



TRANSFORMING LIVES **ONE**  
PATIENT AT A TIME

2012 Annual Report

**nps**  

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pharmaceuticals

## CORPORATE PROFILE

**NPS Pharmaceuticals** is a biopharmaceutical company pioneering and delivering therapies that transform the lives of patients with rare diseases worldwide. The company's lead product, Gattex<sup>®</sup> (U.S.)/Revestive<sup>®</sup> (EU) 0.05 mg/kg/d (teduglutide [rDNA origin]) for injection is approved for adult short bowel syndrome (SBS). NPS is also developing Natpara<sup>®</sup> (rhPTH [1-84]) for the treatment of adult hypoparathyroidism and, subject to the resolution of certain manufacturing issues, expects to submit its Biologic License Application (BLA) to the FDA in 2013.

NPS's earlier stage pipeline includes two calcilytic compounds, NPSP790 and NPSP795, with potential application in rare disorders involving increased calcium receptor activity, such as autosomal dominant hypocalcemia with hypercalciuria (ADHH). NPS complements its proprietary programs with a royalty-based portfolio of products and product candidates that includes agreements with Amgen, GlaxoSmithKline, Janssen Pharmaceuticals, and Kyowa Hakko Kirin.



# GATTEX

“NPS has now entered a period of growth and opportunity that is uncommon in our industry and important for our future.” -Francois Nader, M.D.

	Product/Product Candidate	Indication	Preclinical	P1	P2	P3	Market	Rights
Proprietary	Gattex® (U.S.)/Revestive® (EU)	Short Bowel Syndrome						Worldwide Ex-Israel
	Natpara®	Hypoparathyroidism						Worldwide
	Pretact®	Osteoporosis						Worldwide
	NPSP790 & NPSP795	ADHH*						Worldwide
	Teduglutide	Pediatric/Other						Worldwide Ex-Israel
Royalty-based	Sensipar®/Mimpara®	Secondary & Primary Hyperparathyroidism						Amgen (Worldwide Ex-Asia)
	REGPARA®	Secondary Hyperparathyroidism						Kyowa Hakko Kirin (Asia)
	NUCYNTA®	Moderate to severe pain						Janssen (United States)
	Cinacalcet HCl	Post Renal Transplant						Amgen (Worldwide Ex-Asia)
	Ronacaleret	Stem Cell Mobilization						GlaxoSmithKline (Worldwide)

\*Autosomal dominant hypocalcemia with hypercalciuria



## TO OUR SHAREHOLDERS:

The FDA approval of Gattex® (teduglutide [rDNA origin]) for injection in 2012 was a historic milestone that has fundamentally established NPS Pharmaceuticals as a leading orphan specialty company focused on pioneering and delivering therapies that transform the lives of patients with rare diseases worldwide.

Gattex is being used to treat adult patients with short bowel syndrome, or SBS, who depend on parenteral support. SBS is a debilitating malabsorption disorder associated with serious life-threatening complications especially in those patients who require chronic parenteral support. We launched Gattex in February 2013 and our entire organization is dedicated to the flawless execution of our commercial plan. We are introducing Gattex to physicians, payers, and patient support groups nationwide—and have established a specialty distribution and clinical-care network. The launch is proceeding well and we are gratified that commercial patients are now taking Gattex.

Our commitment to rare disorders is also reflected in the progress we have made in developing Natpara® (recombinant human parathyroid hormone (rhPTH1-84)) as the first parathyroid hormone replacement to treat the underlying cause of hypoparathyroidism. Hypoparathyroidism is a rare endocrine disorder in which the body produces insufficient levels of parathyroid hormone, which can cause a number of debilitating physical and neurological symptoms. It is the only remaining classic endocrine condition for which there are no FDA-approved replacement therapies. We are now preparing our Biologics License Application to submit to the FDA in the second half of 2013 to market this much-needed therapy in the U.S.

To ensure that we deliver long-term value for patients and shareholders, we are advancing the development of new compounds and indications. In 2013, we will be working with the FDA to develop a program to extend the Gattex indication to pediatric patients with SBS. In addition, we plan to begin a development program for our calcilytic compounds, which we believe may have clinical application in treating rare endocrine disorders and contribute to the build-out of our endocrinology franchise. In addition, our growth strategy includes looking outward for additions to our product portfolio via in-licensing.

2012 was also a successful year from a financial point of view. We exceeded our financial guidance for 2012 and ended the year with over \$100 million in cash and investments. This was largely the result of careful expense control and the innovative restructuring of our royalty agreement with Amgen for Sensipar®/Mimpara®. Our agreement with Amgen is now generating more than \$64 million in annual cash flows that are expected to increase to more than \$100 million after we complete repayment of a royalty advance. Importantly, we believe our current cash balance is sufficient to support our operations until we become cash-flow positive.

Georges Gemayel, Ph.D., joined our board of directors in 2012 and has brought valuable industry and orphan-drug expertise. I am grateful to him and the rest of our board for their support and guidance during this important time in our history.

NPS has now entered a period of growth and opportunity that is uncommon in our industry and important for our future. We are confident that we have all the requisite capabilities to succeed in this challenging and competitive field.

In closing, I wish to congratulate my colleagues on their remarkable success in 2012. Their commitment, talent and perseverance have enabled the approval of Gattex and changed the course of treatment for people with SBS. I also wish to thank the patients and the clinical investigators for their commitment to Gattex and their help in bringing the product through clinical trials and into the marketplace.

In the year ahead, we expect to build on this record of achievement by successfully commercializing Gattex and pursuing the regulatory path forward for Natpara as we look forward to bringing this second orphan product to the market.

Sincerely,

Francois Nader, M.D.  
President and Chief Executive Officer



## DEVERA

### DEVERA MARSHALL

San Diego, CA

Devera was enjoying life until five years ago when she was diagnosed with short bowel syndrome. Rather than planning her days around her children and her love of tennis, Devera's frequent bouts with diarrhea made her instead plan her days around where bathrooms were located. And, her nights were planned around parenteral support, as she infused 1.5 liters of fluid and nutrients for 10 hours every night of the week. Recently, since receiving Gattex as part of its clinical trials, Devera has not only reduced her dependence on parenteral support, but achieved complete independence from it. Now, Devera's days aren't dictated by her symptoms or parenteral support. She's back to playing tennis, has energy to be a full-time mom again, and even went on a family vacation recently, free of parenteral support.



## KATHRYN

### KATHRYN BUNDY

Los Angeles, CA

After living with Crohn's disease for 15 years, Kathryn received a radical resection and a diagnosis of short bowel syndrome. Following surgery, she infused four to five liters of parenteral support every night for 12 hours at a time for many years. Since receiving Gattex as part of its clinical trials, Kathryn has steadily reduced her dependence on parenteral support, lowering the amount significantly and eliminating her need for it seven nights per week. Kathryn now infuses 3.5 liters of parenteral support over three to four nights per week. Reducing her dependence on parenteral support has allowed Kathryn to rejuvenate her career as a Hollywood actress and return to the theater. Kathryn continues to strive for complete independence from parenteral support and a more fulfilling, enriched life.



