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, 2005

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

2000 Sierra Point Parkway, Suite 400
Brisbane, CA 94005
(650) 624-4900
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

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

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

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

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

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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

The aggregate market value of the registrant's common stock, $0.001 par value, held by non-affiliates of the registrant as of June 30, 2005 was $114,824,133 (based upon the closing sales price of such stock as reported in the Nasdaq National Market on such date). Excludes an aggregate of 18,357,639 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, 2005. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

As of February 24, 2006, there were 37,485,469 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 2006 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.

TERCICA, INC.

FORM 10-K ANNUAL REPORT
FOR THE YEAR ENDED DECEMBER 31, 2005

TABLE OF CONTENTS

PART I

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

Item 1. Business.

We are a biopharmaceutical company focused on the development and commercialization of new therapeutics for the treatment of short stature and other endocrine disorders. Our first commercial product is Increlex™, (mecasermin [rDNA origin] injection), a DNA-derived recombinant human insulin-like growth factor-1, or rhIGF-1. We obtained approval for the long-term treatment of growth failure in children with severe primary insulin-like growth factor deficiency, or severe Primary IGFD, from the U.S. Food and Drug Administration, or FDA, in August 2005, based on Phase III clinical trial data. In January 2006, we launched Increlex in the United States. In December 2005, we submitted a Marketing Authorization Application to the European Medicines Agency, or EMEA, seeking approval of long-term Increlex replacement therapy for severe Primary IGFD.

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 current focus is on marketing and selling Increlex for the treatment of severe Primary IGFD and 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.

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 be used to successfully treat GHD. However, we believe that 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 most recent Phase III clinical trial results reflect the treatment of 76 children with severe Primary IGFD with rhIGF-1 replacement therapy for an average of 4.4 years, with some patients being treated for up to 12 years. None of the children withdrew from the study due to adverse events. Of these children, 62 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 that 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 compared to baseline were also observed for 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 Phase IIIb clinical trial of Increlex in children with Primary IGFD, which includes children with a less severe form of IGFD. In mid 2005 we initiated another Phase III study of Increlex in Primary IGFD, in which we are investigating once-daily dosing of Increlex. We are also 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. We believe that severe Primary IGFD constitutes approximately 20%, or 12,000, of the total population in the United States and Western Europe with Primary IGFD.

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 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, 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.

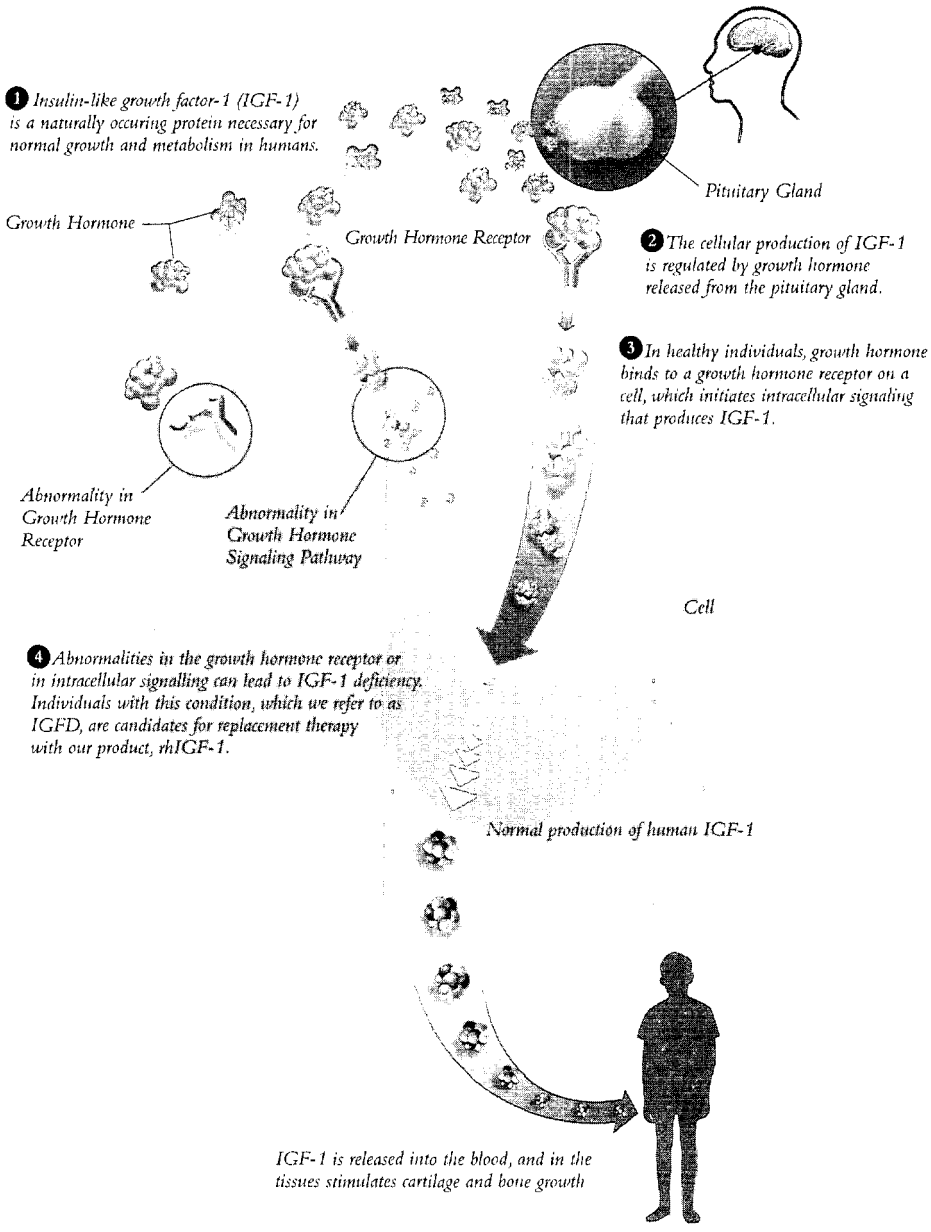
As children with IGFD become adults, they continue to suffer from the effects of IGF-1 deficiency. Since the growth plates in the long bones fuse and additional cartilage and bone growth can no longer occur after puberty, rhIGF-1 replacement therapy does not cause growth in adults. However, low levels 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 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.

IGF-1 Deficiency



Indications

Increlex Indication	Development Status	Commercialization Rights
Severe Primary IGFD	Approved in the U.S.; Marketing Authorization Application submitted to the European Medicines Agency in December 2005	Worldwide
Primary IGFD	Phase IIIb trial initiated late 2004	Worldwide
Primary IGFD	Once-daily dosing trial initiated mid-2005	Worldwide
Adult IGFD	Assessing potential development strategy	Worldwide

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.

Severe Primary IGFD. We obtained approval of long-term Increlex replacement therapy for severe Primary IGFD from the FDA in August 2005, based on Phase III clinical trial data. In January 2006, we launched Increlex in the United States. In December 2005, we submitted a Marketing Authorization Application to the European Medicines Agency, or EMEA, seeking approval of long-term Increlex replacement therapy for severe Primary IGFD.

Our product label defines severe Primary IGFD to mean a child who has a Height SDS and IGF-1 SDS of minus three or less and normal growth hormone levels. These children do not respond or respond poorly to growth hormone therapy. If their deficit in growth continues unchanged, children with severe Primary IGFD who are untreated will typically attain a final height of no more than approximately 5'1" for boys and 4'9½" for girls. We estimate that a total of 12,000 children in the United States and Western Europe have severe Primary IGFD.

We have Phase III results from the treatment of 76 children with severe Primary IGFD with rhIGF-1 replacement therapy for an average of 4.4 years, with some patients being treated for up to 12 years. None of the children withdrew from the study due to adverse events. 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, 62 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 compared to baseline were also observed for each of the first eight years of rhIGF-1 treatment ($p<0.001$).

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.

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

Expand the severe Primary IGFD indication to Primary IGFD. Our goal is to capitalize on the opportunities presented by Increlex for the treatment of short stature. 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 FDA-approved NDA for severe Primary IGFD. We believe that this will expand the market for Increlex from the approximately 12,000 children with severe Primary IGFD to encompass the approximately 60,000 children with Primary IGFD, including severe Primary 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.

Grow Increlex revenues for severe Primary IGFD. Our sales and marketing force targets the approximately 500 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 our focused marketing organization and specialized sales force can effectively serve them. In addition, we conduct medical education programs, medical symposia, and regional speaker programs aimed at establishing awareness of Increlex and severe Primary IGFD 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. In December 2005, we submitted a Marketing Authorization Application to the EMEA seeking approval of long-term Increlex replacement therapy for severe Primary IGFD.

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 believe that the risks and time required to obtain FDA approval of Increlex for new disease indications may be reduced as a result of the FDA's approval of Increlex for the treatment of severe Primary IGFD.

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 IGFBP-3, for a broad range of indications. The rights are exclusive with respect to our development and sale of rhIGF-1 and non-exclusive with respect to our manufacture of rhIGF-1. Indications not covered by our licenses from Genentech include diseases and conditions of the central nervous system. In addition, we need to enter into a written agreement with another company if we desire to commercialize rhIGF-1 for diabetes outside of the United States.

Under both the U.S. 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 and $1.4 million related to rights related to the license to Genentech's rights to IGF-1 combined with IGFBP-3. In connection with the approval of our NDA in August 2005, we paid Genentech a $1.0 million milestone payment related to the United States License and Collaboration Agreement. We also agreed to pay to Genentech royalties on the sales of rhIGF-1 products and certain one-time payments upon the occurrence of specified milestone events, such as attaining rhIGF-1 indication approvals and aggregate sales levels with respect to rhIGF-1. We are subject to the following milestone payments to Genentech as of December 31, 2005:

- 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 $33 million.
- If we develop rhIGF-1 in combination with IGFBP-3, we would be subject to these same milestone events and, upon achievement of all of the milestones, would owe Genentech up to an additional aggregate of approximately $32.5 million.

Accordingly, we would owe Genentech up to an aggregate of approximately $65.5 million in milestone payments if we achieved all of these milestone events for both rhIGF-1 and for rhIGF-1 in combination with IGFBP-3. Both agreements require us to fulfill certain obligations to maintain our licenses. These obligations include a requirement to use reasonable business efforts to meet specified milestones, including filing for regulatory approval with the FDA for either diabetes or a substitute indication, subject to Genentech's consent, by December 31, 2008. 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 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 by 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 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, which we have completed as of 2005. 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 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 believe that there is an increasing acceptance by the FDA and European Medicines 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 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 are focused on the market for endocrine growth disorders, targeting the approximately 500 active pediatric endocrinologists practicing in the United States. Pediatric endocrinologists

are the physicians who generally treat children with severe Primary IGFD. Because these pediatric endocrinologists are primarily hospital-based and concentrated in major metropolitan areas, we believe that our focused marketing organization and specialized sales force can effectively serve them. We are conducting a variety of programs aimed at establishing physician awareness of Increlex as a treatment for severe Primary IGFD, including medical education, symposiums and regional speaker programs. We are also conducting post-marketing studies and are developing a patient registry in order to provide further data on the safety and efficacy. In addition, 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 principal experience has been developing a late-stage product candidate and commercializing it. 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, Increlex, is FDA-approved for the long-term treatment of growth failure in children with severe Primary IGFD, and we intend to develop other potential indications for rhIGF-1 for which we may contract with third parties for support. Research and development expenses consist primarily of costs associated with manufacturing development activities and clinical and regulatory activities. Manufacturing development activities include pre-FDA approval preparation activities for current good manufacturing practices (cGMP), regulatory inspection preparation, technology transfer, process development and validation, quality control and assurance activities, analytical services, personnel and related benefits and depreciation. Clinical and regulatory activities include the preparation, implementation, management of our clinical trials and assay development, as well as regulatory compliance, data management and biostatistics. Our research and development expenses were $21.6 million for the year ended December 31, 2005, $27.9 million for the year ended December 31, 2004 and $19.2 million for the year ended December 31, 2003.

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 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 Insmed in the United Kingdom and against Insmed in the United States to enforce patent rights we licensed from Genentech. We cannot predict the outcome of such litigation. 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 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

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.

We cannot at this time predict the relative competitive position of Increlex. However, we expect that the following factors, among others, will determine our ability to compete effectively:

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

- product price;
- manufacturing costs;
- the effectiveness of our sales and marketing efforts;
- storage requirements and ease of administration;
- dosing regimen;
- safety and efficacy;
- prevalence and severity of side effects; and
- competitive products.

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.

Insmed Incorporated's combination product, when launched commercially, will compete with Increlex for the treatment of patients with severe Primary IGFD. Insmed's combination product was recently approved by the FDA for the treatment of patients with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone.

