

TERCICA INC  
Form 10-K  
February 29, 2008  
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**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, 2007

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)

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

**26-0042539**  
(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:**

Title of Each Class	Name of Each Exchange on Which Registered
<b>Common Stock, \$0.001 par value</b>	<b>The NASDAQ Stock Market LLC</b>

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

**None**

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, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

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 29, 2007 was \$139,860,651 (based upon the closing sales price of such stock as reported on the Nasdaq Global Market on such date). Excludes an aggregate of 22,789,851 shares of the registrant's common stock held by officers, directors and affiliated stockholders. For purposes of determining whether a stockholder was an affiliate of the registrant at June 29, 2007, the registrant has assumed that a stockholder was an affiliate of the registrant at June 29, 2007 if such stockholder (i) beneficially owned 10% or more of the registrant's common stock and/or (ii) was affiliated with an

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executive officer or director of the registrant at June 29, 2007. Exclusion of such shares should not be construed to indicate that any 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 22, 2008, there were 51,583,550 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 2008 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.

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**TERCICA, INC.**

**FORM 10-K ANNUAL REPORT**

**FOR THE YEAR ENDED DECEMBER 31, 2007**

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

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

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

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

*Increlex<sup>®</sup>.* We market Increlex<sup>®</sup> as a long-term replacement therapy for the treatment of short stature in children with severe primary insulin-like growth factor-1 deficiency, or severe Primary IGFD, and for children with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. We obtained approval for the long-term treatment of severe Primary IGFD from the U.S. Food and Drug Administration, or FDA, in August 2005, and we launched Increlex<sup>®</sup> in the United States in January 2006. The FDA has granted Increlex<sup>®</sup> orphan drug exclusivity in the United States, providing seven years of marketing exclusivity for the approved indication. During the year ended December 31, 2007, net product sales of Increlex<sup>®</sup> were \$9.6 million. We are currently conducting a Phase IIIb clinical trial for the use of Increlex<sup>®</sup> for the treatment of short stature in children with Primary IGFD, a less severe and more prevalent form of insulin-like growth factor-1 deficiency, or IGFD. Patient enrollment for this trial was completed in July 2007 and we expect to present data from this trial at a medical conference in the fourth quarter of 2008.

In August 2007, the European Commission granted marketing authorization for Increlex<sup>®</sup> in the European Union for the long-term treatment of growth failure in children and adolescents with severe Primary IGFD. The European Medicines Agency, or EMEA, granted Increlex<sup>®</sup> orphan drug exclusivity for the treatment of severe Primary IGFD, providing a ten-year period of marketing exclusivity for the approved indication. Pursuant to our



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

*Somatuline<sup>®</sup> Depot.* Pursuant to our worldwide strategic collaboration with Ipsen, we have the exclusive right under Ipsen's patents and know-how to develop and commercialize Somatuline<sup>®</sup> Depot in the United States and in Canada for all indications other than ophthalmic indications. In territories outside the United States including Canada, the product is known as Somatuline<sup>®</sup> Autogel<sup>®</sup>. On August 30, 2007, Ipsen received notice of approval from the FDA for marketing Somatuline<sup>®</sup> Depot in the United States for the long-term treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. Acromegaly is a hormonal disorder that results when a tumor in the pituitary gland produces excess growth hormone, resulting in overproduction IGF-1. The FDA has also granted Somatuline<sup>®</sup> Depot orphan drug exclusivity for the treatment of acromegaly, providing a seven-year period of marketing exclusivity. We launched Somatuline<sup>®</sup> Depot in November 2007 in the United States. In July 2006, Somatuline<sup>®</sup> Autogel<sup>®</sup> was approved for marketing by Health Canada for the same indication. Somatuline<sup>®</sup> Autogel<sup>®</sup> has received provincial formulary listings for reimbursement approval in the provinces of Quebec, Nova Scotia, New Brunswick, Saskatchewan, and for Alberta Blue Cross, and we are awaiting reimbursement approval in the province of Ontario. At present, we have contracted sales and marketing operations in Canada to a third party.

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

*Growth hormone/IGF-1 Combination Product Candidates.* In July 2007, we entered into a Combination Product Development and Commercialization Agreement with Genentech that governs the development, manufacture and worldwide commercialization of two product candidates containing Nutropin AQ<sup>®</sup>, Genentech's rhGH, and Increlex<sup>®</sup> for the treatment of all indications except those of the central nervous system. Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> were originally designed and formulated so that the products could be combined and potentially given as a single, daily injection. We are currently developing the co-mixable combination product configuration based on the specific clinical requirements for use in adult growth hormone deficiency, or AGHD, and short-stature. We believe that treatment with a combination of both Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> may be superior to monotherapy of either component alone, particularly for certain patients with short stature associated with low IGF-1 levels, AGHD and potentially other metabolic disorders. In January 2008, we began dosing the first patients in a Phase II clinical study evaluating the combination of the Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> for the treatment of short stature associated with low IGF-1 levels. The primary objective of this trial is to assess the efficacy, measured as first-year height velocity, and safety of three different combination regimens of Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> compared to Nutropin AQ<sup>®</sup> alone in the treatment of short stature associated with low IGF-1 levels. The initial patients enrolled in this trial will receive separate injections of each of Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup>, but the goal of the study is to provide a majority of patients enrolled in the trial with a co-mixture of Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> administered as a single injection.

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**Scientific Background Short Stature**

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

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

We believe that approximately 6,000 children in the United States suffer from severe Primary IGFD, and an additional 24,000 children suffer from Primary IGFD. We believe that the number of children in Europe suffering from severe Primary IGFD and Primary IGFD is approximately the same as in the United States.

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

The cellular production of IGF-1 is regulated by growth hormone. Growth hormone deficiency leads to inadequate IGF-1 production, which results in short stature in children. Growth hormone replacement therapy, which increases IGF-1 levels, can often be used to successfully treat children suffering from growth hormone deficiency. However, we believe many individuals with short stature, despite normal growth hormone secretion, are IGF-1 deficient, because their cells do not respond normally to growth hormone. These children are IGF-1 deficient usually because of abnormalities in either their growth hormone receptors or in their growth hormone signaling pathways. These abnormalities make them unable to produce sufficient levels of IGF-1. 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.



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

*Increlex® and Severe Primary IGFD.* Increlex® is identical to naturally occurring human IGF-1 and we believe it performs the same functions in the body. The product label for Increlex® defines severe Primary IGFD to mean a child who has a height SDS and IGF-1 SDS of minus three or less and normal growth hormone levels. These children do not respond to or respond poorly to growth hormone therapy. If their deficit in growth continues unchanged, children with severe Primary IGFD who are untreated will typically attain a final height of no more than approximately 5'1" for boys and 4'8" for girls. Increlex® therapy supplies these children with the IGF-1 that their bodies are not producing enough of.

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

*Increlex® and Primary IGFD.* Although our first indication is for severe Primary IGFD, we are evaluating the use of Increlex® for the treatment of short stature in children with Primary IGFD, a less severe and more prevalent form of 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.

We completed enrollment of our Phase IIIb clinical trial in Primary IGFD in July 2007, which is intended to serve as the basis for a supplemental NDA filing for this indication. 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 using twice-daily injections. In May 2007, we also completed enrollment in another clinical trial to investigate once-daily dosing of Increlex® in Primary IGFD.

### **Scientific Background Acromegaly**

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

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

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

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

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

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

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

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

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

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

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

Somatuline® Depot has marketing authorizations in over 50 countries for the treatment of acromegaly and neuroendocrine tumors. In 2007, Somatuline® and Somatuline® Depot generated worldwide sales outside of the United States and Canada of 103.6 million (approximately \$152 million), up 12.4% in local currency versus 2006.

In July 2006, Somatuline® Autogel® was approved for marketing by Health Canada for the treatment of acromegaly. In August 2007, Ipsen received notice of approval from the FDA for marketing Somatuline® Depot in the United States for the long-term treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The FDA has also granted Somatuline® Depot orphan drug exclusivity for the treatment of acromegaly, providing a seven-year period of marketing exclusivity. In May 2007, we initiated an open-label clinical study, which we refer to as SALSA, to assess self or partner administration with Somatuline® Depot in patients with acromegaly. We expect that the study will enroll approximately 60 patients in 15 centers in the United States.

### **Scientific Background Adult Growth Hormone Deficiency (AGHD)**

Growth hormone plays an important role in various metabolic functions in adults and low levels of growth hormone in adults are frequently associated with metabolic disorders including lipid abnormalities, decreased bone density, body composition (increase in fat and decreased muscle mass), decreased cardiac performance and insulin resistance. These disorders typically become increasingly apparent after a prolonged period of growth hormone deficiency, as occurs in adults with AGHD. Patients with AGHD are therefore typically treated with growth hormone replacement therapy. AGHD is an FDA approved indication for several growth hormone products on the market today.

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**Potential of GH/IGF-1 combination product candidate for AGHD.** As part of our Combination Products Agreement with Genentech, one combination product candidate containing Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> will be studied in the AGHD population. Patients with AGHD typically have metabolic disorders including abnormalities in body composition. Preclinical studies have suggested that co-administration of rhGH and rhIGF-1 result in synergistic effects on body composition by decreasing body fat and increasing lean muscle mass. In addition, we also believe that when Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> are delivered together as a combination product, some of the negative effects of each individual component could potentially be mitigated by the positive effects of the other, especially their effects on insulin resistance. Upon review of the clinical data in AGHD, we and Genentech will evaluate the potential of this combination product candidate in treating other adult metabolic disorders.

### **Strategy**

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

**Grow Increlex<sup>®</sup> usage in severe Primary IGFD.** We believe that for the approximately 6,000 children in the United States who suffer from severe Primary IGFD, Increlex<sup>®</sup> provides a favorable efficacy and safety profile. Through our sales and marketing efforts, we make pediatric endocrinologists aware of the risks and benefits of Increlex<sup>®</sup> therapy, including conducting medical education programs, medical symposia, and regional speaker programs aimed at increasing physician awareness of Increlex<sup>®</sup> and severe Primary IGFD. We have also established a patient registry to provide additional data on the safety and efficacy of Increlex<sup>®</sup>. In addition, we seek to increase formulary acceptance of Increlex<sup>®</sup> so it can be reimbursed in a timely manner following the writing of a prescription.

**Expand the Increlex<sup>®</sup> indication to include Primary IGFD.** We are seeking to maximize the opportunities presented by Increlex<sup>®</sup> for the treatment of short stature by attempting to expand the use of Increlex<sup>®</sup> to encompass children with Primary IGFD in the United States. If the data from our Phase IIIb clinical trial evaluating twice-daily dosing of Increlex<sup>®</sup> in children with Primary IGFD are positive, we intend to submit a supplemental NDA to expand the use of Increlex<sup>®</sup> to encompass children with Primary IGFD in the United States. If approved for Primary IGFD in the United States, the market for Increlex<sup>®</sup> would expand from the approximately 6,000 children with severe Primary IGFD to encompass the approximately 30,000 children with Primary IGFD, including severe Primary IGFD.

**Successfully Commercialize Somatuline<sup>®</sup> Depot in Canada and the United States.** We launched Somatuline<sup>®</sup> Depot in November 2007 in the United States for the treatment of acromegaly. There are approximately 1,000 adult endocrinologists who specialize in pituitary disorders in the United States that prescribe approximately 90% of the prescriptions for acromegaly. We plan to conduct medical education programs, medical symposia, and regional speaker programs aimed at establishing awareness of Somatuline<sup>®</sup> Depot and its role in treating patients with acromegaly in the physician community. In July 2006, Somatuline<sup>®</sup> Autogel<sup>®</sup> was also approved for marketing by Health Canada for the same indication. The product received provincial formulary listings for reimbursement approval in the provinces of Quebec, Nova Scotia, New Brunswick, Saskatchewan, and for Alberta Blue Cross, and we are awaiting reimbursement approval in the province of Ontario. At present, we have contracted sales and marketing operations in Canada to a third party.

**Broaden our endocrinology development portfolio.** We intend to pursue the development and commercialization of additional products for the treatment of short stature, acromegaly and other metabolic disorders. We are seeking to in-license products that may benefit from our expertise in the field of endocrinology. In addition, as part of our strategic collaboration with Ipsen, we have granted to each other a right of first negotiation with respect to the development and commercialization of products in our respective endocrine pipelines. Ipsen has several endocrinology compounds in early stage development including BIM 23A760 (Dopastatin). BIM 23A760 (Dopastatin), a chimeric molecule directed towards somatostatin and

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dopamine receptors, is targeted at the possible treatment of pituitary adenomas, including those causing acromegaly, Cushing's disease and hyperprolactinemia as well as non-functional pituitary adenomas. The product entered Phase I clinical trials in 2007.

**Key Relationships Genentech**

*rhIGF-1.* We entered into a U.S. License and Collaboration Agreement with Genentech in April 2002, which was amended in July and November 2003 and in July 2007. In addition, we entered into an International License and Collaboration Agreement with Genentech in July 2003, which expands certain of the rights granted to us under the U.S. License and Collaboration Agreement to the remaining territories of the world outside of the United States. Under these agreements, we have certain rights and licenses to Genentech's intellectual property to research, develop, use, manufacture and market rhIGF-1, alone or in combination with IGF binding protein-3, which we refer to in this document as IGFBP-3, for a broad range of indications. The rights are exclusive with respect to our development and sale of rhIGF-1 and non-exclusive with respect to our manufacture of rhIGF-1. Indications not covered by our licenses from Genentech include diseases and conditions of the central nervous system. In addition, we would be obligated to enter into a written agreement with another company if we desire to commercialize rhIGF-1 for diabetes outside of the United States.

Under both the U.S. License and Collaboration Agreement and the International License and Collaboration Agreement, Genentech agreed to transfer to us its pre-clinical and clinical data related to rhIGF-1. This includes data resulting from extensive animal testing as well as Phase I, Phase II and Phase III clinical trials with respect to rhIGF-1. In addition, under these agreements Genentech agreed to transfer its manufacturing technology and know-how to us. In consideration of this transfer, we paid Genentech \$1.0 million in cash and approximately \$4.1 million in Series A preferred stock upon execution of the U.S. License and Collaboration Agreement. We paid Genentech \$1.7 million upon execution of the International License and Collaboration Agreement and \$1.4 million related to the license to Genentech's rights to IGF-1 combined with IGFBP-3. In connection with the approval of our Increlex® NDA in August 2005, we paid Genentech a \$1.0 million milestone payment related to the U.S. License and Collaboration Agreement. We also agreed to pay to Genentech royalties on the sales of rhIGF-1 products and certain one-time payments upon the occurrence of specified milestone events, such as attaining rhIGF-1 indication approvals and aggregate sales levels with respect to rhIGF-1. We are subject to the following milestone payments to Genentech as of December 31, 2007:

In addition to the amounts already paid to Genentech, if we achieve all of the additional milestones related to reaching cumulative sales targets for rhIGF-1 and approval of rhIGF-1 in additional indications under the U.S. License and Collaboration Agreement and the International License and Collaboration Agreement, we will owe Genentech up to an aggregate of approximately \$32.5 million; and

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

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

Under the U.S. License and Collaboration Agreement, Genentech has exclusively licensed to us its right to develop and commercialize rhIGF-1 products in the United States for all indications other than diseases and conditions of the central nervous system. Genentech has a right, the Opt-In Right, to elect, within a limited period of time following an NDA-enabling clinical trial, to participate jointly with us in the development and commercialization of rhIGF-1 products we develop for diabetes indications and for all non-orphan indications. Orphan indications are generally diseases or conditions that affect fewer than 200,000 individuals in the United States. If Genentech elects to exercise its Opt-In Right for a particular indication, Genentech will pay us more than 50% of the past development costs associated with that indication. In addition, after Genentech exercises its

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

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

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

*Growth hormone/IGF-1 combination products.* In July 2007, we entered into a Combination Product Development and Commercialization Agreement, or Combination Product Agreement, with Genentech that governs the worldwide development and commercialization of combination products containing Increlex® and Genentech's rhGH for the treatment of all indications except those of the central nervous system. Under the terms of the Combination Product Agreement, the parties contemplate the development of two combination products for the following indications: one product formulation for certain defined short stature indications and another separately formulated combination product for AGHD indications and potential other indications. Initially, we will be responsible for the development and commercialization of all combination products under the Combination Product Agreement and have agreed to pay Genentech a royalty on net sales of combination products covered by Genentech's (or the parties' joint) patents, subject to Genentech's right to opt-in, as described below.

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Under the Combination Product Agreement, Genentech has a right to opt-in to development and commercialization of such combination products following the FDA's acceptance of our Investigational New Drug Application, or IND, for the first Phase II clinical trial for certain of the Short Stature or AGHD Indications. If Genentech does not exercise this first option, it would then have the right to acquire a second right to opt-in after the Company obtains Phase II clinical trial data that is pivotal study-enabling for certain of the short stature, AGHD or the other indications. If Genentech opts in, it would then become the lead party with respect to the development and commercialization of combination products for other indications, and it may also choose to become the lead party in development and commercialization for AGHD. Upon opt-in, Genentech may also choose to exercise a commercial option to acquire the right for the deciding vote in all commercialization matters pertaining to combination product candidates in short stature indications. We would remain the lead commercialization party for short stature indications and in AGHD indications. The lead commercialization party would determine the commercialization plan for such combination products for such indications, and the non-lead party would have the right to co-promote such combination products.

Upon opting in, Genentech would become obligated to reimburse us for a portion of the development costs incurred since July 2007 and a cash payment if Genentech chooses to acquire the right for the deciding vote in all commercializing matters pertaining to combination product candidates in short stature indications and in AGHD indications, and thereafter the parties would share future costs and all operating profits and losses. Genentech would receive such profit share in lieu of its royalty payment. If Genentech opts in, it would have the right to subsequently elect to opt out of such development and commercialization of combination products, but only for all indications. In addition, following an opt-in by Genentech, we would have the right to subsequently elect to opt out of the joint development and commercialization of the combination products for AGHD and the other indications only, but not for the short stature indications. If a party elects to opt out, the other party would have a limited period of time in which it could also elect to opt out, in which case the parties would wind down development and commercialization of the applicable products. After opting out, a party would remain responsible for its share of operating profits and losses for a transition period only, after which time such party would be entitled to a royalty payment from the continuing party on net sales of such combination product. If Genentech opts in and neither party elects to opt out before a combination product receives regulatory approval for any Other Indication, Genentech would owe us a cash milestone payment. Under the Combination Product Agreement, the parties have granted each other sublicenseable licenses under their respective technology. The parties will share manufacturing responsibilities and costs depending on which opt-in or opt-out rights have been exercised, but in general the parties contemplate that we will supply rhIGF-1 needed for the combination products, and Genentech will supply human growth hormone for such products.

The Combination Product Agreement will remain in effect until all payment obligations have expired and two years have elapsed since the parties developed or commercialized combination products for indications for which the parties will be sharing operating profits and losses under the Combination Product Agreement. In addition, either party has the right to terminate the Combination Product Agreement in its entirety or on a per-product basis depending on the circumstances, in the event of an uncured material breach by the other party. If Genentech terminates the Combination Product Agreement as to a given product for our material breach, Genentech's rights would revert to it, and it would also receive licenses from us to exclusively develop and commercialize the terminated product, subject to payment to us of a royalty on Genentech's net sales of the terminated product. Similarly, if we terminate the Combination Product Agreement for Genentech's material breach, we would retain or be granted all needed license rights from Genentech to exclusively develop and commercialize the terminated product, subject to payment to Genentech of a royalty on our net sales of the terminated product.

In connection with the Combination Product Agreement we entered into a Stock Purchase Agreement with Genentech pursuant to which Genentech purchased 708,591 shares of our common stock in July 2007 for an aggregate purchase price of \$4.0 million. In the event that Genentech acquires a second right to opt-in under the Combination Product Agreement, Genentech would, subject to customary closing conditions, purchase up to 842,105 shares of our common stock in a subsequent closing at a price per share equal to the average of the

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closing prices of our common stock for the 20 trading days ending on the trading date immediately prior to the expiration of Genentech's first right to opt-in under the Combination Product Agreement. However, Genentech may purchase no more than \$4,000,000 of our common stock in this closing and this closing would be at our option (and subject to approval by Ipsen) if the price per share is below \$4.75. In the event that Genentech opts in, neither party elects to opt out and a combination product receives regulatory approval for any indication other than short stature or AGHD, upon our request, Genentech would, subject to customary closing conditions, purchase up to 1,052,632 shares of our common stock in a subsequent closing at a price per share equal to the average of the closing prices of our common stock for the 20 trading days ending on the trading date immediately prior to the effective date of regulatory approval of a combination product for any such other indication. However, Genentech may purchase no more than \$5,000,000 of our common stock in this closing and this closing would be subject to approval by Ipsen if the price per share is below \$4.75. For additional information on our Combination Product Agreement with Genentech, please refer to Note 8, Combination Product Development and Commercialization Agreement, in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K.

### **Key Relationships Ipsen**

In October 2006, we completed the first closing of the transactions contemplated by the Stock Purchase and Master Transaction Agreement we entered into with Ipsen in July 2006. At the closing, we issued 12,527,245 shares of our common stock to an affiliate of Ipsen for an aggregate purchase price of \$77.3 million, a 30.0% premium to the volume-weighted average closing price of our common stock over the preceding 15 trading days ending on July 17, 2006, and issued to Ipsen a convertible note in the principal amount of \$25.0 million and a warrant to purchase a minimum of 4,948,795 shares of our common stock, which warrant is exercisable at any time during the five-year period after the initial closing and carries an initial exercise price equal to \$7.41 per share. The number of shares that Ipsen can purchase by exercising the warrant can increase over time. Simultaneously with the initial closing, we and Ipsen (and/or affiliates thereof) entered into licensing agreements with respect to Somatuline<sup>®</sup> Depot and Increlex<sup>®</sup>, and entered into certain other agreements, including the Affiliation Agreement described below. Additionally, we effected certain amendments to our charter and bylaws and adopted a rights agreement implementing a stockholder rights plan. In September 2007, we issued a second convertible note and a third convertible note to Ipsen in the principal amounts of \$30.0 million (or \$44.2 million at December 31, 2007) and \$15.0 million, respectively. Each of the three convertible notes we issued to Ipsen mature in October 2011 and carry a coupon of 2.5% per annum from the date of issuance, compounded quarterly, and are convertible into shares of our common stock at an initial conversion price per share equal to \$7.41 per share (or \$5.92 per share with respect to the \$30.0 million principal amount convertible note). As of December 31, 2007, approximately 15,574,519 million shares of our common stock were issuable to Ipsen upon exercise of the warrant and conversion of the convertible notes we issued to Ipsen. Together with the shares we have issued to Ipsen to date, the conversion of all three convertible notes and the exercise of the warrant in full would enable Ipsen to acquire an ownership interest in us of approximately 40% on a fully diluted basis. We also granted Ipsen a preemptive right to purchase its pro rata portion of new securities that we may offer in the future in order to maintain its percentage ownership interest.

*Affiliation Agreement.* In connection with the first closing of the transactions contemplated by the Stock Purchase and Master Transaction Agreement, we entered into an Affiliation Agreement with Ipsen with respect to certain corporate governance matters and providing Ipsen with the right to nominate a certain number of directors for election to our board of directors. Under the Affiliation Agreement, Ipsen is entitled to nominate up to two out of the nine authorized members of our board of directors, provided that in the event Ipsen holds at least 60% of our then outstanding shares of common stock, Ipsen is entitled to nominate an unlimited number of directors to our board of directors. Ipsen is also entitled to nominate additional independent director nominees (which nominees must be independent of Ipsen) for election to our board of directors starting in 2008, as follows: one nominee in 2008, two nominees in 2009 and four nominees in 2010, provided that these rights would terminate if Ipsen holds less than 15% of the outstanding shares of our common stock and are also be subject to reduction under certain circumstances. The Affiliation Agreement also includes certain provisions with respect to the establishment and composition of the standing committees of our board of directors.



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Under the Affiliation Agreement, the approval of Ipsen is required for us to take certain actions, including, but not limited to:

entering into most material transactions or agreements;

merging or consolidating with other entities;

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

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

incurring capital expenditures of more than \$2.0 million in any given year;

making any investment, other than certain permitted investments;

entering into any transaction that results in competition with Ipsen;

declaring or paying any cash dividends;

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

issuing or selling shares of our capital stock, other than issuances or sales after October 13, 2008 that may not exceed \$25.0 million in any three-year period, and other limited exceptions.

Under the terms of the Affiliation Agreement, Ipsen is not permitted, without our prior written consent, to sell, transfer or dispose of any shares of our common stock to any person or persons known to Ipsen or its affiliates to be a group (within the meaning of Section 13(d)(3) of the Securities Exchange Act of 1934, as amended) who would, to Ipsen's or its affiliates' knowledge, beneficially own more than 14.9% of our then-outstanding common stock. In addition, during the period commencing on October 13, 2007 and expiring on the fourth anniversary of such date, Ipsen is not permitted, without our written consent, to take any action to effect, directly or indirectly, the acquisition of beneficial ownership by Ipsen of any additional shares of our common stock from persons other than us, other than certain permitted offers and acquisitions in connection with maintenance of Ipsen's percentage ownership interest in us, acquisitions by other stockholders and an increase in Ipsen's ownership position to at least 60% (subject to adjustment) of our outstanding common stock. If at any time Ipsen and/or its affiliates beneficially own 90% or more of our outstanding common stock such that, upon all such common stock being held either by Ipsen (or an affiliate of Ipsen), Ipsen would be entitled to effect a short-form merger with us in accordance with Delaware law, Ipsen will, or will cause its affiliate to, effect such a merger.

*Licensing Agreements.* Pursuant to the licensing agreements we entered into with Ipsen (and/or affiliates thereof) in connection with the initial closing under the stock purchase and master transaction agreement, we granted to Ipsen and its affiliates exclusive rights to develop and commercialize Increlex<sup>®</sup> in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa, and Ipsen granted to us exclusive rights to develop and commercialize Somatuline<sup>®</sup> Depot in the United States and Canada. Further, we and Ipsen granted to each other product development rights and agreed to share the costs for improvements to, or new indications for, Somatuline<sup>®</sup> Depot and Increlex<sup>®</sup>. In addition, we and Ipsen agreed to rights of first negotiation for our

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respective endocrine pipelines. Under the license and collaboration agreement with respect to Increlex<sup>®</sup>, Ipsen made an upfront cash payment to us of 10.0 million (or \$12.4 million) and also made a milestone payment to us of 15.0 million (or \$19.3 million) in connection with the approval of Increlex<sup>®</sup> Marketing Authorization Application, or MAA, in the European Union for the Increlex<sup>®</sup> targeted product label. Increlex<sup>®</sup> was launched in Ipsen's territory in November 2007 for which we receive royalties from Ipsen on a sliding scale from 15% to 25% of net sales, in

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addition to a supply price of 20% of net sales of Increlex<sup>®</sup>. Under the license and collaboration agreement with respect to Somatuline<sup>®</sup> Depot, we made an upfront payment of \$25.0 million to Ipsen, which was financed through the issuance by us to Ipsen of the \$25.0 million principal amount convertible note at the initial closing under the stock purchase and master transaction agreement. In the third quarter 2007, Somatuline<sup>®</sup> Depot was approved in the United States for the targeted product label (and the second closing under the stock purchase and master transaction agreement was consummated) and we made a milestone payment of \$30.0 million (or \$41.6 million) to Ipsen, which was financed through the issuance by us of the \$30.0 million principal amount convertible note to Ipsen. Upon consummation of the second closing, we also issued the \$15.0 million principal amount convertible note to Ipsen and Ipsen delivered \$15.0 million to us, which will be used by us for working capital. Somatuline<sup>®</sup> Depot was launched in our territory in November 2007, for which we pay royalties to Ipsen, on a sliding scale from 15% to 25% of net sales, in addition to a supply price of 20% of net sales of Somatuline<sup>®</sup> Depot. For additional information on our collaboration with Ipsen, please refer to Note 9, License and Collaboration Agreements and Related Party Transactions, in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K.

**Key Relationships Insmed Incorporated**

In March 2007, we, Genentech, Insmed Incorporated and Insmed Therapeutic Proteins, Inc. (collectively, Insmed), entered a Settlement, License and Development Agreement in which we, Genentech and Insmed have settled all outstanding litigation amongst the parties, including the patent infringement suits brought by us and Genentech against Insmed in the United States and United Kingdom, and the unfair business practices suit brought by us against Insmed. In exchange for the settlement and release of all claims, including a waiver by us and Genentech of all damages award by the jury in the U.S. patent infringement litigation, the parties have granted licenses to each other with respect to the development, manufacture and commercialization of products to treat certain indications.