## MILESTONES

jan

U.S. Food and Drug Administration (FDA) accepted NPS' New Drug Application for Gattex® for the treatment of adults with short bowel syndrome.

apr

NPS named one of the "Best Places to Work in New Jersey." In a survey, employees praised the company's collaborative, family-like atmosphere, as well as its focus on patients.

may

NPS reported four additional patients successfully achieved independence from parenteral support while on long-term Gattex therapy in STEPS 2, a 24-month open-label study.

jun

Investigators presented new findings at ENDO 2012 supporting Natpara's therapeutic potential as the first parathyroid hormone replacement therapy for adults with hypoparathyroidism.

jun

NPS significantly enhanced its cash flow through an innovative amendment to its Sensipar®/Mimpara® royalty agreement with Amgen. This agreement is now generating \$64 million of annual cash flows for NPS.

sept

The European Commission granted European market authorization for Revestive® (teduglutide) as a new treatment for adults with short bowel syndrome.

oct

The FDA's Gastrointestinal Drugs Advisory Committee voted unanimously in favor of approval of Gattex for the treatment of adults with short bowel syndrome.

dec

NPS received U.S. FDA approval for Gattex, making it the first major long-term treatment advance for adult short bowel syndrome patients in nearly 40 years.

**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, 2012**

**Commission File Number 0-23272**



pharmaceuticals

**NPS PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other jurisdiction of  
Incorporation or Organization)

**87-0439579**  
(I.R.S. Employer  
Identification No.)

**550 Hills Drive, 3<sup>rd</sup> Floor, Bedminster, New Jersey**  
(Address of Principal Executive Offices)

**07921**  
(Zip Code)

**(908) 450-5300**

(Registrant's Telephone Number, Including Area Code)

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

Title Of Each Class	Name Of Each Exchange On Which Registered
<b>Common Stock, \$.001 Par Value Per Share</b>	<b>The NASDAQ Stock Market LLC</b>
<b>Preferred Share Purchase Rights</b>	<b>(NASDAQ Global Market)</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 Securities Exchange 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 at least the past 90 days. YES  NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES  NO

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," and large "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer  Accelerated Filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

The aggregate market value of the common stock held by non-affiliates of the Registrant was \$748,519,227 as of June 30, 2012, based upon the closing price for the shares of common stock reported on The NASDAQ Global Market on such date.

As of February 14, 2013, there were 86,908,471 shares of common stock, par value \$0.001 per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the Registrant's definitive Proxy Statement for its 2013 Annual Meeting of Stockholders are incorporated by reference into Part II – "Securities Authorized For Issuance Under Equity Compensation Plans" and Part III of this Form 10-K.

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## PART I

Unless the context requires otherwise, references in this report to “NPS”, the “Company”, “we”, “us”, “our” and similar terms mean NPS Pharmaceuticals, Inc. and its subsidiaries.

This Annual Report on Form 10-K and the documents incorporated by reference into this report contain certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on our current expectations and are subject to uncertainty and changes in circumstances. We cannot guarantee the accuracy of such statements, and you should be aware that results and events could differ materially from those contained in such statements. You should consider carefully the statements set forth in Item 1A of this report entitled “Risk Factors” and Item 7 of this report entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

### ITEM 1. Business

#### Overview

NPS is a biopharmaceutical company focused on pioneering and delivering therapies that transform the lives of patients with rare diseases worldwide. We incorporated in Utah in 1986 and reincorporated in Delaware in 1992. Our lead product, Gattex® 0.05 mg/kg/d (teduglutide [rDNA origin]) for injection, for subcutaneous use was approved by the U.S. Food and Drug Administration (FDA) in December 2012 for the treatment of adult patients with short bowel syndrome (SBS) who are dependent on parenteral support. We are also developing Natpara® (rhPTH[1-84]) for the treatment of adult hypoparathyroidism. We have met with FDA to discuss our Human Factors/Usability testing of the Natpara injection pen device. The final study will be initiated in March 2013 with results expected in the second quarter of 2013. We continue to work toward submitting our U.S. Biologics License Application (BLA) for Natpara. In order to complete certain key root cause analyses during the second quarter of 2013. Subject to resolution of the manufacturing issue, we expect to submit our BLA in the second half of 2013. Our earlier stage pipeline includes two calcilytic compounds, NPSP790 and NPSP795, with potential application in rare disorders involving increased calcium receptor activity, such as autosomal dominant hypocalcemia with hypercalciuria (ADHH). We complement our proprietary programs with a royalty-based portfolio of products and product candidates that includes agreements with Amgen, GlaxoSmithKline (GSK), Janssen Pharmaceuticals (Janssen), Kyowa Hakko Kirin, and Takeda GmbH (Takeda).

Gattex is our novel recombinant analog of human glucagon-like peptide 2 (GLP-2), a protein involved in the rehabilitation of the intestinal lining. Gattex is used for the treatment of adults with short bowel syndrome or SBS, who are dependent on parenteral support. SBS is a highly disabling and potentially life-threatening chronic disorder. SBS results from surgical resection, congenital defect or disease-associated loss of absorption in the bowel in which patients are subsequently unable to maintain fluid, electrolyte, and nutrient balances on a conventional diet. Despite an adaptation that occurs generally in the two years after resection, many SBS patients require parenteral support to supplement and stabilize their nutritional and hydration needs. Parenteral support is associated with shortened life span, life-threatening complications including sepsis, blood clots or liver damage, and reduced quality-of-life due to the time required for and consequences of frequent access to an intravenous pump. A National Institute of Health (NIH) publication reported that the annual mean costs of lifelong, complex home healthcare associated with PN/IV support ranged from \$185,000 to \$568,000, not including the indirect costs associated with disability and/or the dollar value that could be ascribed to the challenging daily living for these patients (Piamjariyakul 2010). Gattex is the first and only analog of GLP-2 proven to increase intestinal absorption and decrease or eliminate the need for parenteral support.

Natpara is our recombinant full-length human parathyroid hormone (rhPTH [1-84]) that we are developing as the first hormone replacement therapy for hypoparathyroidism, a rare hormone deficiency disorder in which patients are physiologically unable to regulate the levels of calcium and phosphates in their blood due to insufficient levels of endogenous parathyroid hormone (PTH). Endogenous PTH is the body’s principal regulator of serum calcium and phosphate levels. Hypoparathyroidism is associated with hypocalcemia, hyperphosphatemia, hypercalciuria (excessive urinary calcium excretion), and increased bone mineral density. It typically results from permanent injury to the parathyroid gland(s) during thyroid or parathyroid surgery or other surgical procedures in the neck, radiation to the neck region, autoimmune destruction of the parathyroid glands, or their congenital absence. Although rare, hypoparathyroidism can also result from genetic mutations. Current therapy is limited to calcium supplementation and parenteral or metabolic forms of vitamin D. These palliative therapies are sometimes suboptimal and can also contribute to long-term health risks including kidney failure. Hypoparathyroidism is one of the few hormonal deficiency syndromes with no approved replacement therapy using the native hormone. If approved, Natpara could be

the first treatment targeting the underlying cause of hypoparathyroidism by replacing the native hormone. In November 2011, we reported positive top-line results from our Phase 3 registration study of Natpara, known as REPLACE, which met the primary efficacy endpoint with a statistically higher responder rate versus placebo. A responder was defined as a 50 percent or greater reduction in oral calcium supplementation and active vitamin D therapy and a total serum calcium concentration that was maintained compared to baseline. Based on the REPLACE results, we plan to file for U.S. marketing approval of Natpara however, the timing of the filing will be dependent on when the manufacturing issue is resolved.