Growth hormone products will likely compete with Increlex for the treatment of patients with Primary IGFD if Increlex is also approved for that indication. The major suppliers of commercially available growth hormone products in the United States are Genentech, Eli Lilly and Company, Teva Pharmaceutical Industries Ltd., Novo Nordisk A/S, Pfizer Inc and Serono S.A. Investigators from a Novo Nordisk clinical trial recently presented data that demonstrated growth hormone was effective in a population that included children with Primary IGFD. In addition, children with Primary IGFD may be diagnosed as having idiopathic short stature, or ISS. Eli Lilly and Company and Genentech have received FDA approval for their respective growth hormone products for the treatment of children with ISS. Accordingly, we expect that growth hormone products will compete directly with Increlex for the treatment of children with Primary IGFD who may be diagnosed as having ISS.

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

We believe that Bristol-Meyers Squibb Company, Genentech, Merck & Co., Inc., Novo Nordisk and Pfizer Inc have conducted research and development of orally available small molecules that cause the release of growth hormone, known as growth hormone secretagogues. We believe that 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.

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.

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.

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. 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.

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 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.

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

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of Increlex for other indications, including Primary IGFD. We cannot predict the likelihood, nature or extent of adverse governmental regulation, which might arise from future legislative or administrative action, either in the United States or abroad.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat rare diseases or conditions, which are generally diseases or conditions that affect fewer than 200,000 individuals in the 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 or condition for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in limited circumstances, for seven years. The FDA may, however, approve applications to market the same drug for different indications, and applications to market different drugs for the same indication as the drug that has orphan exclusivity.

The FDA granted Increlex seven years of orphan exclusivity for the long-term treatment of growth failure in children with severe Primary IGFD or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to growth hormone. In addition, we intend to file for orphan drug designation for other

rhIGF-1 diseases that meet the criteria for orphan exclusivity. There is no guarantee that we will be awarded orphan exclusivity for any other indications, including Primary IGFD, or other products that we may develop. Obtaining FDA approval to market a product with orphan exclusivity may not provide us with a material commercial advantage, also. For example, the FDA recently approved Insmed Incorporated's combination product for the treatment of severe Primary IGFD and granted Insmed's product orphan drug designation. Accordingly, notwithstanding our orphan drug designation for rhIGF-1, Insmed's combination product for rhIGF-1 and BP-3 was deemed by the FDA to be a different drug than ours, and therefore, it will compete with Increlex for the treatment of patients with severe Primary IGFD, when it is launched commercially.

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

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

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

This new chemical entity exclusivity protects the entire new chemical entity franchise, including all products containing Increlex's active ingredient for any use and in any strength or dosage form. This exclusivity will not, however, prevent the submission or approval of a full NDA, as opposed to an ANDA or 505(b)(2) application, for any drug, including a drug with the same conditions of use, active ingredient, route of administration, dosage form, and strength as Increlex. In addition, an ANDA or a 505(b)(2) application may be submitted after four years, rather than five years, if that ANDA or 505(b)(2) application contains a certification (known as a "Paragraph IV certification") that one of the patents listed with the Increlex NDA is invalid or will not be infringed by the manufacture, use, or sale of the product described in that ANDA or 505(b)(2) application.

The Hatch-Waxman Act also provides three years of new use exclusivity for the approval of NDAs, 505(b)(2) applications, and NDA supplements, where those applications contain the results of new clinical investigations (other than bioavailability studies) essential to the FDA's approval of the applications. Such applications may be submitted for new indications, new dosage forms, new strengths, or new conditions of use of already approved products like Increlex. So long as the new clinical investigations are essential to the FDA's approval of the change, this new use exclusivity prohibits the approval of ANDAs or 505(b)(2) applications for

products with the specific changes associated with those clinical investigations. Should Increlex receive this exclusivity, however, it will not prevent the submission or approval of a full NDA for any drug, including a drug with the same changes as are protected by the exclusivity. It also would not prohibit the FDA from accepting or approving ANDAs or 505(b)(2) applications for other products containing the same active ingredient. It would only protect against the approval of ANDAs and 505(b)(2) applications for products with the specific changes to Increlex that were approved based on the new clinical investigations.

The Hatch-Waxman Act also requires an ANDA or 505(b)(2) applicant that has submitted an ANDA or a 505(b)(2) application with a Paragraph IV certification to notify the owner of the patent that is the subject of the Paragraph IV certification and the holder of the approved NDA of the factual and legal basis for the applicant's opinion that that patent is invalid or will not be infringed by the manufacture, use, or sale of the product described in that ANDA or 505(b)(2) application. The NDA holder or patent owner may then sue such an ANDA or 505(b)(2) applicant for infringement. If the NDA holder or patent owner files suit within 45 days of receiving notice of the Paragraph IV certification, a one-time 30-month stay of the FDA's ability to approve the ANDA or 505(b)(2) application is triggered. However, the FDA may approve the ANDA or 505(b)(2) application before the expiration of the 30-month stay if a court finds the patent invalid or not infringed, or if the court shortens the 30-month period because a party failed to cooperate in expediting the litigation. In addition, if the NDA holder or patent owner chooses not to sue such an ANDA or 505(b)(2) applicant after receiving notification of the Paragraph IV certification, or sues outside of the 45-day window, the FDA may approve the ANDA or 505(b)(2) application whenever all of the other requirements for approval are met.

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

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.

Employees

As of December 31, 2005, we had 89 full-time employees. Of the full-time employees, 39 were engaged in product development and 50 were engaged in selling, general and administrative positions. We believe that our employee base will need to grow in order to execute our development and commercialization plans for rhIGF-1. We believe our relations with our employees are good.

Executive Officers of the Registrant

Our executive officers, their ages and their positions as of March 15, 2006, are as follows:

Name	Age	Position(s)
John A. Scarlett, M.D.	55	President, Chief Executive Officer and Director
Ross G. Clark, Ph.D.	55	Chief Technical Officer and Director
Susan Wong	43	Acting Chief Financial Officer, Vice President, Finance and Chief Accounting Officer
Stephen N. Rosenfield	56	Executive Vice President of Legal Affairs, General Counsel and Secretary
Andrew Grethlein, Ph.D.	41	Senior Vice President, Pharmaceutical Operations
Chris E. Rivera	44	Senior Vice President, Commercial Operations
Thorsten von Stein, M.D., Ph.D.	44	Chief Medical Officer and Senior Vice President of Clinical and Regulatory Affairs

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. 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.

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

Stephen N. Rosenfield has served as our Executive Vice President of Legal Affairs, General Counsel and Secretary since March 2006; and 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.

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

Chris E. Rivera has served as our Senior Vice President of Commercial Operations since April 2005. From September 2003 through December 2004, Mr. Rivera served as Vice President, Sales, at Corixa Corporation, a biopharmaceutical company. From April 2003 until September 2003, Mr. Rivera served as Vice President, Business Development for GeneCraft, Inc. (currently Trubion), also a biopharmaceutical company. From June 1998 until April 2003, Mr. Rivera served at Genzyme Corporation in various commercial positions with increasing responsibilities, the most recent as Senior Vice President, Therapeutics, where he was responsible for the U.S. commercialization of Genzyme Corporation's renal division. From April 1996 until May 1998, Mr. Rivera served as Vice President, Sales for Genzyme Tissue Repair. Prior to serving at Genzyme Corporation, Mr. Rivera helped to build the original commercial organizations at Cephalon, Inc. from 1993 through 1995 and at Centocor, Inc. from 1991 through 1993. Mr. Rivera began his career at E.R. Squibb and Sons (currently known as Bristol Myers-Squibb) in 1986 in a sales capacity, and was promoted to Seattle District Manager in 1989. Mr. Rivera received his B.S. degree in Business Administration at Northwestern Oklahoma State University and his M.S. degree in Audiology at the University of Oklahoma Health Sciences Centery. Mr. Rivera also attended the M.B.A. program at Seattle University's Albers School of Business and Economics, where he studied marketing and management.

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 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.

Corporate Information

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

Available Information

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

Item 1A. Risk Factors.

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

Risks Related to Our Business

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

We are a development stage company focused on the development and commercialization of Increlex ™ for the treatment of short stature and other endocrine disorders. From our inception in October 2000 through December 31, 2005, we have accumulated a deficit of $165.7 million. We have not generated and may not be able to generate significant revenues from operations and may not be able to attain profitability. We incurred a net loss of $46.2 million during the year ended December 31, 2005. We expect to incur substantial net losses, in the aggregate and on a per share basis, for the foreseeable future as we attempt to develop, market and sell Increlex for severe Primary IGFD and Primary IGFD. 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 that we will be able to obtain or maintain governmental regulatory approvals to market Increlex in the United States or rest of the world 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 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 four-year period. We believe that the aggregate numbers of children in Western Europe with Primary IGFD and severe Primary IGFD are substantially equivalent to the numbers in the United States. If the results of Genentech's study or our interpretation and extrapolation of data from the study do not accurately reflect the number of children with Primary IGFD or severe Primary IGFD, our assessment of the market may be incorrect, making it difficult or impossible for us to meet our revenue goals or to 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.

Prior to our January 2006 commercial launch of Increlex in the United States for the treatment of severe Primary IGFD, rhIGF-1 had never been commercialized in the United States or Europe for any indication. Even though the FDA has approved Increlex for sale in the United States, physicians may choose not to prescribe it, 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;
- reimbursement adoption;
- product price;
- the effectiveness of our sales and marketing efforts;
- storage requirements and ease of administration;
- dosing regimen;
- safety and efficacy;
- prevalence and severity of side effects; and
- competitive products.

Reimbursement 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 Increlex, and the timing of reimbursement decisions by these payors, 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 assumptions regarding the timing of reimbursement decisions or the level of reimbursement for Increlex are incorrect, our expected revenues may be delayed or substantially reduced. Since the FDA approved 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. If reimbursement is not available or is available only to limited levels, we may not be able to market and sell Increlex.

We believe that the annual wholesale acquisition cost of Increlex therapy for the treatment of severe Primary IGFD for a 24 kilogram child would be approximately $23,000 per year. The actual cost per year per patient for Increlex will depend on the weight of the child, the treatment dose prescribed and compliance. 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 patient could be less than in subsequent years. If our assumptions regarding the price per patient of Increlex therapy for the treatment of severe Primary IGFD and Primary IGFD are incorrect, the market opportunity for Increlex therapy for the treatment of severe Primary IGFD and Primary IGFD may be substantially reduced.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly 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

market and sell 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.

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.

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

- acceptance of Increlex by physicians and patients as a safe and effective treatment;
- reimbursement adoption;
- product price;
- manufacturing costs;
- the effectiveness of our sales and marketing efforts;
- storage requirements and ease of administration;
- dosing regimen;
- safety and efficacy;
- prevalence and severity of side effects; and
- competitive products.

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.

Insmed Incorporated's combination product, when launched commercially, will compete with Increlex for the treatment of patients with severe Primary IGFD. Insmed's combination product was recently approved by the FDA for the treatment of patients with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone.

Growth hormone products will likely compete with Increlex for the treatment of patients with Primary IGFD if Increlex is also approved for that indication. The major suppliers of commercially available growth hormone

products in the United States are Genentech, Eli Lilly and Company, Teva Pharmaceutical Industries Ltd., Novo Nordisk A/S, Pfizer Inc and Serono S.A. Investigators from a Novo Nordisk clinical trial recently presented data that demonstrated growth hormone was effective in a population that included children with Primary IGFD. In addition, children with Primary IGFD may be diagnosed as having idiopathic short stature, or ISS. Eli Lilly and Company and Genentech have received FDA approval for their respective growth hormone products for the treatment of children with ISS. Accordingly, we expect that growth hormone products will compete directly with Increlex for the treatment of children with Primary IGFD who may be diagnosed as having ISS.

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

We believe that Bristol-Meyers Squibb Company, Genentech, Merck & Co., Inc., Novo Nordisk and Pfizer Inc have conducted research and development of orally available small molecules that cause the release of growth hormone, known as growth hormone secretagogues. We believe that 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.

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

We are currently developing Increlex in clinical trials for the treatment of Primary IGFD, which has substantially more patients than severe Primary IGFD. The FDA has substantial discretion in the approval process and may decide that our data is insufficient to allow approval of Increlex for Primary IGFD. If we do not receive regulatory marketing approval in the United States for Primary IGFD, our business will be harmed. We will also need to file applications with regulatory authorities in foreign countries to market Increlex for Primary IGFD in foreign countries. Although we have submitted a marketing authorization application in Europe for severe Primary IGFD, there is no assurance that we will receive marketing approval in Europe for either severe Primary IGFD or Primary IGFD. If we fail to obtain European marketing approval for Increlex, the geographic market for Increlex would be limited. If such approvals are delayed, it would postpone our ability to generate revenues in Europe.

If our contract manufacturers' facilities and operations do not maintain satisfactory cGMP compliance, we may be unable to market and sell Increlex.