*Tercica/Genentech Indications and Non-Tercica/Genentech Indications.*

Under the terms of the Settlement, License and Development Agreement, Insmed may no longer supply its IGF-1/BP-3 combination product, or IPLEX, in connection with the treatment of certain indications, including severe Primary IGFD, Noonan's Syndrome, Laron Syndrome, growth hormone deficiencies, idiopathic short stature, other short stature indications and growth hormone insensitivity, or the Tercica/Genentech Indications, and agreed to withdraw its IPLEX MAA for the treatment of Primary IGFD and patients with growth hormone gene deletion in the European Union. In exchange, we and Genentech each granted to Insmed a non-exclusive, license with respect to the manufacture, development and commercialization of IPLEX for most non-short stature indications including severe insulin resistance, myotonic muscular dystrophy, retinopathy of prematurity, recovery from burns and trauma, recovery from hip fracture and HIV associated adipose redistribution syndrome, or the Non-Tercica/Genentech Indications, subject to our and Genentech's opt-in rights and certain royalty provisions, as more fully described below. Insmed is permitted to continue to provide IPLEX on a named patient basis for certain of the Non-Tercica/Genentech Indications in the European Union, and for amyotrophic lateral sclerosis, or ALS, in Italy. Any cost reimbursement obtained from such program would be subject to a tiered royalty of 4% to 15% shared between us, Genentech and Ipsen.

*Tercica and Genentech Opt-In Rights.*

Pursuant to the Settlement, License and Development Agreement, we and Genentech have the right to opt-in to participate in Insmed's development and commercialization of IPLEX for each of Non-Tercica/Genentech Indications up to 90 days after Insmed provides Phase III-enabling clinical data. We have the first right to opt-in to orphan indications, or the Tercica Opt-In Right, and Genentech has the first right to opt-in to non-orphan indications, or the Genentech Opt-In Right. If the Tercica Opt-In Right is not exercised, Genentech has the right to exercise the opt-in right in its stead. Similarly, if Genentech does not exercise the Genentech Opt-In Right, we will have the right to exercise the opt-in right in its stead. Prior to an exercise of an opt-in right, Insmed retains

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development control of the product for the treatment of any Non-Tercica/Genentech Indication. Upon exercise of an opt-in right for an opt-in indication, we or Genentech, as applicable, has the right to control the development of such product for such opt-in indication. In addition, once such opt-in right is exercised, and upon product approval, we or Genentech, as the case may be, may elect to enter into a co-promotion relationship with Insmmed for IPLEX with respect to such indication, and such activities will be conducted under a commercialization plan and overseen by a joint commercialization committee. Alternatively, such opt-in party may elect to obtain the sole right to promote IPLEX for such indication and Insmmed has agreed to supply IPLEX to such party under a separate supply agreement.

If the Tercica Opt-In Right is exercised, Insmmed will be reimbursed at the time of exercise for 50% of any expenses then-incurred in connection with the development of such indication and any further development costs will be shared equally between us and Insmmed. Upon commercialization, we and Insmmed have agreed to divide profits equally after accounting for relevant expenses, including sales-based tiered royalties of 6%-15% to Genentech. If the Genentech Opt-In Right is exercised, Insmmed will be reimbursed at the time of exercise for 50% of any expenses incurred in connection with the development of such indication and further development costs and profits will be divided equally between Insmmed and Genentech; provided, however, that no royalty will be paid to us. If neither the Tercica Opt-In Right nor the Genentech Opt-In Right is exercised, Insmmed will pay a 4% royalty on all commercial sales of the approved drug to Genentech.

We, Genentech and Insmmed have also agreed to form a joint development and a joint commercialization committee to guide the development and commercialization of the Non-Tercica/Genentech Indications and to oversee the tracking of sales of the product for use in the treatment of specific indications.

*Termination.*

The Settlement, License and Development Agreement is in effect until the expiration of all payment obligations or the expiration of all Tercica Opt-In Rights and Genentech Opt-In Rights, whichever is later. In addition, each of us and Genentech have the right to terminate the Settlement, License and Development Agreement in its entirety or on an indication by indication basis for any uncured material breach by Insmmed of its obligations. Further, Insmmed has the right to terminate the Settlement, License and Development Agreement in its entirety or on an indication by indication basis in the case of an uncured material breach by us or Genentech. If the Settlement, License and Development Agreement is terminated in its entirety, Insmmed's license to make, use and sell IPLEX will terminate in its entirety as of the effective date of such termination. If either the Tercica Opt-In Right or Genentech Opt-In Right has been exercised for an indication prior to such termination and the Settlement, License and Development Agreement is terminated for such indication, then Insmmed's license to sell IPLEX with respect to such indication will terminate, but we or Genentech have the right to continue selling IPLEX after such termination. Further, Insmmed will be reimbursed for development costs then-incurred for IPLEX for such indication and thereafter receive a royalty at the rate of 4% for the sales of IPLEX, on a country-by-country basis, so long as Insmmed's patents cover the making, using or selling of IPLEX in such country. If Insmmed terminates the Settlement, License and Development Agreement with respect to an indication for which the Tercica Opt-In Right or Genentech Opt-In Right has been exercised, then Insmmed will have the sole and exclusive right to commercialize IPLEX for such indication and either we or Genentech, as the case may be, will be reimbursed for development costs then-incurred for IPLEX for such indication and thereafter receive a royalty at the rate of 4% for the sales of IPLEX, on a country-by-country basis, so long as the licensed patents cover the making, using or selling of IPLEX in such country.

**Manufacturing**

*Increlex*<sup>®</sup>. We have agreements with Lonza Baltimore, Inc., or Lonza Baltimore, and Lonza Hopkinton, Inc., or Lonza Hopkinton, for the manufacture and supply of bulk rhIGF-1. Under our agreement with Lonza Baltimore, Lonza Baltimore is manufacturing bulk rhIGF-1 to support our anticipated clinical and commercial needs until early 2010. This manufacturing is being conducted in a single, large campaign and is expected to

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complete in mid 2008. Upon completion of the 2008 campaign, our agreement with Lonza Baltimore will terminate. Under our current agreement with Lonza Hopkinton, we are working to transfer to and establish commercial manufacturing in Lonza Hopkinton's facility in Hopkinton, Massachusetts, for which we expect to complete our validation (conformance) campaign in 2008. However, it will take significant time and expense to complete the transfer to and validate the Lonza Hopkinton manufacturing facility. Prior to our use, Lonza Hopkinton's facilities and processes will need to undergo pre-approval and/or current good manufacturing practices, or cGMP, compliance inspections. In addition, we need to transfer and validate the processes and certain analytical methods necessary for the production and testing of bulk rhIGF-1 by Lonza Hopkinton. Our current agreement with Lonza Hopkinton provides that Lonza Hopkinton will manufacture and supply bulk rhIGF-1 in support of our needs until our current agreement with Lonza Hopkinton is terminated by our and Lonza Hopkinton's entry into a more detailed agreement for the long-term manufacture of bulk rhIGF-1, or by either our or Lonza Hopkinton's advance written notice of termination of our current agreement effective on the later of the third anniversary of the notice or May 14, 2011. We expect to terminate the agreement with Lonza Hopkinton by execution of the detailed agreement with Lonza Hopkinton for the long-term manufacture of bulk rhIGF-1 in 2008. We will also have a quality agreement with Lonza Hopkinton designed to ensure that product quality, compliance with cGMP, and oversight over all critical aspects of rhIGF-1 production, testing and release is maintained.

In November 2006, we executed a Development and Supply Agreement and a Quality Agreement for drug product filling, packaging, and labeling, with Hospira Worldwide, Inc. or Hospira. These agreements have an initial term of five years from the time of first commercial sale, and thus are anticipated to last through 2013. We expect to complete the technology transfer and manufacturing validation at this manufacturer in the first half of 2008.

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.

Our Combination Product Agreement with Genentech provides us with rights and access to Genentech's Nutropin A® supply, manufacturing technology, and technical documentation associated with Genentech's drug product manufacture and testing of rhGH, including development information for the co-mixable product combination. This includes development reports, analytical methods and regulatory documents.

*Somatuline® Depot.* Ipsen is our sole supplier of Somatuline® Depot. We have no alternative manufacturing facilities or plans for any alternative facilities at this time. We do not have direct control over Ipsen's compliance with regulations and standards. The facilities used by and operations of Ipsen to manufacture Somatuline® Depot must undergo periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations to ensure continued supply of Somatuline® Depot to our U.S. and Canadian (Somatuline® Autogel®) markets. We have a quality agreement with Ipsen designed to ensure that product quality, compliance with cGMP, and oversight over all critical aspects of Somatuline® Depot production, testing and release is maintained.

**Sales and Marketing**

*Increlex®.* Our Increlex® sales and marketing efforts target approximately 500 pediatric endocrinologists practicing in the United States. Pediatric endocrinologists are the physicians who customarily treat children with severe Primary IGFD. Because these pediatric endocrinologists are primarily hospital-based and concentrated in major metropolitan areas, we believe that our focused marketing organization and specialized sales force effectively serves them. We are conducting a variety of programs aimed at establishing physician awareness of Increlex® as a treatment for severe Primary IGFD, including medical education, symposiums and regional

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speaker programs. We have also established a patient registry in order to provide further data on the safety and efficacy of Increlex<sup>®</sup>. In Europe, Ipsen has gained approval for and launched Increlex<sup>®</sup> in 2007 in certain European countries, including Austria, Germany, Great Britain, Greece, Hungary, Spain and the Czech Republic.

*Somatuline<sup>®</sup> Depot.* Patients with acromegaly are typically treated by a subset of adult endocrinologists who sub-specialize in pituitary disorders. We believe there are approximately 1,000 physicians in the United States who write approximately 90% of the prescriptions for this disease. Like pediatric endocrinologists, adult endocrinologists are primarily hospital-based and concentrated in major metropolitan areas. We plan to conduct medical education programs, medical symposia and regional speaker programs aimed at establishing awareness of Somatuline<sup>®</sup> Depot for the treatment of acromegaly. At present, we have contracted sales and marketing operations in Canada to a third party.

For additional information on geographic revenues, please refer to Note 2, Concentrations, in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K.

## **Research and Development**

Our principal experience has been developing late-stage product candidates and commercializing them. We do not conduct any of our own pre-clinical laboratory research. However, we consult with academic research institutions and other companies regarding both IGF-1 and non-IGF-1 related projects in endocrinology. Research and development activities are associated primarily with clinical, regulatory, manufacturing development and acquired rights to technology or products in development. Clinical and regulatory activities include the preparation, implementation, and management of our clinical trials and clinical assay development, as well as regulatory compliance, data management and biostatistics. Our research and development expenses were \$19.1 million for the year ended December 31, 2007, \$42.0 million for the year ended December 31, 2006 and \$21.6 million for the year ended December 31, 2005.

## **Patents and Proprietary Rights**

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

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

We have also licensed from Genentech certain intellectual property rights, including patent rights and pre-clinical and clinical data, and manufacturing know-how, to develop and commercialize growth hormone/rhIGF-1 combination products worldwide for a broad range of indications. The licensed rights include rights to certain U.S. patents that cover methods of using growth hormone/rhIGF-1 combination products and that expire

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between 2009 and 2014. Our U.S. Patent No. 6,331,414 B1 licensed from Genentech will provide protection in the United States for our process of manufacturing IGF-1 for our growth hormone/IGF-1 combination product candidates until it expires in 2018. We have no equivalent patent protection for our process of manufacturing rhIGF-1 in Europe.

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

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

There can be no assurance that our licensed patents will not be successfully circumvented by competitors. In particular, we do not have patent composition coverage on the rhIGF-1 protein alone, and we are aware that Novartis AG (through acquisition of 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 this area.

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

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

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

We have obtained registrations of the trademarks Increte<sup>®</sup>, Tercica and the Tercica logo in the United States.

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### **Competition**

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

We cannot predict the relative competitive positions of Increlex<sup>®</sup>, Somatuline<sup>®</sup> Depot and any growth hormone/IGF-1 combination products that we may develop. However, we expect that the following factors, among others, will determine our ability to compete effectively:

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

reimbursement adoption;

product price;

manufacturing cost containment;

the effectiveness of our and collaboration partners sales and marketing efforts;

storage requirements and ease of administration;

dosing regimen;

safety and efficacy;

prevalence and severity of side effects; and

competitive products.

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

Increlex<sup>®</sup>. Growth hormone products compete with Increlex<sup>®</sup> for the treatment of severe Primary IGFD. If Increlex<sup>®</sup> receives regulatory approval for the treatment of patients with Primary IGFD, growth hormone products will also compete with Increlex<sup>®</sup> for the treatment of patients in that indication. The major suppliers of commercially available growth hormone products in the United States are Genentech, Eli Lilly and Company, Teva Pharmaceutical Industries Ltd., Novo Nordisk A/S, Pfizer Inc., and Merck-Serono International S.A. Investigators from a Novo Nordisk clinical trial in 2003 presented initial data that demonstrated growth hormone was effective in a population that included children with Primary IGFD. We are also aware that several companies are developing long-acting formulations of growth hormone for the treatment of short stature including Altus Pharmaceuticals and LG Life Sciences.



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In addition, children with Primary IGFD may be diagnosed as having ISS. Eli Lilly and Company and Genentech have received FDA approval for their respective growth hormone products for the treatment of children with ISS in the United States. Moreover, biosimilar growth hormone products, including Omnitrope (somatropin) marketed by Sandoz, Accretropin by Cangene, and Valtropin by LG Life Sciences have been approved in the United States and may be approved in other countries. Accordingly, we expect that several growth hormone products will compete directly with Increlex<sup>®</sup> for the treatment of children with Primary IGFD.

In addition, we are aware that Novartis AG has developed a process to manufacture rhIGF-1 using yeast expression and has intellectual property with respect to that process. We use bacterial expression, which differs from yeast expression, to manufacture Increlex<sup>®</sup>.

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We believe that Bristol-Meyers Squibb Company; Genentech; Merck & Co., Inc.; Novo Nordisk and Pfizer have conducted research and development of orally available small molecules that cause the release of growth hormone, known as growth hormone secretagogues. We believe that Sapphire Therapeutics Inc. has licensed certain rights to Novo Nordisk's growth hormone secretagogues and that Elixir Pharmaceuticals Inc. has licensed certain rights to Bristol-Meyers Squibb Company's growth hormone secretagogues and that both companies are actively developing these compounds for use in various indications including cancer cachexia, a wasting disorder affecting some cancer patients. We are also aware that Theratechnologies is developing tesamorelin (TH9507), an analogue of growth hormone-releasing factor, for the treatment of HIV-associated lipodystrophy. Both growth hormone secretagogues and growth hormone-releasing factors work by increasing the levels of rhIGF-1 and, if approved, could potentially compete with Increlex<sup>®</sup>. It is possible that there are other products currently in development or that exist on the market that may compete directly with Increlex<sup>®</sup>.

*Somatuline<sup>®</sup> Depot.* Somatuline<sup>®</sup> Depot is approved in the United States and Canada for the treatment of acromegaly where, the product competes directly with Sandostatin LAR<sup>®</sup> Depot and Somavert<sup>®</sup>. Sandostatin LAR<sup>®</sup> Depot is a somatostatin analogue and has the same mechanism of action as Somatuline<sup>®</sup> Depot. Sandostatin LAR<sup>®</sup> Depot is indicated for long-term maintenance therapy in patients with acromegaly and in the treatment of symptoms related to carcinoid syndrome and vasoactive intestinal peptide tumors. Somavert<sup>®</sup>, a growth hormone antagonist, and Sandostatin LAR<sup>®</sup> Depot are marketed by Pfizer and Novartis, respectively, in the United States and Canada. Moreover, a subset of patients with acromegaly can be treated with radiotherapy and dopaminergic agonists. These therapies are commercially available in the United States and Canada and will also compete with Somatuline<sup>®</sup> Depot for the treatment of patients with acromegaly.

We are aware that Ambrilia Biopharma, QLT Inc., Indevus Pharmaceuticals, Inc. and Camurus AB are conducting research and development programs with long-acting versions of octreotide for the treatment of acromegaly. Octreotide is the generic name of the active molecule in Sandostatin and Sandostatin LAR<sup>®</sup> Depot. We are also aware that Novartis is developing pasireotide (SOM 230), DeveloGen AG is developing Somatoprin (DG 3173), and that Ipsen is developing dopastatin for the treatment of acromegaly and other hormone secreting tumors. If approved, these therapies would compete with Somatuline<sup>®</sup> Depot in these indications. It is possible that there are other products currently in development or that exist on the market that may compete directly with Somatuline<sup>®</sup> Depot.

*Growth hormone/IGF-1 combination products.* If our growth hormone/IGF-1 combination products are approved for commercial sale, they would compete across all their approved indications with all then existing, biosimilar and long acting growth hormone products, growth hormone secretagogue products, IGF-1 product candidates, including Increlex<sup>®</sup>, and other products.

### **Government Regulation and Product Approval**

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

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

pre-clinical laboratory and animal tests;

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



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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 additional approvals for Increlex<sup>®</sup> or Somatuline<sup>®</sup> Depot, or any approvals for our growth hormone/IGF-1 combination product candidates, will be granted on a timely basis, if at all.

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

Prior to commencing a clinical trial, we must submit an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises 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 confirm dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

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

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

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

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

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 involved reviewing 90% of priority applications within six months of filing and 90% of standard applications within ten months of submission of the NDA.

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

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

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

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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<sup>®</sup> for other indications, including Primary IGFD, and Somatuline<sup>®</sup> Depot for other indications, including neuroendocrine tumors. We cannot predict the likelihood, nature or extent of adverse governmental regulation, which might arise from future legislative or administrative action, either in the United States or abroad.

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

The FDA granted Increlex<sup>®</sup> seven years of orphan exclusivity 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. In addition, we intend to file for orphan drug designation for other rhIGF-1 diseases that meet the criteria for orphan exclusivity.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, Congress created an abbreviated FDA review process for generic versions of pioneer (brand name) drug products like Increlex<sup>®</sup>. 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<sup>®</sup> new chemical entity exclusivity, which expires on August 30, 2010.

During this period, the FDA is prohibited from accepting any abbreviated NDA, or an ANDA, for a generic version of Increlex<sup>®</sup>. 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.

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During this exclusivity period, the FDA is also prohibited from accepting any NDA for a modified version of Increlex<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup>'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<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup> 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

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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<sup>®</sup> 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 in 2012, 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. Third-party payors provide reimbursement for Increlex<sup>®</sup> and for Somatuline<sup>®</sup> Depot. 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.

Third party payors increasingly seek to decrease their expenditures for pharmaceuticals. Under the Medicare program, federal legislation changed the payment methodology for most drugs and biologicals starting in 2005 based on an average sales price, or ASP, methodology. While this change applies to drugs and biologicals provided to Medicare beneficiaries, private payors often utilize Medicare payment rates when determining what they will pay. Individual state Medicaid programs also have utilized different mechanisms to decrease payments for drugs and biologicals, sometimes through legislation. Private insurers likewise employ various payment mechanisms to reimburse for drugs and biologicals and, in doing so, often attempt to reduce their payments for drugs and biologicals.

Effective January 1, 2006, an expanded prescription drug benefit for all Medicare beneficiaries known as Medicare Part D commenced to provide Medicare beneficiaries with drug coverage for self-administered drugs and biologicals and other drugs and biologicals not covered by Medicare, including many vaccines. This is a voluntary benefit that is being implemented through private plans under contractual arrangements with the federal government. Like pharmaceutical coverage through private health insurance, Medicare Part D plans establish formularies and use other utilization management tools when determining the drugs and biologicals that are offered by each plan. These formularies can change on an annual basis, subject to federal governmental review. These plans may also require beneficiaries to provide out-of-pocket payments for such products.

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

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

## **Employees**

As of December 31, 2007, we had 126 full-time employees. Of the full-time employees, 44 were engaged in research and product development and 82 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 our products and product candidates. We believe our relations with our employees are good.



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Our executive officers, their ages and their positions as of February 28, 2008, are as follows:

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
John A. Scarlett, M.D.	56	Chief Executive Officer and Director
Ross G. Clark, Ph.D.	57	Chief Technical Officer and Director
Ajay Bansal	46	Chief Financial Officer and Executive Vice President of Finance
Richard A. King	43	President and Chief Operating Officer
Stephen N. Rosenfield	58	Executive Vice President of Legal Affairs, General Counsel and Secretary
Andrew J. Grethlein, Ph.D.	43	Senior Vice President, Pharmaceutical Operations
Thorsten von Stein, M.D., Ph.D.	46	Chief Medical Officer and Senior Vice President of Clinical and Regulatory Affairs
Susan Wong	45	Vice President, Finance and Chief Accounting Officer

*John A. Scarlett, M.D.*, has served as our Chief Executive Officer and as a member of our board of directors since February 2002. He also served as our President from February 2002 until February 2008. From March 1993 to May 2001, Dr. Scarlett served as President and Chief Executive Officer of Sensus Drug Development Corporation, a development stage pharmaceutical company. In 1995, he co-founded Covance Biotechnology Services, Inc., a biotechnology contract manufacturing company, and served as a member of its board of directors from inception to 2000. From 1991 to 1993, Dr. Scarlett headed the North American Clinical Development Center and served as Senior Vice President of Medical and Scientific Affairs at Novo Nordisk Pharmaceuticals, Inc., a wholly owned subsidiary of Novo Nordisk A/S, a pharmaceutical company. From 1985 to 1990, Dr. Scarlett served as Vice President, Clinical Affairs and headed the clinical development group at Greenwich Pharmaceuticals, Inc., a pharmaceutical company. From 1982 to 1985, Dr. Scarlett served as Associate Director and, subsequently, as Director, of Medical Research and Services at Ortho-McNeil Pharmaceuticals, a wholly owned subsidiary of Johnson & Johnson. Dr. Scarlett received his B.A. degree in chemistry from Earlham College and his M.D. from the University of Chicago, Pritzker School of Medicine.

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

*Ajay Bansal* has served as our Chief Financial Officer and Executive Vice President of Finance since December 2007. He also served as our Chief Financial Officer and Senior Vice President of Finance from March 2006 until December 2007. From February 2003 to January 2006, Mr. Bansal served as Vice Present of Finance and Administration and Chief Financial Officer of Nektar Therapeutics. From July 2002 until February 2003, Mr. Bansal served as Director of Operations Analysis at Capital One Financial. From August 1998 to June 2002, Mr. Bansal was at Mehta Partners LLC, a financial advisory firm where he was named partner in January 2000. Prior to joining Mehta Partners, Mr. Bansal spent more than 10 years in management roles at Novartis and in consulting at Arthur D. Little, Inc., McKinsey & Company, Inc. and ZS Associates. Mr. Bansal holds a Bachelor of Technology degree from the Indian Institute of Technology (Delhi), an M.S. in Operations Management from Northwestern University and an M.B.A. from Northwestern University.

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*Richard A. King*, has served as our President and Chief Operating Officer since February 2008, and served as our Chief Operating Officer from February 2007 to February 2008. Prior to joining us in February 2007, Mr. King was a private investor. From January 2002 to September 2006, Mr. King served as Executive Vice President, Commercial Operations of Kos Pharmaceuticals, Inc., where he was responsible for sales, marketing, managed care, sales operations and customer service functions. From January 2000 to January 2002, Mr. King served as Senior Vice President of Commercial Operations at Solvay Pharmaceuticals. From January 1992 to January 2000, Mr. King held various marketing positions at SmithKline Beecham Pharmaceuticals. Mr. King began his career in the pharmaceutical industry at Lederle Laboratories, Ltd. Mr. King received his B.S. degree in chemical engineering from the University of Surrey and his M.B.A. from Manchester Business School.

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

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

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

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

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**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.

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**Item 1A. Risk Factors.**

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

**Risks Related to Our Business**

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

We have a limited operating history. Through December 31, 2007, we had an accumulated deficit of \$289.2 million. We incurred a net loss of \$40.5 million during the year ended December 31, 2007. We may not be able to generate significant revenues from operations and may not be able to attain profitability. Although we had net revenues of \$31.0 million during the year ended December 31, 2007, of which \$20.3 million resulted from a milestone payment we received from Ipsen, we expect to incur substantial net losses, in the aggregate and on a per share basis, for the foreseeable future as we attempt to develop, market and sell Increlex<sup>®</sup> for severe Primary IGFD and Primary IGFD and Somatuline<sup>®</sup> Depot for acromegaly, and as we attempt to develop growth hormone/IGF-1 combination product candidates under our Combination Product Agreement with Genentech. We are unable to predict the extent of these future net losses, or when we may attain profitability, if at all. These net losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and net current assets.

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

*If there are fewer children with severe Primary IGFD or Primary IGFD than we estimate, our ability to generate revenues sufficient to fund our development and commercialization efforts may be curtailed.*

We estimate that the number of children in the United States with short stature is approximately 1,000,000, of which approximately 380,000 are referred to pediatric endocrinologists for evaluation. We believe that approximately 30,000 of these children have Primary IGFD, of which approximately 6,000 have severe Primary IGFD. Our estimate of the size of the patient population is based on published studies as well as internal data, including our interpretation of a study conducted as part of Genentech's National Cooperative Growth Study program. This study reported results of the evaluation of the hormonal basis of short stature in approximately 6,450 children referred to pediatric endocrinologists over a four-year period. We believe that the aggregate numbers of children in Western Europe with Primary IGFD and severe Primary IGFD are substantially equivalent to the numbers in the United States. If the results of Genentech's study or our interpretation and extrapolation of data from the study do not accurately reflect the number of children with Primary IGFD or severe Primary IGFD, our assessment of the market may be incorrect, making it difficult or impossible for us to meet our revenue goals or to receive royalties from our collaboration with Ipsen to the extent that we currently anticipate.

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

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

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

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

reimbursement adoption;

product price;

the effectiveness of our and collaboration partners sales and marketing efforts;

storage requirements and ease of administration;

dosing regimen;

safety and efficacy;

prevalence and severity of side effects; and

competitive products.

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

We are currently developing Increlex<sup>®</sup> for the treatment of Primary IGFD. The FDA has substantial discretion in the approval process and may decide that the data from our clinical trial is insufficient to allow approval of Increlex<sup>®</sup> for Primary IGFD. If we do not receive regulatory marketing approval in the United States for Primary IGFD, our business will be harmed. We will also need to file applications with regulatory authorities in foreign countries to market Increlex<sup>®</sup> for Primary IGFD. There is no assurance that we will receive marketing approvals in any foreign countries for Primary IGFD.

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

Even though Somatuline<sup>®</sup> Depot has received marketing approval from the FDA, the approval may not be maintained. We may also elect not to, or we may be unable to develop or obtain FDA approval of Somatuline<sup>®</sup> Depot for indications other than acromegaly, such as neuroendocrine tumors. Further, Ipsen may be unable to maintain the supply of the product. In addition, revenues from sales of Somatuline<sup>®</sup> Depot in the United States and Canada may not meet our expectations, including as a result of competing products or unavailable or limited reimbursement by third-party payers. Under the license and collaboration agreement with respect to Somatuline<sup>®</sup> Depot, Ipsen may terminate the agreement in a particular country if we fail to meet certain minimum sales and promotional requirements with respect to that country. It is also possible that

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Ipsen will not be successful in marketing and selling Increlex<sup>®</sup> in the licensed territories, or may be delayed in doing so, in which case we would not receive royalties on the timeframe and to the extent that we currently anticipate. We also may not be able to successfully develop additional products or improvements to, or new indications for, Somatuline<sup>®</sup> Depot and/or Increlex<sup>®</sup> or share the costs of such developments in a manner that is commercially feasible for us. In addition to cross-licensing agreements for Somatuline<sup>®</sup> Depot and Increlex<sup>®</sup>, we and Ipsen have granted to each other a right of first negotiation for products in our respective endocrine pipelines and have agreed on a framework for joint clinical development and subsequent commercialization of endocrine products on a

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worldwide basis. However, the development of Ipsen's endocrine pipeline may not advance at the rate we currently expect, or at all, and in any event, we cannot assure you that we will be able to reach an agreement with Ipsen on reasonable terms, or at all, for any of these endocrine pipeline products. The license and collaboration agreements would also be terminable by Ipsen under certain circumstances, including certain change of control transactions. In any such or similar events, we may not realize the anticipated benefits from our collaboration with Ipsen.

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

***We may not realize the anticipated benefits from our growth hormone/IGF-1 combination product candidates or from the related agreement with Genentech.***

Our two growth hormone/IGF-1 combination product candidates may not enter clinical trials or receive U.S. or other countries' regulatory approval, in a timely manner, for the labels that we anticipate, or at all. We may encounter development difficulties that delay, increase the costs of, or preclude any further progress of either or both of our growth hormone/IGF-1 combination product candidates. In addition, the FDA and other countries' regulatory authorities have substantial discretion in the approval process. They may decide that our pre-clinical data, chemistry, manufacturing and controls data; and/or clinical data are insufficient to warrant timely, or any, entry into Phase I, Phase II or Phase III clinical trials, and/or that the data from our Phase III clinical trials are insufficient to allow marketing approval of our growth hormone/IGF-1 combination product candidates for their target labels. If we do not receive regulatory marketing approvals for the target labels, our business will be harmed.