While SBS and hypoparathyroidism are relatively rare disorders, we believe these indications represent substantial commercial opportunities to us due to the significant unmet need and lack of effective therapies, as well as the serious complications and chronic nature of both disorders.

Our earlier stage pipeline includes two calcilytic compounds, NPSP790 and NPSP795, which have been evaluated in preclinical animal studies and Phase 1 human studies. Calcilytics are small molecule antagonists of the calcium receptor. Initially developed to stimulate parathyroid hormone secretion and bone formation for the treatment of osteoporosis and other bone metabolism disorders, other calcilytics have been shown to increase serum calcium and decrease urinary calcium excretion in a Phase 2 study of patients with osteoporosis. We believe calcilytics may have clinical application in treating rare endocrine disorders involving increased calcium receptor activity, such as autosomal dominant hypocalcemia with hypercalciuria (ADHH).

We have collaborations or royalty agreements with a number of pharmaceutical companies. In 2012, we recorded \$130.6 million of royalty revenue that was driven by (i) Amgen's sales of Sensipar<sup>®</sup> and Mimpara<sup>®</sup> (cinacalcet HCl), (ii) Kyowa Hakko Kirin's sales of REGPARA<sup>®</sup> (cinacalcet HCl) in Japan, (iii) Takeda's sales of Preotact<sup>®</sup>, which is our rhPTH (1-84) compound that is approved for the treatment of osteoporosis in postmenopausal women at high risk of fractures in the European Union and (iv) Janssen's sales of Nucynta<sup>®</sup> (tapentadol) in the U.S. As described further herein, we have partially monetized our royalty rights related to Sensipar and Mimpara under our agreement with Amgen through the issuance of non-recourse debt and we have sold certain of our rights to receive royalty payments arising from sales of REGPARA and Preotact under our agreements with Kyowa Hakko Kirin and Takeda. Due to a technical production issue, Takeda is presently unable to have batches of finished product manufactured that are consistently within specification and we have been informed that as a result Takeda is experiencing an out-of-stock situation for Preotact which began in certain countries in August 2012. We understand that Takeda has taken a number of actions to resolve the manufacturing issue and to accelerate a return to normal supply situation. It is our understanding that Takeda is no longer selling Preotact in their territories and we have not received any information as to when or if Takeda will re-introduce Preotact in the future. In 2007, we granted Takeda the rights to develop and market teduglutide outside of North America that may provide future milestone payments and royalties. The two companies collaborated and shared certain external development costs for the adult SBS indication.

We consider our operations to be a single reportable segment. Financial results of this reportable segment are presented in our audited consolidated financial statements.

### Proprietary Product Candidates and Royalty-Based Agreements

The table below summarizes our internal development pipeline and certain royalty-based agreements.

Product/Product Candidate	Indication	Status	Market	Rights
<b>Proprietary Product Candidates:</b>				
Gattex <sup>®</sup> (teduglutide) for injection	Adult SBS	Market	N. America	Proprietary
Natpara <sup>®</sup> (recombinant human parathyroid hormone 1-84)	Hypoparathyroidism	Phase 3	N. America <sup>4</sup>	Proprietary
Teduglutide	Crohn's disease <sup>1</sup>	Phase 2	N. America	Proprietary
NPSP790	Autosomal dominant hypocalcemia with hypercalciuria (ADHH)	Phase 1	Worldwide	Proprietary
NPSP795	ADHH	Phase 1	Worldwide	Proprietary
Teduglutide	Pediatric indications	Preclinical	N. America	Proprietary

### **Royalty-Based Agreements:**

Sensipar <sup>®</sup> /Mimpara <sup>®</sup> (cinacalcet HCl) <sup>2</sup>	Secondary hyperparathyroidism	Market	Worldwide Ex-Asia	Amgen
Sensipar <sup>®</sup> (cinacalcet HCl) <sup>2</sup>	Hypercalcemia in parathyroid cancer	Market	Worldwide Ex-Asia	Amgen
Cinacalcet HCl	Primary hyperparathyroidism	Market	Worldwide Ex-Asia	Amgen
REGPARA <sup>®</sup> (cinacalcet HCl) <sup>3</sup>	Secondary hyperparathyroidism	Market	Asia	Kyowa Hakko Kirin
Preotact <sup>®</sup> (parathyroid hormone 1-84) <sup>3</sup>	Osteoporosis	Market	Worldwide Ex-U.S., Ex-Israel, Ex-Japan <sup>3</sup>	Takeda
NUCYNTA <sup>®</sup> (tapentadol)	Moderate to severe acute pain	Market	U.S.	Janssen
Revestive <sup>®</sup> (teduglutide)	Adult SBS	Market	Worldwide Ex-N. America	Takeda
Ronacaleret (calcilytic compound)	Stem cell mobilization	Phase 2	Worldwide	GlaxoSmithKline

<sup>1</sup> This indication is outside of our core focus and would only be pursued as a specialty indication or on a partnered basis.

<sup>2</sup> We currently receive cash payments for royalties earned in excess of \$8.0 million per quarter related to Amgen's sales of Sensipar and Mimpara. The \$8.0 million per quarter services non-recourse debt.

<sup>3</sup> We currently do not receive cash payments related to our REGPARA and Preotact royalties as we have sold certain of our rights to receive these payments to service our non-recourse debt.

<sup>4</sup> If we receive U.S. approval for Natpara, Takeda's license in Canada and Mexico reverts to us or a licensee.

### **Proprietary Commercial Product**

#### *Gattex (Teduglutide [rDNA] origin) for injection*

Gattex (teduglutide [rDNA origin] for injection) is a novel, recombinant analog of human glucagon-like peptide 2, a protein involved in the rehabilitation of the intestinal lining. In December 2012, the FDA approved Gattex for the treatment of adult patients with SBS who are dependent on parenteral support. Significant reductions in mean parenteral support volume from baseline to end of treatment were seen in the Phase 3 studies of Gattex. In addition, some patients were able to achieve independence from parenteral support during these trials. The most common side effects of Gattex include stomach area (abdomen) pain or swelling, skin reaction where the injection was given, nausea, headache, cold or flu like symptoms, vomiting, and holding too much fluid in the body (swelling of face, ankles, hands or feet).

In 2007, NPS granted Takeda, the rights to develop and commercialize teduglutide outside the United States, Canada, Mexico and Israel. NPS retains all rights to teduglutide in North America. The European Commission granted European market authorization in August 2012 for the medicinal product teduglutide (trade name in Europe: Revestive<sup>®</sup>) as a once-daily treatment for adult patients with short bowel syndrome. Our agreement with Takeda is discussed in 'Royalty-Based Products and Product Candidates'. Gattex has received orphan drug designation for the treatment of SBS from the FDA and the European Medicines Agency (EMA).

#### *SBS*

Short bowel syndrome (SBS) is a very rare and highly disabling condition that can impair a patient's quality of life and lead to serious life-threatening complications. SBS typically arises after extensive resection of the bowel due to Crohn's disease, ischemia or other conditions. SBS patients often suffer from malnutrition, severe diarrhea, dehydration, fatigue, osteopenia, and weight loss due to the reduced intestinal capacity to absorb nutrients, water and electrolytes. Before the approval of Gattex, the only long-term treatment available for SBS was parenteral support to supplement and stabilize hydration and nutritional needs.