The facilities used by and operations of our contract manufacturers to manufacture and test Increlex must undergo continuing inspections by the FDA for compliance with cGMP regulations in order to maintain our Increlex approval for the treatment of severe Primary IGFD. As an example, Cambrex Bio Science Baltimore, Inc. is our sole provider of bulk rhIGF-1. We have no alternative manufacturing facilities or plans for additional facilities at this time. We do not know if the Cambrex Baltimore facilities or their operations required for the commercial manufacture of Increlex will continue to receive satisfactory cGMP inspections. In the event these facilities or operations do not continue to receive satisfactory cGMP inspections for the manufacture of our product, or for the operation of their facilities in general, we may need to invest in significant compliance improvement programs, fund additional modifications to our manufacturing processes, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as result in a delay or prevention of commercialization, and may result in our failure to maintain approval. In addition, Cambrex Baltimore, and any alternative contract manufacturer we may utilize, will be

subject to ongoing periodic inspection by the FDA and corresponding state and foreign agencies for compliance with cGMP regulations and similar foreign standards. We do not have direct control over our contract manufacturers' compliance with these regulations and standards. Any of these factors could delay or suspend clinical trials, regulatory submissions or regulatory approvals, entail higher costs and result in our being unable to effectively market and sell Increlex or maintain Increlex in the marketplace, which would adversely affect our ability to generate revenues.

Our inability to enter into a commercial agreement on commercially reasonable terms with a single-source manufacturer to fill-finish our approved product could adversely affect our commercial supply and ability to grow revenues.

We currently source all of our fill-finish manufacturing and portions of release testing through a single-source third-party supplier. This single-source supplier is the only approved supplier currently available to us, and could only be replaced by qualification of a new site for the same operations. We are currently negotiating a commercial agreement with this fill-finish manufacturer, which has agreed to provide commercial product under an existing agreement. However, if we are unable to enter into such a commercial agreement with this single-source third-party supplier, we may be unable to fill-finish our commercial product until we could move our process to another fill-finish manufacturer. It would take a significant amount of time and expense to arrange for an alternative manufacturer. If we need to change to another commercial fill-finish manufacturer, this manufacturer's facilities and processes, prior to our use, would have to undergo pre-approval and/or cGMP compliance inspections. In addition, we would need to transfer and validate the processes and certain analytical methods necessary for the production and testing of rhIGF-1 to this new manufacturer. Such a transfer may result in a shortage of our commercial product and a loss of revenues.

We rely solely on single-source third parties in the manufacture, testing, storage and distribution of our products.

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

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

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

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

Difficulties or delays in product manufacturing due to advance scheduling requirements and/or capacity constraints at our third-party manufacturers could harm our operating results and financial performance.

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

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

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

If other companies overcome our U.S. orphan drug marketing exclusivity or obtain marketing exclusivity in Europe, they will be able to compete with us, and our revenues will be diminished.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The company that obtains the first FDA approval for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of seven years. Increlex has received from the FDA orphan drug marketing exclusivity for the long-term treatment of patients with severe Primary IGFD. However, more than one product may be approved by the FDA for the same orphan indication or disease. As a result, even though our product has been approved and has received marketing

exclusivity for severe Primary IGFD, the FDA can still approve other drugs for use in treating the same indication or disease covered by our product, which would create a more competitive market for us. For example, the FDA recently approved Insmed Incorporated's combination product for the treatment of severe Primary IGFD and granted Insmed's product orphan drug designation. Accordingly, notwithstanding our orphan drug designation for rhIGF- 1, Insmed's combination product for rhIGF-1 and BP-3 was deemed by the FDA to be a different drug than ours, and therefore, it will compete with Increlex for the treatment of patients with severe Primary IGFD, when it is launched commercially.

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

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

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

Although we have obtained regulatory approval for Increlex in the United States for the treatment of severe Primary IGFD, this product and our manufacturing processes are subject to continued review and ongoing regulation by the FDA post approval, including, for example, changes to manufacturing process standards or good manufacturing practices, changes to product labeling, revisions to existing requirements or new requirements for manufacturing practices, or changing interpretations regarding regulatory guidance. Such changes in the regulatory environment and requirements could occur at any time during the commercialization of Increlex. This could adversely affect our ability to maintain our approval or require us to expend significant resources to maintain our approval, which could result in the possible withdrawal of Increlex from the marketplace, which would harm our business and negatively impact our financial performance.

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

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

Competitors could challenge our patents and file an Abbreviated New Drug Application (ANDA) or a 505(b)(2) new drug application for an IGF-1 product and adversely affect the competitive position of Increlex.

Products approved for commercial marketing by the FDA are subject to the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, or "Hatch-Waxman Act." The Hatch-Waxman Act

provides companies with marketing exclusivity for varying time periods during which generic or modified versions of a drug may not be marketed and allows companies to apply to extend patent protection for up to five additional years. It also provides a means for approving generic versions of a drug once the marketing exclusivity period has ended and all relevant patents have expired. The period of exclusive marketing, however, may be shortened if a patent is successfully challenged and defeated. Competitors with a generic IGF-1 product or a modified version of IGF-1 may attempt to file an ANDA or a 505(b)(2) NDA and challenge our patents and marketing exclusivity. Such applications would have to certify that one of the patents in the Increlex NDA is invalid or not infringed by the manufacture, use, or sale of the product described in that ANDA or 505(b)(2) application under the Hatch-Waxman Act. If successful, a competitor could come to market at an earlier time than expected. We can provide no assurances that we can prevail in a challenge or litigation related to our patents or exclusivity.

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 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 Insmed Incorporated in the United Kingdom and against Insmed Incorporated in the United States to enforce patent rights we licensed from Genentech. The United States action, among other things, alleges infringement of United States Patent No. 6,311,414 B1 identified above. If the court finds any of the patents at issue in those litigations, including United States Patent No. 6,311,414 B1, to be invalid or unenforceable, we would be prevented from enforcing such patents against third parties in the future, thus preventing us from using the affected patents to exclude others from competing with us. 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 Insmed Incorporated in the United Kingdom and against Insmed in the United States to enforce patent rights we licensed from Genentech. We cannot predict the outcome of such litigation. These actions have required a substantial diversion of financial and personnel resources and could expose us to liability for costs or other awards of damages. Declaratory judgments of invalidity against our patents asserted in such actions could prevent us from using the affected patents to exclude others from competing with us.

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

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 either a diabetes indication or a substitute indication by December 31, 2008. 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, market and sell 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.

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

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

- the FDA or other regulatory authorities either do not approve a clinical trial protocol or place a clinical trial on clinical hold;
- patients do not enroll in clinical trials at the rate we expect (for example, in one of our current Phase III clinical trials of rhIGF-1 in Primary IGFD, patients have not enrolled at the rate we expected);
- patients experience adverse side effects;
- patients develop medical problems that are not related to our products or product candidates;

- third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- contract laboratories fail to follow good laboratory practices;
- interim results of the clinical trial are inconclusive or negative;
- sufficient quantities of the trial drug may not be available, or available drug may become unusable;
- our trial design, although approved, is inadequate to demonstrate safety and/or efficacy;
- re-evaluation of our corporate strategies and priorities; and
- limited financial resources.

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

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

To gain approval to market a product for treatment of a specific disease, we must provide the FDA and foreign regulatory authorities with clinical data that demonstrate the safety and statistically significant efficacy of that product for the treatment of the disease. Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. If a clinical trial failed to demonstrate safety and statistically significant efficacy, we would likely abandon the development of that product, which could harm our business and may result in a precipitous decline in our stock price.

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

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

We may need others to market and sell Increlex in Europe.

We may need others to market and sell Increlex in Europe. If we receive marketing approval for Increlex in Europe and decide to sell Increlex in Europe through one or more third parties, we will need to enter into marketing arrangements with them. We may not be able to enter into marketing arrangements with third parties on favorable terms, or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed Increlex entirely on our own. In the event that 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 market and sell 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.

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.

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

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

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

- a minimum price for our common stock;
- the accuracy of representations and warranties made to Kingsbridge;
- compliance with laws;
- effectiveness of the registration statement, filed by us with the U.S. Securities and Exchange Commission, or SEC, for the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant we issued to Kingsbridge in connection with the entering into of the CEFF; and
- the continued listing of our stock on the Nasdaq Stock Market.

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

The terms of the CEFF require us to pay certain liquidated damages in the event that the registration statement filed by us with the SEC is not available for the resale of securities purchased by Kingsbridge under the CEFF or upon exercise of the warrant we issued to Kingsbridge. Except for certain periods of ineffectiveness permitted under the CEFF, we are obligated to pay to Kingsbridge an amount equal to the number of shares purchased under the CEFF and held by Kingsbridge at the date the registration statement becomes unavailable, multiplied by any positive difference in price between the volume weighted average price on the trading day prior to such period of unavailability and the volume weighted average price on the first trading day after the period of unavailability. In addition, we are entitled in certain circumstances to deliver a "blackout" notice to Kingsbridge to suspend the use of the registration statement and prohibit Kingsbridge from selling shares under the registration statement. If we deliver a blackout notice in the 15 trading days following a settlement of a draw down, then we must make a blackout payment to Kingsbridge as liquidated damages, or issue Kingsbridge additional shares in lieu of this payment, calculated by means of a varying percentage of an amount based on the number of shares purchased and held by Kingsbridge and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout payment could be significant and could adversely affect our liquidity and our ability to raise capital.

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, cash equivalents and short-term investments as of December 31, 2005, together with the net proceeds from our public offering of common stock in January 2006 and our CEFF, will be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2007 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:

- our ability to market and sell sufficient quantities of Increlex;
- the status of competing products;
- the commercial status of the Increlex bulk drug manufacturing operations at Cambrex Baltimore, including the success of our cGMP production activities;
- the success of Increlex final drug product manufacturing;
- the costs, timing and scope of additional regulatory approvals for Increlex;
- the rate of progress and cost of our future clinical trials and other research and development activities; and
- the pace of expansion of administrative expenses.

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, and the CEFF. However, there can be no assurance that additional financing will be available when needed, or, if available, that the terms will be favorable. If additional funds are not available, we may be forced to curtail or cease operations.

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

Our ability to implement our business plan requires an effective planning and management process. As of December 31, 2005, we had 89 full-time employees, and we expect to hire additional employees in the near term. Our offices are located in the San Francisco Bay area where competition for personnel with biopharmaceutical skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

We expect that our anticipated future growth will place a significant strain on our management, systems and resources. In particular, to fulfill our strategy to market and sell Increlex in the United States, we may need to hire a significant number of additional employees. To manage the anticipated growth of our operations, we will need to increase management resources 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 study results from the treatment of 76 children with severe Primary IGFD with Increlex for an average of 4.4 years, with some patients being treated for over 12 years. None of the children withdrew from the study due to adverse events.

However, some patients experienced hypoglycemia, or low blood glucose levels. Other side effects noted in some patients include hearing deficits, enlargement of the tonsils and intracranial hypertension.

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, market and sell Increlex 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.

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 have upgraded our finance and accounting systems, procedures and controls and will need to continue to implement additional procedures and controls as we grow our business and organization and to satisfy new reporting requirements. Section 404 requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accountants attesting to and reporting on these assessments. If we are unable to complete the required assessment as to the adequacy of our internal control reporting or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our internal control over financial reporting, which could adversely affect our stock price.

If we are unable to attract and retain additional qualified personnel, our ability to market and sell 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 and Dr. Ross G. Clark, our Chief Technical Officer, whose knowledge of our industry and technical expertise would be extremely difficult to

replace. We have at will employment contracts with all of our executive officers. They may terminate their employment without cause or good reason and without notice to us.

Risks Related to Our Common Stock

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

While research analysts and others have published forecasts as to the amount and timing of our future revenues and earnings, we have stated that we will not be providing any forecasts of the amount and timing of our future revenues and earnings until after the assessment of two quarters of product sales. 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 entitled "Risks Related to Our Business" above. 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.

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

As of December 31, 2005, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 66.7% of our common stock. Our greater than five percent beneficial owners include entities affiliated with MPM Capital, which beneficially owned 21.7%; entities affiliated with Prospect Management Co. II, LLC, which beneficially owned 9.7%; MedImmune, Inc., which beneficially owned 9.5%; entities affiliated with Rho Ventures, which beneficially owned 9.5%; The Bank of New York, which beneficially owned 5.9%; and State of Wisconsin Investment Board, which beneficially owned 5.6%. 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
- 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.

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

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

Our stock price may be volatile, and an investment in our stock could decline in value.

The trading price of our common stock has fluctuated significantly since our initial public offering in March 2004, and is likely to remain volatile in the future. The trading price of our common stock could be subject to wide fluctuations in response to many events or factors, including the following:

- announcements by us or our competitors of regulatory developments, clinical trial results, clinical trial enrollment, regulatory filings, new products and product launches, significant acquisitions, strategic partnerships or joint ventures;
- estimates of our business potential and earnings prospects;
- deviations from analysts' projections regarding business potential, costs and/or earnings prospects;
- quarterly variations in our operating results;
- significant developments in the businesses of biotechnology companies;
- changes in financial estimates by securities analysts;
- changes in market valuations or financial results of biotechnology companies;
- additions or departures of key personnel;
- changes in the structure of healthcare payment or reimbursement systems, regulations or policies;
- activities of short sellers and risk arbitrageurs;
- future sales of our common stock;
- 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.

