of its growth hormone in IGF-1 deficient patients.

In addition, we believe that Bristol-Meyers Squibb Company, Genentech, Merck & Co., Inc., Novo Nordisk A/S and Pfizer Inc. have previously conducted research and development of orally-available small molecules that cause the release of growth hormone, known as growth hormone secretagogues. We are not aware of any continued clinical development of these molecules by these companies. We believe that Rejuvenon Corporation 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.

Many companies are seeking to develop products and therapies for the treatment of diabetes. Our competitors include multinational pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions.

## **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:

preclinical laboratory and animal tests;

submission of an investigational new drug, or 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.

## **Table of Contents**

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

Once a pharmaceutical candidate is identified for development it enters the preclinical testing stage. During preclinical 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, preclinical tests evaluate the safety of drug candidates. Preclinical tests must be conducted in compliance with good laboratory practice regulations. In some cases, long-term preclinical 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 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.

## **Table of Contents**

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 preclinical 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, preclinical 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. We submitted our NDA for Increlex electronically. We have discussed the format of such filing with the appropriate FDA officials and do not foresee any significant risk with regard to our use of such application or FDA rejection of the application on this ground. However, the FDA could disagree. 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.

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. In response to a request from Tercica, the FDA declined to grant Increlex fast-track status. In a pre-NDA meeting, however, the FDA indicated that it is at this time in favor of granting priority review for Increlex and will make a final decision on the issue at the time the NDA submission is accepted for filing. There can be no assurance that the FDA will grant Increlex priority review however.

## **Table of Contents**

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 filing.

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 believe that our NDA for Severe Primary IGFD, if accepted for filing by the FDA, may qualify for priority review because there currently is no approved therapy for that indication. Such priority review status might not be available or remain available if, for example, another product were to be approved for Severe Primary IGFD or comparable indication either before our NDA is accepted for filing or during the FDA's review of our NDA. The FDA will inform us of its decision regarding this issue if our NDA is accepted for filing.

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 presubmission 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 United States or foreign governmental action.

**Table of Contents**

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 rhIGF-1. 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 a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. 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 for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. This exclusivity, however, also could block the approval of our product for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product is determined to be contained within the competitor's product for the same indication or disease. We intend to file for orphan drug designation for those rhIGF-1 diseases that meet the criteria for orphan exclusivity and have received orphan drug designation for Increlex for the indication of GHIS. There is no guarantee that we will be awarded orphan exclusivity for any of our products or indications. Obtaining FDA approval to market a product with orphan drug exclusivity may not provide us with a material commercial advantage.

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 for conducting research about the safety 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, 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



## **Table of Contents**

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 the 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 market 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 with the FDA or, if there is no written agreement, in accordance with 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 our current plans to study rhIGF-1 in children could make rhIGF-1 eligible for the additional six months of pediatric exclusivity, although there can be no assurances that FDA will grant such additional exclusivity. The current pediatric exclusivity provision is scheduled to end on October 1, 2007 and there can be no assurances that it will be reauthorized.

## **Reimbursement**

Sales of biopharmaceutical products depend in significant part on the availability of third-party reimbursement. We anticipate third-party payors will provide reimbursement for Increlex. 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, imposes 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 company placing the medicinal product on the market.

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.

**Table of Contents****Employees**

As of December 31, 2004, we had 60 full-time employees. Of the full-time employees, 29 were engaged in product development and 31 were engaged in selling, general and administrative positions. We believe that our employee base will need to grow rapidly in order to execute our development and commercialization plans for rhIGF-1. We believe our relations with our employees are good.

**Executive Officers of the Registrant**

Our executive officers, their ages and their positions as of March 11, 2005, are as follows:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
John A. Scarlett, M.D.	54	President, Chief Executive Officer and Director
Ross G. Clark, Ph.D.	54	Chief Technical Officer and Director
Thomas H. Silberg	58	Chief Operating Officer
Timothy P. Lynch	35	Chief Financial Officer, Treasurer and Senior Vice President, Finance and Administration
Stephen N. Rosenfield	55	Senior Vice President of Legal Affairs, General Counsel and Secretary
Thorsten von Stein, Ph.D.	43	Chief Medical Officer and Senior Vice President of Clinical and Regulatory Affairs
Andrew Grethlein, Ph.D.	40	Vice President, Manufacturing
Michael Parker	53	Vice President, Quality

*John A. Scarlett* 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* 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.

## **Table of Contents**

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.

*Thomas H. Silberg* has served as our Chief Operating Officer since April 2004. From June 2003 to April 2004, Mr. Silberg was an independent consultant. From January 2000 to May 2003, Mr. Silberg served as Executive Vice President and Chief Operating Officer at Ligand Pharmaceuticals, Inc., a pharmaceutical company. From 1972 to 2000, Mr. Silberg served in positions of increasing responsibilities at Roche Pharmaceuticals, a pharmaceutical corporation. From 1995 to January 2000, Mr. Silberg served as Vice President of Business Operations at Roche Pharmaceuticals. From 1988 to 1994, Mr. Silberg served as Vice President of Health Systems Management for Roche Pharmaceuticals. From 1985 to 1988, Mr. Silberg served as Assistant Vice President and Director of Marketing Research of Roche Pharmaceuticals. Mr. Silberg received his B.S. degree in marketing and advertising from the University of Minnesota.

*Timothy P. Lynch* has served as our Treasurer since November 2003 our Chief Financial Officer and our Senior Vice President, Finance and Administration since October 2002. From November 1999 to June 2002, Mr. Lynch served as Chief Financial Officer of InterMune, Inc., a biopharmaceutical company. From July 1999 to October 1999, he served as Director of Business Development at ePhysician Inc., a provider of electronic services for physicians. From August 1997 to July 1999, Mr. Lynch served as Director of Strategic Planning and as a pharmaceutical sales representative at Elan Corporation, plc, a pharmaceutical company. From 1993 to 1995, Mr. Lynch served as an investment banker for Goldman, Sachs & Co. From 1992 to 1993, Mr. Lynch served as an investment banker for Chase Securities, Inc. Mr. Lynch received his B.A. degree in economics from Colgate University and his M.B.A. from the Harvard Graduate School of Business.

*Stephen N. Rosenfield* has served as our Senior Vice President of Legal Affairs, General Counsel and Secretary since July 2004. 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.

*Thorsten von Stein* 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

## **Table of Contents**

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.

*Andrew Grethlein* has served as our Vice President, Manufacturing since April 2003. 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.

*Michael Parker* has served as our Vice President, Quality since February 2003. From July 2001 to July 2002, Mr. Parker served as Vice President of Quality for the Biological Products Division of Bayer Corporation, a pharmaceutical company. From January 1999 to June 2001, he served as Bayer Corporation's Director of Quality Assurance. From July 1997 to January 1999, Mr. Parker served as Head of Quality Affairs, United Kingdom for Medeva Pharma Ltd, a pharmaceutical company. From 1993 to 1997, Mr. Parker served in various capacities for Medeva Pharma Ltd, including Head of Quality, Quality Assurance Group Manager and Technical Group Manager. From 1990 to 1993, Mr. Parker served as Quality Assurance Manager for Centocor BV, a pharmaceutical company. Mr. Parker received his B.Sc. degree in microbiology and biochemistry from the University of Glasgow.

## **Key Employees**

*George Bright* has served as our Vice President, Clinical Affairs since June 2003. From April 1999 to June 2003, Dr. Bright served as Director of Growth Hormone Clinical Research at Novo Nordisk Pharmaceuticals Inc., a subsidiary of Novo Nordisk A/S, a pharmaceutical company. From July 1989 to December 1998, he served as a pediatric endocrinologist at Nemours Children's Clinic. From 1982 to 1989, Dr. Bright served as a pediatric endocrinologist at the Medical University of South Carolina. Dr. Bright received his B.S. degree in biochemistry from Southern Connecticut State College and his M.D. from the University of Connecticut Medical School.

*Ira Wallis* has served as our Vice President, Regulatory Affairs since March 2003. From May 2001 to January 2003, he served as Senior Director and Head of Regulatory

## **Table of Contents**

Affairs at Dynavax Technologies Corporation, a biopharmaceutical company. From July 1996 to April 2001, he served as Director and Head of Regulatory Affairs and lead regulatory representative for the drug portion of a combination drug/device pathogen inactivated blood product at Cerus Corporation, a medical systems and biopharmaceutical company. From 1990 to 1996, Dr. Wallis served as Associate Director and Manager of Regulatory Affairs at Genentech, Inc. From 1987 to 1989, Dr. Wallis served as Manager of Regulatory Affairs for Sandoz Pharmaceutical Corporation, now Novartis AG, a pharmaceutical company. Dr. Wallis received his B.A. degree in zoology from American International College and his Ph.D. in neurophysiology from the State University of New York, Buffalo.

*Susan Wong* has served as our Vice President, Finance and Controller since January 2004. 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.

*Carl H. Worrell* has served as our Vice President, Sales since June 2004 and served as our Vice President, Sales and Marketing from October 2003 to June 2004. From March 2003 to October 2003, Mr. Worrell served as Director of Marketing for Schering-Plough Corporation, a pharmaceutical company. From November 1999 to March 2002, Mr. Worrell served as Senior Director, Endocrine Care for Pharmacia Corp., USA, a pharmaceutical company. From 1997 to November 1999, he served as National Sales Director for Pharmacia Corp., USA. From 1995 to 1997, Mr. Worrell served as Vice President, Sales and Marketing for Pharmacia & Upjohn, Inc., Canada. Mr. Worrell received his B.A. degree in philosophy from Dartmouth College.

## **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 United States Securities and Exchange Commission 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**

**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. This section should be read in conjunction with the Financial Statements and Notes thereto, and Management's Discussion and Analysis of Financial Condition and Results of Operations.*

**Risks Related to Our Business**

*We are a development stage company with a limited operating history and may not be able to commercialize any products, generate revenue or attain profitability.*

We are a development stage company focused on the development and commercialization of Increlex for the treatment of short stature and other endocrine disorders. From our inception in October 2000 through December 31, 2004, we have accumulated a deficit of \$119.5 million. We have not generated and may not be able to generate any revenue from operations and may not be able to attain profitability. We incurred a net loss of \$41.0 million during the year ended December 31, 2004. 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 and commercialize Increlex for Severe Primary IGFD and Primary IGFD. 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 solely dependent on the successful commercialization of Increlex for the treatment of Severe Primary IGFD and Primary IGFD. There is no assurance we will be able to obtain governmental regulatory approval to market Increlex in the United States or Western Europe for these indications or any other indication. If we are unable to generate significant revenue from Increlex or attain profitability, we will not be able to sustain our operations.

*If we do not receive a regulatory marketing approval of Increlex for Severe Primary IGFD, our business will be harmed.*

We need FDA approval to market Increlex for therapeutic uses in the United States. We are currently developing Increlex for the treatment of Severe Primary IGFD and Primary IGFD. We submitted an NDA in the United States for marketing Increlex for the treatment of Severe Primary IGFD in February 2005. The FDA has substantial discretion in the approval process and may:

refuse to accept our NDA for filing;

**Table of Contents**

decide after review of our NDA that our data is insufficient to allow approval of Increlex for Severe Primary IGFD; and/or

limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD.

We cannot predict the size of the subset of patients with Severe Primary IGFD to which the FDA may limit any marketing approval and labeling for Increlex. If we fail to obtain the FDA's approval for the marketing of Increlex for this indication, we will not be able to commercialize Increlex in the near term, and our business will be harmed.

In the protocol for the Phase III clinical trial that we are using to support our NDA filing for Severe Primary IGFD, the disease being treated was identified as growth hormone insensitivity syndrome, or GHIS. Everywhere in this document where we discuss existing Phase III clinical trial results for rhIGF-1, such results were from children identified at the time as having GHIS. However, there are varying academic and clinical terminologies that describe children with GHIS and IGF-1 deficiency. We believe that the disease described by the term Severe Primary IGFD is substantially equivalent to the disease described by the term GHIS, relates to approximately the same number of pediatric patients and accurately describes the pediatric patient population for which we will be filing our NDA and seeking regulatory marketing approval.

If the FDA disagrees with us and determines that Severe Primary IGFD is not substantially equivalent to GHIS and/or that the number of children with GHIS are less than those with Severe Primary IGFD, the FDA may:

determine that our data do not support an NDA filing for Severe Primary IGFD;

may not accept or approve our NDA for the treatment of Severe Primary IGFD; and/or

may limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD.

Even if the FDA agrees with us that Severe Primary IGFD is substantially equivalent to GHIS, the FDA may:

still determine that our data do not support an NDA filing for Severe Primary IGFD or GHIS;

not accept or approve our NDA for the treatment of Severe Primary IGFD or GHIS; and/or

limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD.

Since our NDA filing and marketing approval for Severe Primary IGFD are key to our business plan and development of Increlex, any of the FDA's determinations, requirements or labeling restrictions discussed above would substantially harm our business.

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

The means by which the FDA could restrict our marketing labeling could include, for example, requiring us to include in our Increlex labeling additional specific diagnostic tests to establish the diagnosis of Severe Primary IGF1 and/or requiring that children



## **Table of Contents**

must fail to respond to treatment with growth hormone prior to being treated with Increlex. Such requirements would add additional cost and complexity in making the diagnosis of Severe Primary IGFD and substantially limit the number of patients for whom Increlex is prescribed, which would substantially harm our business.

The regulatory review and marketing approval process in the United States, which includes evaluation of preclinical studies and clinical trials of our rhIGF-1 for Severe Primary IGFD, as well as the evaluation of our manufacturing process and our contract manufacturers' facilities, is lengthy, expensive and uncertain. Securing FDA approval for Increlex for Severe Primary IGFD will require the submission of extensive preclinical and clinical data and supporting information to the FDA to establish Increlex's safety and effectiveness for this indication, as well as for any additional indications for which we seek marketing approval. We have limited experience in filing and pursuing applications necessary to gain FDA approvals.

We have completed the manufacturing of the conformance lots in our process validation campaign. If the FDA is not satisfied with our validation data, we may need to expend additional resources to conduct further studies to obtain manufacturing data that the FDA believes is sufficient. Depending on the extent of these additional studies, approval of our NDA or other applications may be delayed by several years, or may require us to expend more resources than we have planned or are available. It is also possible that additional studies may not suffice to make our NDA or other applications approvable. If any of these outcomes occur, we may be forced to abandon our NDA or other applications for approval, which might cause us to cease operations.

We will need to file similar applications with regulatory authorities in foreign countries to market Increlex for any indications in those countries. We have not yet initiated the regulatory process in Europe. If we fail to obtain European approval, the geographic market for Increlex would be limited. If such approval is delayed, it would postpone our ability to generate revenues in Europe.

***If there are fewer children with Severe Primary IGFD or Primary IGFD than we estimate, we may not generate sufficient revenues to continue development of other products or to continue operations, or we may not be able to complete our clinical trials.***

If there are fewer children with Severe Primary IGFD or Primary IGFD than we estimate, we may not generate sufficient revenues to continue development of other indications or products and may cease operations. 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

## **Table of Contents**

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 of and extrapolation 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 enroll a sufficient number of patients in our clinical trials on a timely basis, or at all.