Parenteral support does not improve the body's own ability to absorb nutrients and it is associated with serious complications, such as infections, blood clots or liver damage, and the risks increase the longer patients are on parental support. Patients on parental support often experience poor quality of life with difficulty sleeping, and frequent urination. Patients receiving chronic parental support often experience a loss of independence.

We have estimated that there are between 3,000 to 5,000 addressable patients in the U.S. who are eligible for Gattex therapy. Gattex is the first long-term therapy approved for adult SBS patients. Currently two products - somatropin (rDNA origin) for injection (human growth hormone) and L-glutamine powder for oral solution - are approved for the treatment of SBS for up to four and 16 weeks, respectively. The goal of treatment with Gattex is to enhance absorption by increasing villus height and crypt depth of the intestinal mucosa and to reduce or eliminate dependence on parenteral support. We believe the SBS market is attractive because of the lack of effective drug therapies in this rare indication, the high cost of parenteral support, the serious complications and morbidities associated with parenteral support, and the clinical benefits and improvements that we believe patients will experience with Gattex therapy.

### *Gattex for SBS*

Gattex is the first and only analog of GLP-2 proven to increase intestinal absorption and decrease or eliminate the need for parenteral support.

Our clinical development program for Gattex is the largest and most comprehensive conducted in adult SBS patients to date, consisting of 15 clinical studies. Across all clinical studies, 566 subjects were exposed to at least one dose of Gattex, of whom 134 had SBS and were treated with 0.05 mg/kg/day Gattex. The FDA's approval of Gattex was based on an international, 24-week, double-blind, placebo-controlled, pivotal Phase 3 trial, known as STEPS. The primary endpoint of STEPS was defined as a 20 percent or greater reduction in parenteral support volume demonstrated at week 20 and sustained at week 24. The study's other endpoints included reductions in parenteral support volume and additional days off therapy. Key findings from the STEPS trial include:

- In an intent-to-treat analysis at weeks 20 and 24, 63 percent of patients treated with Gattex achieved at least a 20 percent reduction in weekly parenteral support volume when compared to baseline, versus 30 percent for placebo (p=0.002).
- After 24 weeks of treatment, parenteral support volume declined by 32 percent (4.4 L/week) in Gattex-treated patients, versus 21 percent (2.3 L/week) in the placebo group (p<0.001).
- After 24 weeks of treatment, 54 percent of Gattex-treated patients were able to reduce the number of infusion days per week by one or more days, compared to 23 percent of those treated with placebo (p=0.005).

The most common adverse reactions ( $\geq 10$  percent) across all studies with Gattex include stomach area (abdomen) pain or swelling, skin reaction where the injection was given, nausea, headache, cold or flu like symptoms, vomiting, and holding too much fluid in the body (swelling of face, ankles, hands or feet). In addition, vomiting and fluid overload were reported in the Phase 3 SBS studies at rates  $\geq 10$  percent.

### **Proprietary Product Candidates**

#### *Natpara® (recombinant human parathyroid hormone 1-84 [rDNA origin] injection)*

Natpara is our proprietary recombinant, full-length (1-84), human parathyroid hormone (PTH 1-84) that we are developing in the U.S. as a potential treatment for hypoparathyroidism.

Hypoparathyroidism is a rare endocrine disorder in which the body produces insufficient levels of parathyroid hormone. Parathyroid hormone is an 84-amino acid polypeptide that regulates the amount of calcium and phosphorus in bone and blood. A lack of parathyroid hormone leads to decreased blood levels of calcium (hypocalcemia) and increased levels of blood phosphorus (hyperphosphatemia). Patients with hypoparathyroidism are unable to regulate serum calcium and phosphate handling physiologically. Calcium plays a central role in the activity of many physiological systems, including the health and functioning of the skeletal, muscular, nervous, urinary, and cardiovascular systems. Hypoparathyroidism can affect all aspects of calcium metabolism with consequences that include abnormal calcium and phosphate handling by the kidneys, altered absorption of calcium, decreased activation of vitamin D, and abnormal bone quality.

Hypocalcemia is the characteristic clinical feature of hypoparathyroidism. The duration, severity, and rate of development of hypocalcemia determine the nature of the symptoms associated with the condition. Hypocalcemia can present dramatically as tetany, seizures, altered mental status, refractory congestive heart failure or stridor. Generally, neuromuscular symptoms are the most prominent and include muscle cramping; twitching; numbness and paresthesias of the mouth and/or extremities; laryngeal chord or bronchial spasms; and seizures. Other complications include

damage to soft tissues, including the kidneys, the brain, and the lenses of the eye due to calcification from the abnormal calcium-phosphate levels associated with hypoparathyroidism and exacerbated by existing therapies.

### *Hypoparathyroidism Market Opportunity*

Epidemiological data on hypoparathyroidism are limited given its rarity and the variability in the severity of the symptoms associated with this disorder. Based on third-party preliminary market research, we believe the U.S. prevalence of hypoparathyroidism is at least 80,000 patients, with cases ranging from mild to severe. A population-based study conducted by investigators at the Mayo Clinic found that hypoparathyroidism affects approximately 100,000 Americans with a substantial burden of co-morbid conditions and medical costs triple those of the general population. The most common cause of hypoparathyroidism is injury to or removal of the parathyroid glands during neck surgery. The definition of permanent post-surgical hypoparathyroidism is generally accepted to be insufficient parathyroid hormone to maintain normal calcium levels six months after surgery. Hypoparathyroidism can also be associated with autoimmune or other disorders or it can be idiopathic in nature.

Hypoparathyroidism is one of the few hormonal deficiency syndromes in which replacement therapy using the native hormone is not clinically available. Treatment of hypoparathyroidism is further complicated by the lack of national or international consensus management guidelines.

Presently, the only available treatments for hypoparathyroidism sanctioned by regulatory oversight are oral supplementation of calcium and active vitamin D metabolites or analogs. These supplements are often taken for life. The goal of current therapies is to reduce the severity of symptoms; however, these therapies do not return calcium metabolism to a normal or physiological state and present specific challenges for adequate clinical care. Under-treatment or missed doses may result in persistent symptoms; whereas, treatment with high doses of oral calcium can contribute to soft tissue calcification and organ damage, with the kidneys being especially vulnerable to hypercalciuria, hypercalcemia, nephrolithiasis, nephrocalcinosis, and renal failure, a common and severe adverse outcome in hypoparathyroidism patients.

Because Natpara is identical in structure to the 84-amino acid single-chain polypeptide human parathyroid hormone and mimics the action of natural parathyroid hormone, we believe it has the ideal mechanism of action to fulfill the unmet need of this chronic condition and offer a more physiological treatment outcome than is possible with existing treatments.

In 2007, the FDA granted orphan drug status for Natpara for the treatment of hypoparathyroidism.

### *Natpara for Hypoparathyroidism*

We plan to submit our U.S. marketing application for Natpara for the treatment of hypoparathyroidism however, the timing of the filing will be dependent on when the manufacturing issue is resolved.