We are at risk of securities class action litigation.

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

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

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options or issued pursuant to the CEFF, the market price of our common stock may decline. In addition, the perceived risk of dilution from sales of our common stock to or by Kingsbridge in connection with the CEFF may cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. As of February 1, 2006, we had 37,422,622 outstanding shares of common stock. Of these shares, the 18,975,000 shares sold in our public offerings that were outstanding as of February 1, 2006 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, and other than shares subject to lock-up agreements that the holders of these shares entered into with the underwriter of our public offering in January 2006. These lock-up agreements expired on March 11, 2006. The remaining 18,447,622 shares outstanding as of February 1, 2006 were freely tradable (subject to certain restrictions on sales by affiliates and vesting in the case of early exercised options) other than the shares subject to the lock-up agreements referred to above.

We have filed a registration statement covering shares of common stock issuable upon exercise of options and other grants pursuant to our stock plans. In September 2005, we filed a shelf registration statement pursuant to which we may, from time-to-time, sell shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings. In November 2005, we also filed a registration statement for the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant we issued to Kingsbridge in connection with our entering into the CEFF. In addition, certain holders of shares of our common stock that are parties to our amended and restated investors' rights agreement are entitled to registration rights.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our facilities consist of approximately 28,000 square feet of office space located in Brisbane, California that is leased to us until October 2011. We have no laboratory or research facilities. We believe that our Brisbane facilities will be adequate for our near-term needs and that suitable additional space will be available on commercially reasonable terms to accommodate expansion of our operations, if any.

Item 3. Legal Proceedings.

On December 20, 2004, we initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. There is no trial date set for this action. On December 23, 2004, we, with Genentech, initiated patent infringement proceedings against Insmed Incorporated in the U.S. District Court for the Northern District of California. We initiated these proceedings because we believe that Insmed and Avecia are infringing and/or have infringed on our patents that cover Insmed's product's use and manufacture. The trial date is November 6, 2006; however on March 8, 2006, we filed a motion to accelerate the trial date.

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

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.

On December 6, 2005, we filed a complaint against Insmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court, Northern District of California. The complaint alleges that Insmed made false, misleading and deceptive statements about Increlex and its product. We are seeking monetary and injunctive relief. We filed an amended complaint on December 15, 2005. Defendant Insmed filed a Motion to Dismiss on January 13, 2006. The motion is scheduled to be heard on March 28, 2006. Discovery has not commenced, and no trial date has been set.

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, 2005.

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
Fiscal 2005:		
First Fiscal Quarter	$10.55	$7.63
Second Fiscal Quarter	9.21	7.14
Third Fiscal Quarter	12.65	8.41
Fourth Fiscal Quarter	11.94	6.74
Fiscal 2004:		
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 46 holders of record of our common stock as of February 24, 2006. 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 a public offering price of $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 and underwriting discounts and commissions were $50,021,000.

- None of the expenses were paid, directly or indirectly, to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates

We are using, and intend to continue to use, these proceeds for general corporate purposes, including research and development expenses, manufacturing expenses, clinical trials and selling, general and administrative expenses. No such payments were made to directors, officers of persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for Board or Board committee service.

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.

Issuer Purchases of Equity Securities

The following table sets forth information regarding our repurchases of common stock during the quarter ended December 31, 2005:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Number of Shares that May Yet Be Purchased Under the Programs
October 1 through October 31, 2005	22,136	$0.40	—	—
November 1 through November 30, 2005	—	—	—	—
December 1 through December 31, 2005	—	—	—	—
	22,136	$0.40	—	—

The repurchase of shares of common stock indicated in the table above was not made pursuant to a publicly announced program. The shares were repurchased from the purchaser upon termination of the purchaser's employment with us pursuant to our right to repurchase shares that had not yet vested as of the termination date. The repurchase price was equivalent to the purchase price paid by the purchaser for the shares.

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, 2005, for each of the three years in the period ended December 31, 2005, and the selected balance sheet data as of December 31, 2005 and 2004 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 for the nine months ended December 31, 2001 and for the year ended December 31, 2002, and the selected balance sheet data as of December 31, 2003, 2002 and 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 December 31, 2005
	2005	2004	2003	2002		
Statements of Operations Data (in thousands, except per share data):						
Costs and expenses:						
Research and development	$ 21,587	$ 27,918	$ 19,246	$ 1,974	$ 307	$ 71,212
Selling, general and administrative	25,913	12,552	4,834	1,978	510	45,903
Acquired in-process research and development	—	1,417	1,670	5,071	—	8,158
Total costs and expenses	(47,500)	(41,887)	(25,750)	(9,023)	(817)	(125,273)
Interest expense	(1,080)	—	—	(106)	—	(1,186)
Interest and other income, net	2,347	885	327	177	9	3,746
Net loss	(46,233)	(41,002)	(25,423)	(8,952)	(808)	(122,713)
Deemed dividend related to beneficial conversion features of convertible preferred stock	—	—	(44,153)	—	—	(44,153)
Net loss allocable to common stockholders	$(46,233)	$(41,002)	$(69,576)	$(8,952)	$ (808)	$(166,866)
Basic and diluted net loss per share allocable to common stockholders(1)	$ (1.51)	$ (2.12)	$ (38.59)	$ (5.76)	$(0.90)	
Shares used in computing basic and diluted net loss per share allocable to common stockholders(1)	30,590	19,302	1,803	1,555	895	

	December 31,				
	2005	2004	2003	2002	2001
Balance Sheet Data (in thousands):					
Cash, cash equivalents and short-term investments	$ 58,626	$ 52,001	$ 37,313	$15,870	$ 168
Working capital	54,210	45,542	33,346	15,707	29
Total assets	66,316	55,022	42,484	16,348	198
Total liabilities	9,518	7,345	7,045	568	149
Convertible preferred stock	—	—	68,637	24,693	—
Deficit accumulated during the development stage	(165,741)	(119,508)	(78,506)	(8,930)	(1,103)
Total stockholders' equity (deficit)	56,798	47,677	(33,198)	(8,913)	48

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

Changes in Results From Reported Earnings

On February 15, 2006, we reported preliminary unaudited financial results for the fourth quarter and year ended December 31, 2005. The financial results in this report on Form 10-K differ from those preliminary results as follows:

- Subsequent to February 15, 2006, we revised the accounting for the warrant issued to Kingsbridge Capital Limited in connection with our $75 million Committed Equity Financing Facility ("CEFF"). The value assigned to the warrant was previously reported as a transaction cost associated with accessing the CEFF and thus was recorded to non-operating expense. The value of this warrant is now accounted for in stockholders' equity. This revised accounting resulted in a decrease in non-operating expense and an increase in additional-paid-in-capital included in "Total stockholders' equity (deficit)", of $1,196,000 in the accompanying financial statements for the year ended December 31, 2005.
- This was a non-cash transaction.
- The revised accounting discussed above had no impact on 2005 operating loss.
- Net loss for 2005 decreased from $47,429,000 to $46,233,000.
- Basic and diluted net loss per share for 2005 decreased from $1.55 to $1.51.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

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

Overview

We are a biopharmaceutical company focused on the development and commercialization of new therapeutics for the treatment of short stature and other endocrine disorders. Our first commercial product is Increlex, a DNA-derived recombinant human insulin-like growth factor-1, or rhIGF-1. We obtained approval of long-term Increlex replacement therapy for severe primary insulin-like growth factor deficiency, or severe Primary IGFD, from the FDA in August 2005, and Increlex was granted seven years of orphan drug marketing exclusivity for the long-term treatment of growth failure in children with severe Primary IGFD. See the section entitled "Risks Related to our Business" under Item 1A above for further details related to our orphan drug marketing exclusivity. In January 2006, we launched Increlex in the United States. We also submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMEA, for approval to market Increlex in the European Union for the long-term treatment of growth failure in children with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone, or GH. We licensed the rights of Genentech, Inc. to develop, manufacture and commercialize rhIGF-1 products for a broad range of indications, including short stature, worldwide. Our current focus is on marketing and selling Increlex for the treatment for severe Primary IGFD, and 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 are developing Increlex for use in the broad population of children with Primary IGFD. We are currently conducting two late-stage clinical trials for the use of rhIGF-1 in Primary IGFD. We are assessing our Increlex development strategy for other indications.

Tercica, Inc.'s predecessor, 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 to Tercica, Inc. In early 2002, Tercica, Inc. 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.

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 for the treatment of diabetes outside of the United States.

In January 2005, we entered into a loan agreement with Venture Leasing & Lending IV, Inc., or VLL, under which we had the option to draw down funds in the aggregate principal amount of up to $15.0 million. This facility expired on December 31, 2005 with no borrowings from this facility.

In October 2005, we entered into a committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, which entitles us to sell and obligates Kingsbridge to purchase a maximum of approximately 6.0 million newly issued shares of our common stock over a three-year period for cash up to an aggregate of $75.0 million, subject to certain conditions and restrictions. See the discussion below under "Committed Equity Financing Facility" for further details on the CEFF. As of December 31, 2005, we had not issued any shares under this facility.

As of December 31, 2005, we had approximately $58.6 million in cash, cash equivalents and short-term investments. We have funded our operations since inception through the private placement of equity securities and public offerings of our common stock. 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 a follow-on public offering of common stock in which we raised net cash proceeds of approximately $51.1 million. On January 27, 2006, we completed another follow-on public offering of common stock in which we raised net cash proceeds of approximately $34.1 million.

Revenues

We began generating revenue from the sale of our current product, Increlex, in January 2006.

Research and Development Expenses

Research and development expenses consist primarily of costs associated with manufacturing development activities and clinical and regulatory activities. Manufacturing development activities include pre-FDA approval preparation activities for current good manufacturing practices (cGMP), regulatory inspection preparation, technology transfer, process development and validation, quality control and assurance activities, analytical services, personnel and related benefits and depreciation. Clinical and regulatory activities include the preparation, implementation, management of our clinical trials and assay development, as well as regulatory compliance, data management and biostatistics. Our research and development activities are primarily focused on manufacturing development activities at our contract manufacturers, including clinical supplies manufacturing, manufacturing process development, validation and qualification activities, analytical development, and compliance-related support, inspection preparation and clinical and regulatory development activities related to severe Primary IGFD and Primary IGFD. Prior to receiving regulatory approval, we charged all drug supply production costs to research and development. Some of these drug supply costs incurred subsequent to August 2005 are included in inventory as our product received regulatory approval that month, and the subsequent cost of sales of these inventories may not be indicative of future costs of sales. Because we licensed non-clinical, clinical and manufacturing data and know-how related to rhIGF-1 from Genentech in 2002, we did not incur

significant development expenses prior to 2002. During 2003, our research and development activities were primarily focused on two projects: the transfer of our rhIGF-1 manufacturing process and the development project for Primary IGFD. At the end of 2003, we began to manage the development project for severe Primary IGFD as a separate project from the development project for Primary IGFD and completed the technology transfer of our manufacturing process to our contract manufacturers. Our primary focus in research and development in 2004 was associated with the establishment and validation of our rhIGF-1 manufacturing process at our contract manufacturers and preparations for the anticipated NDA filing for severe Primary IGFD. During 2005, our research and development activities primarily centered around our NDA filing, process validation, quality control and assurance, and analytical services in preparations for FDA inspections at our contract manufacturers and development projects for severe Primary IGFD and Primary IGFD. Development projects for severe Primary IGFD and Primary IGFD consists primarily of clinical and regulatory activities, including costs associated with clinical trials. The FDA approved our NDA in August 2005 and granted Increlex seven years of orphan drug marketing exclusivity for the long-term treatment of growth failure in children with severe Primary IGFD. We expect 2006 to be primarily focused on clinical activities 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 associated with sales and marketing personnel, executive management, corporate administration, legal fees, pre-launch commercial planning activities, facility costs, insurance, information technology and accounting services. During 2004, we continued to expand our corporate staffing and infrastructure and initiated planning for sales and marketing activities. During 2005, we expanded our corporate staffing and infrastructure, increased our pre-launch activities and implemented Section 404 of the Sarbanes-Oxley Act of 2002. We expect total selling, general and administrative expenses in 2006 to increase primarily due to commercial activities associated with marketing Increlex for severe Primary IGFD, partially offset by decreased legal costs associated with our litigation with Insmed Incorporated and Avecia Limited.

Critical Accounting Policies and the Use of Estimates

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

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

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.

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, 2005, we had a total of $2.6 million of deferred stock compensation remaining to be amortized over the vesting period of the stock options of approximately two years. In the year ended December 31, 2005, we reversed $1.7 million of deferred 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: $1.7 million for the year ending December 31, 2006 and $0.9 million for the year ending December 31, 2007.