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

rhIGF-1 has never been commercialized in the United States or Western Europe for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe Increlex, in which event we may be unable to generate significant revenue or become profitable.

Acceptance of Increlex will depend on a number of factors including:

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

adequate reimbursement by third parties;

relative convenience and ease of administration of Increlex;

prevalence and severity of side effects; and

competitive product approvals.

***Reimbursement may not be available for Increlex, which could diminish our sales and impact our ability to achieve profitability.***

Market acceptance, our sales of Increlex and our profitability will depend on reimbursement policies and health care reform measures. The levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, reimburse the price patients pay for our product will affect the commercialization of Increlex. We believe that Increlex will be reimbursed to a similar extent that growth hormone therapy is reimbursed. If our assumption regarding reimbursement for Increlex is incorrect, our expected revenues may be substantially reduced. We cannot be sure that reimbursement in the United States or elsewhere will be available for Increlex. If the FDA approves Increlex for Severe Primary IGFD, only prescriptions for that indication may be reimbursable. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, Increlex. We have not commenced efforts to have Increlex reimbursed by governments or third-party payors. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize Increlex.

We believe that the price per patient of Increlex therapy for the treatment of Primary IGFD will not be less than approximately \$20,000 per year. However, we have not yet determined what the actual price per patient will be. In addition, it is possible that the children receiving Increlex

therapy during the first few years of our launch are younger and/or smaller than those children receiving the drug in ensuing years, and the price per

## **Table of Contents**

patient could be less than in subsequent years. If our assumptions regarding the price per patient of Increlex therapy for the treatment of Primary IGF1 are incorrect, the market opportunity for Increlex therapy for the treatment of Primary IGF1 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 the countries of the European Union, the pricing of prescription drugs is subject to government control. If our product becomes subject to government legislation that limits or prohibits payment for Increlex, or that subjects the price of our product to governmental control, we may not be able to generate revenues, attain profitability or commercialize our product. 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 payors 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. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which, in turn, will put pressure on the pricing of drugs.

***If we are unable to establish with the FDA that our rhIGF-1 is comparable to that produced by Genentech, our ability to commercialize rhIGF-1 may be delayed or prevented.***

Until January 2004, all of our clinical trials were conducted using rhIGF-1 manufactured and released by Genentech. In order to obtain FDA approval of Increlex, we submitted a comprehensive assessment program to demonstrate structural and functional comparability between the Genentech-manufactured rhIGF-1 and Increlex as part of our NDA. If the FDA determines that this approach is insufficient to assess whether the manufacturing changes have affected the final product safety, identity, purity or potency of Increlex compared to the rhIGF-1 used in the existing clinical studies, then the FDA could require us to conduct additional clinical trials in order to demonstrate comparability as part of the Increlex approval process. Any additional clinical trial would require us to incur significant expenses and significantly delay or prevent the commercialization of Increlex.

The differences between the production of the Genentech-manufactured rhIGF-1 and Increlex include:

relocation of the manufacturing facility for bulk rhIGF-1 product from Genentech to Cambrex Bio Science Baltimore, Inc.;

use of a new master cell bank derived from the Genentech master cell bank;

**Table of Contents**

change of some of the raw material suppliers;

change of the final vial size, configuration and site of manufacture;

process changes;

analytical methods changes;

equipment used; and

a solvent used in the purification process.

Our comparability assessment required the evaluation of a number of technical parameters, such as the impurity profile and stability. Any of these factors could affect the comparability of the Genentech-manufactured rhIGF-1 and Increlex and, as a result, delay or prevent our ability to commercialize Increlex.

*If our contract manufacturers facilities and operations do not achieve a satisfactory cGMP inspection or if our contract manufacturers facilities become unavailable, we may be unable to sell Increlex.*

The facilities used by and operations of our contract manufacturers to manufacture Increlex must undergo an inspection by the FDA for compliance with cGMP regulations before Increlex can be approved. Currently, Cambrex Baltimore is our sole provider of bulk rhIGF-1. We have no alternative manufacturing facilities or plans for additional facilities at this time. Cambrex Baltimore has never commercially manufactured rhIGF-1 for any party, including us. We do not know if the Cambrex Baltimore facilities or their operations required for the commercial manufacture of Increlex will receive a satisfactory cGMP inspection. In the event these facilities or operations do not receive a satisfactory cGMP inspection for the manufacture of our product, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in or prevent us from obtaining an approval for Increlex. In addition, Cambrex Baltimore, and any alternative contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA and corresponding state and foreign agencies for compliance with GMP regulations and similar foreign standards. We do not have direct control over our contract manufacturers compliance with these regulations and standards.

If Cambrex Baltimore's facilities become unavailable to us for any reason, including failure to comply with cGMP regulations, damage from any event, including fire, flood, earthquake, or terrorism or if they fail to perform under our agreement with them, we may be delayed or unable to complete validation of Increlex or manufacture Increlex. This could delay or prevent the approval of our NDA and our clinical trials, 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 agreements, we will need to find alternative facilities. 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

## **Table of Contents**

manufacturers' facilities and processes, prior to our use, would likely have to undergo 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.

Any of these factors could delay or suspend clinical trials, regulatory submissions, regulatory approvals or commercialization of Increlex, entail higher costs and result in our being unable to effectively commercialize Increlex. Furthermore, if Cambrex Baltimore fails to deliver commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we are unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and on a timely basis, we will likely be unable to meet demand for Increlex, and we would lose potential revenues.

### ***Delays in performing testing and characterization work on Increlex may delay or prevent our NDA approval.***

We have contracted with AAI Development Services, a division of aaiPharma Inc., or AAI, to perform some of the testing and characterization work on Increlex. AAI has publicly disclosed that it has financial difficulties, a substantially new management team and that it is pursuing asset sales. If there are business interruptions at AAI resulting from its financial condition, or for any other reason, we may need to reassign all or a portion of AAI's work to an alternative contractor, and our NDA approval may be delayed or prevented.

### ***If another party obtains orphan drug and/or pediatric exclusivity for rhIGF-1 for children with IGFD, we may be precluded from commercializing Increlex in that indication.***

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. If a competitor obtains approval before us of the same drug as defined by the FDA, or if our drug is determined to be contained within that drug, for the same indication, we would be blocked from obtaining approval for our product for seven years, unless our product can be shown to be clinically superior. In addition, more than one product may be approved by the FDA for the same orphan indication or disease as long as the products are different drugs. As a result, if our product is approved and receives orphan drug status, the FDA can still approve other drugs for use in treating the same indication or disease covered by our product, which could create a more competitive market for us.

In some cases, pediatric exclusivity can provide an additional six months of market exclusivity. Under Section 505a of the Federal Food, Drug, and Cosmetic Act, 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

**Table of Contents**

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 the 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 market 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 with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles. There is no guarantee that FDA will issue a Written Request for such studies or accept the reports of the studies. Although we intend to file for pediatric exclusivity where appropriate, we have not yet sought pediatric exclusivity for any indication.

Increlex has received from the FDA orphan drug designation for the treatment of GHIS. We believe that the disease described by the term Severe Primary IGFD is substantially equivalent to the disease described by the term GHIS, relates to approximately the same number of pediatric patients, and accurately describes the pediatric patient population for which we will be filing our NDA and seeking regulatory marketing approval. However, with respect to orphan drug designation, the FDA may determine that Severe Primary IGFD is not substantially equivalent to GHIS and/or that the number of children who have GHIS are less than those with Severe Primary IGFD. Accordingly, even if we were to receive an FDA marketing approval for Severe Primary IGFD, our orphan drug marketing designation and exclusivity may be limited to a small subset of children with Severe Primary IGFD. We cannot predict the size of the subset of children with Severe Primary IGFD to which our orphan drug marketing exclusivity may be limited. If we do not obtain orphan drug marketing exclusivity for Severe Primary IGFD, we could face competition for these patients and our business would be harmed.

We are aware of a drug being developed by Insmmed Incorporated, which we believe is a combination product containing rhIGF-1 that is in development for the treatment of GHIS. In January 2005, Insmmed announced that it had filed an NDA for its combination product for the GHIS indication, and in March 2005, Insmmed announced that the FDA had accepted Insmmed's NDA for filing. This product has received an orphan drug designation from the FDA, and in Europe, the European Medicines Agency, or EMEA, for the treatment of GHIS. The FDA and EMEA could determine that this other product is the same drug as our product or that our product is contained within this other product and is used for the same indication. If the FDA and EMEA makes this determination and the other product is approved first, the approval of Increlex for either Severe Primary IGFD or Primary IGFD could be blocked for up to seven and one-half years in the United States, and ten years in Europe, which could force us to curtail or cease our operations. Even if our product is approved first, we may not be able to benefit from the orphan drug marketing exclusivity if this other product is determined by the FDA and EMEA to be clinically superior because products that are clinically superior may be approved for marketing by the FDA and EMEA notwithstanding our initial approval and our initial orphan drug marketing exclusivity.

## **Table of Contents**

*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 and expertise in developing and commercializing products.

Since Increlex is under development, we cannot predict the relative competitive position of Increlex if it is approved for use. However, we expect that the following factors will determine our ability to compete effectively: safety and efficacy; product price; ease of administration; and marketing and sales capability.

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 Increlex. 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 Increlex.

There is no drug in the United States or Europe approved as a replacement therapy for the treatment of Severe Primary IGFD, Primary IGFD or Adult IGFD. In January 2005, Insmmed announced that it had filed an NDA for its combination product for the treatment of GHIS, and in March 2005, Insmmed announced that the FDA had accepted Insmmed's NDA for filing. 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.

Growth hormone may also be a competitive product for the treatment of some patients with Primary IGFD or Adult IGFD. Higher doses of growth hormone may be effective in patients with Primary IGFD and Adult Primary IGFD that are resistant to lower doses of growth hormone. The major suppliers of commercially available growth hormone are Genentech., Eli Lilly and Company, Novo Nordisk A/S, Pfizer Inc. and Serono S.A. In 2003, Eli Lilly and Company received FDA approval for its growth hormone, Humatrope, for the treatment of children with idiopathic short stature, or ISS. Children with Primary IGFD may be diagnosed as having ISS, which may cause growth hormone to be competitive with Increlex. We believe that Novo Nordisk is conducting or has completed clinical trials for the use of its growth hormone in IGF-1 deficient patients.

In addition, we believe that Bristol-Meyers Squibb Company, Genentech, Inc., Merck & Co., Inc., Novo Nordisk A/S and Pfizer Inc. have previously conducted research and development of orally available small molecules that cause the release of growth hormone, known as growth hormone secretagogues. We are not aware of any continued clinical development of these molecules by these companies. We believe that



## **Table of Contents**

Rejuvenon Corporation 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.

Many companies are seeking to develop products and therapies for the treatment of diabetes. These competitors include multinational pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions. Insmed has also conducted clinical trials using a product that contains rhIGF-1 for the treatment of diabetes. It is possible that there are other products currently in development or that exist on the market that may compete directly with Increlex.

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

Although we are not aware of any other company currently marketing rhIGF-1 in the United States for any human therapeutic indication, rhIGF-1 manufactured by other parties may be approved for use in the United States in the future. 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 rhIGF-1 to treat the indications for which Increlex receives approval. This is commonly referred to as off-label use. While under FDA regulations a competitor is not allowed to promote off-label use of its product, the FDA does not regulate the practice of medicine and as a result cannot direct physicians as to what rhIGF-1 to prescribe to their patients. As a result, we would have limited ability to prevent off-label use of a competitor's 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.

***If we fail to protect 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 technologies from Genentech. 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 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 United States and foreign courts use to interpret patents, are not the same and are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the United States may differ

## **Table of Contents**

substantially from that obtained in various foreign countries. In some instances, patents have issued in the United States while substantially less or no protection has been obtained in Europe or other countries. Our United States Patent No. 6,331,414 B1 licensed from Genentech is directed to methods for bacterial expression of rhIGF-1 and expires in 2018. We have no equivalent European patent. The European Patent Office has determined that the claims of Genentech's corresponding European patent application are not patentable under European patent law in view of public disclosures made before the application was filed.

We are uncertain of the level of protection, if any, that will be provided by our licensed patents if we attempt to enforce them, and they are challenged in court where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid license. For example, we initiated patent infringement proceedings against Avecia Limited and Insmmed Incorporated in the United Kingdom and against Insmmed Incorporated in the United States to enforce patent rights we licensed from Genentech. The United States action, among other things, alleges infringement of United States Patent No. 6,311,414 B1 identified above. If the court finds any of the patents at issue in those litigations, including United States Patent No. 6,311,414 B1, to be invalid or unenforceable, we would be prevented from enforcing such patents against third parties in the future, thus preventing us from using the affected patents to exclude others from competing with us. 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 similar technology.

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

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

## **Table of Contents**

In addition, a third party may claim that we are using its inventions covered by its patents and may go to court 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 our licensor's issued patents or our pending applications or our licensor's pending applications or that we or our licensors were the first to invent the technology because:

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

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

publications in the scientific literature often lag behind actual discoveries and the filing of patents relating to those discoveries.

**Table of Contents**

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

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

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

We have licensed intellectual property rights and technology from Genentech, under our U.S. and International License and Collaboration agreements with Genentech. Under each agreement, Genentech has the right to terminate our license if we are in material breach of our obligations under that agreement 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 filing for regulatory approval in the United States for an IGFD indication by December 31, 2005, which we have accomplished, and for either a diabetes indication or a substitute indication by December 31, 2006. Additionally, we are obligated to file for regulatory approval in either the European Union or Japan for an IGFD indication by December 31, 2007. If we fail to use reasonable business efforts to meet our development milestones for either agreement, Genentech may terminate that agreement. If either agreement were terminated, then we would lose our rights to utilize the technology and intellectual property covered by that agreement to develop, manufacture and commercialize Increlex for any indication. 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.*

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.

**Table of Contents**

*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;

patients experience adverse side effects;

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

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

contract laboratories fail to follow good laboratory practices;

interim results of the clinical trial are inconclusive or negative;

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

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

re-evaluation of our corporate strategies and priorities; and

limited financial resources.

In addition, we may choose to cancel, change or delay certain planned clinical trials, or replace one or more planned clinical trials with alternative clinical trials. While we are assessing our potential development strategy for Adult IGFD, we do not currently intend to initiate a clinical trial in this area, and cannot be sure as to when we may initiate clinical trials in this area, if at all. We are currently evaluating multiple, existing trial results from the use of Increlex in diabetes in order to refine our conclusions and potential development plans and timelines for diabetes. 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

## **Table of Contents**

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. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. If a clinical trial failed to demonstrate safety and statistically significant efficacy, we would likely abandon the development of that product, which could harm our business and may result in a precipitous decline in our stock price.

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

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

***If we are unable to establish a direct sales force in the United States, our business may be harmed.***

We currently do not have a sales organization. If Increlex is approved by the FDA for Severe Primary IGFD, we intend to market that therapy directly to pediatric endocrinologists in the United States through our own sales force. We will need to incur significant additional expenses and commit significant additional management resources to establish this sales force. We may not be able to establish these capabilities despite these additional expenditures. If we elect to rely on third parties to sell Increlex in the United States, we may receive less revenue and incur greater costs than if we sold it directly. In addition, we may have little or no control over the sales efforts of those third parties. In the event we are unable to sell Increlex, either directly or through third parties, our business would be harmed.