In November 2011, we announced positive top-line results from REPLACE, a randomized, double-blind, dose-escalating, placebo-controlled Phase 3 registration study that investigated the use of Natpara for the treatment of adults with hypoparathyroidism at more than 30 sites in North America and Europe.

In an intent-to-treat analysis, 53 percent (48/90) of Natpara-treated patients achieved the primary endpoint versus 2 percent (1/44) of placebo-treated patients ( $p < 0.0001$ ). The primary efficacy endpoint of REPLACE was to demonstrate by Week 24 at least a 50 percent reduction from baseline of oral calcium supplementation and active vitamin D metabolite/analog therapy and a total serum calcium concentration that was normalized or maintained compared to baseline ( $\geq 7.5$  mg/dL). At week 24, 43 percent (36/84) of patients treated with Natpara were able to achieve independence from active vitamin D therapy and a calcium supplementation dose of 500 mg/day or less, as compared to five percent (2/37) for patients treated with placebo ( $p < 0.0001$ ).

The REPLACE study showed that Natpara was well-tolerated. Thirteen of the 134 randomized subjects discontinued the study early, of which seven were placebo-treated and six were Natpara-treated. Overall, the incidence of adverse events and serious adverse event were similar among both groups.

REPLACE consisted of an average 10-week screening and stabilization period followed by a 24-week treatment period marked by randomization (2:1) to 50 $\mu$ g once daily Natpara or placebo. Following randomization, subjects underwent staged reductions in calcium and vitamin D supplementation, while maintaining stabilized serum calcium. If needed, step-wise up-titration of study drug (Natpara or placebo) to a dose of 75  $\mu$ g and then if necessary to 100  $\mu$ g over

a six to eight week period was performed. Subjects continued on their final dose through week 24. A follow-up period without study drug lasted from week 24 to week 28.

New data from two investigator-initiated studies of rhPTH 1-84 were presented in 2011 that supported the potential of Natpara as a treatment for hypoparathyroidism. In the first study, which is evaluating bone properties in hypoparathyroidism, investigators from Columbia University reported that 18 patients with hypoparathyroidism maintained serum calcium while reducing calcium and vitamin D supplements and urinary calcium secretion after 48 months of treatment with rhPTH (1-84). In the second study, investigators from Aarhus University Hospital, Denmark, reported data from a 24-week, 62-patient study that evaluated daily subcutaneous 100 mcg rhPTH (1-84) versus placebo. Overall, during the 24 weeks of therapy patients on replacement therapy with rhPTH (1-84) reduced their daily dose of calcium and active vitamin D by 75 percent and 73 percent, respectively.

Results from an investigator-initiated Phase 2 open-label proof-of-concept study demonstrated that rhPTH (1-84) potentially can be used as a therapeutic agent in hypoparathyroidism effectively and safely. Thirty subjects with documented hypoparathyroidism participated in the study, which was conducted at Columbia University's College of Physicians and Surgeons. Subjects were treated with rhPTH (1-84) at a dose of 100 mcg every-other-day by subcutaneous injection for 24 months, with monitoring of calcium and vitamin D supplementation requirements, serum and 24 hour urinary calcium excretion, and bone mineral density. The study showed that rhPTH (1-84) treatment in hypoparathyroidism significantly reduces supplemental calcium and 1,25-dihydroxyvitamin D requirements while maintaining serum calcium levels. These data were published online on January 22, 2010 in the international peer-reviewed journal *Osteoporosis International*.

Based on these data, we believe Natpara has the potential to be the first hormone replacement therapy for chronic hypoparathyroidism.

We have completed an eight-week randomized, dose-blinded study, known as RELAY, which investigated the safety and efficacy of Natpara at fixed doses of 25 mcg and 50 mcg for the treatment of hypoparathyroidism. The primary endpoint of RELAY is to demonstrate oral calcium supplementation of 500 mg or less per day, a reduction in active vitamin D metabolite/analog therapy of 0.25 mcg or less per day, and serum calcium concentrations of between 7.5 mg/dL and the upper limit of normal. The results from RELAY showed that Natpara was well-tolerated and that a 25 mcg dose may be appropriate for a small subset of hypoparathyroidism patients.

We are advancing a 12-month, open-label study, known as RACE, which is investigating the long-term safety and tolerability of Natpara.

Due to a technical production issue, we are presently unable to have batches of finished product of Natpara manufactured that are consistently within our specifications. The required manufacturing specifications related to the current problem are the same for Natpara as for Preotact (marketed in certain countries in the EU by our ex-US partner Takeda). Previously, 140 consecutive production runs for the finished product of this compound had been produced over a five year period for clinical trial and commercial supplies. We are working, and we understand that Takeda is working, with our suppliers to identify the cause of the out-of-specification production runs. A number of actions are ongoing and we expect this issue will be resolved. This issue only pertains to finished product for commercial supply; we currently have sufficient clinical supplies to support our ongoing studies into at least early 2014. It is our understanding that Takeda is no longer selling Preotact in their territories and we have not received any information as to when or if Takeda will re-introduce Preotact in the future.

In September 2012, we received a request from the Medical Device Division of the FDA to modify our instructions for using the injection pen device to deliver Natpara. The FDA has not requested any new clinical data or clinical studies of Natpara. The requested changes will require us to repeat our Human Factors/Usability Testing of the injection pen device using the modified instructions before submitting our BLA.

#### *Teduglutide for Other Indications*

Given the mechanism of action of teduglutide in promoting gastrointestinal rehabilitation, we believe it may have potential in treating other intestinal failure-related conditions, like pediatric SBS, and pediatric feeding intolerance.

Teduglutide may facilitate reducing or even eliminating parenteral support dependence of pediatric patients with SBS. Pediatric SBS is often a result of the surgery needed to treat necrotizing enterocolitis (NEC). NEC is a gastrointestinal or GI disease that primarily affects premature infants. NEC involves infection and inflammation that causes destruction of the bowel or intestine or part of the bowel. The etiology of NEC is unknown, but NEC has

become a more common clinical problem as improvements in neonatal intensive care allow the survival of increasing numbers of premature and low-birth-weight infants. The incidence of NEC has been estimated at 0.7 to 3.0 per 1,000 live births, and approximately one-third of these infants with NEC are expected to undergo intestinal surgery, including resection, frequently resulting in SBS and dependence on PN/IV fluids.

We have completed a Phase 2a proof-of-concept clinical study with teduglutide in patients with Crohn's disease. These results were published in the peer-reviewed journal *Inflammatory Bowel Disease* (Buchman et al. *Inflamm Bowel Dis.* 2010 Jun;16(6):962-73). While we believe the data support further evaluation of teduglutide as a therapy for inducing remission and mucosal healing in patients with moderate-to-severe Crohn's disease, given our strategy to focus on indications with few, if any, therapeutic options and limited competition, we would only pursue the development of teduglutide for Crohn's disease as a specialty indication or on a partnered basis.

#### *NPSP790 and NPSP795*

In August 2011, we entered into a new agreement with GlaxoSmithKline (GSK), that terminated and replaced a prior collaborative research and license agreement from 1993 focused on the discovery and development of small molecule antagonists of the calcium receptor that increase secretion of parathyroid hormone (calcilytics).