On December 16, 2004, the FASB issued an amendment to SFAS No. 123, *Share-Based Payment,* ("SFAS No. 123R"). We have adopted SFAS No. 123R as of January 1, 2006. 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 required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. We have selected the Black-Scholes option-pricing model to be used for valuing share-based payments and will recognize compensation cost on a straight-line basis over the requisite service period of the awards. We have also selected the modified prospective transition method, whereby compensation cost is recognized based on the requirements of SFAS No. 123R beginning with the effective date (a) for all share-based payments granted after the effective date and (b) for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. We believe that the adoption of the new standard will have a material impact on our results of operations. We expect to continue to grant stock-based compensation to employees. Our estimate of future stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in the future, as well as a number of complex and subjective valuation assumptions and the related tax effect. These valuation assumptions include, but are not limited to, the volatility of our stock price and employee stock option exercise behaviors.

Inventories

Inventories are stated at the lower of cost or market and consist of inventories for Increlex, which was approved by the FDA in August 2005. Cost is determined using the first-in, first-out basis. The valuation of inventory requires us to estimate obsolete or excess inventory. The determination of obsolete or excess inventory requires us to estimate the future demands for our products; however, if our current assumptions about future production or inventory levels, demand or competition were to change or if actual market conditions are less favorable than those we have projected, inventory write-downs may be required that could negatively impact our product gross margins and results of operations.

Clinical Trial Expenses

We contract with third-party clinical research organizations to perform various clinical trial activities. We recognize research and development expenses for these contracted activities based upon a variety of factors, including actual and estimated patient enrollment rates, clinical site initiation activities, labor hours and other

activity-based factors. We match the recording of expenses in our financial statements to the actual services received and efforts expended. Depending on the timing of payments to the service providers, we record prepaid expenses and accruals relating to clinical trials based on our estimate of the degree of completion of the event or events as specified in each clinical study or trial contract. We monitor each of these factors to the extent possible and adjust estimates accordingly.

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 surrounding rhIGF-1 generally include completion of clinical trials, completion of manufacturing validation, interpretation of clinical and preclinical data and obtaining marketing approval from the FDA and other foreign regulatory bodies, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist with timely completion of development projects, including clinical trial results, manufacturing process development results, 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.

Results of Operations

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

Revenues. We did not generate any revenues from Increlex for the years ended December 31, 2005 and 2004. We began generating revenue from the sale of Increlex in January 2006.

Research and Development Expenses. Research and development expenses decreased to $21.6 million for the year ended December 31, 2005, from $27.9 million for the same period in 2004. The $21.6 million in expenses for the year ended December 31, 2005 were comprised primarily of personnel and related costs of $10.5 million, costs associated with the process validation, quality control and assurance, analytical services and preparations for pre-approval inspections at our contract manufacturers totaling $5.9 million, costs related to our development projects for Primary IGFD and severe Primary IGFD, which consists primarily of costs associated with the implementation and management of our clinical trials totaling $4.1 million and a milestone payment of $1.0 million to Genentech upon receiving FDA approval of Increlex.

In the year ended December 31, 2005, total research and development expenses decreased by $6.3 million over the same period in 2004. This decrease was primarily due to lower costs related to manufacturing activities, which decreased by $8.8 million from the same period in 2004. Manufacturing development expenses in 2004 included establishment and validation of our rhIGF-1 manufacturing process at our contract manufacturers and cGMP preparations for the anticipated NDA filing in severe Primary IGFD, neither of which were required in 2005. Costs in 2005 associated with our development projects for Primary IGFD and severe Primary IGFD decreased by $1.3 million due primarily to the timing of certain start up clinical trial expenses incurred in 2004. These decreases were partially offset by higher personnel costs of $2.3 million and a milestone payment to Genentech of $1.0 million. We expect 2006 to be primarily focused on clinical activities in Primary IGFD.

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

expect total selling, general and administrative expenses in 2006 to increase primarily due to increased personnel and commercial activities associated with marketing Increlex for severe Primary IGFD, partially offset by decreased legal costs associated with our litigation with Insmed and Avecia.

Acquired In Process Research and Development. Acquired in-process research and development expense was $1.4 million in the year ended December 31, 2004. We did not incur acquired in-process research and development expenses in the same period in 2005. 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.

Interest Expense. Interest expense was $1.1 million for the year ended December 31, 2005. We did not incur any interest expense in the comparable period in 2004. Interest expense in 2005 represented the value of 112,500 shares of common stock we issued in 2005 in connection with our loan agreement with VLL of $1.0 million and $75,000 of commitment fees related to our loan agreement with VLL.

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

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 for the year ended December 31, 2004 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.

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.

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 market and sell 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 income 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.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2005, we had an accumulated deficit of $165.7 million, which was primarily comprised of $122.7 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 through December 31, 2005 with net cash proceeds of $66.0 million in private equity financings and $101.2 million from our public offerings of common stock.

On January 27, 2006, we completed a public offering of our common stock under a shelf registration, in which we raised net cash proceeds of approximately $34.1 million.

We believe that our cash, cash equivalents and short-term investments as of December 31, 2005 of $58.6 million, together with the net proceeds of our public offering completed in January 2006 and our CEFF, will be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2007 based on our current business plan.

Senior Credit Facility

Pursuant to our loan agreement with VLL, we had the option to draw down funds in the aggregate principal amount of up to $15.0 million. We paid a $75,000 fee as part of this loan agreement and issued a total of 112,500 shares of our common stock to an affiliate of VLL. The facility expired on December 31, 2005, and we did not borrow any funds under this facility.

Committed Equity Financing Facility

Under the terms of the CEFF, Kingsbridge committed to purchase a maximum of approximately 6.0 million newly issued shares of our common stock over a three-year period beginning in October 2005, for cash up to an aggregate of $75.0 million, subject to certain conditions. We may draw down under the CEFF in tranches of up to the lesser of $7.0 million or 2% of our market capitalization at the time of the draw down of such tranche, subject to certain conditions. The common stock to be issued for each draw down will be issued and priced over an eight-day pricing period at discounts ranging from 6% to 10% from the volume weighted average price of our common stock during the pricing period. During the term of the CEFF, Kingsbridge may not short our stock, nor may it enter into any derivative transaction directly related to our stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day

pricing period, is determined by the greater of $3.00 or 90% of our closing share price on the trading day immediately prior to the commencement of each draw down. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 260,000 shares of our common stock at an exercise price of $13.12 per share. We intend to exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a need for additional capital and when we believe that sales of our common stock under the CEFF provide an appropriate means of raising capital. However, we are not obligated to sell any of the $75.0 million of common stock available under the CEFF, and there are no minimum commitments or minimum use penalties.

Cash Flow

Cash, cash equivalents and short-term investments totaled $58.6 million at December 31, 2005, compared to $52.0 million at December 31, 2004, and $37.3 million at December 31, 2003. The increase in 2005 was primarily due to net proceeds of $51.1 million from the issuance of common stock in a follow-on public offering, partially offset by cash used in operating activities of $43.4 million. Cash used in operating activities in 2005 includes the receipt of a $1.0 million reimbursement from our landlord for facility improvements which was recognized as deferred rent. 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 2005 operating activities from 2004 was primarily due to the increase of our net loss in 2005 compared to 2004, which is discussed above in the results of operations, and the capitalization of inventory after we obtained FDA approval of Increlex, offset by the recognition of the leasehold improvement allowance received from our landlord. The increase in net cash used in operating activities in 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 IGFD and Primary IGFD.

Net cash used in investing activities totaled $7.7 million in the year ended December 31, 2005, compared to $3.4 million in the year ended December 31, 2004 and $38.2 million in the year ended December 31, 2003. Net cash used in investing activities represent purchases, sales and maturities of investments and purchases of property and equipment net against proceeds received from the sale of equipment. Net purchases of short-term investments were $5.2 million in 2005, an increase of $2.2 million from 2004. Due to the relatively short-term maturities of our investment portfolio during 2004 and 2005, the increases and decreases in net purchases of short-term investments were primarily due to timing of maturities, sales and purchases of short-term investments. Net purchases of short-term investments were $3.0 million in 2004, a decrease of $32.8 million from 2003. The decrease in net purchases of short-term investments in 2004 compared to 2003 was due primarily to the relatively short-term maturities of our investment portfolio during 2004 resulting in lower net purchases of short-term investments and the increased cash inflows from our Series B financing in 2003 resulting in higher net purchases of short-term investments. Purchases of property and equipment were $2.8 million in 2005, an increase of $2.4 million from 2004. The increase in purchases of property and equipment in 2005 primarily relate to the purchase of leasehold improvements and office furniture for our new offices located in Brisbane, California, and the purchase of computer equipment and software for new employees hired in 2005. Proceeds received from the sale of equipment was $0.3 million in 2005, compared to $0 in 2004. Purchases of property and equipment were $0.4 million in 2004, a decrease of $1.9 million from 2003. The decrease in purchases of property and equipment in 2004 primarily relate to the timing of property and equipment purchases in 2003 compared to 2004.

Net cash provided by financing activities for the year ended December 31, 2005 was $51.8 million, compared to $50.3 million for the year ended December 31, 2004, and $44.5 million for the year ended December 31, 2003. Net cash provided by financing activities primarily relate to net proceeds received from our public offerings of common stock and proceeds received from the issuance of common stock under our stock plans. Net proceeds received from our public offerings of common stock were $51.1 million and $50.0 million in 2005 and 2004, respectively. Proceeds from the issuance of common stock under our equity compensation plans were $0.8 million, $0.3 million and $0.5 million for 2005, 2004 and 2003, respectively.

Litigation

On December 20, 2004, we initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. There is no trial date set for this action. On December 23, 2004, we, with Genentech, initiated patent infringement proceedings against Insmed Incorporated in the U.S. District Court for the Northern District of California. We initiated these litigations because we believe that Insmed and Avecia are infringing and/or have infringed on our patents that cover Insmed's product's use and manufacture. The trial date is November 6, 2006; however, on March 8, 2006, we filed a motion to accelerate the trial date.

We cannot predict the outcome of our litigation against Avecia and Insmed in the United Kingdom or the outcome of our litigation against Insmed 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 that a defendant prevails, and the defendant establishes by clear and convincing evidence that the case is exceptional (e.g., our claims of patent infringement were not pursued in good faith), we could be liable for an award of the opposing party's costs and legal fees incurred in connection with the litigation and/or an award of other damages. Any such award or awards to the opposing parties could substantially increase our costs and exacerbate the negative impact that an unfavorable outcome in the case(s) could have on our business. Further, it is not uncommon in cases of this kind for a defendant to assert counterclaims, which could significantly increase our costs, potential liability for damages, and other risks arising from these lawsuits, and a court could find us liable for any such damages caused by Genentech as well.

On December 6, 2005, we filed a complaint against Insmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court, Northern District of California. The complaint alleges that Insmed made false, misleading and deceptive statements about Increlex and its product. We are seeking monetary and injunctive relief. We filed an amended complaint on December 15, 2005. Defendant Insmed filed a Motion to Dismiss on January 13, 2006. The motion is scheduled to be heard on March 28, 2006. Discovery has not commenced, and no trial date has been set.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of December 31, 2005 were as follows (in thousands):

	Payments due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease commitments	$3,742	$116	$1,450	$1,545	$631

Our commitments for operating leases include leases for our present office facility and office equipment. In 2005, we obtained a $340,000 irrevocable letter of credit in conjunction with the lease agreement covering our present facility. This irrevocable letter of credit is collateralized for the same amount by cash, cash equivalents and short-term investments held in a Company bank account and has been recorded as restricted cash.

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

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

Operating Capital and Capital Expenditure Requirements

We believe that our cash, cash equivalents and short-term investments as of December 31, 2005 of $58.6 million, together with the net proceeds from our public offering of common stock in January 2006 of approximately $34.1 million and our CEFF, will be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2007 based on our current business plan. We plan to make significant expenditures to support our marketing, sales, clinical trial, regulatory, and manufacturing development activities. We expect to focus on commercial launch activities for severe Primary IGFD and continue to expand our development projects for severe Primary IGFD and Primary IGFD. We also expect to make significant legal expenditures for our ongoing litigations.

We obtained approval for the long-term treatment of growth failure in children with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone from the FDA in August 2005, and we are marketing Increlex for those indications. In addition, we submitted an MAA to EMEA seeking approval to market Increlex in the European Union for an indication that is similar. We are also conducting two late-stage clinical trials for the use of Increlex in Primary IGFD as well as other clinical activities. Our projects may be subject to change from time-to-time as we evaluate our research and development priorities and available resources. These projects may also yield varying results that could delay, limit or change the timing of a project's advancement through various stages of product development and significantly impact the costs to be incurred in bringing a project to completion. As a result, the costs to complete such projects, as well as the timing of net cash outflows, are not reasonably estimable.

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

- our ability to market and sell sufficient quantities of rhIGF-1;
- the costs, timing and scope of additional domestic and international regulatory approvals for rhIGF-1;
- the status of competing products;
- 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; and
- the pace of expansion of administrative expenses.