***We may need others to market and commercialize Increlex in Europe.***

We may need others to market and commercialize Increlex in Europe. If we decide to sell Increlex in Europe through a third party, we will need to enter into marketing arrangements with them. We may not be able to enter into marketing arrangements with third parties on favorable terms, or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed Increlex entirely on our own. In the event that we are unable to enter into a marketing arrangement for Increlex in Europe, we may not be able to develop an effective sales force to successfully commercialize our product in Europe. If we fail to enter into marketing arrangements for our product and are unable to develop an effective international sales force, our revenues could be limited.

**Table of Contents**

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

We do not conduct any preclinical laboratory 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 new products. If the FDA approves Increlex for Severe Primary IGF1 only, only prescriptions for that indication may be reimbursable. In this event, we would need to invest significant resources to obtain new product candidates.

In addition, we may need additional intellectual property from other third parties to commercialize Increlex for certain diabetes indications. 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.

*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 existing cash and investment securities, including the net proceeds received from our follow-on offering in February 2005, and senior credit facility are sufficient to meet our capital requirements through at least the end of 2006 based on our current business plan. We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations.

Our future capital needs and the adequacy of our available funds will depend on many factors, including:

the costs, timing, scope of domestic and international regulatory approvals for rhIGF-1;

our ability to market and sell rhIGF-1;

the commercial readiness of our rhIGF-1 manufacturing operations at Cambrex Baltimore, including the success of our cGMP production activities;

the success of drug product manufacturing and results of stability and product comparability studies performed at third-party contractors;

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

the pace of expansion of administrative expenses; and

the status of competing products.



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

We have no committed sources of capital and do not know whether additional financing will be available when needed, or, if available, that the terms will be favorable. 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, 2004, we had 60 full-time employees; however, we will need to hire a significant number of 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 expect that our anticipated future growth will place a significant strain on our management, systems and resources. In particular, to fulfill our strategy to commercialize Increlex in the United States, we will need to hire a significant number of additional employees. To manage the anticipated growth of our operations, we will need to increase management resources, secure additional office space and implement new financial and management controls, reporting systems and procedures. If we are unable to manage our growth, we could be unable to execute our business strategy.

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

One potential risk of using growth factors like rhIGF-1 is that it may increase the likelihood of developing cancer or, if patients already have cancer, that the cancer may develop more rapidly. Increlex may also increase the risk that diabetic patients may develop or worsen an existing retinopathy, which could lead to the need for additional therapy such as laser treatment of the eyes or result in blindness. We have Phase III results from the treatment of 71 children with Severe Primary IGFD with rhIGF-1 replacement therapy for an average of 3.9 years, with some patients being treated for as long as 11.5 years. None of the 71 children discontinued rhIGF-1 treatment due to safety concerns. However, some patients experienced hypoglycemia, or low blood glucose levels. Hearing deficits and enlargement of the tonsils were also noted in some patients.

There may also be other adverse events associated with the use of Increlex, which may result in product liability suits being brought against us. While we have licensed the rights to develop and commercialize rhIGF-1 in certain indications, we are not indemnified by any third party, including our contract manufacturers, for any liabilities arising out of the development or use of rhIGF-1.

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 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.

**Table of Contents**

***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 an emerging company with limited resources, and because research and development is an expensive process, we must regularly assess the most efficient allocation of our research and development resources. Accordingly, 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, which could cause us to fall behind our initial timetables for development. As a result, we may not be able to fully realize the value of some of our product candidates in a timely manner, since they will be delayed in reaching the market, or may not reach the market at all.

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

As a public reporting company, we must comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and other requirements will increase our costs and require additional management resources. We recently have been upgrading our finance and accounting systems, procedures and controls and will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new reporting requirements. Compliance with Section 404 will apply in 2005, and 404 reporting will first occur in our Form 10-K for our fiscal year ending December 31, 2005. If we are unable to complete the required assessment as to the adequacy of our internal control reporting or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal controls over financial reporting as of December 31, 2005, investors could lose confidence in the reliability of our internal controls over financial reporting, which could adversely affect our stock price.

***If we are unable to attract and retain additional qualified personnel, our ability to commercialize Increlex 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; Dr. Ross G. Clark, our Chief Technical Officer; Thomas H. Silberg, our Chief Operating Officer; Timothy P. Lynch, our Chief Financial Officer and Treasurer; Dr. Thorsten von Stein, our Chief Medical Officer; and Stephen N. Rosenfield, our General Counsel and Secretary, whose

## **Table of Contents**

knowledge of our industry and technical expertise would be extremely difficult to replace. In addition, we have not obtained life insurance benefiting us if any of our key employees left or was seriously injured and unable to work.

We have employment contracts with all of our executive officers. Each of these employment relationships is at will. All of our executive officers may terminate their employment without notice and without cause or good reason, except for Mr. Lynch. Mr. Lynch may terminate his employment with two weeks notice to us and without cause or good reason. We may terminate any of our executive officers without cause, in which event they would be entitled to severance payments. In the event of a change in control, we may be obligated to make severance payments and to accelerate the vesting of certain stock options.

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

*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 February 15, 2005, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 62.4% of our common stock. Our greater than five percent beneficial owners include entities affiliated with MPM Capital, which beneficially owned 22.4%; entities affiliated with Prospect Management Co. II, LLC, which beneficially owned 12.1%; entities affiliated with MedImmune Ventures, which beneficially owned 9.5%; and entities affiliated with Rho Ventures, which beneficially owned 9.5%. 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.

*Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.*

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

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

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

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



**Table of Contents**

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.

*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:

estimates of our business potential and earnings prospects;

an assessment of our management;

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;

announcements by us or our competitors of new trial results, regulatory filings or developments, new products, significant acquisitions, strategic partnerships or joint ventures;

deviations from projections regarding business potential and earnings prospects;

additions or departures of key personnel;

changes in the structure of healthcare payment or reimbursement systems, regulations or policies;

activities of short sellers and risk arbitrageurs;

future sales of our common stock;

general economic, industry and market conditions; and

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

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

**Table of Contents**

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

*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, the market price of our common stock may decline. 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, 2004, we had 24,595,869 outstanding shares of common stock. Of these shares, the 6,325,000 shares sold in our initial public offering that were outstanding as of December 31, 2004 were freely tradable without restriction or further registration, other than shares purchased by our officers, directors or other affiliates within the meaning of Rule 144 under the Securities Act of 1933. The remaining 18,270,869 shares outstanding as of December 31, 2004 are now freely tradable, subject to volume limitations, certain restrictions on sales by affiliates and vesting in the case of early exercised options.

We have filed a registration statement covering shares of common stock issuable upon exercise of options and other grants pursuant to our stock plans. The holders of 17,285,928 shares of our common stock outstanding as of December 31, 2004 are entitled to registration rights.



## **Table of Contents**

### **Item 2. Properties.**

#### **Facilities**

Our facilities consist of approximately 22,000 square feet of office space located in South San Francisco, California that is leased to us until June 2005. In March 2005, we entered into a lease agreement for approximately 22,850 square feet of office space for a term of 75 months, with a five year renewal option, at 2000 Sierra Point Parkway in Brisbane, California. We have no laboratory or research facilities. We believe that our new Brisbane facilities will be adequate for our near-term needs and that suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

### **Item 3. Legal Proceedings.**

On December 20, 2004, we initiated patent infringement proceedings against Avecia Limited and Insmmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. In these proceedings, we allege that the activities of Insmmed and/or Avecia related to the manufacture, use and/or sale of a product containing rhIGF-1, or the Somatokine product candidate, and/or its associated drug substance for the treatment of GHIS in the United Kingdom infringe European Patent No. 0 571 417 of Genentech. We hold a license under Genentech's rights to European Patent No. 0 571 417.

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. In these proceedings, we and Genentech allege that the activities of Insmmed related to the manufacture, use, and importation of the Somatokine product and/or its associated drug substance in the United States and the activities of Insmmed related to its preparation for commercialization of the Somatokine product in the treatment of GHIS in the United States infringe and/or will infringe U.S. Patent Nos. 5,187,151 and 6,331,414 of Genentech. We hold a license under Genentech's rights to U.S. Patent Nos. 5,187,151 and 6,331,414. On February 23, 2005 Avecia and Insmmed initiated a separate proceeding against Genentech in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. In this separate proceeding, Genentech is named as the sole defendant of Avecia's and Insmmed's claim for revocation of European Patent No. 0 571 417 on grounds of invalidity. On February 16, 2005, we and Genentech filed a First Amended Complaint in our litigation against Insmmed in U.S. District Court. The First Amended Complaint reiterates our claims against Insmmed for infringement of U.S. Pat. Nos. 5,187,151 and 6,331, 414, and introduces new claims alleging that the activities of Insmmed infringe and/or will infringe U.S. Pat. No. 5,258,287 of Genentech and Central Sydney Area Health Service. We hold a license under Genentech's rights to U.S. Pat. No. 5,258,287.

We cannot predict the outcome of our litigation against Avecia and Insmmed in the United Kingdom or the outcome of our litigation against Insmmed in the United States. Moreover, we cannot predict the cost of such litigation, which may require a substantial diversion of our financial assets and other resources and consequently prevent us from allocating sufficient resources to the development of our rhIGF-1 programs, and which

---

**Table of Contents**

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

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

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

There were no matters submitted to a vote of security holders during the quarter ended December 31, 2004.

**Table of Contents****PART II****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 National 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 National Market.

	Prices	
	High	Low
<b>Fiscal 2004:</b>		
First Fiscal Quarter (beginning March 17, 2004)	\$ 10.22	\$ 8.42
Second Fiscal Quarter	11.90	7.78
Third Fiscal Quarter	9.45	7.70
Fourth Fiscal Quarter	10.97	8.47

There were approximately 53 holders of record of our common stock as of March 11, 2005. In addition, we believe that a significant number of beneficial owners of our common stock hold their shares in street name.

**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.

**Use of Proceeds From Registered Securities**

On March 22, 2004, we completed our initial public offering of 5,500,000 shares of our common stock at \$9 per share. On April 2, 2004, we received net cash proceeds from the issuance of 825,000 shares of common stock in connection with the underwriters' exercise of the over-allotment option. The shares of common stock sold in the offering were registered under the Securities Act of 1933, as amended, on a Registration Statement on Form S-1 (File No. 333-108729) that was declared effective by the SEC on March 16, 2004. The aggregate purchase price of the offering was \$56,925,000. The net offering proceeds to us after deducting total expenses were \$50,021,000.

There were no direct or indirect payments to:

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

directors or officers of the issuer or their associates;

persons owning ten (10) percent or more of any class of equity securities of the issuer; and

affiliates of the issuer; or

direct or indirect payments to others.

The net offering proceeds have been invested into short-term investment-grade securities and cash equivalents.

We will retain broad discretion over the use of the net proceeds received from our initial public offering. The amount and timing of our actual expenditures may vary significantly depending on numerous factors, such as the progress of our product development and commercialization efforts and the amount of cash used by our operations.

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

The following selected financial data should be read in conjunction with, and are qualified by reference to, our financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations. The selected statements of operations data for the period from October 1, 2000 (inception) through December 31, 2004, for each of the three years in the period ended December 31, 2004, and the selected balance sheet data as of December 31, 2004 and 2003 are derived from, and qualified by reference to, the audited financial statements included in Item 8 of this Form 10-K. The selected statements of operations data for the period from October 1, 2000 (inception) through March 31, 2001 and for the nine months ended December 31, 2001, and the selected balance sheet data as of December 31, 2002 and 2001, and March 31, 2001, are derived from audited financial statements not included in this Form 10-K. The historical results are not necessarily indicative of results to be expected in any future period. In October 2001, we changed our fiscal year end from March 31 to December 31.

	Year ended December 31,			Nine months ended December 31, 2001	Period from October 1, 2000 (inception) through March 31, 2001	Period from October 1, 2000 (inception) through December 31, 2004
	2004	2003	2002			
<b>Statements of Operations Data (in thousands, except share and per share data):</b>						
Costs and expenses:						
Research and development	\$ 27,918	\$ 19,246	\$ 1,974	\$ 307	\$ 180	\$ 49,625
Selling, general and administrative	12,552	4,834	1,978	510	116	19,990
Acquired in-process research and development	1,417	1,670	5,071			8,158
Total costs and expenses	(41,887)	(25,750)	(9,023)	(817)	(296)	(77,773)
Interest expense			(106)			(106)
Interest and other income, net	885	327	177	9	1	1,399
Net loss	(41,002)	(25,423)	(8,952)	(808)	(295)	(76,480)
Deemed dividend related to beneficial conversion features of convertible preferred stock		(44,153)				(44,153)
Net loss allocable to common stockholders	\$ (41,002)	\$ (69,576)	\$ (8,952)	\$ (808)	\$ (295)	\$ (120,633)
Basic and diluted net loss per share allocable to common stockholders(1)	\$ (2.12)	\$ (38.59)	\$ (5.76)	\$ (0.90)	\$ (12.09)	
Shares used in computing basic and diluted net loss per share allocable to common stockholders(1)	19,301,702	1,803,166	1,555,258	895,183	24,390	

	December 31,				March 31, 2001
	2004	2003	2002	2001	
<b>Balance Sheet Data (in thousands):</b>					
Cash, cash equivalents and short-term investments	\$ 52,001	\$ 37,313	\$ 15,870	\$ 168	\$ 59
Working capital	45,542	33,346	15,707	29	36
Total assets	55,022	42,484	16,348	198	88

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

Total liabilities	7,345	7,045	568	149	30
Convertible preferred stock		68,637	24,693		
Deficit accumulated during the development stage	(119,508)	(78,506)	(8,930)	(1,103)	(295)
Total stockholders' equity (deficit)	47,677	(33,198)	(8,913)	48	58

(1) See Note 3 to the financial statements for information regarding the computation of per share amounts.

**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 below, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.*

**Overview**

We are focused on the development and commercialization of new therapeutics for the treatment of short stature and other related metabolic disorders. Our current product candidate is Increlex, recombinant human insulin-like growth factor-1, or rhIGF-1. We licensed the rights of Genentech to develop, manufacture and commercialize rhIGF-1 products for a broad range of indications, including short stature, worldwide. Our initial focus is on developing Increlex as a replacement therapy for primary IGF-1 deficiency, or Primary IGFD. We define the indication Primary IGFD to mean a child who has a height standard deviation score, or Height SDS, and an IGF-1 standard deviation score, or IGF-1 SDS, of less than minus two, and the indication Severe Primary IGFD to mean a child who has a Height SDS and IGF-1 SDS of minus three or less, in each case in the presence of normal or elevated levels of growth hormone. We submitted an NDA, seeking approval of long-term rhIGF-1 replacement therapy for Severe Primary IGFD to the FDA, in February 2005 based on Phase III clinical trial data.