As part of the agreement, GSK assigned to us the investigational new drug filings for two calcilytic compounds, NPSP790 and NPSP795. Both compounds have been evaluated in preclinical animal studies and Phase 1 human studies. We believe calcilytics may have clinical application in treating rare disorders involving increased calcium receptor activity, such as autosomal dominant hypocalcemia with hypercalciuria (ADHH).

ADHH is a rare endocrine disorder caused by a gain-of-function mutation in the calcium-sensing receptor gene. The enhanced calcium sensitivity of the receptor to extracellular calcium results in decreased parathyroid secretion, which leads to chronically low blood levels of calcium or hypocalcemia, and in the kidneys, there is a high urinary calcium excretion (hypercalciuria) despite hypocalcemia. Calcium plays a central role in the activity of many physiological systems, including the health and function of the skeletal, muscular, nervous, urinary, and cardiovascular systems. Raising the patient's serum calcium concentrations with supplementation of calcium and active metabolites of vitamin D does not treat the underlying physiological defect and can worsen hypercalciuria. Chronic hypercalciuria carries the risks of nephrocalcinosis, nephrolithiasis, and renal impairment. There is currently no approved treatment for ADHH.

Calcilytics are small molecule antagonists of the calcium receptor. Initially developed to stimulate parathyroid hormone secretion and bone formation for the treatment of osteoporosis and other bone metabolism disorders, they have been shown to increase serum calcium and decrease urinary calcium excretion in a Phase 2 study of patients with osteoporosis. Calcilytics could be a novel treatment for disorders involving increased calcium receptor activity.

#### **Royalty-Based Products and Product Candidates**

We complement our proprietary clinical programs with collaborative development or commercial agreements with Amgen, Janssen, GlaxoSmithKline, Kyowa Hakko Kirin, and Takeda. Generally, these agreements provide for payments to us for the achievement of specified milestones, and royalties on sales of products developed under the terms of the particular agreement. In return for these financial benefits, we grant the particular company a license to the technology that is the subject of the collaboration or to intellectual property that we own or control. We believe that collaborating with pharmaceutical and biotechnology companies with relevant expertise in areas that are outside of our proprietary therapeutic or geographic focus will accelerate the development and commercialization of our products. Additional information about these arrangements is set forth in Note 2, *Collaborative and License Agreements*, in "Notes to Consolidated Financial Statements" in Part II of this annual report on Form 10-K, which information is incorporated into this item by reference.

#### *Amgen and Kyowa Hakko Kirin (Cinacalcet HCl)*

Cinacalcet HCl is a small molecule compound used in treating hyperparathyroidism in patients with chronic kidney disease on dialysis and hypercalcemia in patients with parathyroid cancer. Hyperparathyroidism is a medical condition in which excessive amounts of parathyroid hormone circulate in the blood. It is typically characterized as being either primary or secondary hyperparathyroidism. Cinacalcet HCl is a calcimimetic compound that interacts with the calcium receptor on parathyroid cells and thereby decreases the production of parathyroid hormone in such cells.

In 1995, we licensed cinacalcet HCl to Kyowa Hakko Kirin Pharma, a wholly-owned subsidiary of Kyowa Hakko Kirin Holdings, on an exclusive basis for the drug's development and commercial sale in China, Japan, North and South Korea, and Taiwan. In 1996, we licensed worldwide rights (with the exception of the previously licensed Asian territories) to Amgen, Inc. on an exclusive basis to develop and commercialize cinacalcet HCl for the treatment of hyperparathyroidism.

Cinacalcet HCl is approved in the U.S. under the brand name Sensipar® and is indicated for (i) secondary hyperparathyroidism in patients with chronic kidney disease on dialysis, (ii) hypercalcemia in patients with parathyroid carcinoma, and (iii) severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy.

The European Medicines Agency has approved Cinacalcet HCl under the brand name Mimpara® for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy. Mimpara is also indicated for the reduction of hypercalcemia in patients with (i) parathyroid carcinoma or (ii) primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated.

Cinacalcet is approved and commercialized by Kyowa Hakko Kirin as REGPARA® for the treatment of secondary hyperparathyroidism in Japan, Hong Kong, Malaysia, Macau, Singapore, and Taiwan.

#### *Cinacalcet HCl for Secondary Hyperparathyroidism*

Parathyroid hormone is produced by the four parathyroid glands located in the neck. Serum levels of parathyroid hormone directly influence serum levels of calcium. The parathyroid glands regulate the amount of parathyroid hormone in the body by releasing more parathyroid hormone as the body needs additional calcium and less when there is excess serum calcium.

Secondary hyperparathyroidism most commonly results from chronic renal disease, which can develop in hemodialysis patients. Chronic hypocalcemia and secondary hyperparathyroidism can also be products of pseudohypoparathyroidism, vitamin D deficiency, and intestinal malabsorption syndromes that are characterized by inadequate vitamin D and calcium absorption. Parathyroid hormone acts in the kidneys and bones to elevate levels of calcium in the blood. Normal functioning healthy kidneys convert the parent vitamin D into the active form of vitamin D. Vitamin D helps in intestinal absorption of dietary calcium. Chronic kidney disease generally results in (i) reduced intestinal absorption of calcium due to reduced vitamin D levels, and (ii) reduced removal of phosphorus from the blood, elevating serum phosphate, which then combines with serum calcium to further reduce serum calcium levels. This in turn leads to the chronic overproduction of parathyroid hormone as the body tries to raise serum calcium levels. Symptoms of secondary hyperparathyroidism include excessive bone loss, bone pain and chronic, severe itching. Current treatments for secondary hyperparathyroidism, in addition to cinacalcet HCl, include phosphate binders and vitamin D supplements.

In October 2003, the National Kidney Foundation released Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. These guidelines set goals for the four key measures involved in managing secondary hyperparathyroidism: the serum level of parathyroid hormone; the serum level of calcium; the serum level of phosphorus; and the product of the serum level of calcium multiplied by the serum level of phosphorus ("Ca x P"). Traditional therapies such as phosphate binders and vitamin D supplements lower parathyroid hormone levels only by increasing one or more of the other measures, particularly calcium and/or Ca x P levels. Thus, under traditional therapies, patients and their physicians have typically had to choose between elevated parathyroid hormone or elevated calcium and/or Ca x P levels. Elevated parathyroid hormone levels cause excessive bone loss, bone pain and chronic, severe itching, while elevated calcium and/or Ca x P levels can lead to calcification of the heart and blood vessels and increases the risk of kidney stones.

Cinacalcet HCl is the only FDA-approved medication that simultaneously lowers all four of the key measures. By directly suppressing production of parathyroid hormone, cinacalcet HCl also causes serum levels of calcium, phosphorus and Ca x P to decline, providing patients and their physicians an effective treatment to avoid elevated parathyroid hormone, calcium and Ca x P.

In June 2012, Amgen reported results of its Phase 3 EVOLVE™ (EValuation Of Cinacalcet HCl Therapy to Lower CardioVascular Events) trial, which evaluated Sensipar®/Mimpara® for the reduction of the risk of mortality and cardiovascular (CV) events among 3,883 patients with secondary hyperparathyroidism and chronic kidney disease receiving dialysis. The primary endpoint of the study was time to the composite event comprising all-cause mortality or first non-fatal cardiovascular event, including myocardial infarction, hospitalization for unstable angina, heart failure or



peripheral vascular event. Although patients in the Sensipar/Mimpara arm experienced numerically fewer composite primary events, the results were not statistically significant, and the trial did not meet its primary endpoint in the intent-to-treat analysis.