Even if our combination product candidates were to receive such regulatory marketing approvals, the approvals may not be maintained. In addition, revenues from worldwide sales of these two product candidates may not meet our expectations, including, as a result of competing products or unavailable or limited reimbursement by third-party payers. We also may not be able to successfully develop improvements to, or new indications for, our combination product candidates or receive financial consideration from sub-licensees in a manner that is commercially feasible for us. In connection with our agreement with Genentech for our combination product candidates, Genentech may opt into the programs and obtain a share of the financial benefit going forward. In any such or similar events, we may not realize the anticipated benefits from our combination product candidates. There can be no assurance that we will receive all or any remaining portion of the anticipated proceeds from our agreement with Genentech, nor can there be an assurance that we would achieve the anticipated benefits from our agreement with Genentech.

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

To gain approval to market a product for treatment of a specific disease, we must provide the FDA and foreign regulatory authorities with clinical data that demonstrate the safety and statistically significant efficacy of that product for the treatment of the disease. Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. For example, we are seeking to develop our growth hormone/IGF-1 combination product candidates for short stature, AGHD, and potentially other metabolic disorders, but we may determine that such trials are prohibitively expensive and ultimately may not proceed with such trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Success in pre-clinical testing or in early clinical trials does not ensure that later clinical trials will be successful. If a clinical trial failed to demonstrate safety and statistically significant efficacy, we would likely abandon the development of that product, which could harm our business.

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

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

the FDA or other regulatory authorities do not approve an investigational new drug application or a clinical trial protocol, or they place a clinical trial on clinical hold;

patients do not enroll in clinical trials at the rate we expect or they withdraw at a greater rate than expected;

patients experience adverse side effects;

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

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

contract laboratories fail to follow good laboratory practices;

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

interim results of the clinical trial are inconclusive or negative;

trial drug may not be available, may not be available in sufficient quantities, 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 our products.

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



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

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

We believe that the annual wholesale acquisition cost, at present, of Somatuline<sup>®</sup> Depot therapy for the treatment of acromegaly is approximately \$28,800 at 100% compliance of the 90 microgram dose. The actual cost per year will depend on the price charged by wholesalers and distributors that purchase from Tercica, and will vary by the treatment dose prescribed and the level of compliance. If our assumptions regarding the average treatment dose per patients or revenue per patient for the treatment of acromegaly are incorrect, our expected revenues and the market opportunity for Somatuline<sup>®</sup> Depot for the treatment of acromegaly may be substantially reduced.

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

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

***We are dependent on our collaboration with Ipsen for the development and commercialization of Increlex<sup>®</sup> outside of the United States, Canada and Japan, and for a certain period of time, certain countries of the Middle East and North Africa and Taiwan. We may also be dependent upon additional collaborative arrangements in the future. These collaborative arrangements may place the development and commercialization of our product candidates outside of our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.***

Under the terms of our collaboration with Ipsen, we granted Ipsen the exclusive right to develop and commercialize Increlex<sup>®</sup> in all regions of the world except the United States, Japan, and Canada, and for a certain period of time, certain countries of the Middle East and North Africa and Taiwan. We may also enter into additional collaborations with third parties to develop and commercialize our product candidates such as our agreement with Genentech for our growth hormone/IGF-1 combination product candidates. Dependence on collaborators for the development and commercialization of our product candidates subjects us to a number of risks, including:

we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of product candidates or to their marketing and distribution, which could adversely affect our ability to obtain milestone and royalty payments;

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collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;

our collaborators may experience financial difficulties;

collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to expose us to potential litigation, jeopardize or lessen the value of our proprietary information, or weaken or destroy our intellectual property rights;

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

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

the collaborations may be terminated or allowed to expire, which would delay product development and commercialization efforts.

***We face significant competition from large pharmaceutical, biotechnology and other companies that could harm our business.***

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

We cannot predict the relative competitive positions of Increlex<sup>®</sup>, Somatuline<sup>®</sup> Depot and any growth hormone/IGF-1 combination product candidates that we may develop. However, we expect that the factors set forth under Item 1A. Risk Factors Our products may fail to achieve market acceptance, which could harm our business, among others, including manufacturing cost containment, will determine our ability to compete effectively.

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

Growth hormone products compete with Increlex<sup>®</sup> for the treatment of severe Primary IGFD. If Increlex<sup>®</sup> receives regulatory approval for the treatment of patients with Primary IGFD, growth hormone products will also compete with Increlex<sup>®</sup> for the treatment of patients in that indication. The major suppliers of commercially available growth hormone products in the United States are Genentech Inc., Eli Lilly and Company, Teva Pharmaceutical Industries Ltd., Novo Nordisk A/S, Pfizer Inc and Merck-Serono International S.A. Investigators from a Novo Nordisk clinical trial in 2003 presented initial data that demonstrated growth hormone was effective in a population that included children with Primary IGFD.

In addition, children with Primary IGFD may be diagnosed as having idiopathic short stature, or ISS. Eli Lilly and Genentech have received FDA approval for their respective growth hormone products for the treatment of children with ISS in the United States. Moreover, biosimilar growth hormone products, including Omnitrope<sup>®</sup> marketed by Sandoz, Accretropin<sup>®</sup> by Cangene, and Valtropin<sup>®</sup> by LG Life Sciences have been



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approved in the United States and may be approved in other countries. Accordingly, we expect that several growth hormone products will compete directly with Increlex<sup>®</sup> for the treatment of children with Primary IGFD. We are also aware that several companies are developing long-acting formulations of growth hormone for the treatment of short stature including Altus Pharmaceuticals and LG Life Sciences.

In addition, we are aware that Novartis AG has developed a process to manufacture rhIGF-1 using yeast expression and has intellectual property with respect to that process. We use bacterial expression, which differs from yeast expression, to manufacture Increlex<sup>®</sup>.

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

If our growth hormone/IGF-1 combination products are approved for commercial sale, they would compete across all their approved indications with all then existing, biosimilar and long acting growth hormone products, growth hormone secretagogue products, IGF-1 products, including Increlex<sup>®</sup>, and other products.

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

We are aware that Ambrilia Biopharma Inc., QLT Inc., Indevus Pharmaceuticals Inc. and Camurus AB are conducting research and development programs with long-acting versions of octreotide for the treatment of acromegaly. Octreotide is the generic name of the active molecule in Sandostatin and Sandostatin LAR<sup>®</sup> Depot. We are also aware that Novartis is developing pasireotide (SOM 230), DeveloGen AG is developing Somatoprin (DG 3173), and that Ipsen is developing dopastatin for the treatment of acromegaly and other hormone secreting tumors. If approved, these therapies would compete with Somatuline<sup>®</sup> Depot in these indications. It is possible that there are other products currently in development or that exist on the market that may compete directly with Increlex<sup>®</sup> or Somatuline<sup>®</sup> Depot.

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

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

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

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

***Our inability to timely transfer to an alternate single-source manufacturer to fill-finish Increlex<sup>®</sup> could adversely affect our commercial supply and ability to grow revenues.***

We currently source all of our Increlex<sup>®</sup> fill-finish manufacturing and portions of release testing through a single-source third-party supplier. This supplier is the only FDA-approved manufacturer currently available to us, and could only be replaced by qualification of a new site for the same operations. We have negotiated a short-term commercial agreement with this fill-finish manufacturer and during the term of this agreement, we are attempting to move our process to Hospira Worldwide, Inc., or Hospira. It will take a significant amount of time and expense to complete the transfer to Hospira and validate Hospira as an alternative manufacturer. For us to complete the transfer to Hospira, Hospira's facilities and processes, prior to our use, may need to undergo pre-approval and/or cGMP compliance inspections. In addition, we need to transfer and validate the processes and certain analytical methods necessary for the production and testing of Increlex<sup>®</sup> by Hospira. If we are not able to complete the transfer of fill-finish manufacturing to Hospira, our ability to obtain commercial supplies of Increlex<sup>®</sup> and our revenue growth could be adversely affected. A delay in this transfer may also result in a shortage of Increlex<sup>®</sup> and a loss of revenues.

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

We currently source all of our Increlex<sup>®</sup> bulk manufacturing and portions of release testing through a single-source third-party supplier, Lonza Baltimore, Inc. This supplier is the only FDA-approved manufacturer currently available to us, and could only be replaced by qualification of a new manufacturing site for the same operations. We have negotiated a short-term commercial agreement with Lonza Baltimore, and during the term of this agreement, we are attempting to move our bulk manufacturing process from Lonza Baltimore to Lonza Hopkinton. It will take a significant amount of time and expense to complete the transfer to and validate the Lonza Hopkinton manufacturing facility. For us to change to this new bulk manufacturing site, Lonza Hopkinton's facilities and processes, prior to our use, will need to undergo pre-approval and/or cGMP compliance inspections. In addition, we need to transfer and validate the processes and certain analytical methods necessary for the production and testing of bulk Increlex<sup>®</sup> by Lonza Hopkinton. A delay in this transfer could result in a shortage of bulk Increlex<sup>®</sup> and a significant loss of revenues. If we are not able to complete this transfer, our ability to supply Increlex<sup>®</sup> will be impaired and our business will suffer irreparable harm.

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

The facilities and operations of our contract manufacturers to manufacture and test Increlex®, and of Ipsen to manufacture and test Somatuline® Depot, must undergo continuing inspections by the FDA for compliance with cGMP regulations in order to maintain their respective approvals. Currently, Lonza Baltimore is our sole provider of bulk rhIGF-1, and Ipsen is our sole provider of Somatuline® Depot. Other than with respect to our agreement with Lonza Hopkinton, we have no alternative manufacturing facilities or plans for additional facilities at this time. We do not know if the Lonza Baltimore or Ipsen's facilities or their operations required for the commercial manufacture of Increlex® and Somatuline® Depot will continue to receive satisfactory cGMP inspections, and we do not know whether Lonza Hopkinton will receive a satisfactory cGMP inspection. In the event these facilities or operations do not receive, or continue to receive, satisfactory cGMP inspections for the manufacture of our products, or for the operation of their facilities in general, we may need to invest in significant compliance improvement programs, fund additional modifications to our manufacturing processes, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as result in a delay or prevention of commercialization, and may result in our failure to obtain or maintain approvals. In addition, Lonza Baltimore, Lonza Hopkinton, Ipsen and any alternative contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA and corresponding state and foreign agencies for compliance with cGMP regulations and similar foreign standards. We do not have direct control over Ipsen's or our contract manufacturers' compliance with these regulations and standards. Any of these factors could delay or suspend clinical trials, regulatory submissions or regulatory approvals, entail higher costs and result in us being unable to effectively market and sell our products or maintain our products in the marketplace, which would adversely affect our ability to generate revenues.

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

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

***Difficulties or delays in product manufacturing due to advance scheduling requirements, capacity constraints and/or manufacturing lot failures at our third-party manufacturers or Ipsen could harm our operating results and financial performance and jeopardize our orphan drug marketing exclusivity.***

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

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could negatively affect our operating results and our ability to meet our supply obligations to Ipsen. If we are unable to supply our products to all the patients that need them, the FDA could rescind our orphan drug marketing exclusivity to enable competitors to serve the affected markets. Further, our operating results and financial performance may suffer if we experience more than anticipated manufacturing lot failures or delivery delays.

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

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

***If other companies overcome our U.S. orphan drug marketing exclusivity for Increlex<sup>®</sup> or Somatuline<sup>®</sup> Depot, or obtain marketing authorization in Europe for the treatment of severe Primary IGFD, they will be able to compete with us, and our revenues will be diminished.***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The company that obtains the first FDA approval for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of seven years from the date of approval. The orphan drug rules are similar in the European Union and marketing exclusivity is for a period of ten years from the date of approval.

The FDA has granted Increlex<sup>®</sup> orphan drug marketing exclusivity for the long-term treatment of patients with severe Primary IGFD and has granted Somatuline<sup>®</sup> Depot orphan drug marketing exclusivity for the long-term treatment of acromegaly. In the European Union, the European Medicines Agency (EMA) has granted Increlex orphan drug marketing exclusivity for the long-term treatment of patients with severe Primary IGFD. Although Increlex<sup>®</sup> and Somatuline<sup>®</sup> Depot have received marketing exclusivity, the FDA and EMA can still approve different drugs for use in treating the same indication or disease covered by our products, which would create a more competitive market for us.

Furthermore, drugs considered to be the same as Increlex<sup>®</sup> or Somatuline<sup>®</sup> Depot that demonstrate clinical superiority or provide a major contribution to patient care may be approved for marketing by the FDA and EMA notwithstanding the grant of orphan drug marketing exclusivity. If other companies are able to overcome our U.S. orphan drug exclusivity, they will be able to compete with us, and our revenues will be diminished.

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

Our products and manufacturing processes are subject to continued review and ongoing regulation by the FDA and foreign regulatory authorities post approval, including, for example, changes to manufacturing process standards or good manufacturing practices, changes to product labeling, revisions to existing requirements or



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new requirements for manufacturing practices, or changing interpretations regarding regulatory guidance. Such changes in the regulatory environment and requirements could occur at any time during commercialization. Changes in the regulatory environment or requirements could adversely affect our ability to maintain our approval or require us to expend significant resources to maintain our approvals, which could result in the possible withdrawal of our products from the marketplace, which would harm our business and negatively impact our financial performance.

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

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

***Competitors could challenge our patents and file an Abbreviated New Drug Application, or ANDA, or a 505(b)(2) new drug application for an IGF-1 or Somatuline<sup>®</sup> Depot product and adversely affect the competitive position of each.***

Products approved for commercial marketing by the FDA are subject to the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act. The Hatch-Waxman Act provides companies with marketing exclusivity for varying time periods during which generic or modified versions of a drug may not be marketed and allows companies to apply to extend patent protection for up to five additional years. It also provides a means for approving generic versions of a drug once the marketing exclusivity period has ended and all relevant patents have expired. The period of exclusive marketing, however, may be shortened if a patent is successfully challenged and defeated. Competitors with a generic IGF-1 or Somatuline<sup>®</sup> Depot product or a modified version of IGF-1 or Somatuline<sup>®</sup> Depot may attempt to file an ANDA or a 505(b)(2) NDA and challenge our patents and marketing exclusivity. Such applications would have to certify that one of the patents in the Increlex<sup>®</sup> or Somatuline<sup>®</sup> Depot NDA is invalid or not infringed by the manufacture, use, or sale of the product described in that ANDA or 505(b)(2) application under the Hatch-Waxman Act. If successful, a competitor could come to market at an earlier time than expected. We can provide no assurances that we can prevail in a challenge or litigation related to our patents or exclusivity.

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

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

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

If we are not able to protect our proprietary technology, trade secrets and know-how, our competitors may use our inventions to develop competing products. We have licensed intellectual property rights, including patent rights, relating to rhIGF-1, our growth hormone/IGF-1 combination product candidates, and Somatuline<sup>®</sup> Depot technologies from Genentech and Ipsen, respectively. However, these patents may not protect us against our competitors. Patent litigation is very expensive, and we therefore may be unable to pursue patent litigation to its conclusion because currently we do not generate meaningful revenues.

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

We do not have composition of matter patent coverage on the lanreotide molecule (the active pharmaceutical ingredient of Somatuline<sup>®</sup> Depot) alone. We have licensed from Ipsen its rights to formulation and method of use patents for Somatuline<sup>®</sup> Depot that expire between 2015 and 2019. However, there can be no assurance that we have patent rights sufficient to prevent others from competing with us.

We do not have composition of matter patent coverage on either the growth hormone or the IGF-1 component of our growth hormone/IGF-1 combination product candidates. Our U.S. Patent No. 5,374,620 and our equivalent European Patent No. 0 536 226 B1, both of which are licensed from Genentech, are composition of matter patents covering combinations of growth hormone and IGF-1 and expire in 2009 and 2011, respectively. Therefore, it is likely that these patents will expire before we are able to launch any growth hormone/IGF-1 combination product in the U.S. or in European markets. We have also licensed from Genentech certain method of use patents for our growth hormone/IGF-1 combination product candidates that expire between 2009 and 2014. Our U.S. Patent No. 6,331,414 B1 licensed from Genentech will provide protection in the United States for our process of manufacturing IGF-1 for our growth hormone/IGF-1 combination product candidates until it expires in 2018. We have no equivalent patent protection for our process of manufacturing IGF-1 in Europe.

If we attempt to enforce against a competitor the patent rights we have licensed from Ipsen or the patent rights we have licensed from Genentech, and if such patents are challenged in court by defenses the competitor may raise, such as invalidity, unenforceability or possession of a valid license, we may fail to stop the competitor and we may lose the ability to assert the affected patents against other competitors as well. If we assert the patents we licensed from Ipsen or the patents we licensed from Genentech in an infringement proceeding against a competitor, and if the court were to find in favor of any defense of invalidity or unenforceability raised by the competitor against the asserted patents, we would be unable to use the affected patents to exclude others from competing with Somatuline<sup>®</sup> Depot or Increlex<sup>®</sup>. In addition, the type and extent of patent claims that will be issued to us in the future are uncertain. Any patents that are issued may not contain claims that will permit us to stop competitors from using technology similar to our Increlex<sup>®</sup>, or any growth hormone/IGF-1 combination product or Somatuline<sup>®</sup> Depot technologies.

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

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

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

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

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

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

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.

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

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

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

Based on its significant ownership position through certain protective provisions, Ipsen has the ability to significantly influence the outcome of certain actions by our Board of Directors and those requiring the approval of our stockholders. Our other stockholders may be unable to prevent actions taken by Ipsen. Together with the 13,046,346 shares of our common stock that we have issued to Ipsen (and/or an affiliate of Ipsen), the conversion of the convertible notes and the exercise of the warrant that we have also issued to Ipsen would enable Ipsen to acquire an ownership interest in us of approximately 40% on a fully diluted basis, with the opportunity to increase its ownership position to 60% or greater through market purchases. Ipsen was also granted a preemptive right to purchase its *pro rata* portion of new securities that we may offer in the future to maintain its percentage ownership interest. In addition, under the terms of our affiliation agreement with Ipsen, so long as Ipsen holds at least 15% of the outstanding shares of our common stock, Ipsen is entitled to nominate two out of the nine directors on our Board of Directors. In the event that Ipsen holds at least 10% of the outstanding shares of our common stock, but less than 15%, it would be entitled to nominate one director to our Board of Directors. Our affiliation agreement with Ipsen also provides that in the event Ipsen holds at least 60% of the outstanding shares of our common stock, Ipsen is entitled to nominate an unlimited number of directors to our Board of Directors. For so long as Ipsen holds at least 15% of the outstanding shares of our common stock, Ipsen is also entitled to nominate additional independent director nominees, who must be independent of Ipsen, starting in 2008. Our certificate of incorporation was also amended in connection with our collaboration with Ipsen to waive the corporate opportunity provisions under Delaware law and the corporate opportunity doctrine with respect to opportunities of which Ipsen and Ipsen's designees to our Board of Directors may become aware as a result of their affiliation with us. Additionally, our certificate of incorporation provides that any person purchasing or acquiring an interest in shares of our common stock shall be deemed to have consented to these provisions of our certificate of incorporation. This deemed consent might restrict the ability to challenge transactions carried out in compliance with these provisions. We make no assurances that Ipsen will not seek to influence our business in a manner that is contrary to our goals or strategies or the interests of other stockholders. Moreover, persons who are directors and/or officers of Ipsen and who also serve on our Board of Directors may decline to take action in a manner that might be favorable to us but adverse to Ipsen. Currently, one of our directors, Christophe Jean, also serves as the Chief Operating Officer of Ipsen.

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

We have licensed intellectual property rights and technology from Genentech and from Ipsen. Under our license and collaboration agreements with Genentech and Ipsen, each of Genentech and Ipsen have the right to terminate our licenses if we are in material breach of our obligations under our agreements with them and fail to cure that breach. Under the terms of the agreements, we are obligated, among other things, to use reasonable business efforts to meet specified milestones. If any of these agreements are terminated, then we would lose our rights to utilize the technology and intellectual property covered by that agreement to develop, manufacture, market and sell Increlex<sup>®</sup> for any indication, to develop, market and sell Somatuline<sup>®</sup> Depot, and to develop, manufacture, market and sell our growth hormone/IGF-1 combination product candidates. This may prevent us from continuing our business.

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***We are subject to Genentech's option rights with respect to the commercialization of Increlex® for all diabetes and non-orphan indications in the United States; Ipsen's right of first negotiation to develop and commercialize other endocrine products subsequently acquired or owned by us; and Genentech's option rights with respect to our growth hormone/IGF-1 combination product candidates.***

Under our U.S. license and collaboration agreement with Genentech for Increlex®, Genentech has the option to elect to jointly commercialize rhIGF-1 for all diabetes and non-orphan indications in the United States. Orphan indications are designated by the FDA under the Orphan Drug Act, and are generally rare diseases or conditions that affect fewer than 200,000 individuals in the United States. With respect to those non-orphan and diabetes indications in the United States, once Genentech has exercised its option to jointly develop and commercialize, Genentech has the final decision on disputes relating to the development and commercialization of such indications. Our ability to sublicense the development and commercialization of such products requires the consent of Genentech. Under a letter agreement of July 2007, we and Genentech amended the U.S. license and collaboration agreement to provide that until such time as we initiate the development of rhIGF-1 for diabetes (or a substitute indication mutually agreed to by us and Genentech that has a potential market of greater than \$250 million and is not an indication for the central nervous system), Genentech may elect to initiate such development for diabetes or, upon our and Genentech's mutual agreement, the development of a substitute indication that has a potential market size of greater than \$250 million and is not an indication of the central nervous system. In addition, if we elect to discontinue the development of rhIGF-1 for diabetes or a substitute indication selected by us with Genentech's consent, Genentech has the right to assume development of such indication. In the event that Genentech initiates the development of rhIGF-1 for any such indication before we do or assumes the development of rhIGF-1 for any such indication after such development is discontinued by us, our rights under the agreement for such indication would terminate and Genentech would be granted a non-exclusive license under our rhIGF-1 intellectual property and technology to manufacture, use and sell rhIGF-1 products for diabetes, or if applicable the substitute indication, subject to an obligation to pay us milestone payments and/or royalties to be negotiated by Genentech and us in good faith on sales of these products.

Under our license and collaboration agreement with Ipsen with respect to Increlex®, Ipsen has a right of first negotiation to develop and commercialize, in Ipsen's territory, other products subsequently acquired or owned by us in the field of endocrinology. Accordingly, we may not receive a reasonable return on our investment if we develop new endocrinology products. In its territory, Ipsen also has the exclusive right to sublicense our growth hormone/IGF-1 combination product candidates. Accordingly, we have limited ability to sublicense these candidates to other parties.

Under our development and commercialization agreement with Genentech with respect to our growth hormone/IGF-1 combination product candidates, Genentech has a right to opt into our development and commercialization for short stature indications, AGHD and certain other indications. If Genentech opts in, it would still have the right to subsequently elect to opt out of such development and commercialization of such combination product candidates and products, but only for all indications. Following an opt-in by Genentech, Genentech would control the joint development and commercialization of the combination product candidates and products for certain other indications and could assume control of the joint development and/or commercialization of products for the treatment of AGHD. Upon opt-in, Genentech may also choose to exercise a commercial option to acquire the right for the deciding vote on all commercialization matters pertaining to short stature indications; however, we would remain the lead commercialization party for Short Stature Indications. Because of Genentech's ability to control the timing and extent of such joint development and commercialization activities and our obligation to co-fund such activities, Genentech may induce us to bear an excessive financial burden in support of or to opt out of the joint development and commercialization of our combination product candidates and/or products for AGHD and certain other indications. In addition, our ability to sublicense the development and commercialization of our growth hormone/IGF-1 combination product candidates requires the consent of Genentech.

Accordingly, because of these various option, limits on sublicensing, and right of first negotiation rights, we may not receive a reasonable return on our investment for developing and/or commercializing Increlex® or our growth hormone/IGF-1 combination product candidates.

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

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

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

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

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

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

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

a minimum price for our common stock;

the accuracy of representations and warranties made to Kingsbridge;

compliance with laws;

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

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

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



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

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

Under the terms of our collaboration with Ipsen, we issued to Ipsen convertible notes in the principal amounts of \$25.0 million, \$30.0 million and \$15.0 million. All of these notes mature on the later of October 13, 2011 or two years from the date of notification of non-convert, and carry a 2.5% coupon per annum from the date of issuance, compounded quarterly. If Ipsen (or a subsequent holder) chooses not to convert these notes, we would be required to pay to Ipsen the principal amount of the notes plus accrued interest at maturity. We are also subject to currency risk on the \$30.0 million principal amount convertible note that we issued to Ipsen which, if the note is not converted, may result in the need to raise a greater amount of U.S. dollars to repay this note at maturity than would be required based on a conversion of this note to U.S. dollars at the time we entered into the stock purchase and master transaction agreement with Ipsen in July 2006 or issuance of the note. If we are required to repay the notes in cash, we will likely need to raise such amounts from the capital markets or through a strategic transaction. There is no assurance that we would be able to do so in a timely manner or on reasonable terms. If we are unable to do so, we may be required to delay or curtail our development and commercialization efforts, which would harm our business.

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

increasing our vulnerability to general adverse economic and industry conditions;

limiting our ability to obtain additional financing;

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

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



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

We believe that our cash, cash equivalents and short-term investments as of December 31, 2007 as well as internally generated funds will be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2008 based on our current business plan. However, our future capital needs and the adequacy of our available funds will depend on many factors, including:

changes to our business plan;

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

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

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

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

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

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

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

any required repayment of the convertible notes we issued to Ipsen;

the status of competing products;

the rate of progress and cost of our future clinical trials and other research and development activities, including research and development activities and clinical trial costs in connection with our growth hormone/IGF-1 combination product candidates; and

the pace of expansion of administrative and legal expenses.

We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations. We expect that we may require and attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources, including potentially the CEFF. However, there can be no assurance that additional financing will be available when needed, or, if available, that the terms will be favorable. In addition, under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, we have only a limited ability to raise capital through the sale of our equity without first obtaining Ipsen's approval. Although we have entered into a stock purchase agreement with Genentech pursuant to which we may issue up to an additional 1,894,737 shares of common stock (or up to a maximum of \$9.0 million of shares of common stock) to Genentech, such issuances are subject to various conditions, including a Genentech opt in and the achievement of a regulatory approval milestone, and there can be no assurance that we will receive additional funds from Genentech pursuant to the stock purchase agreement. Further, we must first obtain Ipsen's approval to issue shares of common stock to

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Genentech under our stock purchase agreement with Genentech at a price per share less than \$4.75, which we may not be able to obtain. If additional funds are not available, we may be forced to curtail or cease operations.

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

Our ability to implement our business plan requires an effective planning and management process. As of December 31, 2007, we had 126 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.

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

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

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

Somatuline<sup>®</sup> Depot is a member of a class of products known as somatostatin analogs, which have the potential to cause gallstones and other disorders associated with obstruction of the biliary tract, including pancreatitis. These products also alter the balance between the counter-regulatory hormones insulin, glucagon and growth hormone, which may result in hypoglycemia or hyperglycemia, and suppress secretion of thyroid stimulating hormone, which may result in hypothyroidism. Cardiac conduction abnormalities have also occurred during treatment with this class of drugs.

There may also be other adverse events associated with the use of Increlex<sup>®</sup> or Somatuline<sup>®</sup> Depot, and adverse events may arise that are related to our growth hormone/IGF-1 combination product candidates, which may result in product liability suits being brought against us. While we have licensed the rights to develop, market and sell Increlex<sup>®</sup>, Somatuline<sup>®</sup> Depot and our growth hormone/IGF-1 combination product candidates in certain indications, with the exception of certain liabilities covered up to certain limits by our insurance policies, we are not indemnified by any third party, including our contract manufacturers, for any liabilities that we bear and that arise out of our development or use of any of these products or product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

As of December 31, 2007, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 80.8% of our common stock. Our greater than five percent beneficial owners include Ipsen and its affiliates, which beneficially owned 42.6% (not including shares subject to limited voting agreements with certain of our stockholders); entities affiliated with MPM BioVentures III LLC, which beneficially owned 13.4%; entities affiliated with Prospect Management Co. II, LLC, which beneficially owned 5.9%; MedImmune, Inc., which beneficially owned 5.8%; and entities affiliated with Rho Capital Partners, which beneficially owned 5.8%. Our directors, executive officers and principal stockholders and their affiliates collectively have the ability to determine the election of all of our directors and to determine the outcome of most corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of other stockholders.

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

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

entering into most material transactions or agreements;

merging or consolidating with other entities;

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

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

incurring capital expenditures of more than \$2.0 million in any given year;

making any investment, other than certain permitted investments;

entering into any transaction that results in competition with Ipsen;

declaring or paying any cash dividends;

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

issuing or selling shares of our capital stock, other than issuances or sales after October 13, 2008 that may not exceed \$25.0 million in any three-year period, and other limited exceptions.

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

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

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

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

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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.