Tercica, Inc. was formed in December 2001 as a Delaware corporation. In March 2002, Tercica, Inc. acquired an immaterial amount of assets, including intellectual property rights, from Tercica Limited, a New Zealand company that had been formed in October 2000. Tercica Limited then made a liquidating distribution to its stockholders in March 2002. Tercica Limited and Tercica, Inc. shared a common business strategy and overlapping stockholders. As such, our financial statements include the activities of Tercica Limited, as the predecessor to Tercica, Inc., from October 1, 2000.

## **Table of Contents**

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

As of December 31, 2004, we had approximately \$52.0 million in cash, cash equivalents and short-term investments. We have funded our operations since inception through the private placement of equity securities and public offerings of common stock. In 2002, we raised \$20.0 million through the sale of shares of our Series A preferred stock. In 2003, we raised \$43.8 million through the sale of shares of our Series B preferred stock. On March 22, 2004, we completed our initial public offering of common stock in which we raised net cash proceeds of approximately \$43.1 million and received an additional \$6.9 million of net cash proceeds on April 2, 2004 in connection with the underwriters exercise of their option to purchase additional shares. On February 11, 2005, we completed our follow-on public offering of common stock in which we raised net cash proceeds of approximately \$51.2 million.

On January 21, 2005, we entered into a Loan Agreement, or Loan Agreement, with Venture Leasing & Lending IV, Inc., or VLL, under which we have the option to draw down funds in the aggregate principal amount of up to \$15,000,000. We paid a \$75,000 fee as part of this Loan Agreement and issued VLL 75,000 shares of our common stock, which are held in escrow, subject to certain conditions. The \$75,000 fee will be refunded to us if we borrow funds under this facility. The option to draw funding under this Loan Agreement will continue to be available to us through June 30, 2005, subject to certain extensions and additional issuances of up to a maximum of 150,000 shares of our common stock. Any funding drawn down will have a three-year term from the date of funding. Any borrowings are subject to cash payments of principal and interest at an interest rate of 7.5% per annum, as well as a terminal interest payment at the end of the three year term equal to 9.2% of the aggregate principal amount borrowed during the term of the loan. Under the terms of the Loan Agreement and an intellectual property security agreement, we would grant to VLL a first priority security interest on certain assets, including limited intellectual property assets, in the event any borrowings occur. We may terminate this facility at any time without penalty as long as no borrowings have been drawn down from the facility.

## ***Revenues***

We have not generated any operating revenues since our inception and do not expect to generate any revenue from the sale of our current product candidate, Increlex, until at least late 2005, if at all.



## **Table of Contents**

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

Research and development expenses consist primarily of contract manufacturing expenses, clinical activities, regulatory activities, payroll and related costs and non-cash stock compensation. Our research and development activities are primarily focused on validating our manufacturing process at our contract manufacturer, using that process to make drug product suitable for clinical use and commercial sale and development activities related to Severe Primary IGFD and Primary IGFD. Because we licensed non-clinical, clinical and manufacturing data and know-how related to rhIGF-1 from Genentech in 2002, we did not incur significant development expenses prior to 2002. However, we expect to fund our own development activities and will continue to incur significant costs in the future. During 2003, our research and development activities were primarily focused on two projects: the transfer of our rhIGF-1 manufacturing process and the development project for Primary IGFD. At the end of 2003, we began to manage the development project for Severe Primary IGFD as a separate project from the development project for Primary IGFD and completed the technology transfer of our manufacturing process to our contract manufacturer. Our primary focus in research and development in 2004 was associated with the establishment and validation of our rhIGF-1 manufacturing process at our contract manufacturer and preparations for the anticipated NDA filing in Severe Primary IGFD. With our NDA submitted to the FDA in February 2005, we expect the remainder of 2005 to be focused on the preparation for pre-approval inspections at our contract manufacturer, the completion of our development project for Severe Primary IGFD and increased activities associated with our development project for Primary IGFD. In 2005, we expect that our project costs will be focused on FDA inspection preparation activities at our contract manufacturers and costs related to clinical trials in Primary IGFD. 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, non-cash stock compensation, facility costs, insurance, information technology, legal fees and accounting services. Other costs include sales and marketing activities such as pre-launch planning and medical education activities. During 2004, we continued to expand our corporate staffing and infrastructure and initiated planning for sales and marketing activities. We expect selling, general and administrative expenses in 2005 to increase due to associated costs with the annualized effect of 2004 personnel additions, personnel additions in 2005, increased pre-launch activities and the activities associated with the implementation of Section 404 of the Sarbanes-Oxley Act of 2002.

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

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States, or GAAP, 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.

---

## **Table of Contents**

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

### ***Stock Compensation***

We account for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB No. 25*, and related interpretations and have adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation*.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. We have elected to continue to follow the intrinsic value method of accounting as prescribed by APB No. 25. The information regarding net loss as required by SFAS No. 123 has been determined as if we had accounted for our employee stock options under the fair value method of that statement. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years vesting.

Stock compensation expense, which is a non-cash charge, results from stock option grants at exercise prices below the reassessed fair value of the underlying common stock resulting in our recording stock compensation associated with these grants. Stock compensation expense is amortized over the vesting period of the underlying option, generally four years. From inception through January 31, 2004, we recorded deferred stock compensation of \$10.9 million. At December 31, 2004, we had a total of \$6.4 million of deferred stock compensation remaining to be amortized over the vesting period of the stock options of approximately three years. In the year ended December 31, 2004, we reversed \$0.8 million of previously recognized stock compensation due to the forfeiture of unvested stock options from employee terminations. We have not recorded any additional deferred stock compensation subsequent to January 31, 2004.

The total unamortized deferred stock compensation recorded for all option grants through January 31, 2004, net of the amounts reversed associated with forfeited stock options will be amortized as follows: \$2.6 million for the year ending December 31, 2005; \$2.5 million for the year ending December 31, 2006; and \$1.3 million for the year ending December 31, 2007.

### ***Recent Accounting Development***

On December 16, 2004, the FASB issued an amendment to SFAS No. 123, *Share-Based Payment*, ( SFAS No. 123R ), which is effective for public companies in periods beginning after June 15, 2005. We are required to implement the proposed standard no later than the quarter that begins July 1, 2005. SFAS No. 123R addresses the accounting

---

**Table of Contents**

for transactions in which an enterprise receives employee services in exchange for equity instruments of the enterprise or liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, and requires instead that such transactions be accounted for using a fair-value-based method. Companies are required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include modified prospective and modified retrospective adoption options. Under the modified prospective method, compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. The modified retrospective method includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures, either (a) all prior periods presented or (b) prior interim periods of the year of adoption. We are currently evaluating option valuation methodologies and assumptions and therefore have not fully assessed the impact of adopting SFAS No. 123R. We have not yet determined the method of adoption or the effect of adopting SFAS 123R, and we have not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately adopted by us. We expect to continue to grant stock-based compensation to employees, and the adoption of the new standard may have a material impact on our results of operations.

***Acquired In-Process Research and Development***

Acquired in-process research and development relates to in-licensed technology, intellectual property and know-how. The nature of the efforts for completion of research and development activities generally include completion of clinical trials, completion of manufacturing validation, interpretation of clinical and preclinical data and obtaining marketing approval from the FDA and other foreign regulatory bodies, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist with timely completion of development projects, including clinical trial results, manufacturing process development results, and 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, we charge in-licensed intellectual property and licenses for unapproved products to acquired in-process research and development.

---

**Table of Contents**

***Clinical Trial Expenses***

In the normal course of business, 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. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials are recognized based on our estimate of the degree of completion of the event or events as specified in each clinical study or trial contract.

**Results of Operations**

***Year Ended December 31, 2004 compared to Year Ended December 31, 2003***

***Research and Development Expenses.*** Research and development expenses increased to \$27.9 million for the year ended December 31, 2004, from \$19.2 million for the same period in 2003. The \$27.9 million in expenses were comprised of project costs associated with the establishment and validation of our rhIGF-1 manufacturing process at Cambrex Baltimore totaling \$14.7 million, internal personnel and other costs totaling \$8.2 million, and our development projects for Severe Primary IGFD and Primary IGFD totaling \$5.0 million.

In the year ended December 31, 2004, project costs for the establishment and validation of our rhIGF-1 manufacturing process increased \$1.5 million from the same period in 2003, and were driven primarily by production and validation activities at Cambrex Baltimore. The costs associated with our development projects for Severe Primary IGFD and Primary IGFD for the year ended December 31, 2004 increased by approximately \$3.5 million from the same period in 2003. The Severe Primary IGFD and Primary IGFD project costs related primarily to conducting several small studies, the analyses of clinical trial data, NDA filing preparations for Severe Primary IGFD and start-up costs related to the trials in Primary IGFD. Personnel costs for the year ended December 31, 2004 increased \$3.6 million from the same period in 2003. In 2005, we expect that our project costs will be focused on inspection preparation activities at our contract manufacturers and costs related to clinical trials in Primary IGFD.

***Selling, General and Administrative Expenses.*** Selling, general and administrative expenses increased to \$12.6 million for the year ended December 31, 2004, from \$4.8 million for the same period in 2003. This increase of \$7.7 million was attributable to increased personnel costs of \$4.8 million, increased sales and marketing expenses of \$1.6 million and increased corporate administration expenses such as legal, insurance, information technology and other expenses of \$1.3 million. We expect selling, general and administrative expenses in 2005 to increase due to associated costs with the annualized effect of 2004 personnel additions, personnel additions in 2005, increased pre-launch activities and the activities associated with the implementation of Section 404 of the Sarbanes-Oxley Act of 2002.

## **Table of Contents**

*Acquired In-Process Research and Development.* Acquired in-process research and development expense decreased to approximately \$1.4 million for the year ended December 31, 2004 from \$1.7 million in the same period in 2003. The costs in 2004 resulted from a \$1.2 million payment to Genentech related to the exclusive license to Genentech's worldwide rights, including the United States, to IGF-1 combined with IGFBP-3 for all indications, other than diseases and conditions of the central nervous system, and \$250,000 of costs resulting from the execution of a patent license. The costs in 2003 resulted from the execution of our International License and Collaboration Agreement with Genentech and were comprised of cash of \$1.7 million. This agreement allows us to commercialize Increlex outside of the United States for all indications other than diseases or conditions of the central nervous system.

*Interest and Other Income, net.* Interest and other income, net, increased to \$0.9 million for the year ended December 31, 2004, from \$0.3 million for the same period in 2003. The increase was due to interest on higher average cash, cash equivalents and short-term investment balances as a result of the cash proceeds received from the issuance of Series B preferred stock in July 2003 and from our initial public offering in March 2004.

*Preferred Stock Dividend.* In July 2003, we sold 8,830,646 shares of Series B preferred stock at \$5.00 per share, for total cash proceeds of approximately \$43.8 million. The difference between the preferred stock sales price and the reassessed value per share of common stock on the transaction date resulted in a beneficial conversion feature in the amount of \$44.2 million. The beneficial conversion feature has been reflected as a preferred stock dividend in the statement of operations for the year ended December 31, 2003.

### ***Year Ended December 31, 2003 compared to Year Ended December 31, 2002***

Prior to April 2002, our operations consisted primarily of negotiating our U.S. License and Collaboration Agreement with Genentech and our costs were minimal, largely consisting of staffing and payroll related costs. We expanded our research and development and general and administrative activities following the execution of our U.S. license with Genentech.

*Research and Development Expenses.* Research and development expenses increased to \$19.2 million for the year ended December 31, 2003 from \$2.0 million for the year ended December 31, 2002. Costs associated with the transfer and validation of our rhIGF-1 manufacturing process to Cambrex Baltimore totaled \$13.3 million for the year ended December 31, 2003, which represented a \$12.7 million increase from the year ended December 31, 2002. Costs of \$1.4 million associated with our rhIGF-1 development project for Primary IGFD for the year ended December 31, 2003 increased by approximately \$913,000 from December 31, 2002. The Primary IGFD project costs related primarily to the review and analyses of the Phase III clinical trial data in preparation for the NDA filing. Other costs for the year ended December 31, 2003 of \$4.5 million increased \$3.5 million from December 31, 2002, which primarily related to increased personnel costs of \$3.1 million.

## **Table of Contents**

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased to \$4.8 million for the year ended December 31, 2003 from \$2.0 million for the year ended December 31, 2002. The increase was primarily attributable to higher payroll and non-cash stock compensation expenses of \$1.7 million, legal, consulting and professional fees of \$612,000 and general office expenses of \$557,000.

*Acquired In-Process Research and Development.* Acquired in-process research and development expense decreased to \$1.7 million for the year ended December 31, 2003 from \$5.1 million for the year ended December 31, 2002. The costs in 2002 resulted from our U.S. License and Collaboration Agreement with Genentech and were comprised of cash and 1,017,666 shares of our Series A preferred stock for total consideration of \$5.1 million. In exchange, we received from Genentech certain preclinical and clinical data, manufacturing technology and know-how, and intellectual property rights to develop and commercialize rhIGF-1. The costs in 2003 resulted from the execution of our International License and Collaboration Agreement with Genentech and were comprised of cash of \$1.7 million. This agreement allows us to commercialize rhIGF-1 outside of the United States.

*Interest Expense.* Interest expense decreased to \$0 for the year ended December 31, 2003 from \$106,000 for the year ended December 31, 2002. The interest expense in 2002 related to the estimated fair value of warrants issued in conjunction with a convertible note we entered into in January 2002.

*Interest and Other Income, net.* Interest income increased to \$327,000 for the year ended December 31, 2003 from \$177,000 for the year ended December 31, 2002. The increase was due to interest on higher average cash and cash equivalents balances.

*Preferred Stock Dividend.* In July 2003, we sold 8,830,646 shares of Series B preferred stock at \$5.00 per share, for total cash proceeds of approximately \$43.8 million. The difference between the preferred stock sales price and the reassessed value per share of the common stock on the transaction date resulted in a beneficial conversion feature in the amount of \$44.2 million. The beneficial conversion feature has been reflected as a preferred stock dividend in the statement of operations for the year ended December 31, 2003.

## **Liquidity and Capital Resources**

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

As of December 31, 2004, we had an accumulated deficit of \$119.5 million, which is primarily comprised of \$76.5 million of accumulated net losses and \$44.2 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 with net cash proceeds of \$66.4 million in private equity financings and \$50.0 million from our initial public offering of common stock.

On February 11, 2005, we completed our follow-on public offering of common stock in which we raised net cash proceeds of approximately \$51.2 million.



---

**Table of Contents**

***Cash Flow***

Cash, cash equivalents and short-term investments totaled \$52.0 million at December 31, 2004, compared to \$37.3 million at December 31, 2003, and \$15.9 million at December 31, 2002. The increase in 2004 was primarily due to net proceeds of \$50.0 million from the issuance of our common stock in our initial public offering, partially offset by cash used in operating activities of \$34.7 million. The increase in net cash used in operating activities for 2004 was due to increased personnel and infrastructure costs, the establishment and validation of our rhIGF-1 manufacturing process at Cambrex Baltimore, and our development projects for Severe Primary IGF1 and Primary IGF1. The increase in cash, cash equivalents and short-term investments in 2003 was primarily due to net proceeds from the issuance of Series B preferred stock of \$43.8 million and proceeds from issuance of common stock associated with the early exercise of employee stock options of \$511,000, partially offset by cash used to fund operations of \$20.2 million and purchases of property and equipment of \$2.3 million. Included in cash used in operations of \$20.2 million at December 31, 2003 was a \$4.9 million increase in accounts payable that consisted primarily of amounts due to Cambrex Baltimore in connection with the transfer and validation of our rhIGF-1 manufacturing process.