#### *Cinacalcet HCl for Primary Hyperparathyroidism*

Generally, primary hyperparathyroidism is an age-related disorder that results from one or more non-cancerous tumor(s) causing the affected parathyroid gland(s) to become enlarged and overactive, secreting excessive levels of parathyroid hormone. As a result, serum calcium levels become high, bones may lose calcium, and kidneys may excrete too much calcium. Symptoms may include loss of bone density, muscle weakness, depression and cognitive dysfunction. Surgical removal of the affected parathyroid gland(s) from the neck region is presently the only effective treatment.

#### *Payments from Amgen for Cinacalcet HCl*

Cumulatively through December 31, 2012, Amgen has paid us \$40.5 million, which consists of license fees, research support payments, milestone payments (including the milestone payment for the filing of an NDA) and equity purchases of our common stock. Amgen will pay us up to an additional \$5.0 million if it achieves other development and regulatory milestones. In addition to these milestones, we earn royalties on Amgen's sales of cinacalcet HCl in its licensed territories. This agreement was amended in June 2012, whereby we exchanged our rights to receive royalties under the license agreement that are earned after December 31, 2018 in all countries except for Japan, China, North Korea, South Korea and Taiwan in return for a one-time non-refundable \$25.0 million payment that we received in July 2012.

We have partially monetized our royalty revenue and future milestone payments from Amgen through the issuance of non-recourse debt that is both serviced and secured by our Sensipar and Mimpara royalty revenue and future milestone payments. In December 2004, we completed a private placement of \$175.0 million in Secured 8.0% Notes due March 30, 2017, or Class A Notes, and in August 2007, we completed a private placement of \$100.0 million in Secured 15.5% Class B Notes due 2017, or Class B Notes. The Class A Notes and Class B Notes were non-recourse to us and were secured by our royalty and milestone payment rights under our agreement with Amgen. The Class A Notes and the Class B Notes were paid in full on March 30, 2011 and September 30, 2011, respectively.

In August 2011, we amended our agreement with Amgen that became effective after the retirement of the Class B Notes. Under the Amgen agreement, Amgen advanced \$145.0 million of Sensipar and Mimpara royalties to us (which we refer to as the Sensipar Notes). The repayment of the royalty advance and discount shall be satisfied solely by Amgen's withholding of royalties and except in the event of default, we will have no obligation to repay any unsettled amount. We further amended the agreement with Amgen in June 2012, limiting the royalty offset of the royalty advance up to \$8.0 million per quarter with royalties in excess of \$8.0 million paid to us for the respective quarter, thereby extending the royalty advance repayment period. After the payment of the royalty advance and a 9% per annum discount on the balance of the advance, Amgen will resume paying us all royalties earned through December 31, 2018. We received net proceeds from the issuance of the Sensipar Notes of approximately \$144.9 million, after deducting costs associated with the transaction. The Sensipar Notes accrue interest at an annual rate of 9%, compounded quarterly and payable forty-five days after the close of each quarter, which is satisfied solely by the withholding of royalties by Amgen. Under our agreements for the Sensipar Notes, we would potentially be liable for our breaches or defaults, if any.

#### *Payments from Kyowa Hakko Kirin for Cinacalcet HCl*

Cumulatively through December 31, 2012, Kyowa Hakko Kirin has paid us \$25.0 million in license fees, research and development support payments and milestone payments, which include a \$2.0 million milestone payment we received in October 2007 after the approval of cinacalcet HCl in Japan. Under the terms of our agreement, Kyowa Hakko Kirin is required to pay royalties on any sales of cinacalcet HCl in its territories.

On February 26, 2010, we sold our royalty rights from sales of REGPARA<sup>®</sup> (brand name for cinacalcet HCl in Japan) to an affiliate of DRI Capital, Inc. or DRI for \$38.4 million. Royalties will revert to us once DRI receives cumulative royalties of \$96 million or 2.5 times the amount paid to us. Under the agreement, DRI is entitled to receive royalty payments related to net sales of REGPARA occurring on or after July 1, 2009. We received approximately \$3.5 million in cumulative royalty revenue on net sales of REGPARA prior to July 1, 2009. In connection with this agreement, we granted DRI a security interest in our license agreement with Kyowa Hakko Kirin and certain of our patents related to REGPARA and other intellectual property underlying that agreement. In the event of a default by us

under the agreement with DRI, DRI would be entitled to enforce its security interest against us and the property described above.

*Takeda GmbH (Preotact<sup>®</sup> (parathyroid hormone 1-84 [rDNA origin] injection))*

In April 2004, we signed a distribution and license agreement with Takeda GmbH, formerly known as Nycomed (the “2004 Agreement”), in which we granted Takeda the exclusive right to develop and market Preotact in Europe, the Commonwealth of Independent States and Turkey. Preotact is the brand name that Takeda uses to market parathyroid hormone 1-84 [rDNA origin] injection. Takeda also made an equity investment in our business of \$40.0 million through the purchase of 1.3 million shares of our common stock in a private placement, which closed in July 2004. The 2004 Agreement required Takeda to pay us up to €21.0 million in milestone payments upon the receipt of specified regulatory approvals and the achievement of certain sales targets, to purchase drug product and devices from us, and to pay us royalties on product sales. In July 2007, we entered into a new license agreement with Takeda (“2007 Agreement”), as described below, which superseded the 2004 Agreement.

Under the 2007 Agreement, we granted to Takeda an exclusive license to sell, market and commercialize Preotact in all non-U.S. territories, excluding Japan and Israel. We also granted Takeda a non-exclusive license to manufacture and develop Preotact. If parathyroid hormone 1-84 [rDNA origin] injection is approved in the U.S., Takeda’s licensed rights in Canada and Mexico will revert to us or to a third-party whom we select. We also granted Takeda a right to negotiate for any new product we offer via a competitive process. Takeda is required to commercialize Preotact in most countries in Europe. If Takeda unreasonably delays the launch of Preotact in any country, then we have the right to ensure the launch of Preotact in that country. Takeda also assumed primary responsibility for manufacturing Preotact and for its further development and improvement. As part of Takeda’s assumption of manufacturing responsibility for Preotact, Takeda paid us \$11.0 million during 2007 for a significant portion of our existing bulk drug inventory.

The 2007 Agreement requires Takeda to make milestone payments similar to those in the 2004 Agreement upon the receipt of certain approvals in Europe and the achievement of certain sales targets for Preotact. Takeda is also required to pay us a royalty on a quarterly basis based upon sales of Preotact in the European Union, European countries outside the European Union, the Commonwealth of Independent States and Turkey. Takeda is also responsible to maintain our patents in its territories under the 2007 Agreement. If Takeda reasonably determines that it has no prospects for making a reasonable profit under the 2007 Agreement, and it is unable to agree to terms on a renegotiated agreement with us within eight weeks, Takeda may terminate the agreement by providing us with six months prior written notice; provided, however, that, upon any such termination the ownership of all rights to the Preotact trademarks previously transferred by us to Takeda will revert to us and Takeda will allow certain regulatory authorizations to be transferred to us. Cumulatively through December 31, 2012, we have received €7.1 million in milestone payments from Takeda under the 2004 and 2007 Agreements. Due to a technical production issue, Takeda is presently unable to have product meeting specifications manufactured and the Company has been informed that as a result Takeda is experiencing an out-of-stock situation for Preotact which began in certain countries in August 2012. We understand that Takeda has taken a number of actions to resolve the manufacturing issue and to accelerate a return to normal supply situation. It is our understanding that Takeda is no longer selling Preotact in their territories and we have not received any information as to when or if Takeda will re-introduce Preotact in the future.