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

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

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

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

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

announcements by us, Ipsen, Genentech, our suppliers and key third-party vendors, or our competitors of regulatory developments, product development agreements, clinical trial results, clinical trial enrollment, regulatory filings, new products and product launches, significant acquisitions, strategic partnerships or joint ventures;

estimates of our business potential and earnings prospects;

deviations from analysts' projections regarding business potential, costs and/or earnings prospects;

developments with respect to our collaboration with Ipsen;

quarterly variations in our operating results;

significant developments in the businesses of biotechnology companies;

changes in financial estimates by securities analysts;

changes in market valuations or financial results of biotechnology companies;

additions or departures of key personnel;

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

activities of short sellers and risk arbitrageurs;

future sales of our common stock, including potential sales of a substantial number of shares by Ipsen and its affiliates, or the perception that such sales are likely to occur;

general economic, industry and market conditions; and

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



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

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

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

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

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

As of December 31, 2007, we had 51,532,229 outstanding shares of common stock. As of December 31, 2007, we had 5,419,638 shares subject to outstanding options granted under our equity compensation plans. In addition, as of December 31, 2007, 15,574,519 shares were issuable upon the exercise of the warrant and conversion of the three convertible notes, which we have issued to Ipsen. Further, the terms of the warrant we issued to Ipsen provide that the number of shares of our common stock subject to the warrant may increase in the event of certain issuances of equity securities by us that dilute Ipsen's percentage ownership interest in us. Moreover, the initial exercise price of the warrant, and the conversion price of convertible notes we have issued to Ipsen, are subject to certain weighted-average price-based antidilution adjustments. These terms of the warrant and convertible notes may entitle Ipsen to acquire a greater number of shares of our common stock than we currently anticipate.

We have filed a registration statement covering shares of common stock issuable upon exercise of options and other grants pursuant to our stock plans. In September 2005, we filed a shelf registration statement pursuant to which we may, from time-to-time, sell shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings. In November 2005, we also filed a registration statement for the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant we issued to Kingsbridge in connection with our entering into the CEFF. Moreover, we have agreed that, upon Ipsen's request after October 13, 2007, we would file one or more registration statements in order to permit Ipsen and its affiliates to offer and sell a substantial number of shares of our common stock, including the 13,046,346 shares we issued to an affiliate of Ipsen and the shares issuable upon exercise of the warrant and conversion of the convertible notes we issued to Ipsen. In addition, certain holders of shares of our common stock that are parties to our amended and restated investors' rights agreement, including Genentech, are entitled to registration rights.

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None.

**Item 2. Properties.**

Our facilities consist of approximately 34,400 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.**

None.

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

Not applicable.

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

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

	Prices	
	High	Low
<b>Fiscal 2007:</b>		
First Fiscal Quarter	\$ 5.92	\$ 4.64
Second Fiscal Quarter	6.83	5.10
Third Fiscal Quarter	7.17	4.71
Fourth Fiscal Quarter	7.77	5.71
<b>Fiscal 2006:</b>		
First Fiscal Quarter	\$ 7.90	\$ 6.29
Second Fiscal Quarter	6.88	3.07
Third Fiscal Quarter	6.70	4.21
Fourth Fiscal Quarter	6.24	4.90

There were approximately 37 holders of record of our common stock as of February 28, 2008. 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. In addition, the consent of Ipsen (or any subsequent holders of the convertible notes that we issued to Ipsen) is required for us to declare or pay any cash dividends pursuant to the terms of the convertible notes that we issued to Ipsen. Suraypharm, S.A.S., an affiliate of Ipsen, also must consent to our declaration or payment of any cash dividends under the terms of the affiliation agreement that we entered into with Ipsen and Suraypharm in October 2006.



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**Stockholder Return Comparison<sup>(1)</sup>**

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

\* \$100 invested on 3/17/04 in stock or on 2/28/04 in index-including reinvestment of dividends. Fiscal year ending December 31.

- (1) This section is not soliciting material, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Tercica, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

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

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

	Year Ended December 31,				
	2007	2006	2005	2004	2003
<b>Statements of Operations Data (in thousands, except per share data):</b>					
Net revenues:					
Net product sales	\$ 9,809	\$ 1,315	\$	\$	\$
License revenue	21,119	194			
Royalty revenue	51				
Total net revenues:	30,979	1,509			
Costs and expenses:					
Cost of sales	5,540	1,667			
Manufacturing start-up costs	3,065				
Research and development	19,136	42,034	21,587	29,335	20,916
Selling, general and administrative	43,186	44,248	25,913	12,552	4,834
Amortization of intangibles	468				
Total costs and expenses	71,395	87,949	47,500	41,887	25,750
Loss from operations	(40,416)	(86,440)	(47,500)	(41,887)	(25,750)
Interest expense	(1,937)	(162)	(1,080)		
Other expense(4)	(3,071)				
Interest and other income, net	5,975	4,226	2,347	885	327
Loss before income taxes	(39,449)	(82,376)	(46,233)	(41,002)	(24,423)
Provision for income taxes(5)	(1,017)	(621)			
Net loss	(40,466)	(82,997)	(46,233)	(41,002)	(25,423)
Deemed dividend related to beneficial conversion features of convertible preferred stock(3)					(44,153)
Net loss allocable to common stockholders	\$ (40,466)	\$ (82,997)	\$ (46,233)	\$ (41,002)	\$ (69,576)
Basic and diluted net loss per share allocable to common stockholders(1)	\$ (0.80)	\$ (2.09)	\$ (1.51)	\$ (2.12)	\$ (38.59)
Shares used in computing basic and diluted net loss per share allocable to common stockholders(1)	50,717	39,789	30,590	19,302	1,803
	2007	2006	December 31, 2005	2004	2003
<b>Balance Sheet Data (in thousands):</b>					
Cash, cash equivalents and short-term investments	\$ 113,485	\$ 125,575	\$ 58,626	\$ 52,001	\$ 37,313
Working capital	101,923	123,181	53,752	45,542	33,346

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Total assets	176,683	137,687	66,316	55,022	42,484
Long-term convertible notes, net(2)	86,691	25,172			
Convertible preferred stock					68,637
Accumulated deficit	(289,204)	(248,738)	(165,741)	(119,508)	(78,506)
Total stockholders' equity (deficit)	63,159	89,931	56,798	47,677	(33,198)

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- (1) See Note 3 of the Notes to Financial Statements for information regarding the computation of per share amounts.
- (2) See Note 6 of the Notes to Financial Statements for information regarding the long-term convertible notes.
- (3) We recorded a deemed dividend of \$44,153,000 associated with this issuance of preferred shares to reflect the value of the beneficial conversion feature embedded in the Series B convertible preferred stock. The deemed dividend increases the net loss allocable to common stockholders in the calculation of basic and diluted net loss per common share for the year ended December 31, 2003.
- (4) See Note 6 of the Notes to Financial Statements for information regarding the valuation adjustments to the Euro-denominated convertible note.
- (5) See Note 12 of the Notes to Financial Statements for information regarding the withholding taxes associated with milestone payments received from Ipsen.

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

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

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

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

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

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

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

In August 2007, the European Commission granted marketing authorization for Increlex<sup>®</sup> in the European Union for the long-term treatment of growth failure in children and adolescents with severe Primary IGFD. Pursuant to our worldwide strategic collaboration with Ipsen that was completed in October 2006, we granted to Ipsen and its affiliates the exclusive right under our patents and know-how to develop and commercialize Increlex<sup>®</sup> in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa for all indications, other than treatment of central nervous system and diabetes indications. In 2007, Ipsen launched Increlex<sup>®</sup> in Austria, Germany, Great Britain, Greece, Hungary, Spain and the Czech Republic and expects to launch Increlex<sup>®</sup> in additional European countries during 2008. Increlex<sup>®</sup> generated net product revenues of \$9.6 million in the year ended December 31, 2007.





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***Somatuline® Depot.*** Pursuant to our worldwide strategic collaboration with Ipsen, we have the exclusive right under Ipsen's patents and know-how to develop and commercialize Somatuline® Depot in the United States and in Canada for all indications other than ophthalmic indications. In territories outside the United States including Canada, the product is known as Somatuline® Autogel®. On August 30, 2007, Ipsen received notice of approval from the FDA for marketing Somatuline® Depot in the United States for the long-term treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. Acromegaly is a hormonal disorder that results when a tumor in the pituitary gland produces excess growth hormone, resulting in overproduction of IGF-1. We launched Somatuline® Depot in November 2007 in the United States. In July 2006, Somatuline® Autogel® was approved for marketing by Health Canada for the same indication. Somatuline® Autogel® has received provincial formulary listings for reimbursement approval in the provinces of Quebec, Nova Scotia, New Brunswick, Saskatchewan, and for Alberta Blue Cross and we are awaiting reimbursement approval in the province of Ontario. At present, we have contracted sales and marketing operations in Canada to a third party.

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

As of December 31, 2007, we had approximately \$113.5 million in cash, cash equivalents and short-term investments. We have generated limited revenues from product sales to date and we have funded our operations since inception primarily through the private placements of equity securities and public offerings of our common stock, as well as through our collaboration with Ipsen. Since our inception we have incurred substantial net losses and we expect to incur substantial net losses for the foreseeable future as we attempt to develop, market and sell Increlex® and Somatuline® Depot, and as we attempt to develop growth hormone/IGF-1 combination products under our combination product collaboration with Genentech. We are unable to predict the extent of any future losses or when we will become profitable, if ever.

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

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

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

#### ***Revenue Recognition***

We recognize revenue from the sale of our products and license and collaboration agreements pursuant to Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force (EITF) Issue 00-21 *Revenue Arrangements with Multiple Deliverables*. Multiple element agreements entered into are evaluated under the provision of EITF 00-21. We evaluate whether there is stand-alone value for the delivered elements and objective and reliable evidence of fair value to allocate revenue to each element in multiple element

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agreements. When the delivered element does not have stand-alone value or there is insufficient evidence of fair value for the undelivered element(s), we recognize the consideration for the combined unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is generally ratably over the longest period of involvement.

*Product revenues.* We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed or determinable and collectibility is reasonably assured. We record provisions for discounts to customers and rebates to government agencies and international distributors, which are based on contractual terms and regulatory requirements. The rebates and discounts may require management judgment to estimate percentage of eligible sales to these customers. Our product returns policy only allows for the return of product damaged in transit, product shipped in error by us, or discontinued, withdrawn or recalled merchandise. To date, product returns have been de minimis and based on our historical experience as well as the specialized nature of our products, we historically have not provided a reserve for product returns. We will continue to monitor returns in the future and will reassess the need to estimate a product returns reserve if the returns experience increases.

*License revenues.* License revenue generally includes upfront and continuing licensing fees and milestone payments. Nonrefundable upfront fees that require our continuing involvement in the manufacturing or other commercialization efforts by us are recognized as revenue ratably over the contractual term. Fees associated with substantive milestones, which are contingent upon future events for which there is reasonable uncertainty as to their achievement at the time the agreement was entered into, are recognized as revenue when these milestones, as defined in the contract, are achieved.

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

**Stock-based Compensation**

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R, which requires the measurement and recognition of non-cash compensation expense for all share-based payment awards made to employees and directors including employee stock options and employee stock purchases related to our 2004 Employee Stock Purchase Plan based on estimated fair values. SFAS No. 123R supersedes our previous accounting under Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107, or SAB 107, relating to SFAS No. 123R. We have applied the provisions of SAB 107 in its adoption of SFAS No. 123R. Refer to Note 11, *Stock-Based Compensation*, in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K for further information on these matters.

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

As a result of adopting SFAS No. 123R, we recognized stock-based compensation expense of \$5.9 million and \$5.7 million during the years ended December 31, 2007 and 2006, respectively, which primarily affected our reported research and development and selling, general, and administrative expenses during those periods. Approximately \$1.8 million and \$4.1 million are included in research and development expenses, and selling, general and administrative expenses, respectively, for the year ended December 31, 2007. Approximately \$2.0 million and \$3.7 million are included in research and development expenses, and selling, general and

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administrative expenses, respectively, for the year ended December 31, 2006. We calculated these expenses based on the fair values of the stock-based compensation awards as estimated using the Black-Scholes model. Use of this model requires us to make assumptions about expected future volatility of our stock price and the expected term of the options that we grant. Calculating stock-based compensation expense under SFAS No. 123R also requires us to make assumptions about expected future forfeiture rates for our option awards. As of December 31, 2007, total unrecognized compensation expense related to unvested share-based compensation arrangements previously granted under our various plans was \$10.5 million, which we expect to recognize over a weighted-average period of 2.6 years. However, it is difficult to predict the actual amount of share-based compensation expense that we will recognize in future periods as that expense can be affected by changes in the amount or terms of our share-based compensation awards issued in the future, changes in the assumptions used in our model to value those future awards, changes in our stock price, and changes in interest rates, among other factors.

***Inventories***

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out basis. The valuation of inventory requires management to estimate obsolete or excess inventory based on analysis of future demand for our products. Due to the nature of our business and our target market, levels of inventory in the distribution channel, changes in demand due to price changes from competitors and introduction of new products are not significant factors when estimating our excess or obsolete inventory for Increlex<sup>®</sup> but can be significant factors in estimating excess or obsolete inventories for Somatuline<sup>®</sup> Depot. If inventory costs exceed expected market value due to obsolescence or lack of demand, inventory write-downs may be recorded as deemed necessary by management for the difference between the cost and the market value in the period that impairment is first recognized. Inventories may include products manufactured at facilities awaiting regulatory approval and are capitalized based on our judgment of probable near term regulatory approval. In addition, inventories include employee stock-based compensation expenses capitalized under FAS 123R.

In general, the process for evaluating whether there exists excess or obsolete inventory is not a complex process and does not require significant management judgment. The factors considered in evaluating whether there exists excess or obsolete inventory are:

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

the expiration date for each lot manufactured;

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

In May 2007, we began to transfer our manufacturing process to new facilities and as such, there will be a period of time where the Company will need to cease production of Increlex<sup>®</sup> until the new manufacturing facilities are fully validated, approved by the FDA, and operational. We are increasing our inventory levels in an effort to ensure that we have adequate supplies to meet future demand and therefore our long-term Increlex<sup>®</sup> sales forecast will become more critical in management's evaluation of excess Increlex<sup>®</sup> inventories over the next few quarters. Once the transfer of manufacturing facilities is complete, we will have more flexibility in the manufacturing schedule to ensure inventory supply is in line with a shorter forward demand forecast for Increlex<sup>®</sup>. At December 31, 2007, we had inventories recorded in work-in-process of \$6.1 million that are under evaluation for manufacturing process transfer approval. The FDA requires that when technical processes are transferred to a new manufacturer, a certain number of conformance lots must be produced using the new manufacturer's facilities and evaluated for process consistency. Refer to Note 7, Commitments and Contingencies Manufacturing Services Agreement, in the Note to Financial Statements of Part II, Item 8 of this Form 10-K for further discussion regarding inventory purchase commitments.

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**Table of Contents*****Valuation of Derivative Instruments***

We issued a convertible note in September 2007 and valued certain features embedded therein as derivative liabilities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. We estimate the fair value of our derivative liabilities each quarter using the Black-Scholes-Merton valuation model. This model is complex and requires significant judgments in the estimation of fair values based on certain assumptions. Factors affecting the amount of these liabilities include changes in the market value of our common stock, changes in Euro to Dollar currency exchange rates and other assumptions. Changes in value are recorded as non-cash valuation adjustments within other expense in our statement of operations. These changes in the carrying value of derivatives can have a material impact on our financial statements (see Part II, Item 7A – Qualitative and Quantitative Disclosures about Market Risk of this Form 10-K). The derivative liabilities may be recorded into stockholders' equity upon conversion, payment or expiration of the convertible notes, the timing of which is outside our control.

The embedded derivative liability does not qualify for hedge accounting under SFAS 133 and therefore, subsequent changes in fair value are recorded as non-cash valuation adjustments within other expense in the statements of operations.

***Valuation of Warrants***

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

***Intangible Assets***

We capitalize fees paid to our licensors related to license agreements for approved products or technology that has alternative future uses, as intangible assets in accordance with Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* ( SFAS 142 ), when we have obtained rights to develop and commercialize licensed products. We amortize these intangible assets with definite lives on a straight-line basis over their estimated useful lives, and review for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values.

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

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### ***Accounting for Income Taxes***

On January 1, 2007, we adopted FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes*, which clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAS No. 109, *Accounting for Income Taxes*. Our policy is to recognize interest and/or penalties related to income tax matters in income tax expense. There were no accrued interest or penalties associated with uncertain tax positions as of December 31, 2007. We had \$3.8 million of unrecognized tax benefits as of December 31, 2007 and we do not expect our unrecognized tax benefits to change significantly over the next twelve months.

We utilize the liability method of accounting for income taxes as required by SFAS No. 109. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The provision for income taxes for the years ended December 31, 2007 and 2006 represent \$1.0 million and \$0.6 million, respectively, of French foreign income taxes withheld on upfront license fees received from Ipsen under the Increlex<sup>®</sup> license. There is no domestic provision for income taxes for the years ended December 31, 2007, 2006 and 2005 because we have incurred operating losses to date.

### ***Recent Accounting Pronouncements***

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

In June 2007, the EITF ratified the consensus on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 concludes that nonrefundable advance payments for future research and development activities should be deferred and capitalized and recognized as expense as the related goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We expect that the adoption of 07-3 will not have an impact on our financial position or results of operations.

In December 2007, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 110, or SAB 110. SAB 110 was effective January 1, 2008 and expresses the views of the Staff of the SEC regarding the use of the simplified method, as discussed in SAB No. 107, in developing an estimate of the expected term of plain vanilla share options in accordance with SFAS No. 123R. We are currently evaluating the impact of applying the provisions of SAB 110 on our financial position and results of operations.

**Table of Contents****Results of Operations**

	2007	2006 (In thousands)	2005
Net product sales	\$ 9,809	\$ 1,315	\$
Period over period increase	8,494	1,315	
License revenue	21,119	194	
Period over period increase	20,925	194	
Royalty revenue	51		
Period over period increase	51		
Cost of sales	5,540	1,667	
Period over period increase	3,873	1,667	
Manufacturing start-up costs	3,065		
Period over period increase	3,065		
Research and development expenses	19,136	42,034	21,587
Period over period increase (decrease)	(22,898)	20,447	
Selling, general and administrative expenses	43,186	44,248	25,913
Period over period increase (decrease)	(1,062)	18,335	
Amortization of intangible assets	468		
Period over period increase	468		
Interest expense	(1,937)	(162)	(1,080)
Period over period increase	(1,775)	(918)	
Interest and other income, net	5,975	4,226	2,347
Period over period increase	1,749	1,879	
Other expense	(3,071)		
Period over period increase	(3,071)		
Provision for income taxes	1,017	621	
Period over period increase	396	621	

**Net Revenues**

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

**Net Product Sales**

Net product sales increased \$8.5 million from \$1.3 million in 2006 to \$9.8 million in 2007, primarily due to growth in Increlex<sup>®</sup> net product sales. In March 2007, we announced agreements that settled all prior litigation against Insmmed Incorporated. One of the key terms in the settlement agreement stipulated that Insmmed will no longer provide IPLEX to patients with severe Primary IGF1D and other short stature indications. Following the settlement agreement with Insmmed, a number of patients receiving IPLEX, a product marketed by Insmmed, switched to treatment with Increlex<sup>®</sup>. This along with continued expansion of our patient base and two price increases during 2007 led to the growth of net Increlex<sup>®</sup> product sales in 2007. In the fourth quarter of 2007, we began shipment of Increlex<sup>®</sup> to Ipsen for European Union commercial distribution which added \$0.3 million to





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net product sales. In November 2007, we launched Somatuline<sup>®</sup> Depot in the United States, which added \$0.2 million to net product sales. We began shipment of Increlex<sup>®</sup> to specialty pharmacy distributors in January 2006 and recorded net product sales of \$1.3 million in 2006.

Net product sales of \$9.6 million and \$0.2 million, for Increlex<sup>®</sup> and Somatuline<sup>®</sup> Depot, respectively in 2007, consisted primarily of gross product sales less provisions for discounts to customers, rebates to government agencies, product returns and other adjustments. In 2007, we recorded discounts to product sales of \$1.2 million in government rebates to state Medicaid agencies and rebates for shipments to our international distributors.

Net product sales of \$1.3 million in 2006 consisted primarily of gross Increlex<sup>®</sup> product sales less provisions for discounts to customers, rebates to government agencies and product returns. There were minimal rebates to state government Medicaid agencies and to international distributors. There were no Somatuline<sup>®</sup> Depot sales in 2006.

We expect both Increlex<sup>®</sup> and Somatuline<sup>®</sup> Depot product sales to increase over the next several quarters, however, we do not expect net Increlex<sup>®</sup> product sales to increase at the same rate on a year over year basis as we experienced from 2006 to 2007.

### *License Revenue*

License revenue increased \$20.9 million from \$0.2 million in 2006 to \$21.1 million in 2007. In September 2007, per our Increlex<sup>®</sup> license and collaboration agreement with Ipsen, we received a milestone payment from Ipsen of \$20.3 million (or \$19.3 million net of withholding taxes) upon the grant of marketing authorization for Increlex<sup>®</sup> in the European Union for the targeted product label. Additionally, we received an upfront payment of 10.0 million, or \$12.4 million, upon execution of our collaboration agreement with Ipsen in 2006, which we are amortizing over a period of approximately 16 years based on the expected term of the license under this agreement. License revenue in 2007 represents the \$20.3 million milestone payment as well as \$0.8 million amortization of the 2006 upfront payment. At present, we do not anticipate any significant additional licensing or milestone payments related to or for Increlex<sup>®</sup> in future periods.

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

### *Royalty Revenue*

We recorded royalty revenue of \$0.05 million in 2007 from shipments of Increlex<sup>®</sup> in the European Union by Ipsen. There were no royalty revenues in 2006 or 2005. We expect our royalty revenues to increase in 2008 as Ipsen continues to expand their Increlex<sup>®</sup> distribution in the European Union.

### *Cost of Product Sales*

Our cost of sales represents the cost of production, royalties owed to our licensors, distribution shipping and handling costs, inventory write-downs/write-offs based on our review of obsolete, excess, expired and failed inventory lots, and other costs related to production activities. Prior to regulatory approval of Increlex<sup>®</sup> in August 2005, drug supply production costs were charged to research and development. Beginning in the fourth quarter of 2005, with the marketing approval of Increlex<sup>®</sup> by the FDA, we began capitalizing these production costs to inventory and began to charge cost of sales in the first quarter of 2006 as units of Increlex<sup>®</sup> were sold. In addition to these capitalized drug supply production costs, there are also certain variable and fixed shipping, distribution and handling costs charged to cost of sales.

Cost of product sales increased \$3.8 million from \$1.7 million in 2006 to \$5.5 million in 2007. The increase in 2007 was primarily due to higher sales volume as more Increlex<sup>®</sup> units were sold and we commenced marketing of Somatuline<sup>®</sup> Depot. There was no product revenue or related cost of sales in 2005.

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Cost of sales as a percentage of net product sales in 2007 was lower than 2006 primarily due to reduced manufacturing lot failures, as well as the absorption of fixed costs over increased production volume.

We expect cost of sales as a percentage of net product sales to decrease in future periods as fixed costs are absorbed over larger production volumes, as our sales mix changes over time, as we execute our production activities, and as the percentage of manufacturing lots that are successfully completed improves. However, there can be no assurances that cost of sales as a percentage of net product sales will decrease due to uncertainties inherent in the manufacturing process.

### ***Manufacturing Start-up Costs***

Manufacturing start-up costs were \$3.1 million during 2007 and represent amortized costs associated with the transfer of our manufacturing operations to alternate sites. An additional \$2.4 million of manufacturing start-up costs associated with this project will be amortized over the remaining transfer period which is expected to occur through June 2008. There may also be additional associated transfer activities and costs that will continue through the end of 2008, as we prepare for FDA site approval.

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

Research and development expenses consisted primarily of costs associated with clinical, regulatory, manufacturing development and acquired rights to technology or products in development. Clinical and regulatory activities included the preparation, implementation, and management of our clinical trials and clinical assay development, as well as regulatory compliance, data management and biostatistics. The costs associated with conducting clinical trials and post-marketing expenses, which Phase IV and investigator-sponsored trials and product registries, are included in research and development expenses. Manufacturing development activities included pre-regulatory approval activities associated with technology transfer, pharmaceutical development, process and development and validation, quality control and assurance, analytical services, as well as preparations for current good manufacturing practices, or cGMP, and regulatory inspections. In addition to these manufacturing development and clinical activities, license payments for patents and know-how to develop and commercialize products, are also recorded as research and development expense.

Research and development expenses decreased \$22.9 million from \$42.0 million in 2006 to \$19.1 million in 2007. Research and development expenses were \$21.6 million in 2005.

The decrease in 2007 compared to 2006 was primarily due to a license fee of \$25.0 million paid in October 2006 to Ipsen related to our Somatuline® License and Collaboration Agreement (See Note 9 in the Notes to the Financial Statements for further details on our collaboration with Ipsen). This decrease was partially offset by an increase in payroll related costs of \$0.8 million, clinical drug supply costs of \$0.8 million and third party contractor costs of \$0.6 million. The increase in payroll related costs in 2007 was primarily due to increased personnel compared to 2006. The increase in third party contractor costs in 2007 was primarily due to an increase in clinical activities associated with Somatuline® Depot and growth hormone/IGF-1 combination product candidates as well as the Increlex® product registry, partially offset by a decrease in activities associated with our European marketing authorization application, or MAA, and clinical activities associated with Primary IGFD and severe Primary IGFD.

The increase in 2006 compared to 2005 was primarily due to a license fee of \$25.0 million paid to Ipsen in October 2006 related to our Somatuline® License and Collaboration Agreement, partially offset by \$3.8 million in lower external project costs primarily due to lower manufacturing development activities in 2006 and \$1.0 million paid in 2005 to Genentech related to Increlex®. Manufacturing development in 2005 was focused on production and validation of our rhIGF-1 manufacturing process and pre-NDA activities.

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The \$19.1 million in research and development expense in 2007 was comprised primarily of personnel and related costs of \$11.5 million, third party contract costs related to our clinical activities for Increlex<sup>®</sup> Primary IGFD and severe Primary IGFD of \$5.2 million, Somatuline<sup>®</sup> Depot in acromegaly of \$0.9 million, clinical drug supply of \$0.8 million and Increlex<sup>®</sup> activities in support of our MAA of \$0.5 million. The \$42.0 million in research and development expense in 2006 was comprised primarily of the \$25.0 million license fee paid to Ipsen, personnel and related costs of \$10.7 million, external project costs related to our clinical activities for Increlex<sup>®</sup> Primary IGFD and severe Primary IGFD of \$4.7 million, and costs associated with our Increlex<sup>®</sup> MAA filing activities of \$1.3 million.

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

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

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

Selling, general and administrative expenses decreased \$1.0 million from \$44.2 million in 2006 to \$43.2 million in 2007. Selling, general and administrative expenses in 2006 were \$18.3 million higher than in 2005.

The decrease in 2007 compared to 2006 was due primarily to decreased expenses associated with litigation and consulting expenses of \$11.3 million, largely offset by an increase in sales and marketing expenses of \$6.3 million and payroll and related costs of \$4.8 million. The increase in sales and marketing activities was primarily related to increased costs associated with product promotions, medical education, costs in support of Increlex<sup>®</sup> and the launch of Somatuline<sup>®</sup> Depot in the U.S. and Canada, as well as costs associated with free goods. The increase in payroll and related expenses was due primarily to additional sales and medical science personnel and non-cash stock compensation expense.

The increase in 2006 compared to 2005 was primarily attributable to additional expenditures associated with sales and marketing activities of \$7.9 million, increased general and administrative personnel and other costs of \$3.2 million, increased legal expenses primarily associated with litigation with Insmed of \$2.8 million, increased expenses of \$2.3 million associated with medical education and free goods expense of \$1.5 million, of which \$0.8 million was related to inventory write-offs due to manufacturing lot failures and \$0.1 million for inventory write-downs.

The \$43.2 million in selling, general and administrative expenses for the year ended December 31, 2007 was comprised primarily of payroll and related costs of \$26.4 million, sales and marketing activities including cost of free drug of \$9.6 million, professional services including legal and accounting services of \$4.3 million, medical education activities of \$1.9 million and other general administrative activities of \$1.0 million.

The \$44.2 million in selling, general and administrative expenses for the year ended December 31, 2006 was comprised primarily of payroll and related costs of \$21.6 million, professional services including legal and accounting services of \$15.4 million, sales and marketing activities including cost of free drug of \$5.8 million, other general administrative activities of \$0.9 million and medical education activities of \$0.5 million.

We expect total selling, general and administrative expenses to increase in 2008 as we support a full year of commercial activities for Somatuline<sup>®</sup> Depot and realize the annualized effect of the additional sales and medical science personnel hired in 2007.