Net cash used in investing activities totaled \$3.4 million in the year ended December 31, 2004, compared to \$38.2 million in the year ended December 31, 2003, and \$106,000 in the year ended December 31, 2002. Net cash used in investing activities represent purchases, sales and maturities of investments and purchases of property and equipment. Net purchases of short-term investments were \$3.0 million in 2004, a decrease of \$32.8 million from 2003. The decrease in net purchases of short-term investments was due to timing of maturities, sales and purchases of short-term investments. In 2003, we did not have any short-term investments. Purchases of property and equipment were \$407,000, \$2.3 million and \$106,000 in 2004, 2003 and 2002, respectively.

Net cash provided by financing activities for the year ended December 31, 2004 was \$50.3 million, compared to \$44.5 million for the year ended December 31, 2003, and \$20.6 million for the year ended December 31, 2002. Net cash provided by financing activities primarily relate to net proceeds received from our initial public offering and issuance of preferred stock and proceeds received from the issuance of common stock under our employee stock purchase and stock option plans. Net proceeds received from our initial public offering were \$50.0 million in 2004, and net proceeds received from the issuance of preferred stock were \$43.8 million and \$20.0 million for 2003 and 2002, respectively. Net cash received from the issuance of common stock under our employee stock purchase and stock options plans were \$300,000, \$517,000 and \$82,000 in 2004, 2003 and 2002, respectively.

***Senior Credit Facility***

On January 21, 2005, we entered into a Loan Agreement with VLL under which we have the option to draw down funds in the aggregate principal amount of up to \$15,000,000. We paid a \$75,000 fee as part of this Loan Agreement and issued VLL 75,000 shares of our common stock, which are held in escrow, subject to certain



## **Table of Contents**

conditions. The \$75,000 fee will be refunded to us if we borrow funds under this facility. The option to draw funding under this Loan Agreement will continue to be available to us through June 30, 2005, subject to certain extensions and additional issuances of up to a maximum of 150,000 shares of our common stock. Any funding drawn down will have a three-year term from the date of funding. Any borrowings are subject to cash payments of principal and interest at an interest rate of 7.5% per annum, as well as a terminal interest payment at the end of the three-year term equal to 9.2% of the aggregate principal amount borrowed during the term of the loan. Under the terms of the Loan Agreement and an intellectual property security agreement, we would grant to VLL a first priority security interest on certain assets, including limited intellectual property assets, in the event any borrowings occur. We may terminate this facility at any time without penalty as long as no borrowings have been drawn down from the facility.

## ***Litigation***

On December 20, 2004, we initiated patent infringement proceedings against Avecia Limited and Insmmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. On December 23, 2004, we, with Genentech, initiated patent infringement proceedings against Insmmed Incorporated in the United States District Court for the Northern District of California. We cannot predict the outcome of our litigation against Avecia Limited and Insmmed Incorporated in the United Kingdom or the outcome of our litigation against Insmmed in the United States. Moreover, we cannot predict the cost of such litigation, which may require a substantial diversion of our financial assets and other resources and consequently prevent us from allocating sufficient resources to the development of our rhIGF-1 programs, and which may have a material adverse effect on our business. In addition, if the outcome of our litigation in the United Kingdom is not favorable to us, we are likely to be found liable for the opposing parties' costs incurred in connection with the litigation, and we could be found liable for an award of additional damages to the opposing parties if the court decides that our claims of patent infringement are without sufficient merit or not pursued in good faith. If in our litigation in the United States, the court decides Insmmed prevails, and Insmmed establishes by clear and convincing evidence that the case is exceptional (e.g., our claims of patent infringement were not pursued in good faith), we could be liable for an award of the opposing party's costs and legal fees incurred in connection with the litigation and/or an award of other damages. Any such award or awards to the opposing party or parties could substantially increase our costs and exacerbate the negative impact that an unfavorable outcome in the case(s) could have on our business. Further, it is not uncommon in cases of this kind for a defendant to assert counterclaims, which could significantly increase our costs, potential liability for damages, and other risks arising from these lawsuits, and a court could find us liable for any such damages caused by Genentech as well.

**Table of Contents*****Contractual Obligations and Commercial Commitments***

Our contractual obligations as of December 31, 2004 were as follows (in thousands):

	<b>Payments due by period</b>				
	<b>Total</b>	<b>Less than</b>	<b>1-3 years</b>	<b>3-5 years</b>	<b>More than</b>
		<b>1 year</b>			<b>5 years</b>
Operating lease commitments	\$304	\$243	\$43	\$18	\$

Our commitments for operating leases include leases for real estate covering our present facility and office equipment.

In March 2005, we entered into a new lease agreement for a facility in Brisbane, California. The term of the lease is 75 months, and rent is abated for the first 15 months. Under this lease agreement, the future minimum lease commitment for the years ending December 31, 2005, 2006, 2007, 2008 and 2009 are \$0, \$138,000, \$677,000, \$711,000 and \$745,000, respectively.

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 \$1.5 million would be due if milestones relating to the initial product approvals of rhIGF-1 for Severe Primary IGFD in the United States and 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.

Under our agreement with Cambrex Baltimore, we are obligated to reimburse Cambrex Baltimore on a time and materials and per batch basis in connection with the establishment and validation of our rhIGF-1 manufacturing process. We estimate that our total purchase commitment to Cambrex Baltimore is approximately \$3.6 million through December 31, 2005.

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

We believe that our cash, cash equivalents and short-term investments as of December 31, 2004 of \$52.0 million, together with the net proceeds of our follow-on public offering completed in February 2005 and our senior credit facility, will be sufficient to meet our projected operating requirements through at least the end of 2006. We plan to make significant expenditures to operate our rhIGF-1 drug substance manufacturing process at Cambrex Baltimore in a manner consistent with current good manufacturing process ( cGMP ), as well as to support our marketing, sales, regulatory and clinical trial activities. As of December 31, 2004, the establishment and validation of our rhIGF-1 manufacturing process and the development projects for Severe Primary IGFD were substantially complete and we filed our NDA for Severe Primary IGFD in February 2005. In October 2004, we initiated a Phase III clinical trial for Primary IGFD and expect to initiate additional clinical trials. Our projects may be subject to change from time to time as we evaluate our research and development priorities and available resources. These projects may also yield varying results that could delay, limit or change the timing of a project s advancement through various stages of product development,



## **Table of Contents**

and significantly impact the costs to be incurred, and time involved, in bringing a project to completion. As a result, the costs to complete such projects, as well as the timing of net cash outflows, are not reasonably estimable.

Our future capital needs and the adequacy of our available funds will depend on many factors, including:

the costs, timing, scope of domestic and international regulatory approvals for rhIGF-1;

our ability to market and sell rhIGF-1;

the commercial readiness of our rhIGF-1 manufacturing operations at Cambrex Baltimore, including the success of our cGMP production activities;

the success of drug product manufacturing and results of stability and product comparability studies performed at third-party contractors;

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

the pace of expansion of administrative expenses; and

the status of competing products.

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 manufacturing operations and clinical trials may not be favorable. Further, data from clinical trials is subject to varying interpretation, and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, our development projects are subject to risks, uncertainties and changes that may significantly impact cost projections and timelines. As a result, our capital requirements may increase in future periods.

We expect that we will require and attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources. We have no commitments for any additional financings and additional funding may not be available to finance our operations when needed or on acceptable terms. Additional funding may also result in dilution to our stockholders.

### **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 commercial paper, money market funds and corporate debt securities. Our cash and cash equivalents through December 31, 2004 included liquid money market accounts. Our short-term investments included readily marketable debt securities. Due to the short-term nature of these instruments, a 10%

movement in market interest rates would not have a significant negative impact on the total value of our portfolio as of December 31, 2004.

**Table of Contents**

**Item 8. Financial Statements and Supplementary Data.**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	64
<u>Balance Sheets</u>	65
<u>Statements of Operations</u>	66
<u>Statements of Stockholders' Equity (Deficit)</u>	67
<u>Statements of Cash Flows</u>	69
<u>Notes to Financial Statements</u>	70

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders

Tercica, Inc.

We have audited the accompanying balance sheets of Tercica, Inc. (a development stage company) as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2004, and for the period from October 1, 2000 (inception) through December 31, 2004. 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, and for the period from October 1, 2000 (inception) through December 31, 2004, in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Palo Alto, California

March 18, 2005

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****BALANCE SHEETS****(In thousands, except share and per share data)**

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,126	\$ 1,949
Short-term investments	37,875	35,364
Prepaid expenses and other current assets	705	2,772
<b>Total current assets</b>	<b>52,706</b>	<b>40,085</b>
Property and equipment, net	2,266	2,314
Other assets	50	85
<b>Total assets</b>	<b>\$ 55,022</b>	<b>\$ 42,484</b>
<b>Liabilities and stockholders equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 3,967	\$ 5,351
Accrued expenses	3,032	1,214
Liability for early exercise of stock options	165	174
<b>Total current liabilities</b>	<b>7,164</b>	<b>6,739</b>
Liability for early exercise of stock options noncurrent portion	181	306
<b>Commitments and contingencies (Note 7)</b>		
Series A convertible preferred stock, \$0.001 par value: no shares were authorized at December 31, 2004; 6,466,667 shares authorized, 6,466,662 shares issued and outstanding, aggregate liquidation preference of \$25,866,648 at December 31, 2003		24,853
Series B convertible preferred stock, \$0.001 par value: no shares were authorized at December 31, 2004; 8,830,650 shares authorized, 8,830,646 shares issued and outstanding, aggregate liquidation preference of \$44,153,230 at December 31, 2003		43,784
<b>Stockholders equity (deficit):</b>		
Preferred stock, \$0.001 par value: 5,000,000 shares authorized, no shares issued and outstanding at December 31, 2004; no shares authorized at December 31, 2003		
Common stock, \$0.001 par value: 100,000,000 and 20,500,000 shares authorized at December 31, 2004 and 2003, respectively; 24,172,162 and 2,083,741 shares issued and outstanding at December 31, 2004 and 2003, respectively	24	2
Additional paid-in capital	173,621	51,308
Deferred stock compensation	(6,388)	(5,984)



Edgar Filing: TERCICA INC - Form 10-K

Accumulated other comprehensive loss	(72)	(18)
Deficit accumulated during the development stage	(119,508)	(78,506)
	<u>          </u>	<u>          </u>
Total stockholders' equity (deficit)	47,677	(33,198)
	<u>          </u>	<u>          </u>
Total liabilities and stockholders' equity (deficit)	\$ 55,022	\$ 42,484
	<u>          </u>	<u>          </u>

*See accompanying notes.*

Table of Contents

## TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

## STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

	Year ended December 31,			Period from October 1, 2000 (inception) through December 31, 2004
	2004	2003	2002	
Costs and expenses:				
Research and development*	\$ 27,918	\$ 19,246	\$ 1,974	\$ 49,625
Selling, general and administrative*	12,552	4,834	1,978	19,990
Acquired in-process research and development	1,417	1,670	5,071	8,158
Total costs and expenses	(41,887)	(25,750)	(9,023)	(77,773)
Interest expense			(106)	(106)
Interest and other income, net	885	327	177	1,399
Net loss	(41,002)	(25,423)	(8,952)	(76,480)
Deemed dividend related to beneficial conversion feature of convertible preferred stock		(44,153)		(44,153)
Net loss allocable to common stockholders	\$ (41,002)	\$ (69,576)	\$ (8,952)	\$ (120,633)
Basic and diluted net loss per share allocable to common stockholders	\$ (2.12)	\$ (38.59)	\$ (5.76)	
Shares used to compute basic and diluted net loss per share	19,301,702	1,803,166	1,555,258	
<b>* Includes non-cash stock-based compensation expense as follows:</b>				
Research and development	\$ 1,386	\$ 791	\$ 4	\$ 2,181
Selling, general and administrative	1,455	256	2	1,713
Total	\$ 2,841	\$ 1,047	\$ 6	\$ 3,894

*See accompanying notes.*



**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)****(In thousands, except share and per share data)**

	<u>Class A and B</u>		<u>Common Stock</u>		<u>Accumulated</u>			<u>Total</u>	
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Additional Paid-in Capital</u>	<u>Deferred Compensation</u>	<u>Other Comprehensive Income (Loss)</u>		<u>Deficit During Development Stage</u>
<b>Balances at October 1, 2000 (inception)</b>		\$		\$	\$	\$	\$	\$	\$
Issuance of Tercica Limited Class A shares to founders for cash and intellectual property in March 2001	162,360	67							67
Issuance of Tercica Limited Class B shares to founders for cash and intellectual property in March 2001	725,449	465							465
Comprehensive loss:									
Foreign currency translation adjustment							(5)		(5)
Net loss								(294)	(294)
Comprehensive loss									(299)
<b>Balances at March 31, 2001</b>	887,809	532					(5)	(294)	233
Issuance of Tercica Limited Class B shares at \$16.12 per share to founders for cash in July 2001	37,282	601							601
Comprehensive loss:									
Foreign currency translation adjustment							22		22
Net loss								(808)	(808)
Comprehensive loss									(786)
<b>Balances at December 31, 2001</b>	925,091	1,133					17	(1,102)	48
Issuance of common stock to founders at \$0.0062 per share in February 2002			1,480,137	1	8				9
Liquidating distribution to shareholders and retirement of all outstanding Tercica Limited shares in March 2002	(925,091)	(1,133)						1,124	(9)
Issuance of common stock to a founder and employee at \$0.0062 per share in February and May 2002			333,598	1	1				2
Issuance of stock options to consultants in exchange for services					6				6
Comprehensive loss:									
Reversal of foreign currency translation adjustment upon liquidation of Tercica Limited							(17)		(17)
Net loss								(8,952)	(8,952)
Comprehensive loss									(8,969)
<b>Balances at December 31, 2002 (carried forward)</b>		\$	1,813,735	\$ 2	\$ 15	\$	\$	(8,930)	(8,913)

*See accompanying notes.*

Table of Contents

## TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

## STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands, except share and per share data)

	Class A and B		Common Stock		Additional Paid-in Capital	Deferred Stock Compensation	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During Development Stage	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount					
<b>Balances at December 31, 2002 (brought forward)</b>		\$	1,813,735	\$ 2	\$ 15	\$	\$ (8,930)	\$ (8,913)	
Vesting of common stock from early exercises of stock options			255,739		102			102	
Issuance of common stock			14,267		6			6	
Deferred stock compensation					6,888	(6,888)			
Amortization of deferred stock compensation						904		904	
Issuance of stock options to consultants in exchange for services					144			144	
Beneficial conversion feature related to issuance of Series B convertible preferred stock					44,153			44,153	
Deemed dividend related to beneficial conversion feature of convertible preferred stock							(44,153)	(44,153)	
Comprehensive loss:									
Unrealized loss on marketable securities							(18)	(18)	
Net loss							(25,423)	(25,423)	
Comprehensive loss								(25,441)	
<b>Balances at December 31, 2003</b>			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					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)	