Due to the significant risks and uncertainties inherent in the manufacturing, clinical development and regulatory approval processes, the costs to complete our projects through product commercialization are not accurately predictable. Results from regulatory review, manufacturing operations and clinical trials may not be favorable. Further, data from clinical trials is subject to varying interpretation, and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, our development projects are subject to risks, uncertainties and changes that may significantly impact cost projections and timelines. As a result, our capital requirements may increase in future periods.

We expect that we will require and attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources, including the CEFF. However, there is no assurance that additional funding will 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 auction rate debt securities, commercial paper, federal agency bonds, repurchase agreements and money market funds. Our cash and cash equivalents through December 31, 2005 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, 2005.

Item 8. Financial Statements and Supplementary Data.

TERCICA, INC.
(A DEVELOPMENT STAGE COMPANY)
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
Tercica, Inc.

We have audited the accompanying balance sheets of Tercica, Inc. (a development stage company) as of December 31, 2005 and 2004, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2005, and for the period from October 1, 2000 (inception) through December 31, 2005. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Tercica, Inc. at December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, and for the period from October 1, 2000 (inception) through December 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Tercica, Inc.'s internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 13, 2006 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 13, 2006

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
Tercica, Inc.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting at Item 9A, that Tercica, Inc. (a development stage company) maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Tercica, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that Tercica, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Tercica, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets as of December 31, 2005 and 2004, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2005, and for the period from October 1, 2000 (inception) through December 31, 2005 of Tercica, Inc. (a development stage company) and our report dated March 13, 2006 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 13, 2006

TERCICA, INC.
(A DEVELOPMENT STAGE COMPANY)

BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2005	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 14,817	$ 14,126
Short-term investments	43,809	37,875
Inventories	1,636	—
Prepaid expenses and other current assets	1,673	705
Total current assets	61,935	52,706
Property and equipment, net	4,021	2,266
Restricted cash	340	—
Other assets	20	50
Total assets	$ 66,316	$ 55,022
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,245	$ 3,967
Accrued expenses	5,750	3,032
Liability for early exercise of stock options	70	165
Total current liabilities	8,065	7,164
Deferred rent	1,429	—
Other liabilities	24	181
Total liabilities	9,518	7,345
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value: 5,000,000 shares authorized, no shares issued and outstanding at December 31, 2005 and 2004	—	—
Common stock, $0.001 par value: 100,000,000 shares authorized; 31,578,859 and 24,172,162 shares issued and outstanding at December 31, 2005 and 2004, respectively	32	24
Additional paid-in capital	225,100	173,621
Deferred stock compensation	(2,591)	(6,388)
Accumulated other comprehensive loss	(2)	(72)
Deficit accumulated during the development stage	(165,741)	(119,508)
Total stockholders' equity	56,798	47,677
Total liabilities and stockholders' equity	$ 66,316	$ 55,022

See accompanying notes.

TERCICA, INC.
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Year Ended December 31,			Period From October 1, 2000 (Inception) Through December 31, 2005
	2005	2004	2003	
Costs and expenses:				
Research and development*	$ 21,587	$ 27,918	$ 19,246	$ 71,212
Selling, general and administrative*	25,913	12,552	4,834	45,903
Acquired in-process research and development	—	1,417	1,670	8,158
Total costs and expenses	(47,500)	(41,887)	(25,750)	(125,273)
Interest expense	(1,080)	—	—	(1,186)
Interest and other income, net	2,347	885	327	3,746
Net loss	(46,233)	(41,002)	(25,423)	(122,713)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	—	—	(44,153)	(44,153)
Net loss allocable to common stockholders	$(46,233)	$(41,002)	$(69,576)	$(166,866)
Basic and diluted net loss per share allocable to common stockholders	$ (1.51)	$ (2.12)	$ (38.59)	
Shares used to compute basic and diluted net loss per share allocable to common stockholders	30,590	19,302	1,803	
*** Includes non-cash stock-based compensation expense as follows:**				
Research and development	$ 1,188	$ 1,386	$ 791	$ 3,369
Selling, general and administrative	1,006	1,455	256	2,719
Total	$ 2,194	$ 2,841	$ 1,047	$ 6,088

See accompanying notes.

TERCICA, INC.
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(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					
Balances at October 1, 2000 (inception)	—	$ —	—	$—	$—	$—	$ —	$ —	$ —
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)
Balances at March 31, 2001	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)
Balances at December 31, 2001	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)
Balances at December 31, 2002 (carried forward)	—	$ —	1,813,735	$ 2	$15	$—	$ —	$(8,930)	$(8,913)

See accompanying notes.

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					
Balances at December 31, 2002 (brought forward)	—	$—	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)
Balances at December 31, 2003	—	—	2,083,741	2	51,308	(5,984)	(18)	(78,506)	(33,198)
Issuance of common stock upon net exercise of warrants	—	—	139,750	—	—	—	—	—	—
Conversion of Series A convertible preferred stock to common stock	—	—	6,466,662	7	24,846	—	—	—	24,853
Conversion of Series B convertible preferred stock to common stock	—	—	8,830,646	9	43,775	—	—	—	43,784
Issuance of common stock upon initial public offering at $9.00 per share in March and April 2004, net of underwriting discount and offering expenses of $6,905	—	—	6,325,000	6	50,014	—	—	—	50,020
Vesting of common stock from early exercises of stock options	—	—	258,913	—	173	—	—	—	173
Issuance of common stock	—	—	67,450	—	260	—	—	—	260
Deferred stock compensation, net of forfeitures	—	—	—	—	3,138	(3,138)	—	—	—
Amortization of deferred stock compensation	—	—	—	—	—	2,734	—	—	2,734
Issuance of stock options to consultants in exchange for services	—	—	—	—	107	—	—	—	107
Comprehensive loss:									
Unrealized loss on marketable securities	—	—	—	—	—	—	(54)	—	(54)
Net loss	—	—	—	—	—	—	—	(41,002)	(41,002)
Comprehensive loss	—	—	—	—	—	—	—	—	(41,056)
Balances at December 31, 2004 (carried forward)	—	$—	24,172,162	$24	$173,621	$(6,388)	$(72)	$(119,508)	$ 47,677

See accompanying notes.

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					
Balances at December 31, 2004 (brought forward)		$	24,172,162	$ 24	$173,621	$(6,388)	$(72)	$(119,508)	$ 47,677
Issuance of common stock upon initial public offering at $8.00 per share in February 2005, net of underwriting discount and offering expenses of $4,058	—	—	6,900,000	7	51,135	—	—	—	51,142
Vesting of common stock from early exercises of stock options	—	—	201,373	1	140	—	—	—	141
Issuance of common stock	—	—	192,824	—	806	—	—	—	806
Reversal of deferred stock compensation due to forfeitures	—	—	—	—	(1,695)	1,695	—	—	—
Amortization of deferred stock compensation	—	—	—	—	—	2,102	—	—	2,102
Issuance of stock options to consultants in exchange for services	—	—	—	—	72	—	—	—	72
Stock-based compensation recognized due to stock option modifications	—	—	—	—	20	—	—	—	20
Issuance of common stock in connection with senior credit facility, net of issuance costs of $1	—	—	112,500	—	1,001	—	—	—	1,001
Financing cost of warrant issued in connection with committed equity financing facility					(1,196)				(1,196)
Issuance of warrant in connection with committed equity financing facility	—	—	—	—	1,196	—	—	—	1,196
Comprehensive loss:									
Unrealized gain on marketable securities	—	—	—	—	—	—	70	—	70
Net loss	—	—	—	—	—	—	—	(46,233)	(46,233)
Comprehensive loss	—	—	—	—	—	—	—	—	(46,163)
Balances at December 31, 2005	—	$—	31,578,859	$ 32	$225,100	$(2,591)	$ (2)	$(165,741)	$ 56,798

See accompanying notes.

TERCICA, INC.
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,			Period From October 1, 2000 (Inception) Through December 31,
	2005	2004	2003	2005
Cash flows from operating activities:				
Net loss	$ (46,233)	$ (41,002)	$(25,423)	$(122,713)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	707	446	92	1,264
Loss on sale of equipment	76	—	—	76
Property and equipment written-off	—	9	—	17
Amortization of deferred stock compensation, net of forfeitures	2,102	2,734	904	5,740
(Accretion) / Amortization of (discounts) /premiums relating to available-for-sale securities	(701)	454	471	224
Amortization of debt issuance costs	1,002	—	—	1,002
Commitment fee written-off due to termination of senior credit facility	75	—	—	75
Stock compensation to consultants in exchange for services	72	107	143	328
Issuance of warrants in connection with convertible note	—	—	—	105
Issuance of stock in exchange for intellectual property	—	—	—	130
Acquired in-process research and development	—	—	—	4,071
Other	23	—	—	23
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	(938)	2,101	(2,486)	(1,693)
Inventories	(1,636)	—	—	(1,636)
Restricted cash	(340)	—	—	(340)
Accounts payable	(1,722)	(1,384)	4,943	2,246
Accrued expenses	2,718	1,818	1,125	5,750
Deferred rent	1,429	—	—	1,429
Net cash used in operating activities	(43,366)	(34,717)	(20,231)	(103,902)
Cash flows from investing activities:				
Purchases of property and equipment	(2,838)	(407)	(2,298)	(5,678)
Proceeds received from sale of equipment	300	—	—	300
Purchases of available-for-sale securities	(110,641)	(113,184)	(63,653)	(287,478)
Proceeds from maturities and sales of available-for-sale securities	105,475	110,165	27,800	243,440
Net cash used in investing activities	(7,704)	(3,426)	(38,151)	(49,416)
Cash flows from financing activities:				
Net proceeds from issuance of Class A and B shares	—	—	—	1,004
Liquidating distribution to Tercica Limited shareholders	—	—	—	(9)
Net proceeds from issuance of preferred stock	—	—	43,784	63,800
Proceeds from issuance of convertible note	—	—	—	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	806	260	6	1,083
Proceeds from early exercised options	—	40	511	622
Repurchases of unvested early exercised options	(111)	—	—	(111)
Payment of commitment fees for senior credit facility	(76)	—	—	(76)
Net proceeds from public offerings of common stock	51,142	50,020	—	101,162
Net cash provided by financing activities	51,761	50,320	44,461	168,135
Net increase (decrease) in cash and cash equivalents	691	12,177	(13,921)	14,817
Cash and cash equivalents, beginning of period	14,126	1,949	15,870	—
Cash and cash equivalents, end of period	$ 14,817	$ 14,126	$ 1,949	$ 14,817
Supplemental schedule of noncash activities:				
Cash paid during the year for:				
Interest expense	$ 75	$ —	$ —	$ 75
Non-cash investing and financing activities:				
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
Issuance of warrants in connection with convertible note	$ —	$ —	$ —	$ 106
Issuance of warrants as commissions in connection with Series A preferred stock financing	$ —	$ —	$ —	$ 41
Conversion of convertible note into Series A convertible preferred stock	$ —	$ —	$ —	$ 500
Issuance of common stock from vesting of early exercises of stock options	$ 140	$ 173	$ 102	$ 415
Issuance of common stock for senior credit facility	$ 1,001	$ —	$ —	$ 1,001
Issuance of warrant in connection with committed equity financing facility	$ 1,196	$ —	$ —	$ 1,196
Deferred stock compensation, net of forfeitures	$ (1,695)	$ 3,138	$ 6,888	$ 8,331
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	$ —	$ 68,637	$ —	$ 68,637

See accompanying notes.

TERCICA, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS

1. Company and Basis of Presentation

Basis of Presentation

Tercica, Inc. (the "Company") is a biopharmaceutical company focused on the development and commercialization of new therapeutics for the treatment of short stature and other endocrine disorders. The Company's first commercial product is Increlex™, a DNA-derived recombinant human insulin-like growth factor-1 ("rhIGF-1"). The Company obtained approval for the long-term treatment of growth failure in children with severe primary insulin-like growth factor deficiency, or severe Primary IGFD, or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone from the U.S. Food and Drug Administration ("FDA") in August 2005, and Increlex was granted seven years of orphan drug marketing exclusivity for the long-term treatment of growth failure in children with severe Primary IGFD. In January 2006, the Company launched Increlex in the United States. The Company also submitted a Marketing Authorization application ("MAA") in the European Union for the long-term treatment of growth failure in children with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. The Company licensed the rights of Genentech to develop, manufacture and commercialize rhIGF-1 products for a broad range of indications, including short stature, worldwide. The Company's current focus is on marketing and selling Increlex for the treatment severe Primary IGFD, and developing Increlex as a replacement therapy for primary IGF-1 deficiency, or Primary IGFD. The Company defines the indication Primary IGFD to mean a child who has a height standard deviation score ("Height SDS") and an IGF-1 standard deviation score ("IGF-1 SDS"), of less than minus two, and the indication severe Primary IGFD to mean a child who has a Height SDS and IGF-1 SDS of minus three or less, in each case in the presence of normal or elevated levels of growth hormone. The Company is developing Increlex for use in the broad population of children with Primary IGFD. The Company is currently conducting two late-stage clinical trials for the use of rhIGF-1 in Primary IGFD. The Company is also assessing their Increlex development strategy for other indications.