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***Amortization of Intangible Assets***

Amortization of intangible assets of \$0.5 million in 2007 represents expense recorded on a straight-line basis of milestone payments made to Ipsen and to Genentech in connection with the U.S. marketing approval of Somatuline<sup>®</sup> Depot and marketing approval of Increlex<sup>®</sup> in the European Union, respectively. Refer to Note 9, License and Collaboration Agreements and Related Party Transactions, in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K for further information on these milestone payments. We began amortization of these assets in November 2007 and expect to recognize the straight-line expense of \$2.8 million annually through October 2022. There were no amortization of intangibles expense for the years ended December, 31 2006 and 2005.

***Interest expense***

Interest expense increased \$1.7 million from \$0.2 million in 2006 to \$1.9 million in 2007. The interest expense in 2005 was \$1.1 million.

The increase in 2007 compared to 2006 was primarily due to the timing of issuance of the three convertible notes. There was no interest expense for the first nine months of 2006 as the first convertible note was issued to Ipsen in October 2006. The second and third convertible notes were issued in September 2007.

The decrease in 2006 compared to 2005 was primarily due to the issuance of our common stock in 2005 in connection with a loan agreement of \$1.0 million and \$0.1 million of commitment fees related to this loan agreement.

Interest expense of \$1.9 million in 2007 represents interest on the three convertible notes we issued to Ipsen and the related amortization of prepaid financing costs associated with these issuances. We expect interest expense to increase in 2008 as we will realize a full year of interest expense for the three convertible notes. For years thereafter, interest expense should be relatively consistent with 2008 other than increases from compounding of interest as we continue to accrue interest on these convertible notes until exercise or maturity in October 2011. Refer to Note 6, Long-Term Debt, in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K for further information on this transaction.

***Other Expense***

Other expense of \$3.1 million in 2007 was largely due to an unfavorable foreign currency adjustment and an increase in the fair value of the embedded derivative conversion option related to the 30.0 million convertible note we issued to Ipsen in September 2007. The 30.0 million convertible note is denominated in euros and the conversion option is considered an embedded derivative. The note is revalued to U.S. dollars at the end of each reporting period which resulted in a charge of \$1.8 million in 2007. Further, the conversion option must also be revalued at the end of each reporting period which resulted in a charge of \$1.3 million in 2007. There were no such charges in 2006 and 2005.

As currency rates, our stock price and our volatility assumptions change, we may record income or expense to Other Expense related to both the value of the note as well as the value of the embedded derivative. It is difficult to forecast changes to other expense as we are unable to predict fluctuations in currency rates, our stock price and stock price volatility. Refer to Part II, Item 7A Quantitative and Qualitative Disclosures about Market Risk of this Form 10-K.

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

Net interest and other income of \$6.0 million in 2007 increased by \$1.8 million compared to \$4.2 million in 2006 primarily due to interest income on higher average cash, cash equivalents and short-term investment balances during 2007. The higher cash balances in 2007 were due primarily to net cash proceeds from our collaboration with Ipsen. In September 2007, we received net cash proceeds of \$34.3 from Ipsen in connection



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with an Increlex<sup>®</sup> milestone payment, net of withholding taxes, and the issuance of a convertible note to Ipsen in the principal amount of \$15.0 million. Additionally, we received gross cash proceeds of \$6.9 million in July 2007 from the issuance of common stock to Genentech and Ipsen. In October 2006, we received net cash proceeds of \$89.7 million from Ipsen in connection with sale of equity and Increlex<sup>®</sup> license payments.

Net interest and other income increased to \$4.2 million in 2006 from \$2.3 million in 2005. The increase was primarily due to interest income on higher average cash, cash equivalents and short-term investment balances as a result the cash received from our collaboration with Ipsen in October 2006 and the impact of higher interest rates in 2006 compared to 2005.

We expect net interest and other income to decrease in 2008 as we use cash and short-term investments to fund our operations, assuming we do not raise additional financing during 2008.

### ***Provision for income taxes***

The provision for income taxes of \$1.0 million and \$0.6 million in 2007 and 2006, respectively, represents French foreign income taxes withheld on a milestone payment and upfront license fee, respectively, received from Ipsen under the Increlex<sup>®</sup> license. There were no domestic provisions for income taxes in 2007, 2006 and 2005 because we have incurred operating losses to date.

### **Liquidity and Capital Resources**

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

As of December 31, 2007, we had approximately \$113.5 million in cash, cash equivalents and short-term investments. We had an accumulated deficit of \$289.2 million, which was primarily comprised of \$245.1 million of accumulated net losses and \$44.1 million of a non-cash deemed dividend related to the beneficial conversion feature of convertible preferred stock. We have funded our operations and growth from inception through December 31, 2007 primarily from issuance of equity, convertible notes and the receipt of milestone payments. To date we have received net cash proceeds of \$283.2 million from equity issuances including equity sold to Ipsen and Genentech. We have issued three convertible notes to Ipsen from which we received net cash proceeds of \$15.0 million, net of the balance which was used to make milestone payments to Ipsen related to the Somatuline<sup>®</sup> license and collaboration agreement. In addition, we have received \$31.7 million from Ipsen, net of withholding taxes, for milestone payments related to the Increlex<sup>®</sup> license and collaboration agreement.

#### ***Ipsen Collaboration***

On October 13, 2006, we completed the initial closing of the transactions contemplated by the stock purchase and master transaction agreement we entered into with Ipsen in July 2006. At the closing, we issued 12,527,245 shares of our common stock to an affiliate of Ipsen for an aggregate purchase price of \$77.3 million and issued to Ipsen a convertible note in the principal amount of \$25.0 million and a warrant to purchase a minimum of 4,948,795 shares of our common stock, which warrant is exercisable at any time during the five-year period after the initial closing and carries an initial exercise price equal to \$7.41 per share. Under the stock purchase and master transaction agreement with Ipsen we issued a second convertible note and a third convertible note to Ipsen in connection with our Somatuline<sup>®</sup> license and collaboration agreement as described below. Each of the convertible notes that we issued to Ipsen matures on the later of October 13, 2011 or two years from the date of notification of non-convert and carries a coupon of 2.5% per annum from the date of issuance, compounded quarterly, and is convertible into shares of our common stock at an initial conversion price per share equal to \$7.41 per share (or 5.92 per share with respect to the second convertible note). Together with the 13,046,346 shares of our common stock that we have issued to Ipsen (and/or an affiliate of Ipsen) to date, the conversion of all three convertible notes and the exercise of the warrant in full would enable Ipsen to acquire an ownership interest in us of approximately 40% on a fully diluted basis.

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Pursuant to the licensing agreements we entered into with Ipsen (and/or affiliates thereof) in connection with the initial closing under the stock purchase and master transaction agreement, we granted to Ipsen and its affiliates exclusive rights to develop and commercialize Increlex<sup>®</sup> in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa, and Ipsen granted to us exclusive rights to develop and commercialize Somatuline<sup>®</sup> Depot in the United States and Canada. Further, we and Ipsen granted to each other product development rights and agreed to share the costs for improvements to, or new indications for, Somatuline<sup>®</sup> Depot and Increlex<sup>®</sup>. In addition, we and Ipsen agreed to rights of first negotiation for our respective endocrine pipelines. In August 2007, the European Commission granted marketing authorization for Increlex<sup>®</sup> in the European Union for the long-term treatment of growth failure in children and adolescents with severe Primary IGF1D. Under the license and collaboration agreement with respect to Increlex<sup>®</sup>, Ipsen made an upfront cash payment to us of \$9.5 million or \$11.8 million, after tax withholding in October 2006, and paid us an additional milestone of approximately \$14.3 million or \$19.3 million, after tax withholding, in September 2007 for receiving marketing authorization for Increlex<sup>®</sup> in the European Union for the targeted product label. Ipsen is our marketing partner for Increlex<sup>®</sup> in the European Union. In November 2007, Increlex<sup>®</sup> was launched by Ipsen in Ipsen's territory. We are entitled to royalties on Increlex<sup>®</sup> sales made in Ipsen's territory on a sliding scale from 15% to 25% of the average net sales price, in addition to a supply price of 20% of net sales of Increlex<sup>®</sup>.

Under the license and collaboration agreement with respect to Somatuline<sup>®</sup> Depot, we made an upfront payment of \$25.0 million to Ipsen in October 2006, which was financed through the issuance by us of the first convertible note to Ipsen at the initial closing under the stock purchase and master transaction agreement. In August 2007, we received marketing approval for Somatuline<sup>®</sup> Depot in the United States for the targeted product label (and the second closing under the stock purchase and master transaction agreement was consummated). Following receipt of the marketing approval, we made a milestone payment of \$30.0 million or \$41.6 million to Ipsen, which was financed through the issuance by us of the second convertible note to Ipsen at the second closing. The milestone payment was capitalized as an intangible asset and will be amortized over the useful life of the asset. At the second closing, we also issued the third convertible note to Ipsen and Ipsen delivered \$15.0 million to us, which will be used by us for working capital. We launched Somatuline<sup>®</sup> Depot in the United States in November 2007. We pay royalties to Ipsen, on a sliding scale from 15% to 25% of net sales, in addition to a supply price of 20% of the average net sales price of Somatuline<sup>®</sup> Depot.

There can be no assurance that we will achieve the anticipated benefits of our collaboration with Ipsen. Further, we would be required to pay to Ipsen the principal amounts, including accrued interest, under all three convertible notes that we issued to Ipsen if Ipsen elects not to convert these notes into shares of our common stock. For more information on these and other risks and uncertainties related to our collaboration with Ipsen, see the sections entitled "Risks Related to Our Business" and "Risks Related to Our Common Stock" under Part I, Item 1A of this Form 10-K.

### ***Genentech Combination Product Collaboration***

Effective as of July 6, 2007, we and Genentech entered into a combination product development and commercialization agreement which governs the worldwide development and commercialization of two combination product candidates containing Genentech's rhGH, Nutropin AQ<sup>®</sup>, and our rhIGF-1, Increlex<sup>®</sup>, for the treatment of all indications except those of the central nervous system. Initially, we will be responsible for the development and commercialization of all combination product candidates under the combination product agreement and have agreed to pay Genentech a royalty on net sales of combination products covered by Genentech's (or the parties' joint) patents, subject to certain opt-in rights granted to Genentech as described in Note 8, "Combination Product Development and Commercialization Agreement" in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K. Upon opting in, Genentech would become obligated to reimburse us for a portion of the development costs incurred since July 9, 2007, and thereafter we and Genentech would share future costs and all operating profits and losses, and no royalties will be owed to Genentech. Genentech would receive such profit share in lieu of its royalty payment. As described in Note 8, "Combination Product

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Development and Commercialization Agreement, in the Notes to Financial Statements, we may receive a cash milestone payment under certain circumstances and may be entitled to royalties on net sales of certain combination products. In connection with the entering into of the combination product agreement, we issued 708,591 shares of common stock to Genentech at price per share of \$5.645 pursuant to a stock purchase agreement we entered into with Genentech, resulting in gross cash proceeds of approximately \$4.0 million, and we may issue up to an additional 1,894,737 shares of common stock (or up to a maximum of \$9.0 million of shares of common stock) to Genentech pursuant to the stock purchase agreement. However, there can be no assurance that we will receive all or any remaining portion of the anticipated proceeds, including the reimbursement of development costs, the cash milestone payment and additional proceeds from the sale of shares of our common stock to Genentech, nor can there be an assurance that we would achieve the anticipated benefits of our combination product agreement with Genentech. Further, we must first obtain Ipsen's approval to issue shares of common stock to Genentech under the stock purchase agreement at a price per share less than \$4.75 and if we do issue shares to Genentech under the stock purchase agreement at a price per share less than \$4.75, such issuance would trigger certain weighted-average price-based antidilution adjustments to the convertible notes and warrant we issued to Ipsen. Please refer to Note 8, Combination Product Development and Commercialization Agreement, in the Notes to Financial Statements for more detail on the terms of the combination product agreement and stock purchase agreement.

***Ipsen Purchase Agreement***

In conjunction with our issuance of 708,591 shares of common stock to Genentech, we issued 519,101 shares of common stock to Ipsen in July 2007 at price per share of \$5.63, resulting in gross cash proceeds of approximately \$2.9 million. The shares of common stock issued to Ipsen were acquired by Ipsen in exercise of certain pro rata purchase rights in connection with our issuance of shares to Genentech. Under the terms of an affiliation agreement we entered into with Ipsen in October 2006, Ipsen has a right of first offer to purchase up to its pro rata portion of new equity securities offered by us (subject to certain exceptions). Although Ipsen purchased additional shares of common stock from us in exercise of certain pro rata purchase rights granted to Ipsen under the terms of our affiliation agreement with Ipsen, we cannot assure that Ipsen will exercise such rights if we issue additional shares of common stock to Genentech pursuant to the stock purchase agreement with Genentech.

***Committed Equity Financing Facility***

Under the terms of a committed equity financing facility, or CEFF, we entered into with Kingsbridge Capital Limited, or Kingsbridge, Kingsbridge committed to purchase a maximum of approximately 6,000,000 newly issued shares of our common stock over a three-year period beginning in October 2005, for cash up to an aggregate of \$75.0 million, subject to certain conditions. We may draw down under the CEFF in tranches of up to the lesser of \$7.0 million or 2% of our market capitalization at the time of the draw down of such tranche, subject to certain conditions. The common stock to be issued for each draw down will be issued and priced over an eight-day pricing period at discounts ranging from 6% to 10% from the volume weighted average price of our common stock during the pricing period. During the term of the CEFF, Kingsbridge may not short our stock, nor may it enter into any derivative transaction directly related to our stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day pricing period, is determined by the greater of \$3.00 or 90% of our closing share price on the trading day immediately prior to the commencement of each draw down. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 260,000 shares of our common stock at an exercise price of \$13.12 per share. We intend to exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a need for additional capital and when we believe that sales of our common stock under the CEFF provide an appropriate means of raising capital. However, we are not obligated to sell any of the \$75.0 million of common stock available under the CEFF, and there are no minimum commitments or minimum use penalties. Under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, we have only a limited ability to raise capital through the sale of our equity securities, including pursuant to the CEFF, without first obtaining Ipsen's approval.



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	Years ended December 31,		
	2007	2006	2005
	(In thousands)		
Net cash provided by (used in):			
Operating activities	\$ (34,265)	\$ (67,464)	\$ (43,366)
Investing activities	2,112	(41,781)	(7,704)
Financing activities	64,167	134,767	51,761
<b>Net change in cash and cash equivalents</b>	<b>\$ 32,014</b>	<b>\$ 25,522</b>	<b>\$ 691</b>

Cash, cash equivalents and short-term investments totaled \$113.5 million at December 31, 2007, compared to \$125.6 million at December 31, 2006 and \$58.6 million at December 31, 2005. The net decrease in cash, cash equivalents and short-term investments of \$12.1 million in 2007 was due primarily to cash used in operating activities of \$34.2 million as discussed below, partially offset by proceeds received from Ipsen associated with our collaboration agreement and issuances of stock also discussed below.

Cash and cash equivalents totaled \$72.4 million at December 31, 2007, compared to \$40.3 million at December 31, 2006 and \$14.8 million at December 31, 2005. The increase in cash and cash equivalents in 2007 was primarily due to proceeds from a milestone payment received from Ipsen of \$19.3 million, net of withholding taxes, the issuance of a convertible note in the principal amount of \$15.0 million to Ipsen, and the issuance of \$6.9 million of common stock to Ipsen and Genentech. Further, we issued a convertible note to Ipsen in the principal amount of 30.0 million or \$41.6 million, which was used to finance our milestone payment obligation to Ipsen. The increase in 2006 was primarily due to net proceeds of \$34.2 million from the issuance of our common stock in a public offering in January 2006 and net proceeds of \$100.0 million, net of issuance costs, from the issuance of common stock and a convertible note in the principal amount of \$25.0 million to Ipsen, partially offset by cash used in operating activities of \$67.4 million.

**Operating Activities**

Net cash used in operating activities totaled \$34.2 million in 2007. Cash used in operating activities during 2007 was primarily driven by our net losses from operations of \$40.5 million adjusted for the non-cash compensation charge of \$5.9 million related to our adoption of SFAS No. 123R, as well as \$3.8 million related to amortization of the discount and non-cash losses on our Euro-denominated convertible note we issued to Ipsen and non-cash losses on the associated embedded derivative, and by cash used to build inventories of \$8.5. The increase in inventories was primarily due to the manufacture of Increlex<sup>®</sup> and purchases of Somatuline<sup>®</sup> Depot which were partially funded by an increase in accrued expenses.

Net cash used in operating activities totaled \$67.5 million in 2006 which was comprised of net loss of \$83.0 million adjusted for the non-cash compensation charge of \$5.7 million related to our adoption of SFAS No. 123R and the increase in our inventory balance; partially offset by the \$12.4 million received from Ipsen for the upfront Increlex<sup>®</sup> license fee. Cash used in operating activities totaled \$43.4 million in 2005 which was primarily driven by our net losses from operations of \$46.2 million and included the receipt of a \$1.0 million reimbursement from our landlord for facility improvements which was recorded as deferred rent.

**Investing Activities**

Net cash provided by investing activities totaled \$2.1 million in 2007. Cash provided by investing activities represented net proceeds from purchase, sales and maturities of investments, almost completely offset by milestone payments made of \$42.1 million under our licensing agreements with Ipsen for Somatuline<sup>®</sup> Depot and Genentech for Increlex<sup>®</sup>, and purchases of property and equipment of \$0.9 million.



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Net cash used in investing activities totaled \$41.8 million in 2006 and \$7.7 million in 2005, respectively. Cash used in investing activities in 2006 and 2005 represented net purchases, sales and maturities of short-term investments of \$40.7 million and \$5.2 million, respectively, and purchases of equipment of \$1.1 million and \$2.8 million, respectively.

***Financing Activities***

Net cash provided by financing activities totaled \$64.1 million in 2007. Cash provided by financing activities was primarily due to the issuance of two convertible notes to Ipsen in the principal amounts of 30.0 million, or \$41.6 million (used to fund a milestone payment to Ipsen) and \$15.0 million, respectively, and the issuance of common stock to Ipsen and Genentech of \$6.9 million, as well as issuances of common stock under our equity compensation plans of \$0.6 million.

Net cash provided by financing activities totaled \$134.8 million in 2006. Cash provided by financing activities was primarily related to net proceeds received from the issuance of common stock to Ipsen of \$75.5 million, our January 2006 public offering of common stock of \$34.2 million, net proceeds from the issuance to Ipsen of a convertible note of \$24.5 million, as well as issuances of common stock under our equity compensation plans of \$0.5 million.

Net cash provided by financing activities totaled \$51.8 million in 2005. Cash provided by financing activities was primarily due to cash proceeds received from our February 2005 public offering of common stock of \$51.1 million and issuances of common stock under our equity compensation plans of \$0.8 million.

We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations. We believe that our cash, cash equivalents and short-term investments as of December 31, 2007 as well as internally generated funds will be sufficient to meet our projected operating and capital expenditure requirements through at least 2008 based on our current business plan. However, our future capital needs and the adequacy of our available funds will depend on many factors, including:

changes to our business plan;

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

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

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

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

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

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

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

any required repayment of the convertible notes we issued to Ipsen;

the status of competing products;

the rate of progress and cost of our future clinical trials and other research and development activities, including research and development activities and clinical trial costs in connection with our growth hormone/IGF-1 combination product candidates; and

the pace of expansion of administrative and legal expenses.

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

We expect that we will require and will attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources, including potentially the CEFF. However, there can be no assurance that additional financing will be available when needed, or, if available, that the terms will be favorable. In addition, under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, we have only a limited ability to raise capital through the sale of our equity without first obtaining Ipsen's approval. Although we have entered into a stock purchase agreement with Genentech pursuant to which we may issue up to an additional 1,894,737 shares of common stock (or up to a maximum of \$9.0 million of shares of common stock) to Genentech, such issuances are subject to various conditions, including a Genentech opt in and the achievement of a regulatory approval milestone, and there can be no assurance that we will receive additional funds from Genentech pursuant to the stock purchase agreement. If additional funds are not available, we may be forced to curtail or cease operations.

**Contractual Obligations and Commercial Commitments**

Our contractual obligations as of December 31, 2007 were as follows (in thousands):

	Total	Payment due by Period			More than 5 Years
		Less than 1 Year	1-3 Years	3-5 Years	
<b>Contractual Obligations</b>					
Operating lease obligations(1)	\$ 4,075	\$ 1,058	\$ 2,208	\$ 809	\$
Long-term debt obligations(2)	84,224			84,224	
Purchase obligations(3)	16,792	16,792			
Interest expense on long-term debt(2)	9,650			9,650	
Total contractual obligations	\$ 114,741	\$ 17,850	\$ 2,208	\$ 94,683	\$

- (1) Our obligations for operating leases include leases for our present office facilities and office equipment. In 2005, we obtained a \$340,000 irrevocable letter of credit in conjunction with the lease agreement covering our present facilities. 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. The lease agreement covering our present facilities expires October 2011 and includes an option to renew for five years. Please refer to Note 7, Commitments and Contingencies, in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K for further discussion regarding our future operating lease commitments.
- (2) Other long-term debt obligations refers to the long-term convertible notes issued to Ipsen, which accrue interest at a rate of 2.5% per year, compounded quarterly, and are convertible into our common stock at an initial conversion price of \$7.41 per share (or \$5.92 per share with respect to the Euro-denominated convertible note we issued to Ipsen), subject to adjustment. The balance as of December 31, 2007 included accrued interest of \$1.2 million. The entire principal balance and accrued interest under these convertible notes is due and payable on the later to occur of (i) October 13, 2011 or (ii) the second anniversary of the date on which Ipsen (or a subsequent holder of these convertible notes) notifies us that it will not convert these convertible notes in full. However, Ipsen (or subsequent holders of these convertible notes) is entitled to declare all amounts outstanding under these convertible notes immediately due and payable under certain circumstances. Please refer to Note 6, Long-Term Debt Convertible Notes, in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K for further discussion regarding the long-term convertible notes we issued to Ipsen.



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- (3) Purchase obligations include commitments related to manufacturing operations. Includes our purchase obligations under our contract manufacturing arrangements with Lonza Baltimore, for bulk supply of Increlex<sup>®</sup>, and with Hospira Worldwide, Inc., for commercial and clinical quantities of Increlex<sup>®</sup>. Also includes our purchase obligations under our agreement with Lonza Hopkinton. Pursuant to our agreement with Lonza Hopkinton, we have a non-cancelable obligation to pay Lonza Hopkinton a capacity reservation fee related to the technology transfer of manufacturing facilities in the amount of \$5.0 million, of which we paid \$1.3 million in May 2007, and the remaining \$3.7 million will be paid on or before April 1, 2008. In connection with the initiation of construction and purchasing of equipment and other site development activities, Lonza Hopkinton will bear upfront costs of \$6.6 million which we would have to reimburse a portion of in the event we do not fulfill our commitment to purchase a certain number of commercial drug substance batches. Further, we have an obligation to pay Lonza Hopkinton approximately \$1.0 million on or before April 1, 2008 for the production of bulk rhIGF-1 conformance lots, exclusive of required materials. As we reach certain future milestones, we may be committed to commercial production of Increlex<sup>®</sup> on a time and materials basis and per batch basis. Please refer to Note 7, Commitments and Contingencies Manufacturing Services Agreements, in the Note to the Financial Statements of Part II, Item 8 of this Form 10-K for further discussion regarding our purchase obligation commitments.

Under our agreement with Ipsen for Increlex<sup>®</sup>, we are required to provide Ipsen with 100% of their Increlex<sup>®</sup> supply to meet their demand and development activities through the term of our agreement with Ipsen for Increlex<sup>®</sup> which extends 15 years from the first commercial sale by Ipsen (which first occurred in November 2007). Under our agreement with Ipsen for Increlex<sup>®</sup>, we granted to Ipsen an exclusive option for Ipsen to make or have made their Increlex<sup>®</sup> supply if we fail to provide drug product in accordance with the terms of our agreement with Ipsen for Increlex<sup>®</sup>.

**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.

**Interest Rate Risk**

As of December 31, 2007, we held \$72.4 million in cash and cash equivalents consisting of highly liquid investments having original maturity dates of less than 90 days. Declines of interest rates over time would reduce our interest income from our highly liquid short-term investments. Based upon our balance of cash and cash equivalents, a decrease in interest rates of 100 basis points would cause a corresponding decrease in our annual interest income of approximately \$0.7 million for these investments. Due to the nature of our highly liquid cash equivalents, a change in interest rates would not materially change the fair market value of our cash and cash equivalents.

As of December 31, 2007, we held \$41.1 million in short-term investments, which consisted primarily of money market funds held by large institutions in the United States, federal agency bonds, commercial paper, corporate bonds and asset-backed securities maturing in less than twelve months. The weighted average interest rate of our investments held was approximately 5.3% during 2007. A decline in interest rates over time would reduce our interest income from our short-term investments. A decrease in interest rates of 100 basis points would cause a corresponding decrease in our annual interest income of approximately \$0.4 million for these investments. Due to the nature of our highly liquid cash equivalents, a change in interest rates would not materially change the fair market value of our short-term investments.

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**Table of Contents*****Foreign Currency Exchange Risk***

The Euro-denominated convertible note we issued to Ipsen was recorded at 21.5 million or approximately \$30.7 million, net of discount and including accrued interest, at December 31, 2007. The face value of the note is 30.0 million plus accrued interest of 0.2 and the discount of 8.7 million will be accreted over the life of the convertible note. The convertible note accrues interest at a rate of 2.5% per year, compounded quarterly until maturity in October 2011. As currency rates change, the net recorded value of the convertible note (which will also be increasing in value due to the accretion of the discount and accrued interest) will be revalued, and the corresponding translation adjustment will be recorded in the statements of operations. A hypothetical change of 10% in currency rates could result in an adjustment to the consolidated statements of operations of approximately \$3.2 million. Upon maturity of the convertible note in October 2011, if the holder of the note chooses to not convert, we would be required to repay the convertible note of 33.2 million which includes accrued interest. A hypothetical change of 10% in currency rates could result in our paying \$4.9 million more or less in cash than anticipated upon issuance of the convertible note.

Associated with the issuance of this convertible note to Ipsen, we recorded a derivative liability due to a conversion option denominated in a foreign currency. The terms of the convertible note include a conversion option not under our control. This conversion option is considered to be an embedded derivative liability and we determined the fair value of this derivative to be 9.2 million or approximately \$12.8 million on the date of issuance, or September 17, 2007. Due to the quarterly revaluation of the embedded derivative liability and due to foreign currency revaluation, we recorded in our statements of operations other expense of \$1.3 million for the year ended December 31, 2007. At December 31, 2007, the embedded derivative liability was valued at 9.6 million or approximately \$14.1 million. We determine the fair value of the derivative liability using the Black-Scholes-Merton valuation model. The valuations are based on the information available as of the various valuation dates. Factors affecting the amount of this liability include the market value of our common stock, the conversion price of note, volatility of our common stock, the expected life, the Euro to U.S. dollar currency exchange rate and the risk-free interest rate. A change in the market value of our common stock could have a significant impact on the results of our operations; however, there would not be any impact on our cash flows. A hypothetical change of 10% in currency rates could result in an adjustment to the statements of operations of approximately \$1.4 million.



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

**TERCICA, INC.**

**INDEX TO FINANCIAL STATEMENTS**

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**R eport of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of

Tercica, Inc.

We have audited the accompanying balance sheets of Tercica, Inc. as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Tercica, Inc. at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the financial statements, in 2007, Tercica, Inc., changed its method of accounting for stock-based compensation as of January 1, 2006.

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, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 27, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

February 27, 2008

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of

Tercica, Inc.