Edgar Filing: TERCICA INC - Form 10-K

Comprehensive loss									(41,056)
<b>Balances at December 31, 2004</b>	\$	24,172,162	\$ 24	\$ 173,621	\$ (6,388)	\$ (72)	\$ (119,508)	\$	47,677

*See accompanying notes.*

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

	<u>Year ended December 31,</u>			<b>Period from</b>
	<u>2004</u>	<u>2003</u>	<u>2002</u>	<b>October 1, 2000 (inception) through December 31, 2004</b>
<b>Cash flows from operating activities:</b>				
Net loss	\$ (41,002)	\$ (25,423)	\$ (8,952)	\$ (76,480)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	446	92	9	557
Property and equipment written-off	9		8	17
Amortization of deferred stock compensation, net of forfeitures	2,734	904		3,638
Amortization of premiums relating to available-for-sale securities	454	471		925
Stock compensation to consultants in exchange for services	107	143	6	256
Issuance of warrants in connection with convertible note			105	105
Issuance of stock in exchange for intellectual property				130
Acquired in-process research and development			4,071	4,071
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	2,101	(2,486)	(359)	(755)
Accounts payable	(1,384)	4,943	402	3,968
Accrued expenses	1,818	1,125	(54)	3,032
Net cash used in operating activities	<u>(34,717)</u>	<u>(20,231)</u>	<u>(4,764)</u>	<u>(60,536)</u>
<b>Cash flows from investing activities:</b>				
Purchases of property and equipment	(407)	(2,298)	(106)	(2,840)
Purchases of available-for-sale securities	(113,184)	(63,653)		(176,837)
Proceeds from sale of available-for-sale securities	110,165	27,800		137,965
Net cash used in investing activities	<u>(3,426)</u>	<u>(38,151)</u>	<u>(106)</u>	<u>(41,712)</u>
<b>Cash flows from financing activities:</b>				
Net proceeds from issuance of Class A and B shares				1,004
Liquidating distribution to Tercica Limited shareholders			(9)	(9)
Net proceeds from issuance of preferred stock		43,784	20,016	63,800
Proceeds from issuance of convertible note			500	500
Proceeds from issuance of Series A convertible preferred stock for exercise of warrants		160		160
Proceeds from issuance of common stock, excluding early exercised options	260	6	11	277
Proceeds from early exercised options	40	511	71	622
Net proceeds from initial public offering of common stock	50,020			50,020
Net cash provided by financing activities	<u>50,320</u>	<u>44,461</u>	<u>20,589</u>	<u>116,374</u>
Effect of exchange rate changes on cash			(17)	
Net increase (decrease) in cash and cash equivalents	<u>12,177</u>	<u>(13,921)</u>	<u>15,702</u>	<u>14,126</u>
Cash and cash equivalents, beginning of period	1,949	15,870	168	



Edgar Filing: TERCICA INC - Form 10-K

Cash and cash equivalents, end of period	\$ 14,126	\$ 1,949	\$ 15,870	\$ 14,126
<b>Supplemental schedule of noncash activities:</b>				
Issuance of stock in exchange for intellectual property	\$	\$	\$	\$ 129
Issuance of Series A convertible preferred stock to a collaboration partner in exchange for acquired in-process research and development	\$	\$	\$ 4,071	\$ 4,071
Issuance of warrants in connection with convertible note	\$	\$	\$ 106	\$ 106
Issuance of warrants as commissions in connection with Series A preferred stock financing	\$	\$	\$ 41	\$ 41
Conversion of convertible note into Series A convertible preferred stock	\$	\$	\$ 500	\$ 500
Issuance of common stock from vesting of early exercises of stock options	\$ 174	\$ 102	\$	\$ 276
Deferred stock compensation, net of forfeitures	\$ 3,138	\$ 6,888	\$	\$ 10,026
Deemed dividend related to beneficial conversion feature of convertible preferred stock	\$	\$ 44,153	\$	\$ 44,153
Conversion of Series A and B convertible preferred stock into common stock	\$ 68,636	\$	\$	\$ 68,636

*See accompanying notes.*

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS**

**1. Company and Basis of Presentation**

**Basis of Presentation**

Tercica Limited, a New Zealand Company, was formed in October 2000. Tercica Medica, Inc. was incorporated in Delaware in December 2001, adopted the calendar year as its fiscal year and subsequently changed its name in September 2003 to Tercica, Inc. (the Company). In early 2002, the Company acquired (at amounts approximating Tercica Limited's historical net book value) an immaterial amount of assets, including intellectual property rights, from Tercica Limited as its operations were moved from New Zealand to California. In March 2002, Tercica Limited made a final, immaterial distribution to its stockholders in connection with its legal liquidation.

These development stage financial statements and accompanying notes include the results of operations from the inception of Tercica Limited in October 2000 as both entities were under common control as evidenced by the following factors: (i) all of the investors of Tercica Limited were founding stockholders of the Company, (ii) substantially all of the employees of Tercica Limited became employees of the Company, (iii) the nearly identical business plans adopted by both entities and (iv) the commencement of negotiations to obtain the license for recombinant human insulin-like growth factor-1 ( rhIGF-1 ) from Genentech, Inc. by Tercica Limited and the completion of those negotiations by the Company.

The Company is a biopharmaceutical company focused on the development of rhIGF-1 for the treatment of short stature and other related endocrine system disorders. The Company licensed from Genentech, Inc. ( Genentech ) its rights to rhIGF-1 for a broad range of indications, including for short stature worldwide and diabetes in the United States. The Company has Phase III clinical data for the use of rhIGF-1 in Severe Primary IGF-1 deficiency ( IGFD ). The Company submitted a New Drug Application ( NDA ) with the U.S. Food and Drug Administration in February 2005 for this indication.

The Company is considered to be in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital.

**Initial Public Offering**

On March 22, 2004, the Company completed its initial public offering of 5,500,000 shares of its common stock, at \$9.00 per share. Net cash proceeds of the initial public offering were approximately \$43,116,000, after deducting underwriter discounts, commissions and other offering expenses. In conjunction with the closing of the initial public offering, all of the Company's outstanding shares of Series A and Series B convertible preferred stock outstanding at the time of the offering were automatically converted into 15,297,308 shares of common stock.



**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

On March 30, 2004, the underwriters of the Company's initial public offering exercised in full their over-allotment option for 825,000 shares of its common stock. On April 2, 2004, the Company received the net cash proceeds of approximately \$6,905,000, after deducting underwriter discounts, commissions and other offering expenses.

In connection with the Company's initial public offering, all outstanding warrants to purchase 146,250 shares of common stock were net exercised resulting in 139,750 shares of common stock issued, with the warrant for the remaining 6,500 shares relinquished as non-cash payment.

**Follow-on Public Offering**

On February 11, 2005, the Company completed a follow-on public offering of 6,900,000 shares of its common stock, at \$8.00 per share, including the exercise of the over-allotment option by the underwriters. Net cash proceeds from this offering were approximately \$51,200,000 after deducting underwriter discounts and other offering expenses.

**Need to Raise Additional Capital**

The Company has incurred significant net losses and negative cash flows from operations since its inception. At December 31, 2004, the Company had an accumulated deficit of \$119,508,000. After considering the net cash proceeds obtained during February 2005, as described above, management believes that currently available resources, including cash, cash equivalents and short-term investments and available credit facility (see Note 11), will provide sufficient funds to enable the Company to meet its obligations through at least the end of 2006. If anticipated operating results are not achieved, however, management believes that planned expenditures may need to be reduced, extending the time period over which the currently available resources will be adequate to fund the Company's operations. The Company intends to raise additional funds through the issuance of equity securities, if available on terms acceptable to the Company.

**2. Summary of Significant Accounting Policies**

**Use of Estimates**

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

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.

### **Deferred Offering Costs**

In connection with its initial public offering, the Company had \$2,135,000 of deferred offering costs included in prepaid expenses and other current assets in the accompanying balance sheet at December 31, 2003.

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**Reverse Stock Split**

The Company effected a 1-for-4 reverse split of its convertible preferred and common stock on November 5, 2003. All share and per share amounts have been retroactively restated in the accompanying financial statements and notes for all periods presented.

**Concentration of Credit Risk**

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.

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

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.

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.

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

**December 31, 2004**

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Available-for-sale debt securities maturing within 1 year:				
Corporate bonds	\$ 5,815	\$	\$ (14)	\$ 5,801
Commercial paper	9,346		(2)	9,344
Federal agency bonds	19,759		(26)	19,733
Municipal bonds	9,753		(30)	9,723
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total available-for-sale debt securities	\$ 44,673	\$	\$ (72)	\$ 44,601
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)**

	December 31, 2003			Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
Available-for-sale debt securities maturing within 1 year:				
Corporate bonds	\$ 14,758	\$	\$ (13)	\$ 14,745
Federal agency bonds	4,353		(3)	4,350
Floating rate bonds	10,100			10,100
Municipal bonds	6,171	4	(6)	6,169
<b>Total available-for-sale debt securities</b>	<b>\$ 35,382</b>	<b>\$ 4</b>	<b>\$ (22)</b>	<b>\$ 35,364</b>

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

	December 31,	
	2004	2003
Cash	\$ 7,400	\$ 1,949
Cash equivalents	6,726	
<b>Cash and cash equivalents</b>	<b>14,126</b>	<b>1,949</b>
Short-term investments	37,875	35,364
<b>Total</b>	<b>\$ 52,001</b>	<b>\$ 37,313</b>

There were no realized gains or losses on the sale of available-for-sale securities for any period presented.

**Fair Value of Financial Instruments**



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

The carrying amounts of financial instruments, which include cash equivalents, short-term investments, accounts payable, accrued expenses and long-term obligations approximate their fair values due to the relatively short maturities.

### **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 include payroll and personnel expenses, consulting expenses, laboratory supplies, and certain allocated expenses.

### **Acquired In-Process Research and Development**

Acquired in-process research and development relates to in-licensed technology, intellectual property and know-how surrounding rhIGF-1. The nature of the remaining efforts for completion of research and development activities generally include

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

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

***Clinical Trial Expenses***

In the normal course of business, 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 objective of the accrual policy is to match the recording of expenses in the financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials are recognized based on the estimate of the degree of completion of the event or events as specified in the specific clinical study or trial contract.

**Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation. Depreciation is provided using the straight-line method over estimated useful lives of the respective assets, ranging from three to seven years.

**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

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)**

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. Currently, there is no provision for income taxes as the Company has incurred operating losses to date.

**Stock Compensation**

The Company accounts for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board Interpretation ( FIN ) No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB No. 25*, and related interpretations and has adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended.

In December 2002, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure provisions of SFAS No. 123 and APB Opinion No. 28, *Interim Financial Reporting*, to require disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to employee stock compensation on reported net loss.

The Company has elected to continue to follow the intrinsic value method of accounting as prescribed by APB Opinion No. 25. The information regarding net loss as required by SFAS No. 123 has been determined as if the Company had accounted for its employee stock options under the fair value method of that Statement. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years' vesting.

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

	<b>Year ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Risk-free interest rate	2.9%	2.8%	3.5%
Volatility	0.8	0.8	0.8

Edgar Filing: TERCICA INC - Form 10-K

Weighted-average expected life of options (years)	3.8	4.0	3.9
Dividend yield	0.0%	0.0%	0.0%

Table of Contents**TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)**

No employee stock compensation expense is reflected in the Company's reported net loss in any period prior to December 31, 2002 as all options granted had an exercise price equal to the estimated fair value of the underlying common stock on the date of grant. 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 \$6,888,000 was recorded in accordance with APB Opinion No. 25, and is being amortized over the related vesting period of the options. The Company recorded employee stock-based compensation expense of \$2,734,000 and \$904,000 for the years ended December 31, 2004 and 2003, respectively. During the year ended December 31, 2004, the Company reversed \$847,000 of previously recognized stock compensation expense due to the forfeiture of unvested stock options resulting from employee terminations.

The following table illustrates the effect on net loss allocable to common stockholders had the Company applied the fair value provisions of SFAS No. 123 to employee stock compensation (in thousands, except per share data):

	<u>Year ended December 31,</u>			<u>Period from</u>
	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>October 1, 2000</u> <u>(inception) through</u> <u>December 31,</u>
	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2004</u>
Net loss allocable to common stockholders, as reported	\$ (41,002)	\$ (69,576)	\$ (8,952)	\$ (120,633)
Plus: Employee stock compensation expense based on intrinsic value method	2,734	904		3,638
Less: Employee stock compensation expense determined under the fair value method for all awards	(3,307)	(976)	(21)	(4,304)
Pro forma net loss allocable to common stockholders	<u>\$ (41,575)</u>	<u>\$ (69,648)</u>	<u>\$ (8,973)</u>	<u>\$ (121,299)</u>
Net loss per share allocable to common stockholders:				
Basic and diluted, as reported	<u>\$ (2.12)</u>	<u>\$ (38.59)</u>	<u>\$ (5.76)</u>	
Basic and diluted, pro forma	<u>\$ (2.15)</u>	<u>\$ (38.63)</u>	<u>\$ (5.77)</u>	

Stock compensation arrangements to non-employees are accounted for in accordance with SFAS No. 123, as amended by SFAS No. 148, 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.



**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)****Comprehensive Loss**

Comprehensive loss is comprised of net loss, foreign currency translation adjustment 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):

	<b>Year ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net loss, as reported	\$ (41,002)	\$ (25,423)	\$ (8,952)
Change in unrealized losses on marketable securities	(54)	(18)	
Reversal of foreign currency translation adjustment upon liquidation of Tercica Limited			(17)
<b>Comprehensive loss</b>	<b>\$ (41,056)</b>	<b>\$ (25,441)</b>	<b>\$ (8,969)</b>

**Foreign Currency Translation**

The functional currency of Tercica Limited was New Zealand Dollars. Accordingly, through December 31, 2001, the Company's assets and liabilities were translated into U.S. dollars using the exchange rates in effect at each balance sheet date, while income and expense items were translated using average rates of exchange during each period. Gains or losses from translation were included in accumulated other comprehensive loss. Net gains and losses resulting from foreign currency transactions were recorded in net loss in the period incurred and were not significant for any period presented.

**Recent Accounting Pronouncement**

On December 16, 2004, the FASB issued an amendment to SFAS No. 123, *Share-Based Payment*, ( SFAS No. 123R ), which is effective for public companies in periods beginning after June 15, 2005. The Company is required to implement the proposed standard no later than the quarter that begins July 1, 2005. SFAS No. 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for equity instruments of the enterprise or liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, and requires instead that such transactions be accounted for using a fair-value-based method. Companies are



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

required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. Under SFAS No. 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

modified prospective and modified retrospective adoption options. Under the modified prospective method, compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. The modified retrospective method includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures, either (a) all prior periods presented or (b) prior interim periods of the year of adoption. The Company is currently evaluating option valuation methodologies and assumptions and therefore has not fully assessed the impact of adopting SFAS No. 123R. The Company has not yet determined the method of adoption or the effect of adopting SFAS 123R, and has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately adopted by the Company. The Company expects to continue to grant stock-based compensation to employees, and the adoption of the new standard may have a material impact on the Company's results of operations.