The Company's predecessor, Tercica Limited, a New Zealand Company, was formed in October 2000. Tercica Medica, Inc. was incorporated in Delaware in December 2001, adopted the calendar year as its fiscal year and subsequently changed its name in September 2003 to Tercica, Inc. 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 considered to be in the development stage at December 31, 2005, as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, preparing for the commercialization of Increlex 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.

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 Offerings

On February 11, 2005, the Company completed a follow-on public offering of 6,900,000 shares of its common stock, at a price to the public of $8.00 per share, including the exercise of the over-allotment option by the underwriters. Net cash proceeds from this offering were approximately $51,100,000 after deducting underwriter discounts and other offering expenses.

On September 9, 2005, the Company filed a shelf registration statement with the SEC pursuant to which the Company may, from time to time, offer and sell shares of the Company's common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, with a total value of up to $75,000,000, at prices and on terms to be determined by market conditions at the time of any offering made under the shelf registration statement. The SEC declared the shelf registration statement effective on December 1, 2005. On January 27, 2006, the Company completed the sale of 5,750,000 shares of its common stock under this shelf registration statement, at a price to the public of $6.40 per share, including the exercise of the over-allotment option by the underwriters. Net cash proceeds from this offering were approximately $34,100,000 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, 2005, the Company had an accumulated deficit of $165,741,000. After considering the net cash proceeds obtained in January 2006, as described above, management believes that currently available resources, including cash, cash equivalents and short-term investments and the Committed Equity Financing Facility (See Note 8), will provide sufficient funds to enable the Company to meet its projected operating and capital expenditure requirements through at least the end of 2007 based on the Company's current business plan. 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

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.

Concentrations

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

The Company sources all if its bulk manufacturing and fill-finish manufacturing through single-source third-party suppliers and contractors and the Company obtains specific components and raw materials used to manufacture Increlex from either single-source or sole-source suppliers. If these contract facilities, suppliers or contractors become unavailable to the Company for any reason, the Company may be delayed in manufacturing Increlex or may be unable to maintain validation of Increlex, which could delay or prevent the supply of commercial and clinical product, or delay or otherwise adversely affect revenues. The Company believes that it has established guidelines to maintain an adequate level of inventory to mitigate this potential negative impact.

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

The Company considers all highly liquid investments with a remaining maturity of 90 days or less at the date of purchase to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value. The Company's cash equivalents include interest-bearing money market funds. The Company's short-term investments primarily consist of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase.

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

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

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

	December 31, 2004			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
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
Total available-for-sale debt securities	$44,673	$—	$(72)	$44,601

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

	December 31,	
	2005	2004
Cash	$ 873	$ 7,400
Cash equivalents	13,944	6,726
Cash and cash equivalents	14,817	14,126
Short-term investments	43,809	37,875
Long-term restricted cash	340	—
Total	$58,966	$52,001

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

Fair Value of Financial Instruments

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

Inventories

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

Research and Product Development Costs

In accordance with Statement of Financial Accounting Standards ("SFAS") No. 2, *Accounting for Research and Development Costs*, research and development costs are expensed as incurred. Research and development expenses consist primarily of contract manufacturing expenses associated with manufacturing development activities, clinical activities, regulatory activities, payroll and related costs, non-cash stock compensation, laboratory supplies and certain allocated costs. Manufacturing development primarily includes costs associated with process development and validation, quality control and assurance activities, analytical services and preparation for current good manufacturing practices (cGMP) in order to provide clinical drug supply.

Acquired In-Process Research and Development

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

Clinical Trial Expenses

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

Promotional and Advertising Expenses

The Company expenses the costs of promotional and advertising expenses, as incurred. Promotional and advertising expenses consist primarily of promotional materials and activities, design and layout costs of

promotional materials, and direct mail advertising. Promotional and advertising expenses were $1,069,000, $75,000 and $0 in the years ended December 31, 2005, 2004 and 2003, respectively.

Property and Equipment

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

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

Impairment of Long-Lived Assets

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

Income Taxes

The Company utilizes the liability method of accounting for income taxes as required by SFAS No. 109, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Currently, there is no provision for income taxes as the Company has incurred operating losses to date.

Stock Compensation

Through December 31, 2005, the Company accounted 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 adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended.

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

	Year Ended December 31,		
	2005	2004	2003
Risk-free interest rate	3.8%	2.9%	2.8%
Volatility	0.5	0.8	0.8
Weighted-average expected life of options (years)	3.6	3.8	4.0
Dividend yield	0.0%	0.0%	0.0%

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 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 $2,102,000, $2,734,000 and $904,000 for the years ended December 31, 2005, 2004 and 2003, respectively. During the years ended December 31, 2005 and 2004, the Company reversed $1,695,000 and $847,000, respectively, of deferred stock compensation due to forfeitures 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):

	Year Ended December 31,			Period From October 1, 2000 (Inception) Through December 31,
	2005	2004	2003	2005
Net loss allocable to common stockholders, as reported	$(46,233)	$(41,002)	$(69,576)	$(166,866)
Plus: Employee stock compensation expense based on intrinsic value method	2,102	2,734	904	5,740
Less: Employee stock compensation expense determined under the fair value method for all awards	(4,424)	(3,307)	(976)	(8,728)
Pro forma net loss allocable to common stockholders	$(48,555)	$(41,575)	$(69,648)	$(169,854)
Net loss per share allocable to common stockholders:				
Basic and diluted, as reported	$ (1.51)	$ (2.12)	$ (38.59)	
Basic and diluted, pro forma	$ (1.59)	$ (2.15)	$ (38.63)	

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.

On December 16, 2004, the FASB issued an amendment to SFAS No. 123, *Share-Based Payment,* ("SFAS No. 123R"). The Company adopted SFAS No. 123R as of January 1, 2006. 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 required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. The Company has selected the Black-Scholes option-pricing model to be used for valuing share-based payments. The Company has also selected the modified prospective transition method, whereby compensation cost is recognized based on the requirements of SFAS No. 123R beginning with the effective date (a) for all share-based payments granted after the effective date and (b) for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. The Company believes that the adoption of the new standard will have a material impact on the Company's results of operations. The Company expects to continue to grant stock-based compensation to employees. The estimate of the Company's future stock-based compensation expense is affected by the Company's stock price, the number of stock-based awards the Company's board of directors may grant in the future, as well as a number of complex and subjective valuation assumptions and the related tax effect. These valuation assumptions include, but are not limited to, the volatility of the Company's stock price and employee stock option exercise behaviors.

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):

	Year Ended December 31,		
	2005	2004	2003
Net loss, as reported	$(46,233)	$(41,002)	$(25,423)
Change in unrealized losses on marketable securities	70	(54)	(18)
Comprehensive loss	$(46,163)	$(41,056)	$(25,441)

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.

Reclassifications

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 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,		
	2005	2004	2003
	(In thousands, except per share data)		
Historical			
Numerator:			
Net loss allocable to common stockholders	$(46,233)	$(41,002)	$(69,576)
Denominator:			
Weighted-average common shares outstanding	30,619	19,377	1,928
Less: Weighted-average unvested common shares subject to repurchase	(29)	(75)	(125)
Denominator for basic and diluted net loss per share allocable to common stockholders	30,590	19,302	1,803
Basic and diluted net loss per share allocable to common stockholders	$ (1.51)	$ (2.12)	$ (38.59)

	Year Ended December 31,		
	2005	2004	2003
	(In thousands)		
Historical outstanding dilutive securities not included in diluted net loss per share allocable to common stockholders calculation			
Preferred stock	—	—	15,297
Options to purchase common stock	2,851	2,077	1,202
Warrant	260	—	146
	3,111	2,077	16,645

4. Balance Sheet Details

Inventories consisted of the following (in thousands):

	December 31, 2005
Raw materials	$ 319
Work-in-process	1,229
Finished goods	88
Total	$1,636

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

	December 31,	
	2005	2004
Office equipment	$ 292	$ 292
Furniture and fixtures	628	197
Computer equipment and software	1,683	800
Manufacturing equipment	1,004	—
Leasehold improvements	1,450	168
Construction in progress	175	1,352
Less accumulated depreciation and amortization	(1,211)	(543)
Property and equipment, net	$ 4,021	$2,266

Depreciation expense was $707,000, $446,000 and $92,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2005	2004
Accrued compensation and related liabilities	$2,626	$1,555
Accrued professional fees	1,577	460
Accrued contract manufacturing expenses	543	946
Clinical trial costs	276	—
Other accrued liabilities	728	71
	$5,750	$3,032

5. 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 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 and early 2006, the Company paid Genentech cash of $1,100,000 and $100,000, respectively, under this agreement.

On July 25, 2003, the Company entered into an international license and collaboration agreement (the "International License and Collaboration Agreement") with Genentech, obtaining certain rights to develop and commercialize rhIGF-1 for a broad range of indications, including short stature, outside of the United States. The Company paid Genentech cash of $1,670,000 upon the execution of this license in 2003 and $167,000 in 2004. The Company also agreed to pay to Genentech royalties on the sales of rhIGF-1 products and certain one-time payments upon the occurrence of specified milestone events. As the Company was several years away from having an approved product to market, the amount paid for this license was charged to acquired in-process research and development expense.

In addition to the amounts already paid to Genentech, if the Company achieves all of the additional milestones for rhIGF-1 under the U.S. and International License and Collaboration Agreements, the Company will owe Genentech up to an aggregate of approximately $33,000,000 in milestone payments. If the Company develops rhIGF-1 in combination with IGF binding protein-3, the Company would be subject to these same milestone events and, upon achievement of all of the milestones, would owe Genentech up to an additional aggregate of approximately $32,500,000 in milestone payments. In connection with the U.S. License and Collaboration Agreement, the Company paid a $1,000,000 milestone payment to Genentech in the year ended December 31, 2005.

6. Commitments and Contingencies

The Company leases approximately 28,000 square feet of office space in Brisbane, California. The lease expires in October 2011 with an option to renew for five years. This lease agreement includes scheduled rent increases over the lease term and rent abatement for the first 15 months. The Company recognizes rent expense on a straight-line basis over the term that the facility is physically utilized, taking into account the scheduled rent increases, rent abatement, rent holidays and the leasehold improvement reimbursement. In September 2005, the Company received a $1,046,000 reimbursement from the landlord for facility improvements, which was recorded as deferred rent and is being amortized to offset rent expense over the remaining life of the lease. Under the lease agreement, the Company originally provided the landlord with irrevocable letters of credit amounting to $790,000, which were subsequently reduced to $340,000 in September 2005 after the FDA approved Increlex for marketing in late August 2005. The remaining irrevocable letter of credit is collateralized for the same amount by cash, cash equivalents and short-term investments held in a Company bank account. The Company has recorded the collateralized bank account balance as restricted cash.

At December 31, 2005, future minimum lease commitments under operating leases were as follows (in thousands):

Year ending December 31,	
2006	$ 116
2007	710
2008	740
2009	756
2010	789
Thereafter	631
	$3,742

Rent expense was $641,000, $453,000 and $238,000 for the years ended December 31, 2005, 2004 and 2003, 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 has a non-cancelable obligation to reimburse Cambrex Baltimore on a time and materials and per batch basis in connection with the commercial production of Increlex of approximately $4,482,000 through December 31, 2006. Further, as the Company reaches certain milestones, the Company will be committed to make certain future purchases. Payments under this agreement were $6,887,000, $11,699,000 and $7,203,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

Guarantees and Indemnifications

In November 2002, the FASB issued Interpretation No. 45, *Guarantor's 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 guarantee, the guarantor must recognize a liability for the fair value of the obligations it 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, 2005.

Contingencies

On December 20, 2004, the Company initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. There is no trial date set for this action. On December 23, 2004, the Company, with Genentech, initiated patent infringement proceedings against Insmed Incorporated in the U.S. District Court for the Northern District of California. The Company initiated these litigations because it believes that Insmed and Avecia are infringing and/or have infringed on the Company's patents that cover Insmed's product's use and manufacture. The trial date is November 6, 2006; however, on March 8, 2006, we filed a motion to accelerate the trial date.

The Company cannot predict the outcome of its litigation against Avecia and Insmed in the United Kingdom or the outcome of its litigation against Insmed in the United States. Moreover, the Company cannot predict the cost of such litigation, which may require a substantial diversion of the Company's financial assets and other resources and consequently prevent the Company from allocating sufficient resources to the development of its rhIGF-1 programs, and which may have a material adverse effect on the Company's business. In addition, if the outcome of the Company's litigation in the United Kingdom is not favorable to the Company, the Company is likely to be found liable for the opposing parties' costs incurred in connection with the litigation, and the

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

On December 6, 2005, we filed a complaint against Insmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court, Northern District of California. The complaint alleges that Insmed made false, misleading and deceptive statements about Increlex and its product. We are seeking monetary and injunctive relief. We filed an amended complaint on December 15, 2005. Defendant Insmed filed a Motion to Dismiss on January 13, 2006. The motion is scheduled to be heard on March 28, 2006. Discovery has not commenced, and no trial date has been set.