We have audited Tercica, Inc.'s internal control over financial reporting as of December 31, 2007, 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 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, assessing the risk that a material weakness exists, 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, Tercica, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, 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, 2007 and 2006, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007 of Tercica, Inc. and our report dated February 27, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

February 27, 2008

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

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 72,353	\$ 40,339
Short-term investments	41,132	85,236
Accounts receivable (net of allowances: 2007 - \$44; 2006 - \$8; including amounts from related parties: 2007 - \$165; 2006 - \$0)	1,607	335
Inventories	13,891	5,092
Prepaid expenses and other current assets	2,117	1,948
<b>Total current assets</b>	<b>131,100</b>	<b>132,950</b>
Property and equipment, net	3,023	3,861
Intangible assets	41,672	
Restricted cash	440	340
Other assets	448	536
<b>Total assets</b>	<b>\$ 176,683</b>	<b>\$ 137,687</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,366	\$ 2,457
Accrued expenses	11,539	6,214
Liability for early exercise of stock options		32
Other current liabilities	310	290
Deferred revenue, less long-term portion	881	776
<b>Total current liabilities</b>	<b>15,096</b>	<b>9,769</b>
Long-term convertible notes, net (refer to Note 6)	86,691	25,172
Deferred rent	1,062	1,363
Deferred revenue, long-term portion	10,675	11,452
<b>Total liabilities</b>	<b>113,524</b>	<b>47,756</b>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value: 5,000,000 shares authorized, 1,000,000 shares designated as Series A junior participating preferred stock, no shares issued and outstanding at December 31, 2007 and 2006		
Common stock, \$0.001 par value: 100,000,000 shares authorized; 51,532,229 and 50,141,776 shares issued and outstanding at December 31, 2007 and 2006, respectively	52	50
Additional paid-in capital	352,278	338,608
Accumulated other comprehensive income	33	11
Accumulated deficit	(289,204)	(248,738)
<b>Total stockholders' equity</b>	<b>63,159</b>	<b>89,931</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 176,683</b>	<b>\$ 137,687</b>

*See accompanying notes.*



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

	Year Ended December 31,		
	2007	2006	2005
<b>Net revenues:</b>			
Net product sales (including amounts from related parties):			
2007 - \$324; 2006 - \$0)	\$ 9,809	\$ 1,315	\$
License revenue	21,119	194	
Royalty revenue (including amounts from related parties: 2007 - \$43; 2006 - \$0)	51		
<b>Total net revenues</b>	<b>30,979</b>	<b>1,509</b>	
<b>Costs and expenses:</b>			
Cost of sales	5,540	1,667	
Manufacturing start-up costs	3,065		
Research and development*	19,136	42,034	21,587
Selling, general and administrative*	43,186	44,248	25,913
Amortization of intangibles	468		
<b>Total costs and expenses</b>	<b>71,395</b>	<b>87,949</b>	<b>47,500</b>
Loss from operations	(40,416)	(86,440)	(47,500)
Interest expense	(1,937)	(162)	(1,080)
Other expense	(3,071)		
Interest and other income, net	5,975	4,226	2,347
Loss before income taxes	(39,449)	(82,376)	(46,233)
Provision for income taxes	(1,017)	(621)	
<b>Net loss</b>	<b>\$ (40,466)</b>	<b>\$ (82,997)</b>	<b>\$ (46,233)</b>
Basic and diluted net loss per share	\$ (0.80)	\$ (2.09)	\$ (1.51)
Shares used to compute basic and diluted net loss per share	50,717	39,789	30,590
<b>* Includes stock-based compensation expense as follows:</b>			
Research and development	\$ 1,799	\$ 2,043	\$ 1,188
Selling, general and administrative	4,070	3,680	1,006
<b>Total</b>	<b>\$ 5,869</b>	<b>\$ 5,723</b>	<b>\$ 2,194</b>

*See accompanying notes.*



**Table of Contents****T ERCICA, INC.****STATEMENTS OF STOCKHOLDERS EQUITY**

(In thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Deferred Stock Compensation	Accumulated Other Comprehensive Income (Loss)		Deficit Accumulated	Total Stockholders Equity
	Shares	Amount						
<b>Balances at December 31, 2004</b>	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)	
<b>Balances at December 31, 2005</b>	31,578,859	\$ 32	\$ 225,100	\$ (2,591)	\$ (2)	\$ (165,741)	\$ 56,798	
Vesting of common stock from early exercises of stock options	88,513		84				84	
Reversal of deferred stock compensation pursuant to SFAS 123(R) adoption			(2,591)	2,591				
Issuance of common stock in connection with Ipsen, net of issuance costs of \$15,457	12,527,245	12	61,850				61,862	
Issuance of warrant in connection with Ipsen collaboration			13,623				13,623	
Issuance of common stock sold pursuant to public offering, net of issuance costs of \$278	5,750,000	6	34,216				34,222	
Issuance of common stock	197,159		519				519	
Stock-based compensation			5,807				5,807	
Comprehensive loss:								
Unrealized gain on marketable securities					13		13	
Net loss						(82,997)	(82,997)	
Comprehensive loss							(82,984)	

*See accompanying notes.*





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## TERCICA, INC.

## STATEMENTS OF STOCKHOLDERS EQUITY (Continued)

(In thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Deferred Stock Compensation	Accumulated Other Comprehensive Income (Loss)		Deficit Accumulated	Total Stockholders Equity
	Shares	Amount						
<b>Balances at December 31, 2006</b>	50,141,776	\$ 50	\$ 338,608	\$	\$ 11	\$ (248,738)	\$ 89,931	
Vesting of common stock from early exercises of stock options	20,834		33				33	
Issuance of common stock in connection with Ipsen	519,101	1	2,932				2,933	
Issuance of common stock in connection with Genentech	708,591	1	3,999				4,000	
Issuance of common stock	141,927		594				594	
Stock-based compensation			6,112				6,112	
Comprehensive loss:								
Unrealized gain on marketable securities					22		22	
Net loss						(40,466)	(40,466)	
Comprehensive loss							(40,444)	
<b>Balances at December 31, 2007</b>	51,532,229	\$ 52	\$ 352,278	\$	\$ 33	\$ (289,204)	\$ 63,159	

*See accompanying notes.*

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

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (40,466)	\$ (82,997)	\$ (46,233)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,640	1,162	707
Loss on disposal of property and equipment		121	76
(Accretion) / Amortization of (discounts) /premiums relating to available-for-sale securities	(1,018)	(756)	(701)
Stock based compensation	5,869	5,723	2,102
Amortization of debt issuance costs	128	28	1,002
Amortization of discount on convertible note	753		
Amortization of intangibles	468		
F/X gain (loss) on convertible note	1,787		
Derivative gain (loss)	1,284		
Commitment fee written-off due to termination of senior credit facility			75
Stock compensation to consultants in exchange for services			72
Other			23
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(209)	(300)	(938)
Accounts receivable, net	(1,272)	(335)	
Inventories	(8,466)	(3,372)	(1,636)
Restricted cash	(100)		(340)
Accounts payable	(91)	212	(1,722)
Accrued expenses	5,325	464	2,718
Deferred rent	(281)	224	1,429
Deferred revenue	(670)	12,226	
Interest payable (long-term)	1,054	136	
Net cash used in operating activities	(34,265)	(67,464)	(43,366)
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(892)	(1,123)	(2,838)
Proceeds received from sale of equipment			300
Milestone payment to collaboration partners	(42,140)		
Purchases of available-for-sale securities	(117,289)	(92,294)	(110,641)
Proceeds from maturities and sales of available-for-sale securities	162,433	51,636	105,475
Net cash used in investing activities	2,112	(41,781)	(7,704)
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of convertible note, net of issuance costs	56,640	24,555	
Proceeds from issuance of common stock, excluding early exercised options	594	519	806
Proceeds from early exercised options		23	
Repurchases of unvested early exercised options			(111)
Payment of commitment fees for senior credit facility			(76)
Net proceeds from public offerings of common stock		34,186	51,142
Net proceeds from the sale of common stock to Ipsen, S.A.	2,933	75,484	
Net proceeds from the sale of common stock to Genentech	4,000		
Net cash provided by financing activities	64,167	134,767	51,761
Net increase in cash and cash equivalents	32,014	25,522	691
Cash and cash equivalents, beginning of year	40,339	14,817	14,126

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Cash and cash equivalents, end of year	\$ 72,353	\$ 40,339	\$ 14,817
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**Supplemental schedule of noncash activities:**

**Cash paid during the year for:**

Taxes paid	\$ 1,017	\$ 632	\$
Cash paid for interest			75

**Non-cash investing and financing activities:**

Increase in common stock from vesting of early exercises of stock options	\$ 33	\$ 84	\$ 140
Issuance of common stock for senior credit facility			1,001
Issuance of warrant in connection with committed equity financing facility			1,196
Issuance of warrant in connection with Ipsen transaction		13,622	
Deferred stock compensation, net of forfeitures			(1,695)
Bifurcation of embedded derivative	12,797		

*See accompanying notes.*

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**TERCICA, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**1. Description of Business**

**Company**

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

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

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

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

**Use of Estimates and Reclassifications**

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

**2. Summary of Significant Accounting Policies**

**Recent Accounting Pronouncements**

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

In June 2007, the EITF ratified the consensus on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 concludes that nonrefundable advance payments for future research and development activities should be deferred and capitalized and recognized as expense as the related goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company expects that the adoption of 07-3 will not have an impact on its financial position or results of operations.

In December 2007, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 110 (SAB 110). SAB 110 is effective on January 1, 2008, and expresses the views of the staff regarding the use of the simplified method, as discussed in SAB No. 107, in developing an estimate of the expected term of plain vanilla share options in accordance with SFAS No. 123R. The Company is currently evaluating the impact of applying the provisions of SAB 110 on its financial statements.

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**TERCICA, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

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

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

**Fair Value of Financial Instruments**

The fair value of the Company's cash equivalents and marketable securities is based on quoted market prices. The carrying amount of cash equivalents and marketable securities is equal to their respective fair values at December 31, 2007 and 2006.

Other financial instruments, including accounts receivable, accounts payable and accrued expenses, are carried at cost, which the Company believes approximates fair value because of the short-term maturity of these instruments. The fair value of the Company's convertible debt was \$72.6 million and \$25.2 million at December 31, 2007 and 2006, respectively.

**Valuation of Derivative Instruments**

The Company issued a convertible note in September 2007 for 30.0 million or \$44.2 million. The terms of the note provide that the holder may convert the note into shares of the Company's common stock based upon a fixed Euro amount per share. Because the conversion option is not fixed in the Company's functional currency (the U.S. dollar), the conversion option is not considered indexed to the Company's stock. Therefore, under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, the Company accounts for the conversion option as an embedded derivative that is bifurcated and measured separately from the convertible note (the host instrument). The note is denominated in Euros and the liability must be remeasured into U.S. dollars each quarter end based upon the then current Euro-U.S. dollar exchange ratio. The embedded derivative has a carrying value of 9.6 million or \$14.1 million at December 31, 2007. Remeasurement of the liability is recorded as foreign currency gains or losses in other income and expense in the accompanying statements of operations. The Company estimates the fair value of its derivative liabilities each quarter-end using the Black-Scholes-Merton valuation model. This model is complex and requires significant judgments in the estimation of fair values based on various factors including the Company's current stock price and stock price volatility, the volatility of the Euro against the US dollar, and other assumptions. Changes in the fair value of the embedded conversion option are recorded as non-cash gains and losses within other income and expense in the Company's statements of operations with offsetting amounts classified on the balance sheet in the convertible note host debt instrument. Changes in the fair value of the embedded conversion option can have a material impact on the Company's financial statements. Upon conversion of the note into the Company's common stock in accordance with its terms or payment or expiration of the convertible note, the host debt instrument including the fair value of the embedded conversion option will be reclassified into common stock and additional paid in capital at then current estimated fair values. The timing of any such conversion is outside of the Company's control.

The embedded derivative liability does not qualify for hedge accounting under SFAS 133 and therefore, subsequent changes in fair value are recorded as non-cash valuation adjustments within other expense in the statements of operations.

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**TERCICA, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**Trade Accounts Receivable**

Trade accounts receivable are recorded at the invoiced amount. The Company performs evaluations of its customers' financial condition and generally does not require collateral. The Company makes judgments as to its ability to collect outstanding receivables and provide allowances for the portion of receivables when collection becomes doubtful. The Company has not recorded reserves related to the collectibility of its trade accounts receivable for the years ended December 31, 2007 and 2006. All allowances recorded are based on estimated discounts provided to the Company's customers who pay their invoices within specified net payment terms.

**Inventories**

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out basis. The valuation of inventory requires the Company to estimate obsolete or excess inventory based on analysis of future demand for the Company's products. Due to the nature of the Company's business and our target market, we believe levels of inventory in the distribution channel is not significant, and changes in demand due to price changes from competitors and the introduction of new products are not significant factors when estimating the Company's excess or obsolete inventory for Increlex<sup>®</sup> but can be significant factors in estimating excess or obsolete inventories for Somatuline<sup>®</sup> Depot. If inventory costs exceed expected market value due to obsolescence or lack of demand, inventory write-downs may be recorded as deemed necessary by management for the difference between the cost and the market value in the period that impairment is first recognized. Inventories may include products manufactured at facilities awaiting regulatory approval and are capitalized based on management's judgment of probable near term regulatory approval. In addition, inventories include employee stock-based compensation expenses capitalized under FAS 123R.

In general, the process for evaluating whether there exists excess or obsolete inventory is not a complex process and does not require significant management judgment. The factors considered in evaluating whether there exists excess or obsolete inventory are:

the Company's forecast of future demand, which is updated on a quarterly basis;

the expiration date for each lot manufactured; and

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

In May 2007, the Company began to transfer its manufacturing process to new facilities and as such, there will be a period of time where the Company will need to cease production of Increlex<sup>®</sup> until the new manufacturing facilities are fully validated, approved by the FDA, and operational. The Company is increasing its inventory levels in an effort to ensure that the Company has adequate supplies to meet future demand and therefore the Company's long-term Increlex<sup>®</sup> sales forecast will become more critical in management's evaluation of excess Increlex<sup>®</sup> inventories over the next few quarters. Once the transfer of manufacturing facilities is complete, the Company will have more flexibility in the manufacturing schedule to ensure inventory supply is in line with a shorter forward demand forecast for Increlex<sup>®</sup>.

See "Manufacturing Services Agreement" in Note 7 "Commitments and Contingencies," for further discussion regarding inventory purchase commitments.

**Revenue Recognition**

The Company recognizes revenue from the sale of its products and license and collaboration agreements pursuant to Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force (EITF) Issue 00-21 *Revenue Arrangements with Multiple Deliverables*. Multiple element agreements entered into are





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

evaluated under the provision of EITF 00-21. The Company evaluates whether there is stand-alone value for the delivered elements and objective and reliable evidence of fair value to allocate revenue to each element in multiple element agreements. When the delivered element does not have stand-alone value or there is insufficient evidence of fair value for the undelivered element(s), the Company recognizes the consideration for the combined unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is generally ratably over the longest period of involvement.

*Product revenues.* The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed or determinable and collectibility is reasonably assured. The Company records provisions for discounts to customers and rebates to government agencies and international distributors, which are based on contractual terms and regulatory requirements. The Company's product returns policy only allows for the return of product damaged in transit, product shipped in error by the Company, or discontinued, withdrawn or recalled merchandise. To date, product returns have been de minimis and based on the Company's historical experience as well as the specialized nature of the Company's products, the Company historically has not provided a reserve for product returns. The Company will continue to monitor returns in the future and will reassess the need to estimate a product returns reserve if the returns experience increases.

*License revenues.* License revenue generally includes upfront and continuing licensing fees and milestone payments. Nonrefundable upfront fees that require the Company's continuing involvement in the manufacturing or other commercialization efforts by the Company are recognized as revenue ratably over the contractual term. Fees associated with substantive milestones, which are contingent upon future events for which there is reasonable uncertainty as to their achievement at the time the agreement was entered into, are recognized as revenue when these milestones, as defined in the contract, are achieved.

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

**Intangible Assets**

The Company capitalizes fees paid to the Company's licensors related to license agreements for approved products or technology that has alternative future uses, as intangible assets in accordance with Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), when the Company has obtained rights to develop and commercialize licensed products. The Company amortizes these intangible assets with definite lives on a straight-line basis over their estimated useful lives, and reviews for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values.

**Manufacturing Start-up Costs**

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



**Table of Contents****TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****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 activities are associated primarily with clinical, regulatory, manufacturing development and acquired rights to technology or products in development. Clinical and regulatory activities included the preparation, implementation, and management of our clinical trials and clinical assay development, as well as regulatory compliance, data management and biostatistics. The costs associated with conducting clinical trials and post-marketing expenses, which include Phase IV and investigator-sponsored trials and product registries, are included in research and development expenses. Manufacturing development activities included pre-regulatory approval activities associated with technology transfer, pharmaceutical development, process and development and validation, quality control and assurance, analytical services, as well as preparations for current good manufacturing practices, or cGMP, and regulatory inspections. In addition to these manufacturing development and clinical activities, license payments for patents and know-how to develop and commercialize products, are also recorded as research and development expense.

**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 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 \$2,904,000, \$1,396,000 and \$1,069,000 in the years ended December 31, 2007, 2006 and 2005, respectively.

**Property and Equipment**

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

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

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**TERCICA, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**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.

**Accounting for Income Taxes**

On January 1, 2007, the Company adopted FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes* ( FIN 48 ), which clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAS No. 109, *Accounting for Income Taxes*. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. See Note 12 Income Taxes for further detail.

The Company utilizes the liability method of accounting for income taxes as required by SFAS No. 109. 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.

**Valuation of Warrants**

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

**Stock-Based Compensation**

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* ( SFAS No. 123R ) which requires the measurement and recognition of non-cash compensation expense for all share-based payment awards made to employees and directors including employee stock options and employee stock purchases related to the 2004 Employee Stock Purchase Plan ( Purchase Plan ) based on estimated fair values. SFAS No. 123R supersedes the Company's previous accounting under Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees*, for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 ( SAB 107 ) relating to SFAS No. 123R. The Company has applied the provisions of SAB 107 in its adoption of SFAS No. 123R. See Note 11 Stock-Based Compensation for further detail.

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



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

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

	Year Ended December 31,		
	2007	2006	2005
Net loss, as reported	\$ (40,466)	\$ (82,997)	\$ (46,233)
Change in unrealized gains/(losses) on marketable securities, net of taxes	22	13	70
Comprehensive loss	\$ (40,444)	\$ (82,984)	\$ (46,163)

**Concentrations**

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

The Company sources all of its bulk manufacturing and fill-finish manufacturing through single-source third-party suppliers and contractors and the Company obtains specific components and raw materials used to manufacture Increlex<sup>®</sup> 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<sup>®</sup> or may be unable to maintain validation of Increlex<sup>®</sup>, which could delay or prevent the supply of commercial and clinical product, or delay or otherwise adversely affect revenues and the Company's license and collaboration agreement with Ipsen pursuant to which the Company is required to supply Increlex<sup>®</sup> to Ipsen. The Company believes that it has established guidelines to maintain an adequate level of inventory to mitigate this potential negative impact.

The Company sources its entire Somatuline<sup>®</sup> Depot inventory from Ipsen. If Ipsen is unable to supply or is delayed in providing Somatuline<sup>®</sup> Depot to the Company, our revenues could be adversely impacted. The Company believes that it has established guidelines to maintain an adequate level of inventory to mitigate the potential negative impact of supply delays.

The Company promotes its products to medical professionals, but the Company sells its products primarily to distributors and its product revenues and accounts receivable are concentrated with a few customers. Customer concentrations in net product sales that are greater than 10% of the relative total are:

Customer Sales	Year Ended December 31,	
	2007	2006
Customer A	21%	0%
Customer B	19%	24%
Customer C	18%	23%
Customer D	14%	22%
Customer E	5%	14%

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

Customer concentrations in trade accounts receivable that are greater than 10% of the relative total are:

Customer Trade Accounts Receivable	Year Ended December 31,	
	2007	2006
Customer A	15%	0%
Customer B	16%	21%
Customer C	12%	17%
Customer D	21%	11%
Customer E	6%	15%
Customer F	14%	1%
Customer G	10%	8%

Commercialization of Increlex<sup>®</sup> began in 2006 and, therefore, the Company had no sales or accounts receivable in prior years. Sales of Increlex<sup>®</sup> in the United States represented approximately 91% and 92% of total product sales in the years ended December 31, 2007 and 2006, respectively.

**3. Net Loss per Share**

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

	Year Ended December 31,		
	2007	2006	2005
	(In thousands, except per share data)		
<b>Numerator:</b>			
Net loss	\$ (40,466)	\$ (82,997)	\$ (46,233)
<b>Denominator:</b>			
Weighted-average common shares outstanding used to compute basic loss per share	50,717	39,789	30,619
Less: Weighted-average unvested common shares subject to repurchase			(29)
Denominator for basic and diluted net loss per share	50,717	39,789	30,590
Basic and diluted net loss per share	\$ (0.80)	\$ (2.09)	\$ (1.51)

	December 31,		
	2007	2006	2005
	(In thousands)		
<b>Outstanding dilutive securities not included in diluted net loss per share</b>			
Options to purchase common stock	5,420	3,895	2,851

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Convertible notes	10,626	3,397	
Warrants	5,209	5,268	260
	21,255	12,560	3,111



**Table of Contents****TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****4. Balance Sheet Details****Cash, and Cash Equivalents, Short-Term Investments and Restricted Cash**

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

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

The Company has two irrevocable letters of credit amounting to \$440,000. The first letter of credit was obtained in the year ended December 31, 2005 in conjunction with a lease agreement for its facility. The second letter of credit was obtained in the year ended December 31, 2007 in conjunction with obtaining a business license. The letters of credit are collateralized for the same amount by cash, cash equivalents and short-term investments held in a Company bank account and have been recorded as restricted cash in the accompanying balance sheet. Restricted cash was \$440,000 and \$340,000 as of December 31, 2007 and 2006, respectively.

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

	December 31, 2007			Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
Available-for-sale debt securities maturing within 1 year:				
Commercial paper	\$ 34,974	\$ 11	\$	\$ 34,985
Government sponsored entity bonds	14,000	11		14,011
Asset-backed securities	8,809	9		8,818
Corporate bonds	4,660	2		4,662
Total available-for-sale debt securities	\$ 62,443	\$ 33	\$	\$ 62,476

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

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Total available-for-sale debt securities	\$ 121,532	\$	11	\$	\$ 121,543
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**Table of Contents****TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

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

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Cash	\$ 51,449	\$ 4,372
Cash equivalents	20,904	35,967
Cash and cash equivalents	72,353	40,339
Short-term investments	41,132	85,236
Long-term restricted cash	440	340
Total	\$ 113,925	\$ 125,915

Realized losses on the sale of available-for-sale securities for the years ended December 31, 2007, 2006 and 2005 were immaterial.

**Inventories**

Inventories consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Raw materials	\$ 2,453	\$ 1,477
Work-in-process	8,662	3,280
Finished goods	2,776	335
Total	\$ 13,891	\$ 5,092

The Company recorded inventory write-downs of approximately \$612,000 and \$1,566,000, during the years ended December 31, 2007 and 2006, respectively. Inventory write-downs during 2007 and 2006 primarily related to Increlex<sup>®</sup> manufacturing lot failures in the second quarter of 2007 and in the second and third quarters of 2006. Inventory write-downs were recorded to cost of goods sold and selling, general and administrative expense, of \$423,000 and \$189,000, respectively, for the year ended December 31, 2007. Inventory write-downs were recorded to cost of goods sold and selling, general and administrative expenses of \$690,000 and \$876,000, respectively, for the year ended December 31, 2006.

At December 31, 2007, the Company had inventories recorded in work-in-process of \$6.1 million that are validation lots and are under evaluation for manufacturing process transfer approval. The FDA requires that when technical processes are transferred to a new manufacturer, a certain number of conformance lots must be produced using the new manufacturer's facilities and evaluated for process consistency. If the Company does not receive approval from the FDA for the technology process transfer, these conformance lots would not be available for commercial use and therefore would be expensed immediately.



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

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

	December 31,	
	2007	2006
Office equipment	\$ 373	\$ 316
Furniture and fixtures	674	635
Computer equipment and software	2,919	2,291
Manufacturing equipment	1,305	1,240
Leasehold improvements	1,528	1,302
Construction in progress		216
	6,798	6,000
Less accumulated depreciation and amortization	(3,775)	(2,139)
Property and equipment, net	\$ 3,023	\$ 3,861

Depreciation expense was \$1,636,000, \$1,240,000 and \$707,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

**Accrued Liabilities**

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2007	2006
Accrued compensation and related liabilities	\$ 4,885	\$ 2,938
Accrued professional fees	1,259	1,691
Accrued contract manufacturing expenses	3,704	629
Clinical trial costs	248	335
Other accrued liabilities	1,443	621
	\$ 11,539	\$ 6,214

**5. Intangible Assets**

Intangible assets consisted of the following (in thousands):

	Gross Carrying Amount	December 31, 2007 Accumulated Amortization	Net Carrying Amount
Milestone payment to Ipsen	\$ 41,640	\$ (463)	\$ 41,177

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Milestone payment to Genentech	500	(5)	495
<b>Total</b>	<b>\$ 42,140</b>	<b>\$ (468)</b>	<b>\$ 41,672</b>

The Company made milestone payments of \$42.1 million to Ipsen and Genentech in connection with approval of its licensed products which were recorded as intangible assets. The intangible assets will be amortized over 15 years based on the estimated useful life of the assets. The Company began amortization on first commercial sale of the licensed products which was in November 2007 and recognized amortization expense

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

of \$468,000 for the year ended December 31, 2007. Amortization expense is recognized on a straight-line basis at approximately \$2.8 million per year and is recorded to amortization of intangible assets.

The Company reviews this intangible asset for impairment when events or changes in circumstance indicate that the carrying amount of such assets may not be recoverable.

The expected future annual amortization expense of the Company's intangible assets is as follows (in thousands):

Year ending December 31,	
2008	\$ 2,809
2009	2,809
2010	2,809
2011	2,809
2012	2,809
Thereafter	27,627
Total expected future annual amortization	\$ 41,672

**6. Long-Term Debt****Convertible Notes**

In October 2006, the Company issued to Ipsen a convertible note in the principal amount of \$25,037,000 (the First Convertible Note). The First Convertible Note accrues interest at a rate of 2.5% per year, compounded quarterly, and is convertible into the Company's common stock at an initial conversion price of \$7.41 per share, subject to adjustment, which represents 3,482,822 shares at December 31, 2007.

In September 2007, the Company issued to Ipsen two convertible notes in the principal amounts of 30,000,000, or \$41,640,000 (the Second Convertible Note), and \$15,000,000 (the Third Convertible Note). The Second and Third Convertible Notes each accrue interest at a rate of 2.5% per year, compounded quarterly, and are convertible into the Company's common stock at an initial conversion price of 5.92 per share for the Second Convertible Note and \$7.41 per share for the Third Convertible Note, subject to adjustment, which represents 5,104,041 and 2,038,861 shares, respectively, at December 31, 2007.

The conversion price of all the Convertible Notes is subject to certain weighted-average price-based antidilution adjustments, which, if triggered, would result in an increase of the number of shares of common stock issuable upon conversion of the Convertible Notes. The entire principal balance and accrued interest under all the Convertible Notes is due and payable on the later to occur of October 13, 2011 or the second anniversary of the date on which Ipsen (or subsequent holders of the Convertible Notes) notifies the Company that it will not convert the Convertible Notes in full. Notwithstanding the foregoing, Ipsen (or subsequent holders of the Convertible Notes) is entitled to declare all amounts outstanding under the Convertible Notes immediately due and payable: (i) if an event of default occurs (as set forth in the Convertible Notes); (ii) for so long as Ipsen's approval rights as set forth in the affiliation agreement the Company entered into pursuant to its collaboration with Ipsen remain in effect, if any other person or group acquires beneficial ownership of greater than 9.9% of the Company's common stock (or if such person or group that already has beneficial ownership of greater than 9.9% of the Company's common stock increases its beneficial ownership); or (iii) in the event that the Ipsen's approval rights as set forth in the affiliation agreement cease to remain effective, if any other person or group acquires beneficial ownership of greater than 50% of the Company's common stock.





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

Because the Second Convertible Note has a conversion price stated in a foreign currency, the conversion feature constitutes a derivative liability. The Company initially valued the derivative liability associated with the Second Convertible Note at 9.2 million or approximately \$13.1 million on September 17, 2007. This amount was accounted for as a reduction in the initial carrying value of the Second Convertible Note and separately accounted for as a derivative liability. This discount to the Second Convertible Note, as a result of this bifurcation, is being accreted over four years using the effective interest method. The carrying value which approximates the fair value on September 17, 2007 of the Second Convertible Note was 20.8 million or approximately \$28.8 million which is net of the discount plus accretion and accrued interest. The carrying value of the Euro-denominated Note at December 31, 2007 is 21.5 or \$31.7 million which approximates fair value.

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

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Convertible notes	\$ 72,610	\$ 25,172
Embedded derivative liability	14,081	
<b>Total</b>	<b>\$ 86,691</b>	<b>\$ 25,172</b>

As of December 31, 2007, the Company accrued \$771,000 of cumulative interest expense on the First Convertible Note, of which \$635,000 was recorded as interest expense in the year ended December 31, 2007. If not earlier converted or repaid, the amount payable under the First Convertible Note on October 13, 2011 would be \$28,362,000, including cumulative interest of \$3,325,000.

As of December 31, 2007, the Company recorded valuation adjustment expense of \$1,283,000 representing an increase in value of the derivative liability associated with the Second Convertible Note and was recorded to other expense in the statements of operations. The Company accrued \$318,000 of cumulative interest expense in the year ended December 31, 2007, of which \$311,000 was recorded as interest expense in the year ended December 31, 2007. The Company accrued \$770,000 of non-cash accretion charges for the year ended December 31, 2007, of which \$753,000 was recorded as amortization expense for the year ended December 31, 2007. If not earlier converted or repaid, the amount payable under the Second Convertible Note on October 13, 2011 would be 33,206,000, including cumulative interest of 3,206,000.