**Reclassifications**

At December 31, 2003, the Company included approximately \$10,100,000 of floating rate debt in cash and cash equivalents as all the debt had interest rate reset features of not more than every 40 days. As such, while the debt had actual maturity dates extending well beyond 90 days, the interest rate reset feature of the debt was considered to create an effective maturity for the debt of less than 90 days, and therefore, such amounts were included in cash equivalents. Upon further review, these instruments are more appropriately classified in short-term investments. Although certain of these investments may have a contractual maturity greater than one year, the Company has classified all investments as short-term given the fact they are all available for sale and available for use in the Company's current operations. Accordingly, the accompanying unaudited condensed balance sheet and statement of cash flows reflect the reclassification of these amounts from cash equivalents to short-term investments at December 31, 2003.

Certain other amounts in prior periods have been reclassified to conform to the current period presentation.

**3. Net Loss Per Share**

Basic net loss per share allocable to common stockholders is calculated by dividing the net loss allocable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)**

equivalents. Diluted net loss per share allocable to common stockholders is computed by dividing the net loss allocable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, preferred stock, options, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share allocable to common stockholders when their effect is dilutive.

	Year ended December 31,		
	2004	2003	2002
<b>Historical</b>			
Numerator:			
Net loss allocable to common stockholders (in thousands)	\$ (41,002)	\$ (69,576)	\$ (8,952)
Denominator:			
Weighted-average common shares outstanding	19,377,009	1,928,103	1,712,975
Less: Weighted-average unvested common shares subject to repurchase	(75,307)	(124,937)	(157,717)
Denominator for basic and diluted net loss per share allocable to common stockholders	19,301,702	1,803,166	1,555,258
Basic and diluted net loss per share allocable to common stockholders	\$ (2.12)	\$ (38.59)	\$ (5.76)

	Year ended December 31,		
	2004	2003	2002
<b>Historical outstanding dilutive securities not included in diluted net loss per share allocable to common stockholders calculation</b>			
Preferred stock		15,297,308	6,426,662
Options to purchase common stock	2,077,166	1,201,781	777,662
Warrants		146,250	186,250
	2,077,166	16,645,339	7,390,574

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)****4. Property and Equipment**

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

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Office equipment	\$ 292	\$ 277
Furniture and fixtures	197	172
Computer equipment and software	800	413
Leasehold improvements	168	149
Construction in progress	1,352	1,400
Less accumulated depreciation and amortization	(543)	(97)
Property and equipment, net	<u>\$ 2,266</u>	<u>\$ 2,314</u>

Depreciation expense was \$446,000, \$92,000 and \$9,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

**5. Accrued Liabilities**

Accrued liabilities consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Accrued compensation and related liabilities	\$ 1,555	\$ 222
Accrued professional fees	460	735
Accrued manufacturing expenses	946	
Other accrued liabilities	71	257

	\$ 3,032	\$ 1,214
--	----------	----------

**6. License and Collaboration Agreement**

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.

In connection with the U.S. License and Collaboration Agreement, the Company paid \$1,000,000 in cash and issued 1,017,666 shares of Series A convertible preferred stock valued at the time of issuance at \$4,071,000. The Company is required to make cash payments based on the achievement of certain milestones and royalties on future 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

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)**

costs associated with that indication, which would have a one-time positive impact on the Company's operating results. 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, the Company paid Genentech cash of \$1,100,000 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. 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 \$34,000,000 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.

**7. Commitments and Contingencies**

At December 31, 2004, future minimum lease commitments under operating leases were as follows (in thousands):

Year ending December 31,	
2005	\$ 243
2006	22
2007	21
2008	18
2009	
	\$ 304

Rent expense was \$453,000, \$238,000 and \$110,000 for the years ended December 31, 2004, 2003 and 2002, respectively.



**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

In June 2004, the Company entered into an amended lease agreement to extend the lease term on its present facility to June 2005.

In March 2005, we entered into a new lease agreement for a facility in Brisbane, California. The term of the lease is 75 months. This agreement includes scheduled rent increases over the lease term and rent abatement for the first 15 months. The rent increases, net of rent abatement and the impact of the rent holiday from the landlord, shall be recognized as deferred rent expense and amortized on a straight line basis over the term that the facility is physically employed. In addition, the landlord will contribute \$1,046,000 towards facility improvements. This leasehold improvement allowance shall be recognized as deferred rent and amortized as reductions to rent expense on a straight line basis over the term that the facility is physically employed. In addition, the Company provided the landlord with letters of credit amounting to \$790,000, which are collateralized for the same amount by cash, cash equivalents and short-term investments held in a Company bank account. The Company expects to record the collateralized cash, cash equivalents and short-term investments as restricted assets. Under this lease agreement, the future minimum lease commitment for the years ending December 31, 2005, 2006, 2007, 2008 and 2009 are \$0, \$138,000, \$677,000, \$711,000 and \$745,000, 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. The Company's total commitment to Cambrex Baltimore under the *Manufacturing Agreement*, consisting primarily of the reimbursement of manufacturing process development costs incurred by Cambrex Baltimore and minimum commercial purchase commitments, is estimated to approximate \$3,600,000 through December 31, 2005. Further, as the Company reaches certain milestones, the Company will be committed to make certain future purchases. Payments under this agreement were \$11,699,000 and \$7,203,000 for the years ended December 31, 2004 and 2003, respectively.

**Guarantees and Indemnifications**

In November 2002, the FASB issued Interpretation No. 45, *Guarantors' Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others* (FIN No. 45). FIN No. 45 requires that upon issuance of a



**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

guarantee, the guarantor must recognize a liability for the fair value of the obligations in assumes under that guarantee.

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, 2004.

**Contingencies**

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

**8. Stockholders' Equity - Tercica Limited**

**Class A and B Shares**

At December 31, 2001, Tercica Limited was authorized to issue 162,360 shares of its Class A shares and 763,952 shares of its Class B shares.

Holders of the Tercica Limited Class A shares were entitled to 20% of dividends, if any, voting rights, and surplus in the event of a liquidation or winding up of the Company. A shareholder with 10% or more of the Class A shares had the right to appoint one director to the Board.

Holders of the Tercica Limited Class B shares were entitled to 80% of dividends, if any, voting rights, and surplus in the event of a liquidation or winding up of the Company.

**9. Stockholders Equity (Deficit) Tercica, Inc.**

**Common Stock**

At December 31, 2002, 2003 and 2004, the Company was authorized to issue 11,500,000, 20,500,000 and 100,000,000 shares of common stock, respectively.

On September 11, 2003, the Company changed the par value of its common stock from \$0.0064 per share to \$0.001 per share.

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**Convertible Preferred Stock**

At December 31, 2004 and 2003, the Company was authorized to issue 0 and 15,297,317 shares of convertible preferred stock, respectively.

In May and July 2002, the Company issued 6,426,662 shares of Series A convertible preferred stock at \$4.00 per share in exchange for cash proceeds of \$20,016,000 and certain technology, know-how and intellectual property rights (see note 6).

On July 9, 2003, the Company issued 8,830,646 shares of Series B convertible preferred stock at \$5.00 per share resulting in net cash proceeds of \$43,784,000. The Company recorded a deemed dividend of \$44,153,000 associated with this issuance 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. The guidelines set forth in EITF Consensus No. 98-5 limit the amount of the deemed dividend to the amount of the proceeds of the related financing.

The Company initially recorded the Series A and B convertible preferred stock at their fair values on the date of issuance in 2003 and 2002, respectively, net of issuance costs of \$370,000 and \$1,014,000, respectively. A redemption event will only occur upon the liquidation or winding up of the Company, a greater than 50% change of control or sale of substantially all of the assets of the Company. As the redemption event is outside the control of the Company, all shares of convertible preferred stock have been presented outside of permanent equity in accordance EITF Topic D-98, *Classification and Measurement of Redeemable Securities*. Further, the Company has also elected not to adjust the carrying values of the Series A and Series B convertible preferred stock to the redemption value of such shares, since it is uncertain whether or when a redemption event will occur. Subsequent adjustments to increase the carrying values to the redemption values will be made when it becomes probable that such redemption will occur.

In conjunction with the closing of the Company's initial public offering in March 2004, all of the Company's outstanding shares of Series A and Series B convertible preferred stock outstanding at the time of the offering were automatically converted into 15,297,308 shares of common stock.

The rights and features of the Company's convertible preferred stock were as follows:

*Dividends*

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

Holders of shares of convertible preferred stock were entitled to noncumulative dividends of 8% per share if and when declared by the Board of Directors. These dividends were to be paid in advance of any distributions to common stockholders. No dividends have been declared or paid through December 31, 2004.

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

*Conversion*

Each share of convertible preferred stock was convertible at the stockholders' option at any time into common stock on a one-for-one basis, subject to adjustment for antidilution. Conversion would be automatic upon the closing of an underwritten public offering with aggregate offering proceeds of at least \$35,000,000 and an offering price of at least \$12.00 per share (appropriately adjusted for any stock splits, stock dividends, subdivisions, combinations, recapitalizations, and the like) or upon written agreement of at least a majority of all classes of preferred stockholders, including at least 60% of the Series B preferred stockholders.

*Voting*

Each holder of shares convertible preferred stock was entitled to voting rights equivalent to the number of shares of common stock into which their respective shares were convertible.

*Liquidation Preference*

In the event of liquidation or winding up of the Company, holders of Series A and Series B convertible preferred stock had a liquidation preference of \$4.00 and \$5.00 per share, respectively, plus any declared but unpaid dividends. After payment of these preferential amounts, the remaining assets of the Company were to be distributed among the holders of the preferred and common stock pro rata based on the number of shares of common stock held (as though the preferred stock had converted.) If upon liquidation, the assets of the Company were insufficient to provide for the preferential amounts, then the entire assets of the Company would have been distributed with equal priority and pro rata among the holders of the convertible preferred stock, in proportion to the full preferential amount of the respective preferred shares. A change of control or sale of substantially all of the assets of the Company was considered to be a liquidation event.

**Preferred Stock**

As of December 31, 2004, 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, 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.



---

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**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. At December 31, 2003 and 2004, 97,352 and 50,623 of these shares, respectively, were subject to repurchase by the Company. These shares are subject to a repurchase option held by the Company at the original issuance price. This right lapses 25% on the first anniversary of the agreement and in 36 equal monthly amounts thereafter.

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 December 2002 and \$206,000 in cash in January 2003. In 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. 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 425,791 and 674,704 at December 31, 2004 and 2003, respectively, are subject to a repurchase option held by the Company at the original issuance price in the event the optionee's 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.

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 258,913 shares valued at \$173,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2004, and 255,739 shares valued at \$102,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2003. There were no vested shares reclassified into common stock and additional paid-in capital as of December 31, 2002.

**Warrants**

In January 2002, the Company entered into a bridge loan agreement with two investors in which the Company received \$500,000 in exchange for a note payable convertible into the Company's Series A convertible preferred stock. The note payable was converted into 125,000 shares of Series A convertible preferred stock in May 2002. The two investors also made available an additional \$1,000,000 equity line which expired

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)**

on July 31, 2002. There was no stated interest associated with the bridge loan. In connection with the bridge loan, the Company issued warrants to purchase an aggregate of 40,000 shares of the Company's Series A convertible preferred stock at an exercise price of \$4.00 per share. The warrants were exercised in November 2003. In conjunction with the closing of the Company's initial public offering in March 2004, all outstanding shares of Series A convertible stock were automatically converted into shares of common stock on a one-for-one basis.

In accordance with EITF No. 96-18, these warrants were valued on the date of grant using the Black-Scholes method using the following assumptions: a risk-free interest rate of 3.5%, a life of 5.5 years, no dividend yield, and a volatility factor of 0.8. The estimated fair value of the warrants was \$106,000 and was recorded as interest expense in the year ended December 31, 2002.

Additionally, in April 2002, the Company issued warrants to purchase an aggregate of 146,250 shares of the Company's common stock at an exercise price of \$0.40 per share as commissions for a placement agent in connection with the Series A convertible preferred stock financing. The Company recorded the estimated fair value of the warrants of \$41,000 using the Black-Scholes method as an issuance cost of the Series A convertible preferred stock. The assumptions used in calculating the fair value of the warrants were as follows: a risk-free interest rate of 3.5%, a life of five years, no dividend yield, and a volatility factor of 0.8. The warrants are all outstanding as of December 31, 2003. In conjunction with the closing of the Company's initial public offering in March 2004, the outstanding warrants to purchase 146,250 shares of common stock were net exercised resulting in 139,750 shares of common stock issued with the warrant for the remaining 6,500 shares relinquished as non-cash payment.

**Shares Reserved for Issuance**

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

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Conversion of Series A convertible preferred stock		6,466,662
Conversion of Series B convertible preferred stock		8,830,646
2003 Employee Stock Purchase Plan	71,706	100,000
Stock option plans:		
Shares available for grant	1,597,259	2,748,213
Options outstanding	2,054,666	1,201,781
Stock options outstanding (granted outside of stock plans)	22,500	
Warrants outstanding:		
To purchase common stock		146,250



Edgar Filing: TERCICA INC - Form 10-K

To purchase Series A convertible preferred stock

	<u>3,746,131</u>	<u>19,493,552</u>
--	------------------	-------------------

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**2004 Employee Stock Purchase Plan**

The Company's Board of Directors adopted the 2004 Employee Stock Purchase Plan (formerly the 2003 Stock Purchase Plan) in September 2003 and the Company's stockholders approved it in October 2003. The 2004 Employee Stock Purchase Plan ( Purchase Plan ) became effective on March 16, 2004. The Company has reserved a total of 100,000 shares of common stock 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 beginning January 1, 2005. The number of additional shares to be reserved automatically will be equal to the lesser of 125,000 shares, 0.5% of the outstanding shares on the date of the annual increase or such amount as may be determined by the Board of Directors. The Purchase Plan permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. 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 end. 28,294 and 0 shares were issued under the Purchase Plan during the years ended December 31, 2004 and 2003, respectively.

**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 and nonstatutory stock options to employees, directors and consultants. Shares reserved under the 2004 Stock Plan include (a) shares reserved but unissued under the 2002 Executive Stock Plan and the 2002 Stock Plan, (b) shares returned to the 2002 Executive Stock Plan and the 2002 Stock Plan as the result of termination 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 may determine.

The other terms of the 2004 Stock Plan are similar to those of the Company's 2002 Stock Plan.

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

Under the 2002 Stock Plan and 2002 Executive Stock Plan (the Plans ) employees, directors, and consultants of the Company are able to participate in the Company s future performance through awards of nonqualified stock options, incentive stock options and restricted stock.

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)**

Incentive stock options may be granted with exercise prices not less than 100% of estimated fair value, and nonqualified stock options may be granted with an exercise price of not less than 85% of the estimated fair value of the common stock on the date of grant, as determined by the Board of Directors. Options granted to individuals owning over 10% of the total combined voting power of all classes of stock are exercisable up to five years from the date of grant. The exercise price of any option granted to a 10% stockholder will not be less than 110% of the estimated fair value of the common stock on the date of grant, as determined by the Board of Directors. Options granted under the Plans expire no later than 10 years from the date of grant. Options granted under the Plans vest over periods determined by the Board of Directors, generally over four years. The Plans terminate automatically 10 years after their adoption by the Board of Directors.