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

7. Senior Credit Facility

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

8. Committed Equity Financing Facility

On October 14, 2005, the Company entered into a committed equity financing facility ("CEFF") with Kingsbridge Capital Limited ("Kingsbridge"), which entitles the Company to sell and obligates Kingsbridge to purchase, a maximum of approximately 6.0 million newly issued shares of the Company's common stock over a period of three years for cash up to an aggregate of $75,000,000, subject to certain conditions and restrictions. The Company may draw down under the CEFF in tranches of up to the lesser of $7,000,000 or 2% of the Company's market capitalization at the time of the draw down of such tranche, subject to certain conditions. The common stock to be issued for each draw down will be issued and priced over an eight-day pricing period at discounts ranging from 6% to 10% from the volume weighted average price of the Company's common stock during the pricing period. During the term of the CEFF, Kingsbridge may not short the Company's stock, nor may it enter into any derivative transaction directly related to the Company's stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day pricing period, is determined by the greater of $3.00 or 90% of the Company's closing share

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

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

9. 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.

10. Stockholders' Equity (Deficit)—Tercica, Inc.

Common Stock

At December 31, 2004 and 2005, the Company was authorized to issue 100,000,000 shares of common stock.

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

Preferred Stock

As of December 31, 2005 and 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.

Restricted Stock Purchases and Early Exercise of Options

In February 2002, 328,158 restricted shares of common stock were issued to an employee in exchange for $2,000 in cash. As of December 31, 2004 and 2005, 50,623 and 3,895 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. During 2003, the Company issued 237,500 shares of common stock under restricted stock purchase agreements to three employees pursuant to the early exercises of their stock options in exchange for $305,000 in cash. In January 2004, the Company issued 10,000 shares of common stock under a restricted stock purchase agreement to a director pursuant to the early exercise of stock options in exchange for $40,000 in cash. 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 93,700 and 425,791 at December 31, 2005 and 2004, respectively, are subject to a repurchase option held by the Company at the original issuance price in the event the optionees' employment or director's tenure is terminated either voluntarily or involuntarily. These repurchase terms are considered to be a forfeiture provision and do not result in variable accounting. During the year ended December 31, 2005, the Company repurchased 130,718 shares of its common stock for approximately $111,350 under restricted stock purchase agreements due to employee forfeitures.

In accordance with EITF No. 00-23, *Issues Related to the Accounting for Stock Compensation under APB Opinion No. 25*, and FIN No. 44, the shares purchased by the employees pursuant to the early exercise of stock options are not deemed to be issued until those shares vest. Therefore, amounts received in exchange for these shares have been recorded as liability for early exercise of stock options on the balance sheet, and will be reclassified into common stock and additional paid-in capital as the shares vest. There were 201,374 shares at an original purchase price of $141,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2005, 258,913 shares at an original purchase price of $173,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2004 and 255,739 shares at an original purchase price of $102,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2003.

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 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.

In connection with the CEFF (see Note 8), the Company issued a warrant to Kingsbridge to purchase up to 260,000 shares of the Company's common stock at an exercise price of $13.12 per share. The exercise term of the warrant is five years beginning on April 14, 2006. This warrant was valued on the date of grant using the Black-Scholes method using the following assumptions: a risk-free interest rate of 4.1%, a life of 5.5 years, no dividend yield and a volatility factor of 0.54. The estimated value of this warrant was $1,196,000 and was recorded as a contra-equity amount in additional paid-in capital in 2005.

Shares Reserved for Issuance

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

	December 31,	
	2005	2004
2004 Employee Stock Purchase Plan	152,101	71,706
Stock option plans:		
Shares available for grant	1,338,983	1,597,259
Options outstanding	2,945,163	2,054,666
Stock options outstanding (granted outside of stock plans)	—	22,500
Shares available for issuance under the CEFF	6,036,912	—
Warrant outstanding to purchase common stock	260,000	—
	10,733,159	3,746,131

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 222,979 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. 42,584 and 28,294 shares were issued under the Purchase Plan during the years ended December 31, 2005 and 2004, 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.

Under the 2004 Stock Plan, 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.

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 2004 Stock Plan expires no later than 10 years from the date of grant. Options granted under the 2004 Stock Plan vests over periods determined by the Board of Directors, generally over four years. The 2004 Stock Plan terminates automatically 10 years after the adoption by the Board of Directors.

2002 Stock Plan and 2002 Executive Stock Plan

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

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 of all options are as follows:

		Options Outstanding	
	Shares Available for Grant	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
Shares authorized	983,834	—	—
Option granted	(1,959,200)	1,959,200	9.13
Options exercised	—	(351,613)	1.76
Options canceled	586,372	(586,372)	8.18
Options canceled outside of Plans	—	(22,500)	4.00
Options Repurchased	130,718	(130,718)	0.85
Balances at December 31, 2005	1,338,983	2,945,163	$7.49

Options presented as exercised in the table above for the years ended December 31, 2003, 2004 and 2005 includes the exercise of vested options and the vesting of early exercised options in previous periods.

The following table summarizes information concerning total outstanding and vested options as of December 31, 2005:

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.40	302,981	7.1	$ 0.40	294,857	$ 0.40
$1.00 – $1.60	132,283	7.3	$ 1.55	110,511	$ 1.59
$4.00	304,334	8.0	$ 4.00	223,947	$ 4.00
$7.24 – $9.99	1,575,596	9.2	$ 8.49	1,242,752	$ 8.60
$10.05 – $12.65	629,969	9.2	$11.35	270,066	$11.18
	2,945,163			2,142,133	

The weighted-average fair value per share of options granted during the years ended December 31, 2005, 2004 and 2003 were $3.94, $6.13 and $10.23, respectively.

Stock Options Granted to Non-Employees

During the year ended December 31, 2004, the Company granted 24,000 options to purchase shares of its common stock to non-employees. The Company did not grant any stock options to non-employees during the year ended December 31, 2005. These have been accounted for in accordance with SFAS No. 123 and EITF No. 96-18. Compensation expense of $72,000, $107,000 and $143,000 was recorded for the years ended December 31, 2005, 2004 and 2003, respectively.

The following table illustrates the weighted average assumptions for the Black-Scholes model used in determining the fair value of options granted to non-employees:

	Year ended December 31,		
	2005	2004	2003
Risk-free interest rate	4.23%	4.28%	4.36%
Volatility	0.5	0.6	0.8
Maximum contractual life (years)	10.0	10.0	10.0
Dividend yield	0.0%	0.0%	0.0%

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 $2,591,000 and $6,388,000 as of December 31, 2005 and 2004, respectively. The Company recorded amortization of employee stock-based compensation expense of $2,102,000, $2,734,000 and $904,000 for the years ended December 31, 2005, 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: $1,681,000 for the year ending December 31, 2006; $903,000 for the year ending December 31, 2007 and $7,000 for the year ending December 31, 2008.

11. 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,	
	2005	2004
Net operating loss carryforwards	$ 30,403	$ 20,855
Research tax credit carryforwards	3,948	2,753
Orphan drug credits	5,881	3,464
Capitalized license fees	3,168	3,043
Capitalized start-up costs	531	2,619
Other	2,029	1,383
Total deferred tax assets	45,960	34,117
Valuation allowance	(45,960)	(34,117)
Net deferred tax assets	$ —	$ —

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 $11,843,000, $19,040,000 and $11,379,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

As of December 31, 2005, the Company had federal net operating loss carryforwards of approximately $99,919,000. The Company also had California net operating loss carryforwards of approximately $76,146,000. 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 $2,115,000, $2,821,000 and $5,881,000, 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.

12. 401(k) Plan

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

13. Quarterly Financial Data—Unaudited

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

	Net Loss	Net Loss Allocable to Common Stockholders	Basic and Diluted Net Loss Per Share Allocable to Common Stockholders
	(In thousands, except per share data)		
Year ended December 31, 2005			
Fourth Quarter	$(13,206)	$(13,206)	$(0.42)
Third Quarter	$(11,518)	$(11,518)	$(0.37)
Second Quarter	$(12,401)	$(12,401)	$(0.40)
First Quarter	$ (9,108)	$ (9,108)	$(0.32)
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)

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, 2005, our Chief Executive Officer and Acting Chief Financial Officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a–15(e) and 15d–15(e) of the Securities Exchange Act of 1934) are effective to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities and Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Management's Annual Report on Internal Control over Financial Reporting

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Acting Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2005 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework*. Based on this evaluation, our management concluded that as of December 31, 2005, our internal control over financial reporting was effective.

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2005 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 Acting 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

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 2006 (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 our audit committee and audit committee financial expert may be found 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 "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."

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

The following schedule is filed as part of this Form 10-K:

Schedule II- Valuation and Qualifying Accounts for the years ended December 31, 2005, 2004 and 2003.

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

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

Exhibit Number	Description
3.1	Certificate of Incorporation(2)
3.2	Bylaws(1)
4.1	Form of Specimen Stock Certificate(1)
4.3	Warrant issued to Kingsbridge Capital Limited, dated October 14, 2005(10)
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)
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)
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(4)

Exhibit Number	Description
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)†
10.7D	Second Amendment to the License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of November 25, 2003(9)
10.8	Manufacturing Services Agreement between the Registrant and Cambrex Bio Science Baltimore, Inc., dated as of December 20, 2002(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	Intentionally omitted
10.9E	Intentionally omitted
10.9F	Intentionally omitted
10.9G	Employment Letter to Andrew Grethlein dated March 5, 2003(1)*
10.9H	Intentionally omitted
10.9I	Intentionally omitted
10.9J	Intentionally omitted
10.9K	Intentionally omitted
10.9L	Employment Letter to Stephen Rosenfield dated June 23, 2004(3)*
10.9M	Employment Letter to Thorsten von Stein dated December 3, 2004(5)*
10.9N	Amendment to Key Employment Agreement for John A. Scarlett, M.D. dated February 22, 2005(4)*
10.9O	Amendment to Key Employment Agreement for Ross G. Clark dated February 22, 2005(4)*
10.9P	Amendment to Employment Letter for Thomas H. Silberg dated February 22, 2005(4)*
10.9Q	Amendment to Employment Letter for Timothy P. Lynch dated February 22, 2005(4)*
10.9R	Amendment to Employment Letter for Stephen N. Rosenfield dated February 22, 2005(4)*
10.9S	Executive Officer Compensation Arrangements(6)*
10.9T	Non-Employee Director Compensation Arrangements(7)
10.9U	Employment Letter to Christopher E. Rivera, dated March 31, 2005(8)*
10.9V	Separation Agreement and Release, dated May 13, 2005, between Thomas H. Silberg and the Registrant(9)*
10.9W	Tercica, Inc. Incentive Compensation Plan(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)

Exhibit Number	Description
10.12A	Loan Agreement, dated January 21, 2005, between Venture Lending & Leasing IV, Inc. and the Registrant(5)
10.12B	Common Stock Purchase Agreement, dated January 21, 2005, between Venture Lending & Leasing IV, LLC and the Registrant(5)
10.13A	Common Stock Purchase Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005(10)
10.13B	Registration Rights Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005(10)
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 annual report on Form 10-K (File No. 000-50461) filed on March 24, 2005.

(5) 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.

(6) 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, March 18, 2005, August 22, 2005 and February 28, 2006.

(7) Incorporated by reference to the information under the heading "Executive Compensation—Compensation of Directors" in the Registrant's definitive proxy statement filed pursuant to Regulation 14A (File No. 000-50461) on April 29, 2005.

(8) Incorporated by reference to the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on May 16, 2005.

(9) Incorporated by reference to the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on August 4, 2005.

(10) Incorporated by reference to the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on November 4, 2005.

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 15, 2006

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 Susan Wong, 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 15, 2006:

Signature	Title
/s/ JOHN A. SCARLETT, M.D. **John A. Scarlett, M.D.**	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ SUSAN WONG **Susan Wong**	Acting Chief Financial Officer (Principal Accounting and Financial Officer)
/s/ MICHAEL ASTRUE **Michael Astrue**	Director
/s/ ALEXANDER BARKAS, PH.D. **Alexander Barkas, Ph.D.**	Director
/s/ ROSS G. CLARK, PH.D. **Ross G. Clark, Ph.D.**	Director
/s/ KARIN EASTHAM **Karin Eastham**	Director
/s/ DENNIS HENNER, PH.D. **Dennis Henner, Ph.D.**	Director
/s/ MARK LESCHLY **Mark Leschly**	Director
/s/ DAVID L. MAHONEY **David L. Mahoney**	Director
/s/ THOMAS WIGGANS **Thomas Wiggans**	Director