As of December 31, 2007, the Company accrued \$108,000 of cumulative interest expense on the Third Convertible Note, of which \$108,000 was recorded as interest expense in the year ended December 31, 2007. If not earlier converted or repaid, the amount payable under the Third Convertible Note on October 13, 2011 would be \$16,603,000, including cumulative interest of \$1,603,000.

*Valuation of Second Convertible Note and Related Derivative*

The derivative related to the Second Convertible Note has been valued using the Black-Scholes-Merton valuation model. The Company completed the valuation of the conversion option in connection with issuance of the Second Convertible Note. The valuations are based on the information pertinent as of the respective valuation dates.

The inputs for valuation analysis include the market value of the Company's common stock, exercise price of the conversion option, volatility of the Company's common stock, the expected life and the risk-free interest rate.

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

The key inputs for the valuation analysis were as follows:

	September 17, 2007 (issuance date)	December 31, 2007
Market value of Company's common stock(1)	4.36	4.60
Volatility	59.7%	60.3%
Risk free interest rate	4.35%	3.26%
Exercise price of the conversion option	5.92	5.92
Expected life	4.1 years	3.8 years

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

**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. During the fiscal year ended December 31, 2005, the entire amount was recognized as interest expense and the facility expired.

**7. Commitments and Contingencies**

The Company presently leases approximately 34,400 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, which was subsequently amended, 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 has provided the landlord with irrevocable letter of credit in the amount of \$340,000. The 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. In July 2007, the Company entered into an amendment to its amended lease agreement that provides for the expansion of the leased premises by approximately 6,100 square feet, and for a period coterminous with the original lease, as amended.

At December 31, 2007, future minimum lease commitments under operating leases were as follows (in thousands):

Year ending December 31,	
2008	\$ 1,058
2009	1,085
2010	1,124
2011	808
	\$ 4,075



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**TERCICA, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

Rent expense, including the impact of the allowance for leasehold improvements of \$172,000 in 2007 and in 2006, was \$531,000, \$389,000 and \$641,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

**Manufacturing Services Agreements**

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 Cambrex Baltimore to establish the process for rhIGF-1 fermentation and purification. Under the terms of the *Manufacturing Agreement*, Cambrex Baltimore was obligated to annually provide the Company with certain minimum quantities of bulk rhIGF-1. In February 2007, Cambrex Baltimore was acquired by Lonza Group AG (*Lonza*).

In May 2007, the Company amended the *Manufacturing Agreement* with Lonza Baltimore, Inc., a subsidiary of Lonza (*Lonza Baltimore*), to increase the Company's purchase obligation for certain additional quantities of bulk rhIGF-1. Under this amendment, the Company has a non-cancelable obligation to pay Lonza Baltimore on a time and materials and per batch basis in connection with the commercial production of bulk rhIGF-1. At December 31, 2007, the Company estimates that its total purchase commitment to Lonza Baltimore is approximately \$11.8 million through July 31, 2008.

In May 2007, the Company entered into a development and commercial supply agreement with Lonza Hopkinton, Inc., a subsidiary of Lonza, (*Lonza Hopkinton*). The Company has begun to transfer its manufacturing technology to Lonza Hopkinton in order for Lonza Hopkinton to establish the process for rhIGF-1 fermentation and purification at the Lonza Hopkinton facilities. Pursuant to the development and commercial supply agreement with Lonza Hopkinton, the Company has a non-cancelable obligation to pay Lonza Hopkinton a capacity reservation fee related to the technology transfer of manufacturing facilities in the amount of \$5.0 million, of which the Company paid \$1.3 million in May 2007 and the remaining \$3.7 million will be paid on or before April 1, 2008. The total cost of the technology transfer of \$5.0 million is being recognized straight-line over the technology transfer period which the Company expects to conclude in June 2008. In connection with the initiation of construction and purchasing of equipment and other site development activities, Lonza Hopkinton will bear upfront costs of \$6.6 million which the Company would have to reimburse a portion of in the event that the Company does not fulfill its commitment to purchase a certain number of commercial drug substance batches through the term of the agreement. Further, the Company has an obligation to pay Lonza Hopkinton approximately \$1.0 million during the first half of 2008 for the production of bulk rhIGF-1 conformance lots, exclusive of required materials. As the Company reaches certain future milestones, it may be committed to commercial production of Increlex<sup>®</sup> on a time and materials basis and per batch basis.

In November 2006, the Company entered into a development and supply agreement with Hospira Worldwide, Inc. (*Hospira*), a third-party fill and finish agent. At that time, the Company began to transfer its manufacturing technology to Hospira in order for Hospira to establish the process for Increlex<sup>®</sup> fill and finish. Following approval by the FDA of the fill and finish process, Hospira is obligated to annually provide the Company with certain minimum quantities of Increlex<sup>®</sup>. The Company has a non-cancelable obligation to reimburse the agent on a milestone basis in connection with the preparation for commercial production of Increlex<sup>®</sup>. At December 31, 2007, the Company estimates that its total purchase commitment to Hospira to validate the fill and finish processes, which must then be approved by the FDA was approximately \$0.3 million and is expected to be paid by June 30, 2008.

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

The Company, as permitted under Delaware law and in accordance with its Bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The Company may terminate the indemnification agreements with its officers and directors upon 90 days written notice, but termination will not affect claims for indemnification relating to events occurring prior to the effective date of termination. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer liability insurance policy that mitigates 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 had not recorded any liabilities for these agreements as of December 31, 2007.

**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. On December 23, 2004, the Company, with Genentech, initiated patent infringement proceedings against Insmed in the U.S. District Court for the Northern District of California. On June 12, 2006, the Company filed a complaint against Insmed for False Advertising, Unfair Competition and Intentional Interference with Prospective Business Relations, Case No. 3:06cv403, in the U.S. District Court for the Eastern District of Virginia. On March 6, 2007, the Company publicly announced agreements that settled all the ongoing litigation among the companies. The Company also disclosed the settlement in its Form 10-K filed with the SEC on March 9, 2007 and disclosed details of the settlement in its Form 8-K filed with the SEC on March 7, 2007.

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

**8. Combination Product Development and Commercialization Agreement**

Effective as of July 6, 2007, the Company and Genentech, Inc. (Genentech) entered into a combination product development and commercialization agreement (the Combination Product Agreement), that governs the worldwide development and commercialization of combination product candidates containing IGF-1 and human growth hormone for the treatment of all indications except those of the central nervous system. The Combination Product Agreement became effective on July 9, 2007, the date of the satisfaction of all conditions to its effectiveness. Under the terms of the Combination Product Agreement, the parties contemplate the development of two combination product candidates for the following indications: one product formulation for certain defined short stature indications (Short Stature Indications) and another separately formulated combination product for adult growth hormone deficiency (AGHD) and any potential other indications (the Other Indications). Initially, the Company will be responsible for the development and commercialization of all combination products under the Combination Product Agreement and agreed to pay Genentech a royalty on net sales of combination products covered by Genentech's (or the parties' joint) patents, subject to Genentech's right to opt in, as described below.

Under the Combination Product Agreement, Genentech has a right to opt into the Company's development and commercialization of such combination products for the Short Stature Indications, AGHD and the Other Indications following the FDA's acceptance of the Company's Investigational New drug Application for the first Phase II clinical trial for such indication(s) (the First Option). If Genentech does not exercise the First Option,



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

it would then have the right to acquire a second right to opt in (a **Second Option** ) after the Company obtains Phase II clinical trial data that is pivotal study-enabling for the Short Stature Indication at issue, or for AGHD or the Other Indications. If Genentech opts in, it would then become the lead party with respect to the development and commercialization of combination products for Other Indications, and it may also choose to become the lead party in development and commercialization for AGHD. Upon opt-in, Genentech may also choose to exercise a commercial option to become the lead party for commercialization in Short Stature Indications. The lead commercialization party would determine the commercialization plan for such combination products for such indications, and the non-lead party would have the right to co-promote such combination products.

Upon opting in, Genentech would become obligated to reimburse the Company for a portion of the development costs incurred since July 9, 2007 and a milestone payment if Genentech chooses to become the lead commercial party for short stature, and thereafter the parties would share future costs and all operating profits and losses. Genentech would receive such profit share in lieu of its royalty payment. If Genentech opts in, it would have the right to subsequently elect to opt out of such development and commercialization of combination products, but only for all indications. In addition, following an opt in by Genentech, the Company would have the right to subsequently elect to opt out of the joint development and commercialization of the combination products for AGHD and the Other Indications only, but not for the Short Stature Indications. If a party elects to opt out, the other party would have a limited period of time in which it could also elect to opt out, in which case the parties would wind down development and commercialization of the applicable products. After opting out, a party would remain responsible for its share of operating profits and losses for a transition period only, after which time such party would be entitled to a royalty payment from the continuing party on net sales of such combination product. If Genentech opts in and neither party elects to opt out before a combination product receives regulatory approval for any Other Indication (such receipt of regulatory approval, the **Milestone** ), Genentech would owe the Company a cash Milestone payment. Under the Combination Product Agreement, the parties have granted each other sublicenseable licenses under their respective technology. The parties will share manufacturing responsibilities and costs depending on which opt-in or opt-out rights have been exercised, but in general the parties contemplate that the Company will supply IGF-1 needed for the combination products, and Genentech will supply human growth hormone for such products.

**Genentech Purchase Agreement**

In conjunction with the Combination Product Agreement, and effective as of July 6, 2007, the Company and Genentech entered into a common stock purchase agreement (the **Genentech Purchase Agreement** ), pursuant to which the Company agreed to sell, and Genentech agreed to purchase, up to a maximum of 2,603,328 shares of the Company's common stock (the **Genentech Shares** ) in three separate closings. On July 30, 2007, the Company and Genentech consummated the first closing under the Genentech Purchase Agreement pursuant to which the Company issued 708,591 shares of common stock (the **First Closing Shares** ) at price per share of \$5.645, resulting in gross cash proceeds of approximately \$4,000,000.

In the event that Genentech acquires a Second Option, Genentech would, subject to customary closing conditions, purchase up to 842,105 shares of the Company's common stock (the **Second Option Shares** ) in a subsequent closing (the **Second Option Closing** ) at a price per share equal to the average of the closing prices of the Company's common stock for the 20 trading days ending on the trading date immediately prior to the expiration of the First Option (the **Second Option Price** ), provided that Genentech may purchase no more than \$4,000,000 of the Company's common stock in the Second Option Closing. If the Second Option Price is below \$4.75, however, the purchase of the Second Option Shares in the Second Option Closing would be at the Company's option. In the event that the Second Option Price is below \$4.75 and the Company does not elect to have Genentech purchase the Second Option Shares, Genentech may acquire the Second Option without purchasing the Second Option Shares.

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

In the event that Genentech opts in, neither party elects to opt out and the Milestone occurs, upon the Company's request, Genentech would, subject to customary closing conditions, purchase up to 1,052,632 shares of the Company's common stock in a subsequent closing (the Milestone Closing) at a price per share equal to the average of the closing prices of the Company's common stock for the 20 trading days ending on the trading date immediately prior to the effective date of regulatory approval of a combination product for any Other Indication (the Milestone Price), provided that Genentech may purchase no more than \$5,000,000 of the Company's common stock in such closing.

In the event that the Combination Product Agreement is terminated, the Genentech Purchase Agreement would terminate in its entirety.

**Ipsen Purchase Agreement**

In conjunction with the Combination Product Agreement, effective July 30, 2007, the Company issued 519,101 shares of common stock to Ipsen at price per share of \$5.63 pursuant to a common stock purchase agreement (the Ipsen Purchase Agreement), dated July 9, 2007, by and among the Company, Ipsen and Suraypharm (an affiliate of Ipsen), resulting in gross cash proceeds of approximately \$2,923,000. The shares of common stock issued to Ipsen under the Ipsen Purchase Agreement were acquired by Ipsen in exercise of certain pro rata purchase rights in connection with the issuance of the First Closing Shares to Genentech. Under the terms of an affiliation agreement the Company entered into with Ipsen in October 2006, Ipsen has a right of first offer to purchase up to its pro rata portion of new equity securities offered by the Company (subject to certain exceptions).

**9. License and Collaboration Agreements and Related Party Transactions****Ipsen Collaboration**

On July 18, 2006, the Company entered into a Stock Purchase and Master Transaction Agreement (the Purchase Agreement) with Ipsen. Under the terms of the Purchase Agreement, the Company agreed to issue to Ipsen (or its designated affiliate): (i) 12,527,245 shares of common stock (the Shares) for an aggregate purchase price of \$77,318,944; (ii) a convertible note in the principal amount of \$25,037,000 (the First Convertible Note); (iii) a second Euro-denominated convertible note in the principal amount of \$30,000,000, or \$41,640,000 (the Second Convertible Note); (iv) a third convertible note in the principal amount of \$15,000,000 (the Third Convertible Note); and (v) a warrant to purchase a minimum of 4,948,795 shares of the Company's common stock (the Warrant). The initial closing under the Purchase Agreement was consummated on October 13, 2006 (the First Closing) after receiving approval by the Company's stockholders of the required aspects of the transactions contemplated by the Purchase Agreement at a Special Meeting of Stockholders held on October 12, 2006. In accordance with the Purchase Agreement, at the First Closing, the Company issued the Shares, the First Convertible Note and the Warrant, and the Company and Ipsen (and/or affiliates thereof) entered into an Increlex® License and Collaboration Agreement (Increlex® License), a Somatuline® License and Collaboration Agreement (Somatuline® License and together with the Increlex® License, the License Agreements), a Registration Rights Agreement and an Affiliation Agreement. In connection with the First Closing, the Company also adopted certain amendments to its amended and restated certification of incorporation and adopted a Rights Agreement implementing a stockholder rights plan (the Rights Agreement). Pursuant to the Somatuline® License, Ipsen granted to the Company the exclusive right under Ipsen's patents and know-how to develop and commercialize Somatuline® Depot (known as Somatuline® Autogel® in territories outside the United States including Canada) in the United States and Canada for all indications other than ophthalmic indications. Pursuant to the Increlex® License, the Company granted to Ipsen and its affiliates the exclusive right under the Company's patents and know-how to develop and commercialize Increlex® in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of





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

the Middle East and North Africa, for all indications, other than treatment of central nervous system indications and diabetes indications. Ipsen's territory would expand, subject to Genentech's approval, to include Taiwan and any of the excluded countries of the Middle East or North Africa upon termination or expiry of certain third-party distribution agreements in such countries. Pursuant to the License Agreements, the Company and Ipsen granted to each other product development rights and agreed to share the costs for improvements to, or new indications for, Somatuline<sup>®</sup> Depot and Increlex<sup>®</sup>, and also agreed to rights of first negotiation for their respective endocrine pipelines.

At the First Closing, the Company received from Ipsen proceeds of \$77,318,944 for the issuance of the Shares, which Shares represented 25% of the Company's outstanding common stock on a non-diluted basis. Further, the Company received from Ipsen, 10,000,000 or \$12,422,000 as an upfront license fee under the Increlex<sup>®</sup> License. For 2007 and 2006, approximately \$776,000 and \$194,000 was recognized as License Revenue, respectively, and as of December 31, 2007 \$10,675,000 was recorded as long-term deferred revenue and \$776,000 was recorded as short-term deferred revenue. The upfront license fee is amortized over the life of the license agreement which is approximately 16 years. The Company paid an upfront license fee of \$25,037,000 under the Somatuline<sup>®</sup> License and was recorded to research and development for the year ended December 31, 2006. As indicated above, the First Convertible Note in the principal amount of \$25,037,000 was issued to Ipsen at the First Closing. See Note 6 Long-Term Debt for further detail.

Additionally, the Company issued the Warrant to Ipsen, which is exercisable for such number of shares of the Company's common stock equal to the greater of (i) 4,948,795 shares of the Company's common stock (the Baseline Amount) or (ii) the Baseline Amount plus a variable amount of shares of Tercica's common stock, which variable amount will fluctuate throughout the term of the Warrant. The number of common shares exercisable under the Warrant as of the First Closing was 5,026,712 with a fair value of \$13,622,000, estimated using the Black-Scholes-Merton valuation model, and recorded to Additional Paid in Capital. See Note 10 Stockholders' Equity Warrants for further detail.

Upon closing the Ipsen transaction, the Company incurred \$3,004,000 in issuance costs, and allocated these costs to the license, debt and equity components of the transaction based on the relative fair value of the components. Of the issuance costs, \$687,000 was allocated to the License and Collaboration Agreements for Somatuline<sup>®</sup> Depot and Increlex<sup>®</sup> and was expensed to selling, general and administrative expenses as incurred; \$1,835,000 was allocated to the equity financing and recorded to additional paid in capital; and \$482,000 was allocated to the Convertible Note and recorded as a prepaid financing cost. In 2007 and 2006, \$129,000 and \$28,000 of prepaid financing costs was amortized, respectively, and as of December 31, 2007, the remaining balance was \$366,000.

In August 2007, Ipsen received notice of approval from the FDA for marketing Somatuline<sup>®</sup> Depot in the United States. In connection with the notice of marketing approval from the FDA, under conditions set forth in the Company's Somatuline license and collaboration agreement with Ipsen, the Company made a milestone payment of 30.0 million or \$41.6 million to Ipsen in September 2007, which was financed through the issuance by the Company of the Second Convertible Note to Ipsen. In connection with the notice of approval from the FDA, the Company also issued the Third Convertible Note to Ipsen and Ipsen delivered \$15.0 million to the Company, which will be used by the Company for working capital. Somatuline<sup>®</sup> Depot was commercially available in the Company's territory in November 2007. The Company pays royalties to Ipsen, on a sliding scale from 15% to 25% of net sales of Somatuline<sup>®</sup> Depot, in addition to a supply price of 20% of the average net sales price of Somatuline<sup>®</sup> Depot.

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**TERCICA, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

The milestone payment of \$41.6 million was recorded as an intangible asset and capitalized under intangible assets as presented on the balance sheet at December 31, 2007. The intangible asset will be amortized over 15 years, based on the estimated useful life of the asset, and the Company began amortization on the first commercial sale in the United States which was in November 2007. Amortization expense is recognized on a straight-line basis at approximately \$2.8 million per year and is recorded to amortization of intangible assets .

In August 2007, the European Commission granted marketing authorization for Increlex<sup>®</sup> in the European Union for the long-term treatment of growth failure in children and adolescents with severe Primary IGF1D. The European Medicines Agency designated Increlex<sup>®</sup> as an orphan drug for the treatment of severe Primary IGF1D, providing a ten year period of marketing exclusivity for the approved indication. Under the license and collaboration agreement with respect to Increlex<sup>®</sup>, Ipsen paid the Company a milestone of approximately \$20.3 million for receiving marketing authorization of Increlex<sup>®</sup> in the European Union for the targeted product label set forth in the Increlex<sup>®</sup> license and collaboration agreement. Ipsen is the Company's marketing partner for Increlex<sup>®</sup> in the European Union. Increlex<sup>®</sup> was launched in Ipsen's territory in November 2007 and Ipsen began paying royalties to the Company on a sliding scale from 15% to 25% of net sales, in addition to a supply price of 20% of the average net sales price of Increlex<sup>®</sup>. The milestone payment of \$20.3 million was recognized as license revenue in September 2007 since all obligations were satisfied as presented in the statements of operations as of December 31, 2007.

**Related Party Transactions**

The Company enters into transactions with Ipsen and other Ipsen affiliates under existing agreements in the ordinary course of business. The accounting policies the Company applies to its transactions with its related parties are no more favorable to the Company than with independent third-parties.

**Genentech Collaboration**

In connection with the grant of marketing authorization for Increlex<sup>®</sup> in the European Union, the Company paid Genentech a milestone payment of \$0.5 million in September 2007 under the terms of the Company's international license and collaboration agreement with Genentech. The milestone payment was recorded as an intangible asset and capitalized under intangible assets as presented on the balance sheet at December 31, 2007. The intangible asset will be amortized over 15 years, based on the estimated useful life of the asset, and the Company began amortization on the first commercial sale which was in November 2007. Amortization expense will be recognized on a straight-line basis at approximately \$33,000 per year and will be recorded to amortization of intangible assets .

**10. Stockholders' Equity**

**Common Stock**

On January 27, 2006, the Company completed a public offering of 5,750,000 shares of its common stock at a price to the public of \$6.40 per share, including the exercise of the over-allotment option by the underwriters. Net cash proceeds from this offering were approximately \$34,200,000 after deducting underwriter discounts and other offering expenses.

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

Concurrently with the issue of the First Convertible Note, the Company issued a warrant to Ipsen, which is exercisable for such number of shares of the Company's common stock equal to the greater of (i) 4,948,795 shares of the Company's common stock (the Baseline Amount), which Baseline Amount is subject to certain weighted-average price-based anti-dilution adjustments, or (ii) the Baseline Amount plus a variable amount of shares of the Company's common stock, which variable amount will fluctuate throughout the term of the warrant. The number of shares of the Company's common stock issuable upon exercise of the warrant as of October 13, 2006, the date of issue, was 5,026,712, with a fair value of \$13,622,000 estimated using the Black-Scholes-Merton valuation model, which was recorded to additional paid-in capital. The number of shares of the Company's common stock issuable upon exercise of the warrant as of December 31, 2007 was 4,948,795. The exercise term of the warrant is five years beginning on October 13, 2006, and the warrant is exercisable, in full or in part, at an initial exercise price of \$7.41 per share, subject to adjustment, including certain weighted-average price-based anti-dilution adjustments.

**Committed Equity Financing and Related Warrant**

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 6,000,000 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-Merton valuation model 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 on the date of grant and was recorded as a contra-equity amount to 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. Through December 31, 2007, the Company has not drawn down any funds under the CEFF and has not issued any shares pursuant to the CEFF as of December 31, 2007. Under the terms of an affiliation agreement the Company entered into pursuant to its collaboration with Ipsen, the Company has only a limited ability to raise capital through the sale of its equity securities, including pursuant to the CEFF, without first obtaining Ipsen's approval.

**Table of Contents****TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****Restricted Stock Purchases and Early Exercise of Options**

In February 2002, 328,158 restricted shares of common stock were issued to an employee in exchange for \$2,000 in cash. As of December 31, 2007 and 2006 there were no shares subject to repurchase by the Company related to this purchase.

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. In February 2006, the Company issued 15,647 shares of common stock under restricted stock purchase agreements to an employee pursuant to the early exercises of stock options in exchange for \$23,000 in cash. Under the terms of these agreements, these shares generally vest over a four-year period for employees and over a three-year period for the director. Total unvested shares, which amounted to 20,834 at December 31, 2006 which were 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. There were no unvested shares at December 31, 2007. These repurchase terms are considered to be a forfeiture provision and do not result in variable accounting. During the year ended December 31, 2005, the Company repurchased 130,718 shares of its common stock for approximately \$111,350 under restricted stock purchase agreements due to employee forfeitures. In accordance with EITF No. 00-23, *Issues Related to the Accounting for Stock Compensation under APB Opinion No. 25*, and FIN No. 44, the shares purchased by the employees pursuant to the early exercise of stock options are not deemed to be issued until those shares vest. Therefore, amounts received in exchange for these shares have been recorded as liability for early exercise of stock options on the balance sheet, and will be reclassified into common stock and additional paid-in capital as the shares vest. There were no repurchases in the years ended December 31, 2007 and 2006. There were 88,513 shares at an original purchase price of \$84,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2006.

**Shares Reserved for Issuance**

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

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
2004 Employee Stock Purchase Plan	218,659	191,070
Stock option plans:		
Shares available for grant	1,099,517	1,439,865
Options outstanding	5,419,638	3,894,640
Shares available for issuance under the CEFF	6,036,912	6,036,912
Shares available for issuance under the convertible notes	10,625,724	3,397,095
Shares available for issuance under the Genentech Purchase Agreement	1,894,737	
Warrants outstanding to purchase common stock	5,208,795	5,268,429
	<b>30,503,982</b>	<b>20,228,011</b>



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

As of December 31, 2007, the Company was authorized to issue 5,000,000 shares of preferred stock, of which 1,000,000 shares are authorized for issuance as Series A junior participating preferred stock (the "Series A Preferred"). The board of directors has the authority, without action by its stockholders with the exception of stockholders who hold board positions, to designate and issue shares of preferred stock in one or more series. The board of directors may also designate the rights, preferences and powers of each series of preferred stock, any or all of which may be greater than the rights of the common stock including restrictions of dividends on the common stock, dilution of the voting power of the common stock, reduction of the liquidation rights of the common stock, and delaying or preventing a change in control of the Company without further action by the stockholders. To date, no shares of preferred stock have been issued.

**Stockholder Rights Plan**

In October 2006, the Company entered into a Rights Agreement with Computershare Trust Company, N.A., as rights agent (the "Rights Agreement"), that provides for a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of the Company's common stock. Each Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Preferred, at a price of \$40.00 per one one-hundredth of a share of Series A Preferred (the "Purchase Price"), subject to adjustment. Each one one-hundredth of a share of Series A Preferred has designations and powers, preferences and rights, and the qualifications, limitations and restrictions that make its value approximately equal to the value of a share of the Company's common stock. Pursuant to the Rights Agreement, if the Company is restricted from taking certain actions pursuant to the affiliation agreement the Company entered into pursuant to its collaboration with Ipsen, then the Company's board of directors may only take action with respect to the Rights with the concurrence of Ipsen.

The Rights are currently evidenced by the stock certificates representing the Company's common stock outstanding, and no separate Right Certificates, as defined below, have been distributed. Until the earlier to occur of (i) ten business days following the public announcement that a person or group of affiliated or associated persons has become an "Acquiring Person"; or (ii) ten business days (or such later date as may be chosen by the Company's board of directors so long as the "Requisite Percentage" threshold has not been crossed) after such time as a person or group commences or announces its intention to commence a tender or exchange offer, the consummation of which would result in beneficial ownership by such person or group of the "Requisite Percentage" or more of the Company's common stock (the earlier of such dates being called the "Distribution Date"), the Rights will be evidenced, with respect to any of the shares of the Company's common stock outstanding, by such common stock certificates. As a general matter, the "Requisite Percentage" under the Rights Agreement is 9.9% of the Company's outstanding common stock. However, with respect to (i) MPM Capital L.P. and its affiliates so long as they do not acquire any additional shares, the "Requisite Percentage" is the greater of 9.9% and the percentage owned by MPM Capital L.P. and its affiliates; (ii) Ipsen, so long as it does not acquire beneficial ownership of any shares other than shares acquired pursuant to the terms of the stock purchase and master transaction agreement between the Company and Ipsen and the other documents contemplated by such stock purchase and master transaction agreement, the "Requisite Percentage" is the greater of 9.9% and the percentage owned by Ipsen; and (iii) any entity that acquires shares from Ipsen, such entity's "Requisite Percentage" would be 14.9%. An "Acquiring Person" is a person, the affiliates or associates of such person, or a group, which is or becomes the beneficial owner of the "Requisite Percentage".

Until the Distribution Date (or earlier redemption or expiration of the Rights), the Rights are transferable with and only with the Company's common stock. As soon as practicable following the Distribution Date, separate certificates evidencing the Rights ("Right Certificates") will be mailed to holders of record of the

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**TERCICA, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

Company's common stock as of the close of business on the Distribution Date and such separate Right Certificates alone will evidence the Rights. The Rights are not exercisable until the Distribution Date. The Rights will expire on October 26, 2016 (the Final Expiration Date), unless the Rights are earlier redeemed or exchanged by the Company.

In the event a person (or group of affiliated or associated persons) becomes an Acquiring Person, each holder of a Right, other than Rights beneficially owned by the Acquiring Person and its associates and affiliates (which will thereafter be void), will for a 60-day period have the right to receive upon exercise that number of shares of the Company's common stock having a market value of two times the exercise price of the Right (or, if such number of shares is not and cannot be authorized, the Company may issue Series A Preferred, cash, debt, stock or a combination thereof in exchange for the Rights). Furthermore, in the event that the Company is acquired in a merger or other business combination transaction or 50% or more of its consolidated assets or earning power are sold to an Acquiring Person, its associates or affiliates or certain other persons in which such persons have an interest, each holder of a Right will thereafter have the right to receive, upon the exercise thereof at the then current exercise price of the Right, that number of shares of common stock of the acquiring company that at the time of such transaction will have a market value of two times the exercise price of the Right.

The Company's board of directors may redeem the Rights at any time prior to the earliest of (i) the Distribution Date or (ii) the Final Expiration Date at a redemption price of \$0.001 per Right. In addition, the Company's board of directors may, after any time a person becomes an Acquiring Person (but prior to the acquisition by such Acquiring Person of 50% or more of the Registrant's outstanding Common Stock), exchange each Right for one share of common stock of the Company per Right (or, at the election of the Company, the Company may issue cash, debt, stock or a combination thereof in exchange for the Rights), subject to adjustment.