In January 2004, the Board of Directors increased the number of shares of common stock available for future grant under the 2002 Executive Stock Plan to 2,080,000 from 1,330,000 and decreased the number of shares of common stock available for future grant under the 2002 Stock Plan to 2,140,000 from 2,890,000.

A summary of activity is as follows:

	Shares Available for Grant	Options Outstanding	
		Number of Shares	Weighted- Average Exercise Price
Balances at December 31, 2001			\$
Shares authorized	1,750,000		
Options granted	(777,662)	777,662	0.40
Balances at December 31, 2002	972,338	777,662	0.40
Shares authorized	2,470,000		
Options granted	(694,750)	694,750	0.94
Options exercised		(270,006)	0.40
Options canceled	625	(625)	0.40
Balances at December 31, 2003	2,748,213	1,201,781	0.71
Options granted	(1,284,000)	1,284,000	7.38
Option granted outside of Plans		22,500	4.00
Options exercised		(298,069)	0.72
Options canceled	133,046	(133,046)	3.25
Balances at December 31, 2004	1,597,259	2,077,166	\$ 4.72

Options presented as exercised in the table above for the years ended December 31, 2003 and 2004 represent the vesting of common stock associated with the early exercise of stock options in previous periods.

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)**

The following table summarizes information concerning total outstanding and vested options as of December 31, 2004:

<b>Options Outstanding</b>				<b>Options Vested</b>	
<b>Range of Exercise Prices</b>	<b>Number Outstanding</b>	<b>Weighted-Average Remaining Contractual Life</b>	<b>Weighted Average Exercise Price</b>	<b>Number Vested</b>	<b>Weighted Average Exercise Price</b>
\$0.40	606,144	8.0	\$ 0.40	639,883	\$ 0.40
\$1.00 - \$1.60	233,729	8.3	\$ 1.54	105,409	\$ 1.55
\$4.00	517,293	9.0	\$ 4.00	72,910	\$ 4.00
\$8.54 - \$8.85	362,750	9.6	\$ 8.63	4,000	\$ 8.78
\$11.19	357,250	9.3	\$ 11.19		
	<b>2,077,166</b>			<b>822,202</b>	

The following table summarizes information concerning total outstanding and vested options as of December 31, 2003:

<b>Options Outstanding</b>			<b>Options Vested</b>	
<b>Exercise Price</b>	<b>Number Outstanding</b>	<b>Weighted-Average Remaining Contractual Life</b>	<b>Number Vested</b>	<b>Exercise Price</b>
\$0.40	878,531	8.8	39,821	\$ 0.40
\$1.00	25,000	9.5		\$ 1.00
\$1.60	298,250	9.7		\$ 1.60
	<b>1,201,781</b>		<b>39,821</b>	

The weighted-average fair value of options granted during the years ended December 31, 2004 and 2003 were \$6.13 and \$10.23, respectively.

**Stock Options Granted to Non-employees**

During the years ended December 31, 2004 and 2003, the Company granted 24,000 options and 7,500 options, respectively, to purchase shares of its common stock to non-employees. These have been accounted for in accordance with SFAS No. 123 and EITF No. 96-18. Compensation expense of \$107,000 and \$143,000 was recorded for the years ended December 31, 2004 and 2003, respectively.

The fair value of options granted to non-employees during the year ended December 31, 2004 was estimated using the Black-Scholes method with the following assumptions: a dividend yield of zero, risk-free interest rate of 4.28%, volatility of 0.6 and a maximum contractual life of 10 years.

The fair value of options granted to non-employees during the year ended December 31, 2003 was estimated using the Black-Scholes method with the following assumptions: a dividend yield of zero, risk-free interest rate of 4.36%, volatility of 0.8 and a maximum contractual life of 10 years.

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**Deferred Stock Compensation**

In connection with the grant of certain stock options to employees during the year ended December 31, 2003, the Company recorded deferred stock compensation within stockholders' equity (deficit) of \$6,888,000, representing the difference between the reassessed fair value of the common stock and the option exercise price at the date of grant. Such amount is being amortized over the vesting period of the applicable options on a straight-line basis.

During the period from February 1, 2003 through January 31, 2004, certain stock options were granted with exercise prices that were below the reassessed fair value of the common stock at the date of grant. Deferred compensation was recorded in accordance with APB Opinion No. 25, and is being amortized over the related vesting period of the options. The deferred compensation balance was \$6,388,000 and \$5,984,000 as of December 31, 2004 and 2003, respectively. The Company recorded amortization of employee stock-based compensation expense of \$2,734,000 and \$904,000 for the years ended December 31, 2004 and 2003, respectively.

The total unamortized deferred stock compensation recorded for all option grants through January 31, 2004, net of the amounts reversed associated with forfeited stock options, will be amortized as follows: \$2,532,000 for the year ending December 31, 2005; \$2,532,000 for the year ending December 31, 2006; \$1,318,000 for the year ending December 31, 2007 and \$6,000 for the year ending December 31, 2008.



**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)****10. Income Taxes**

There is no provision for income taxes because the Company has incurred losses. 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,	
	2004	2003
Net operating loss carryforwards	\$ 20,855	\$ 9,111
Research tax credit carryforwards	2,753	1,120
Orphan drug credits	3,464	
Capitalized license fees	3,043	2,460
Capitalized start-up costs	2,619	655
Other	1,383	1,731
<b>Total deferred tax assets</b>	<b>34,117</b>	<b>15,077</b>
Valuation allowance	(34,117)	(15,077)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

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 \$19,040,000 and \$11,379,000 for the years ended December 31, 2004 and 2003, respectively.

As of December 31, 2004, the Company had federal net operating loss carryforwards of approximately \$53,156,000. The Company also had California net operating loss carryforwards of approximately \$37,524,000. 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 2013. The Company also has federal research, state research and federal orphan drug credit carryforwards of approximately \$1,626,000, \$1,734,000 and \$3,464,000, 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 may be 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.



**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)****11. Subsequent Event****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 has the option to draw down funds in the aggregate principal amount of up to \$15,000,000. The Company paid a \$75,000 fee as part of this Loan Agreement and issued VLL 75,000 shares of its common stock, which are held in escrow, subject to certain conditions. The \$75,000 fee will be refunded to the Company if it borrows funds under this facility. The option to draw funding under this Loan Agreement will continue to be available to the Company through June 30, 2005, subject to certain extensions and additional issuances of up to a maximum of 150,000 shares of the Company's common stock. Any funding drawn down will have a three-year term from the date of funding. Any borrowings are subject to cash payments of principal and interest at an interest rate of 7.5% per annum, as well as a terminal interest payment at the end of the three-year term equal to 9.2% of the aggregate principal amount borrowed during the term of the loan. Under the terms of the Loan Agreement and an intellectual property security agreement, the Company would grant to VLL a first priority security interest on certain assets, including limited intellectual property assets, in the event any borrowings occur. The Company may terminate this facility at any time without penalty as long as no borrowings have been drawn down from the facility.

**12. 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.

	<u>Net Loss</u>	<u>Net Loss Allocable to Common Stockholders</u>	<u>Basic and Diluted Net Loss Per Share Allocable to Common Stockholders</u>
(In thousands, except per share data)			
Year ended December 31, 2004			
Fourth Quarter	\$ (11,189)	\$ (11,189)	\$ (0.46)
Third Quarter	(10,677)	(10,677)	(0.45)
Second Quarter	(11,447)	(11,447)	(0.48)
First Quarter	(7,690)	(7,690)	(1.47)
Year ended December 31, 2003			
Fourth Quarter	\$ (8,906)	\$ (8,906)	\$ (4.59)
Third Quarter	(8,775)	(52,928)	(28.63)
Second Quarter	(4,832)	(4,832)	(2.77)

Edgar Filing: TERCICA INC - Form 10-K

First Quarter

(2,910)

(2,910)

(1.77)

**Table of Contents**

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

None.

**Item 9A. Controls and Procedures.**

*Evaluation of disclosure controls and procedures*

Based on their evaluation as of December 31, 2004, our Chief Executive Officer and Chief Financial Officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) are effective to ensure that the information required to be disclosed by us in periodic reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

*Changes in internal control over financial reporting*

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*Limitations on the effectiveness of controls*

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

**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 to be held in June 2005 (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 and Executive Officers of the Registrant.**

Information with respect to Directors and Executive Officers may be found under the caption Executive Officers of the Registrant in 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. Information 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 is incorporated herein by reference to the information from the Proxy Statement under the section entitled Executive Compensation.

**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.

**Item 13. Certain Relationships and Related Transactions.**

The information required by this Item is incorporated herein by reference to the information from the Proxy Statement under the section entitled Executive Compensation Certain Relationships and Related Transactions.

**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:*

<b>Exhibit Number</b>	<b>Description</b>
3.1	Certificate of Incorporation(2)
3.2	Bylaws(1)
4.1	Form of Specimen Stock Certificate(1)
10.1A	2002 Stock Plan, as amended(1)*
10.1B	Form of Stock Option Agreement under the 2002 Stock Plan(1)*
10.2A	2002 Executive Stock Plan, as amended(1)*
10.2B	Form of Stock Option Agreement under the 2002 Executive Stock Plan(1)*
10.3A	2004 Stock Plan(1)*
10.3B	Form of Stock Option Agreement under the 2004 Stock Plan(1)*
10.4A	2004 Employee Stock Purchase Plan(1)*
10.4B	Form of Subscription Agreement under the 2004 Employee Stock Purchase Plan(1)*
10.5	Form of Indemnification Agreement(1)*
10.6A	Sublease Agreement dated June 24, 2002 between Elan Pharmaceuticals, Inc. and the Registrant(1)

Edgar Filing: TERCICA INC - Form 10-K

- 10.6B Sublease Agreement dated March 21, 2003 between Elan Pharmaceuticals, Inc. and the Registrant(1)
- 10.6C Lease Agreement dated July 24, 2003 between Gateway Center, LLC and the Registrant(1)
- 10.6D First Amendment to Lease Agreement dated September 24, 2003 between Gateway Center, LLC and the Registrant(1)

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.6E	Second Amendment to Lease Agreement dated June 28, 2004 between Gateway Center, LLC and the Registrant(3)
10.6F	Lease Agreement dated March 7, 2005 between 2000 Sierra Point, LLC and the Registrant
10.7A	License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of April 15, 2002(1)
10.7B	First Amendment to the License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of July 25, 2003(1)
10.7C	International License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of July 25, 2003(1)
10.8	Manufacturing Services Agreement between the Registrant and Cambrex Bio Science Baltimore, Inc., dated as of December 20, 2002(1)
10.9A	Key Employment Agreement for John A. Scarlett, M.D. dated February 27, 2002(1)*
10.9B	Amendment to Key Employment Agreement for John A. Scarlett, M.D. dated May 15, 2002(1)*
10.9C	Key Employment Agreement for Ross G. Clark dated May 15, 2002(1)*
10.9D	Employment Letter to Timothy P. Lynch dated September 10, 2002(1)*
10.9E	Intentionally omitted
10.9F	Intentionally omitted
10.9G	Employment Letter to Andrew Grethlein dated March 5, 2003(1)*
10.9H	Employment Letter to Michael Parker dated December 9, 2002(1)*
10.9I	Intentionally omitted
10.9J	Intentionally omitted
10.9K	Employment Letter to Thomas H. Silberg dated April 14, 2004(2)*
10.9L	Employment Letter to Stephen Rosenfield dated June 23, 2004(3)*
10.9M	Employment Letter to Thorsten von Stein dated December 3, 2004(4)*
10.9N	Amendment to Key Employment Agreement for John A. Scarlett, M.D. dated February 22, 2005*
10.9O	Amendment to Key Employment Agreement for Ross G. Clark dated February 22, 2005*
10.9P	Amendment to Employment Letter for Thomas H. Silberg dated February 22, 2005*
10.9Q	Amendment to Employment Letter for Timothy P. Lynch dated February 22, 2005*

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.9R	Amendment to Employment Letter for Stephen N. Rosenfield dated February 22, 2005*
10.9S	Executive Officer Compensation Arrangements(5)*
10.9T	Non-Employee Director Compensation Arrangements(6)
10.10	Amended and Restated Investors Rights Agreement dated July 9, 2003(1)
10.11	Amendment to Amended and Restated Investors Rights Agreement dated February 27, 2004(1)
10.12A	Loan Agreement, dated January 21, 2005, between Venture Lending & Leasing IV, Inc. and the Registrant(4)
10.12B	Common Stock Purchase Agreement, dated January 21, 2005, between Venture Lending & Leasing IV, LLC and the Registrant(4)
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.

- (1) Incorporated by reference to the Registrant's registration statement on Form S-1 (File No. 333-108729) and amendments thereto, declared effective on March 16, 2004.
- (2) Incorporated by reference to the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on May 13, 2004.
- (3) Incorporated by reference to the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on August 16, 2004.
- (4) Incorporated by reference to the Registrant's registration statement on Form S-1 (File No. 333-122224) and amendments thereto, declared effective on February 7, 2005.

**Table of Contents**

- (5) Incorporated by reference to the information under the heading, Item 1.01. Entry into a Material Definitive Agreement in the Registrant's current reports on Form 8-K (File No. 000-50461) filed on February 28, 2005 and March 18, 2005.
- (6) Incorporated by reference to the information under the heading Management Director Compensation in the Registrant's registration statement on Form S-1 (File No. 333-122224) and amendments thereto, declared effective on February 7, 2005.

**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 24, 2005

**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 Timothy P. Lynch, 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 24, 2005:

<u>Signature</u>	<u>Title</u>
<p>/s/ JOHN A. SCARLETT, M.D.</p> <p>_____ <b>John A. Scarlett, M.D.</b></p>	<p>President, Chief Executive Officer and Director (Principal Executive Officer)</p>
<p>/s/ TIMOTHY P. LYNCH</p> <p>_____ <b>Timothy P. Lynch</b></p>	<p>Chief Financial Officer (Principal Accounting and Financial Officer)</p>
<p>/s/ ALEXANDER BARKAS, PH.D.</p> <p>_____ <b>Alexander Barkas, Ph.D.</b></p>	<p>Director</p>

/s/ ROSS G. CLARK, PH.D.

Director

---

**Ross G. Clark, Ph.D.**

**Table of Contents**

<u>Signature</u>	<u>Title</u>
/s/ KARIN EASTHAM	Director
<b>Karin Eastham</b>	
/s/ DENNIS HENNER, PH.D.	Director
<b>Dennis Henner, Ph.D.</b>	
/s/ WAYNE T. HOCKMEYER, PH.D.	Director
<b>Wayne T. Hockmeyer, Ph.D.</b>	
/s/ OLLE ISAKSSON, PH.D.	Director
<b>Olle Isaksson, M.D., Ph.D.</b>	
/s/ MARK LESCHLY	Director
<b>Mark Leschly</b>	
/s/ DAVID L. MAHONEY	Director
<b>David L. Mahoney</b>	