**11. Stock Based Compensation**

On January 1, 2006, the Company adopted the provisions of SFAS No. 123R, *Share-Based Payment*. SFAS No. 123R establishes accounting for stock-based awards made to employees and directors. Accordingly, stock-based compensation expense is measured at the grant date, based on the fair value of the award, and is recognized as expense over the remaining requisite service period. The Company previously applied APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations and provided the required pro forma disclosures of SFAS No. 123, *Accounting for Stock-Based Compensation*. Total stock-based compensation expense of \$5,869,000 and \$5,723,000 was recorded during the years ended December 31, 2007 and 2006, respectively.

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

**2004 Stock Plan**

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





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**TERCICA, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(c) annual increases in the number of shares available for issuance on the first day of each year beginning on January 1, 2005 equal to the lesser of:

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

1,250,000 shares, or

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

Incentive stock options must be granted with exercise prices not less than 100% of fair market value of the common stock on the date of grant. Nonqualified stock options may be granted with an exercise price as determined by the Company's Board of Directors; however, nonstatutory stock options intended to qualify as performance-based compensation within the meaning of Section 162(m) of the Internal Revenue Code must be granted with exercise prices not less than 100% of fair market value on the date of grant. The exercise price of any incentive stock option granted to a 10% stockholder will not be less than 110% of the fair market value of the common stock on the date of grant. Options granted under the 2004 Stock Plan expire no later than 10 years from the date of grant; however, incentive stock options granted to individuals owning over 10% of the total combined voting power of all classes of stock expire no later than five years from the date of grant. Options granted under the 2004 Stock Plan vests over periods determined by the Company's Board of Directors, generally over four years. The 2004 Stock Plan has a term of 10 years. The Company's Board of Directors approved an increase of 1,250,000 shares to the reserve for the year ended December 31, 2007.

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

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

As of December 31, 2007, there were a total of 7,703,834 shares authorized for issuance under the 2004 Stock Plan and the 2002 Plans.

**2004 Employee Stock Purchase Plan**

The Company's Board of Directors adopted the 2004 Employee Stock Purchase Plan (formerly the 2003 Stock Purchase Plan) in September 2003 and the Company's stockholders approved it in October 2003. The 2004 Employee Stock Purchase Plan (the Purchase Plan) became effective on March 16, 2004. As of December 31, 2007, there were a total of 472,979 shares reserved for issuance under the Purchase Plan. In addition, the Purchase Plan provides for annual increases in the number of shares available for issuance under the Purchase Plan on the first day of each year, beginning with January 1, 2005 equal to the lesser of:

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

125,000 shares, or

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

The Purchase Plan permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Offering periods are successive and overlapping of 24 months duration. Each offering period includes four six-month purchase periods and generally begins on the first trading

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

day on or after May 15 and November 15 of each year. The price at which the stock is purchased is equal to the lower of 85% of the fair market value of the common stock at the beginning of an offering period or after a purchase period ends.

**Adoption of SFAS No. 123R**

On January 1, 2006, the Company adopted SFAS No. 123R using the modified prospective transition method, which requires the measurement and recognition of non-cash compensation expense for all share-based payment awards made to employees and directors including employee stock options and employee stock purchases related to the Purchase Plan based on estimated fair values. Under that transition method, non-cash compensation expense was recognized beginning in the year ended December 31, 2006 and included the following: (a) compensation expense related to any share-based payments granted through, but not yet vested as of January 1, 2006, and (b) compensation expense for any share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. The Company recognizes non-cash compensation expense for the fair values of these share-based awards on a straight-line basis over the requisite service period of each of these awards. Because non-cash stock compensation expense is based on awards ultimately expected to vest, it has been reduced by an estimate for future forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company's financial statements as of and for the years ended December 31, 2007 and 2006 reflects the impact of SFAS No. 123R. In accordance with the modified prospective transition method, the Company's financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123R.

During the period from February 1, 2003 through January 31, 2004, certain stock options were granted with exercise prices that were below the reassessed fair value of the common stock at the date of grant. Total deferred stock compensation of \$10,873,000 was recorded in accordance with APB Opinion No. 25, and was being amortized to expense over the related vesting period of the options. From inception through December 31, 2005, stock-based compensation expense of \$5,740,000 was recognized and \$2,542,000 was reversed as a result of employee terminations. Stock-based compensation expense recognized in the year ended December 31, 2005 was \$2,102,000. The remaining deferred stock compensation balance of \$2,591,000 as of December 31, 2005 was reversed on January 1, 2006 upon adoption in accordance with the provisions of SFAS No. 123R.

The following table presents the pro forma effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to options granted under the Company's share-based compensation arrangements during the year ended December 31, 2005 (in thousands, except per share amounts):

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



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## TERCICA, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

Other than options granted to non-employee service providers and the grant of certain stock options to employees with exercise prices that were below the reassessed fair value of the common stock as the date of the grant, there was no other stock-based compensation recognized during the year ended December 31, 2005.

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

	Year Ended December 31,		
	2007	2006	2005
Expected volatility	62.7%	75.2%	50%
Expected term (years)	6.2	6.2	3.6
Risk-free interest rate	4.6%	5.1%	3.8%
Dividend yield			

The Company's computation of expected volatility for the years ended December 31, 2007 and 2006 is based on an average of the historical volatility of the Company's stock and the historical volatility of a peer-group of similar companies. The Company's computation of expected term in the years ended December 31, 2007 and 2006 utilizes the simplified method in accordance with SAB 107. The risk-free interest rate for periods within the contractual life of the option is based on treasury constant maturities rates in effect at the time of grant. The Company recognizes stock-based compensation expense for the fair values of these awards on a straight-line basis over the requisite service period of each of these awards.

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

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2004	2,077	\$ 4.72		
Options granted	1,959	9.13		
Options exercised	(352)	1.76		
Options cancelled/forfeited	(586)	8.18		
Options cancelled/forfeited outside of Plans	(22)	4.00		
Options repurchased	(131)	0.85		
Outstanding at December 31, 2005	2,945	7.49		
Options granted	1,788	6.71		
Options exercised	(199)	1.04		
Options cancelled/forfeited	(639)	9.06		
Outstanding at December 31, 2006	3,895	7.21		
Options granted	2,134	5.89		
Options exercised	(66)	3.12		
Options cancelled/forfeited	(543)	7.49		
Outstanding at December 31, 2007	5,420	\$ 6.71	8.1	\$ 4,455

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Exercisable at December 31, 2007	4,374	\$ 6.68	7.9	\$ 3,906
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The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value, based on the Company's closing stock price of \$6.78 on December 31, 2007, which would have been received by the option

holders had all option holders exercised their options on December 31, 2007. This amount changes based on the

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

fair market value of the Company's stock. Total intrinsic value of options exercised for the years ended December 31, 2007, 2006 and 2005 were \$219,000, \$1,084,000 and \$2,685,000, respectively. The weighted-average grant date fair value of options granted during the years ended December 31, 2007, 2006 and 2005 were \$3.68, \$4.74 and \$3.94 per share, respectively. Total fair value of options vested for the years ended December 31, 2007, 2006 and 2005 was \$6,058,000, \$4,359,000 and \$4,736,000, respectively.

As of December 31, 2007, unrecognized stock-based compensation expense related to stock options of \$10,522,000 was expected to be recognized over a weighted-average period of 2.6 years.

The following table summarizes information concerning total outstanding and vested options as of December 31, 2007 (in thousands, except per share data and contractual term):

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted-Average Remaining Contractual Term	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$0.40 - \$1.60	217	5.4	\$ 0.61	217	\$ 0.61	
\$3.46 - \$5.94	1,987	8.6	\$ 5.32	1,622	\$ 5.25	
\$6.01 - \$8.85	2,741	8.1	\$ 7.47	2,156	\$ 7.65	
\$9.04 - \$12.65	475	7.4	\$ 10.89	379	\$ 10.74	
	5,420			4,374		

**Employee Stock Purchase Plan**

For the years ended December 31, 2007 and 2006, the Company recorded \$305,000 and \$353,000, respectively, of compensation expense related to the Purchase Plan. During the years ended December 31, 2007, 2006 and 2005, 97,411, 86,031 and 42,584 shares, respectively, were purchased under the Purchase Plan. The fair value of awards issued under the Purchase Plan is measured using assumptions similar to those used for stock options, except that the weighted average term of the awards were 1.53, 1.49 and 1.25 years for the years ended December 31, 2007, 2006 and 2005, respectively.

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

Cash received from option exercises and the Purchase Plan contributions under all share-based payment arrangements for years ended December 31, 2007, 2006 and 2005 was \$594,000, \$542,000 and \$806,000, respectively. Because of the Company's net operating losses, the Company did not realize any tax benefits for the tax deductions from share-based payment arrangements during the years ended December 31, 2007, 2006 and 2005.

**12. Income Taxes**

The provision for income taxes for the years ended December 31, 2007 and 2006 represents \$1,017,000 and \$621,000, respectively, of French foreign income taxes withheld on license fees received from Ipsen under the Increlex License (see footnote 9 License and Collaboration Agreements and Related Party Transactions). There is no domestic provision for income taxes because the Company has incurred operating losses to date. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryovers and temporary





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

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):

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Net operating loss carryforwards	\$ 53,171	\$ 45,705
Capitalized license fees	12,138	13,044
Orphan drug credits	8,536	9,065
Capitalized research expenses	8,052	8,913
Capitalized inventory costs	4,773	2,519
Deferred revenue	4,738	5,013
Litigation costs	3,701	
Research tax credit carryforwards	2,546	4,332
Non-qualified stock option costs	2,207	
Foreign tax credits	1,638	
Capitalized start-up costs		304
Other	2,402	350
<b>Total deferred tax assets</b>	<b>103,902</b>	<b>89,245</b>
Valuation allowance	(103,902)	(89,245)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

Realization of the deferred tax assets is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately \$14,657,000, \$43,285,000 and \$11,843,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

As of December 31, 2007, the Company had federal net operating loss carryforwards of approximately \$133,661,000. The Company also had California net operating loss carryforwards of approximately \$107,133,000. The federal net operating loss carryforwards will expire at various dates beginning in 2022, if not utilized. The California net operating loss carryforwards expire beginning in 2012. The Company also has federal research, state research and federal orphan drug credit carryforwards of approximately \$1,805,000, \$1,141,000 and \$8,536,000, 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 and credit carryforwards is subject to an 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.

On January 1, 2007, the Company adopted the provisions of FIN 48, *Accounting for Uncertainty in Income Taxes*, which clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAS No. 109, *Accounting for Income Taxes*. The following table summarizes the activity related to the Company's gross unrecognized tax benefits:

Balance at January 1, 2007	\$ 2,978
Increases related to prior year tax positions	
Increases related to current year tax positions	849

Balance at December 31, 2007

\$ 3,827

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

At December 31, 2007, the Company had unrecognized tax benefits of \$3,827,000. The unrecognized tax benefits, if recognized, would not have an impact on the Company's effective tax rate. The Company does not expect a significant change to its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may increase or change during the next year for items that arise in the ordinary course of business.

The tax years from 2002 to 2007 remain open to examination by the Internal Revenue Service and the State of California due to our inability to use our net operating losses or tax credits. There were no accrued interest or penalties associated with uncertain tax positions as of December 31, 2007.

**13. 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.

**14. 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.

	March 31	Fiscal year 2007 Quarter Ended		
		June 30	September 30	December 31
		(In thousands, except per share data)		
Total net revenues	\$ 1,285	\$ 2,242	\$ 23,388	\$ 4,064
Net product sales	\$ 1,091	\$ 2,048	\$ 2,851	\$ 3,819
Cost of product sales(1)	\$ 501	\$ 1,131	\$ 1,397	\$ 2,511
Manufacturing start-up costs(1)	\$ 98	\$ 742	\$ 1,063	\$ 1,162
Research and development	\$ 4,912	\$ 4,101	\$ 5,588	\$ 4,535
Selling, general and administrative(1)	\$ 9,551	\$ 10,282	\$ 11,045	\$ 12,308
Net income (loss)	\$ (12,394)	\$ (12,807)	\$ 3,422	\$ (18,687)
Basic and diluted net income (loss) per share	\$ (0.25)	\$ (0.26)	\$ 0.07	\$ (0.36)

- (1) We reclassified \$52,000, 468,000 and \$699,000 from cost of product sales and \$46,000, 274,000 and \$364,000 from selling, general and administrative expense to manufacturing start-up costs for the periods ended March 31, June 30 and September 30, 2007.

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



## **Table of Contents**

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

None.

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

#### ***Disclosure Controls and Procedures***

Based on their evaluation as of December 31, 2007, our Chief Executive Officer and Chief Financial Officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) were effective.

#### ***Management's Annual Report on Internal Control over Financial Reporting***

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007 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, 2007, our internal control over financial reporting was effective.

#### ***Attestation Report of the Registered Public Accounting Firm***

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

#### ***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

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

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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.**

***Resignation and Appointment of Directors***

Effective February 27, 2008, Dennis Henner, Ph.D., resigned from our Board of Directors. On February 27, 2008, the Board, upon recommendation of the Corporate Governance and Nominating Committee of the Board, elected Faheem Hasnain to fill the vacancy created by Dr. Henner's resignation. Mr. Hasnain was also appointed to serve on the Audit Committee and Compensation Committee of the Board, effective immediately.

In connection with his election to the Board, Mr. Hasnain will receive compensation consistent with our compensation arrangements for non-employee directors, including cash compensation in the amount of \$15,000 per year, which accrues quarterly, plus \$2,000 for each Board meeting attended in person and \$1,000 for each Board meeting attended by telephone. We also pay the members, other than the chair, of each committee of the Board \$1,000 per committee meeting, and the chair of each committee \$2,000 per committee meeting. Mr. Hasnain was also granted an option to purchase 22,500 shares of our common stock under our 2004 Stock Plan at an exercise price equal to the fair market value of our common stock on the date of grant. In addition, non-employee directors, including Mr. Hasnain, who have been directors for at least six months, are entitled to receive subsequent annual stock option grants under our 2004 Stock Plan to purchase 11,250 shares of our common stock, or 22,500 shares for a non-employee director who also is the Chairman of the Board, on the date of each annual meeting of our stockholders. Mr. Hasnain's initial option shall become exercisable as to one-third of the shares subject to the option on each anniversary of the date of grant, provided Mr. Hasnain remains a service provider on such dates. Each annual option grant becomes exercisable as to 100% of the shares subject to the option on the first anniversary of the date of grant, provided the non-employee director remains a service provider on such date. Options granted to non-employee directors under the 2004 Stock Plan may be exercised prior to vesting, or early exercised, subject to our repurchase rights that expire over the vesting period. Under our 2004 Stock Plan, in the event of a change in control, the successor corporation may assume or substitute an equivalent award for each outstanding option. If there is no assumption or substitution of outstanding options, our 2004 Stock Plan administrator will provide notice to the recipient that he or she has the right to exercise the option as to all of the shares subject to the award, including shares which would not otherwise be exercisable, for a period of 15 days from the date of the notice. The award will terminate upon the expiration of the 15-day period. Under our 2004 Stock Plan, in the event a non-employee director is terminated on or following a change in control, other than pursuant to a voluntary resignation, his or her options will fully vest and become immediately exercisable.

We also intend to enter into our standard form of indemnification agreement with Mr. Hasnain that will provide that we will indemnify, defend and hold harmless Mr. Hasnain, under the circumstances and to the extent provided for therein, from and against any and all judgments, fines, penalties, amounts paid in settlement and any other amounts reasonably incurred or suffered by Mr. Hasnain, including related expenses incurred by Mr. Hasnain, by reason of the fact that Mr. Hasnain is, was or at any time becomes one of our directors, officers, employees or agents.

***Reconstitution of the Office of President***

Effective February 27, 2008, John A. Scarlett, M.D. resigned from the office of President. Dr. Scarlett will remain our Chief Executive Officer and a member of our Board, and will continue to act as our principal executive officer. In connection with Dr. Scarlett's resignation from the office of President, our Board of Directors appointed Richard A. King, age 43, as our President. Mr. King will also continue to occupy the office of Chief Operating Officer. Prior to his promotion to the office of President, Mr. King served as our Chief Operating Officer since February 2007. Prior to joining us in February 2007, Mr. King was a private investor.

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From January 2002 to September 2006, Mr. King served as Executive Vice President, Commercial Operations of Kos Pharmaceuticals, Inc., where he was responsible for sales, marketing, managed care, sales operations and customer service functions. From January 2000 to January 2002, Mr. King served as Senior Vice President of Commercial Operations at Solvay Pharmaceuticals. From January 1992 to January 2000, Mr. King held various marketing positions at SmithKline Beecham Pharmaceuticals. Mr. King began his career in the pharmaceutical industry at Lederle Laboratories, Ltd. Mr. King received his B.S. degree in chemical engineering from the University of Surrey and his M.B.A. from Manchester Business School.

There were no amendments or modifications to our current compensatory arrangements with Mr. King, nor were there any new compensatory arrangements entered into with Mr. King, in connection with his promotion to the office of President. A description of Mr. King's compensatory arrangements, including a description of the terms of the employment agreement we entered into with Mr. King in February 2007, is included in our Current Report on Form 8-K, filed with the SEC on March 2, 2007.



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**PART III**

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the registrant will file with the U.S. Securities and Exchange Commission a definitive proxy statement pursuant to Regulation 14A in connection with the solicitation of proxies for the Company's Annual Meeting of Stockholders expected to be held in May 2008 (the Proxy Statement) not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information included therein is incorporated herein by reference.

**Item 10. Directors, Executive Officers and Corporate Governance.**

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

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

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

**Item 11. Executive Compensation.**

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

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

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

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

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

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



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

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

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

**Item 14. Principal Accounting Fees and Services.**

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

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

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

*2. Financial Statement Schedules*

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

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

<b>Exhibit Number</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation(1)
3.2	Amended and Restated Bylaws, as amended(2)
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock(3)
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation(3)
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation(2)
4.1	Form of Specimen Stock Certificate(4)
4.2	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5
4.3	Warrant issued to Kingsbridge Capital Limited, dated October 14, 2005(5)
4.4	Warrant issued to Ipsen, S.A., dated October 13, 2006(4)
4.5A	First Senior Convertible Promissory Note issued to Ipsen, S.A., dated October 13, 2006(4)
4.5B	Second Senior Convertible Promissory Note issued to Ipsen, S.A., dated September 17, 2007(6)
4.5C	Third Senior Convertible Promissory Note issued to Ipsen, S.A., dated September 17, 2007(6)
4.6A	Rights Agreement, dated as of October 13, 2006, between the Registrant and Computershare Trust Company, N.A., as Rights Agent(4)
4.6B	Form of Right Certificate(4)
10.1A	2002 Stock Plan, as amended(4)*
10.1B	Form of Stock Option Agreement under the 2002 Stock Plan(7)*
10.2A	2002 Executive Stock Plan, as amended(4)*
10.2B	Form of Stock Option Agreement under the 2002 Executive Stock Plan(7)*
10.3A	2004 Stock Plan(4)*
10.3B	Form of Stock Option Agreement under the 2004 Stock Plan(7)*
10.4A	2004 Employee Stock Purchase Plan(4)*

10.4B Form of Subscription Agreement under the 2004 Employee Stock Purchase Plan(7)\*

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<b>Exhibit Number</b>	<b>Description</b>
10.5	Form of Indemnification Agreement(7)*
10.6A	Sublease Agreement dated June 24, 2002 between Elan Pharmaceuticals, Inc. and the Registrant(7)
10.6B	Sublease Agreement dated March 21, 2003 between Elan Pharmaceuticals, Inc. and the Registrant(7)
10.6C	Lease Agreement dated July 24, 2003 between Gateway Center, LLC and the Registrant(7)
10.6D	First Amendment to Lease Agreement dated September 24, 2003 between Gateway Center, LLC and the Registrant(7)
10.6E	Second Amendment to Lease Agreement dated June 28, 2004 between Gateway Center, LLC and the Registrant(8)
10.6F	Lease Agreement dated March 7, 2005 between 2000 Sierra Point, LLC and the Registrant(9)
10.6G	First Amended to Lease Agreement dated May 1, 2006 between Clarendon Hills Investors, LLC and the Registrant(10)
10.6H	Second Amendment to Lease Agreement dated January 4, 2007 between 2000 Sierra Point Parkway LLC and the Registrant(11)
10.6I	Third Amendment to Lease Agreement, dated July 6, 2007, between Sierra Point Parkway LLC and the Registrant(11)
10.7A	License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of April 15, 2002(7)
10.7B	First Amendment to the License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of July 25, 2003(7)
10.7C	International License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of July 25, 2003(7)
10.7D	Second Amendment to the License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of November 25, 2003(12)
10.7E	Combination Product Development and Commercialization Agreement, dated as of July 6, 2007, between Genentech, Inc. and the Registrant.(11)
10.7F	Letter Agreement, dated as of July 6, 2007, between Genentech, Inc. and the Registrant(11)
10.7G	Common Stock Purchase Agreement, dated as of July 6, 2007, between Genentech, Inc. and the Registrant(11)
10.8A	Manufacturing Services Agreement between the Registrant and Cambrex Bio Science Baltimore, Inc., dated as of December 20, 2002(7)
10.8B	Amendment No. 1 to Manufacturing Services Agreement, dated as of November 10, 2006, by and between Cambrex Bio Science Baltimore, Inc. and Tercica.(13)
10.8C	Addendum to Manufacturing Services Agreement, effective as of May 11, 2007, between the Registrant and Lonza Baltimore, Inc. (as successor in interest to Cambrex Bio Science Baltimore, Inc.)(11)
10.8D	Agreement, dated as of May 14, 2007, between the Registrant and Lonza Hopkinton, Inc.(11)
10.9A	Key Employment Agreement for John A. Scarlett, M.D. dated February 27, 2002(7)*
10.9B	Amendment to Key Employment Agreement for John A. Scarlett, M.D. dated May 15, 2002(7)*

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<b>Exhibit Number</b>	<b>Description</b>
10.9C	Key Employment Agreement for Ross G. Clark dated May 15, 2002(7)*
10.9D	Intentionally omitted
10.9E	Intentionally omitted
10.9F	Intentionally omitted
10.9G	Employment Letter to Andrew Grethlein dated March 5, 2003(7)*
10.9H	Intentionally omitted
10.9I	Intentionally omitted
10.9J	Employment Letter to Susan Wong dated January 9, 2004(7)*
10.9K	Intentionally omitted
10.9L	Employment Letter to Stephen Rosenfield dated June 23, 2004(8)*
10.9M	Employment Letter to Thorsten von Stein dated December 3, 2004(14)*
10.9N	Amendment to Key Employment Agreement for John A. Scarlett, M.D. dated February 22, 2005(9)*
10.9O	Amendment to Key Employment Agreement for Ross G. Clark dated February 22, 2005(9)*
10.9P	Intentionally omitted
10.9Q	Intentionally omitted
10.9R	Amendment to Employment Letter for Stephen N. Rosenfield dated February 22, 2005(9)*
10.9S	2007 Executive Officer Cash Compensation Arrangements(15)
10.9T	Non-Employee Director Compensation Arrangements(16)
10.9U	Employment Letter to Christopher E. Rivera, dated March 31, 2005(17)*
10.9V	Intentionally omitted
10.9W	Tercica, Inc. Incentive Compensation Plan(18)
10.9X	Employment letter to Ajay Bansal, dated February 27, 2006(19)
10.9Y	Employment letter to Richard A. King, dated February 25, 2007(15)
10.9Z	Amendment to Employment Letter for Richard A. King, dated August 1, 2007(11)
10.10	Second Amended and Restated Investors Rights Agreement dated July 30, 2007(11)
10.11A	Intentionally omitted
10.11B	Consent, Waiver and Amendment, dated as of October 13, 2006(20)
10.12A	Intentionally omitted
10.12B	Common Stock Purchase Agreement, dated January 21, 2005, between Venture Lending & Leasing IV, LLC and the Registrant(14)
10.13A	Common Stock Purchase Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005(5)
10.13B	Registration Rights Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005(5)





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<b>Exhibit Number</b>	<b>Description</b>
10.14A	Stock Purchase and Master Transaction Agreement, by and between the Registrant and Ipsen, S.A., dated July 18, 2006(21)
10.14B	Affiliation Agreement, by and between the Registrant, Suraypharm and Ipsen, S.A., dated October 13, 2006
10.14C	Increlex <sup>®</sup> License and Collaboration Agreement, by and between the Registrant and Beaufour Ipsen Pharma, dated October 13, 2006(20)
10.14D	Somatuline <sup>®</sup> License and Collaboration Agreement, by and between the Registrant, SCRAS and Beaufour Ipsen Pharma, dated October 13, 2006(20)
10.14E	Common Stock Purchase Agreement, dated as of July 9, 2007, between the Registrant, Suraypharm and Ipsen, S.A.(11)
10.14F	Amendment No. 1 to Registration Rights Agreement, dated as of July 30, 2007, between the Registrant, Suraypharm and Ipsen, S.A.(11)
10.14G	Registration Rights Agreement, by and between the Registrant, Suraypharm and Ipsen, S.A., dated October 13, 2006
10.15	Settlement, License and Development Agreement, dated as of March 5, 2007, by and between the Registrant, Insmmed Incorporated, Insmmed Therapeutic Proteins, Inc., Celtrix Pharmaceuticals, Inc., and Genentech, Inc.(15)
10.16	Development and Supply Agreement, dated as of November 14, 2006, between Hospira Worldwide, Inc. and the Registrant(22)
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature pages hereto)
31.1	Certification of Chief Executive Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification of Chief Financial Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).
32.1	Certification by the Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
32.2	Certification by the Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).

- \* Management contract or compensation plan or arrangement.  
Confidential treatment has been granted with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.  
Confidential treatment has been requested with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.
- (1) Incorporated by reference to the similarly described exhibit included with the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on May 13, 2004.
  - (2) Incorporated by reference to the similarly described exhibit included with the Registrant's Current Report on Form 8-K (File No. 000-50461) filed on May 25, 2007.
  - (3) Incorporated by reference to the similarly described exhibit included with the Registrant's Current Report on Form 8-K (File No. 000-50461) filed on October 18, 2006.

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- (4) Incorporated by reference to the similarly described exhibit included with the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on November 3, 2006.
- (5) Incorporated by reference to the similarly described exhibit included with the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on November 4, 2005.
- (6) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K (File No. 000-50461) filed on September 18, 2007.
- (7) Incorporated by reference to the similarly described exhibit included with the Registrant s registration statement on Form S-1 (File No. 333-108729) and amendments thereto, declared effective on March 16, 2004.
- (8) Incorporated by reference to the similarly described exhibit included with the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on August 16, 2004.
- (9) Incorporated by reference to the similarly described exhibit included with the Registrant s annual report on Form 10-K (File No. 000-50461) filed on March 24, 2005.
- (10) Incorporated by reference to the similarly described exhibit included with the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on August 9, 2006.
- (11) Incorporated by reference to the similarly described exhibit included with the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on August 2, 2007.
- (12) Incorporated by reference to the similarly described exhibit included with the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on August 4, 2005.
- (13) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K (File No. 000-50461) filed on May 17, 2007.
- (14) Incorporated by reference to the similarly described exhibit included with the Registrant s registration statement on Form S-1 (File No. 333-122224) and amendments thereto, declared effective on February 7, 2005.
- (15) Incorporated by reference to the similarly described exhibit included with the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on May 4, 2007.
- (16) 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 18, 2007.
- (17) Incorporated by reference to the similarly described exhibit included with the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on May 16, 2005.
- (18) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K (File No. 000-50461) filed on February 28, 2006.
- (19) Incorporated by reference to the similarly described exhibit included with the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on May 10, 2006.
- (20) Incorporated by reference to the similarly described exhibit included with the Registrant s annual report on Form 10-K (File No. 000-50461) filed on March 9, 2007.
- (21) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K (File No. 000-50461) filed on July 24, 2006.
- (22) Incorporated by reference to the similarly described exhibit included with the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on November 1, 2007.

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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.

Chief Executive Officer and Director

Dated: February 28, 2008

**POWER OF ATTORNEY**

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

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the Registrant in the capacities indicated on February 28, 2008:

Signature	Title
/s/ JOHN A. SCARLETT, M.D.  <b>John A. Scarlett, M.D.</b>	Chief Executive Officer and Director  (Principal Executive Officer)
/s/ AJAY BANSAL  <b>Ajay Bansal</b>	Chief Financial Officer  (Principal Financial Officer)
/s/ SUSAN WONG  <b>Susan Wong</b>	Chief Accounting Officer  (Principal Accounting Officer)
/s/ ALEXANDER BARKAS, PH.D.  <b>Alexander Barkas, Ph.D.</b>	Director
/s/ ROSS G. CLARK, PH.D.  <b>Ross G. Clark, Ph.D.</b>	Director
/s/ KARIN EASTHAM	Director

**Karin Eastham**

/s/ FAHEEM HASNAIN

Director

**Faheem Hasnain**

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<b>Signature</b>	<b>Title</b>
/s/ MARK LESCHLY <b>Mark Leschly</b>	Director
/s/ DAVID L. MAHONEY <b>David L. Mahoney</b>	Director
/s/ CHRISTOPHE JEAN <b>Christophe Jean</b>	Director