In July 2007, we entered into an agreement with DRI Capital Inc., (DRI) under which we sold to DRI our right to receive future royalty payments arising from sales of Preotact under the 2007 Agreement. Under the agreement, DRI paid us an up-front purchase price of \$50.0 million for the royalty rights. The agreement provides that if DRI receives royalties representing two and a half times the \$50.0 million paid to us, the agreement will terminate and the remainder of the royalties paid by Takeda under the 2007 Agreement, if any, will revert to us. In connection with our agreement with DRI, we granted DRI a security interest in the 2007 Agreement and certain of our patents related to Preotact and other intellectual property underlying that agreement. In the event of a default by us under the agreement with DRI, DRI would be entitled to enforce its security interest against us and the property described above.

*Takeda (Teduglutide, ex-North American Development)*

In September 2007, we entered into a license agreement with Takeda, in which we granted Takeda the right to develop and commercialize teduglutide, outside the United States, Canada and Mexico for the treatment of gastrointestinal disorders. Teduglutide, (trade name in the United States: Gattex<sup>®</sup>) is a novel recombinant analog of GLP-2, a peptide involved in the regeneration and repair of the intestinal lining. A positive opinion was issued in June 2012 by the Committee for Medicinal Products for Human Use, followed by the European Commission granting European market authorization in August 2012 for the medicinal product teduglutide (trade name in Europe:

Revestive®) as a once-daily treatment for adult patients with SBS. We received \$35.0 million in up-front fees shortly after executing the agreement and an additional \$5.0 million milestone in 2011. Under the terms of the agreement, we have the potential to earn an additional \$170.0 million in development and sales milestone payments. Additionally, the agreement provides for royalties on sales in the licensed territories and provides an option for development cost sharing equally for indications that we elect to pursue jointly. The royalties for a particular country may be reduced to zero percent if aggregate sales of any other product containing GLP-2 exceeds a certain percentage during the longer of the first ten years of sales in such country or the expiration of certain patents in such country. Pursuant to a previously existing licensing agreement with a third party, we paid \$6.6 million and \$2.4 million to the licensor in 2007 and in 2011, respectively, and will be required to make future payments based on future Gattex royalties and milestones earned.

Under the terms of the license agreement with Takeda, we were responsible for completing the first Phase 3 Gattex clinical trial in SBS. Takeda is responsible for conducting Phase 4 studies in its licensed territory at its expense. We also may work with Takeda to jointly develop, commercialize and investigate further indications for Gattex in the licensed territories; we would share joint development costs equally for such work. We agreed to advance the STEPS and STEPS 2 studies on a collaborative basis and share certain external development costs for the SBS indication with Takeda. Takeda may terminate on 180-day written notice prior to the first commercial sale under the agreement. Following the first commercial sale, Takeda must provide 365-day written notice in order to terminate. After we have received such a termination notice, we may terminate the agreement at any time prior to the expiration of Takeda's requisite notice period.

#### *Ronacaleret (751689)*

Ronacaleret (751689) is a calcilytic compound developed under a November 1993 collaborative research and worldwide exclusive license agreement with GlaxoSmithKline or GSK for the research, development and commercialization of calcium receptor active compounds for the treatment of osteoporosis and other bone metabolism disorders, excluding hyperparathyroidism. Calcilytic compounds are small molecule antagonists of the calcium receptor that temporarily increase the secretion of the body's own parathyroid hormone, which may result in the formation of new bone. In animal studies, we demonstrated that intermittent increases in circulating levels of parathyroid hormone could be obtained using calcilytics. In these studies, increased levels of parathyroid hormone were achieved by this mechanism and were equivalent to those achieved by an injection of parathyroid hormone sufficient to cause bone growth.

In August 2011, we formed a new agreement with GSK that replaced the 1993 agreement and expanded the licensed field of research for ronacaleret, which was discovered under the 1993 agreement and studied as a treatment for osteoporosis in post-menopausal women. The new agreement allows GSK to pursue stem cell mobilization, in addition to osteoporosis and other bone disorders. GSK will be responsible for all development, manufacturing and commercialization of ronacaleret. We are entitled to development milestones and royalties on any future sales of ronacaleret. GSK will no longer have rights to other calcilytic compounds discovered or developed under the 1993 agreement. GSK has the right to terminate the license upon 30 days notice, on a country-by-country basis for countries for which GSK has reasonably determined that continued development or commercialization in such country is not justified.

#### **Other Royalty Agreements**

##### *Janssen Pharmaceuticals, Inc.*

In December 2006, we entered into an agreement with Janssen Pharmaceuticals, Inc. formerly known as Ortho-McNeil Pharmaceutical (Janssen) pertaining to certain of our patents. Under this agreement, Janssen is required to pay us royalties on any product sales of tapentadol hydrochloride and other related compounds in all countries in which we have patents whose claims cover such sales of such products. We also received an up-front licensing fee. Janssen pays us its royalty on a quarterly basis. We are responsible for patent prosecution and maintenance of the related patents. In November 2008, the U.S. Food and Drug Administration approved tapentadol immediate-release tablets for the relief of moderate to severe acute pain in adults 18 years of age or older. In August 2011, the FDA approved Nucynta ER (tapentadol extended-release) tablets for the management of moderate-to-severe chronic pain in adults. Tapentadol is a centrally acting oral analgesic.

In December 2008, we entered into an agreement with Hoffman-La Roche Inc. and F. Hoffmann-La Roche Ltd. (Roche), under which we granted Roche a non-exclusive license (with the right to grant sublicenses) to develop, make, import, use for sale or sell products covered by patents relating to the modulation of NMDA receptor activity using glycine uptake antagonists. In return, Roche paid us an upfront licensing fee of \$2.0 million in 2008 and agreed to pay us for the achievement of certain regulatory milestones. Further, Roche agreed to pay a royalty on any future sales of licensed products on a quarterly basis.

### **In-licensing Agreements**

In February 1993, we entered into a patent license agreement with The Brigham and Women's Hospital, an affiliate of Harvard University Medical School. The patent license agreement grants us an exclusive license to certain calcium receptor and inorganic ion receptor technology covered by patents we jointly own with the hospital. Under the patent license agreement, we are responsible for all costs relating to obtaining regulatory approval from the FDA or any other federal, state or local government agency and carrying out any clinical studies, relating to the technology. The Brigham and Women's Hospital is also entitled to a royalty on any sales of certain products under the patent license agreement, and we have committed to promote sales of any licensed products for hyperparathyroidism for which we receive regulatory approval. Brigham and Women's Hospital may terminate the patent agreement if we breach the terms of the patent agreement and do not cure the breach within 60 days of receiving notice of the breach. Certain violations of terms of the patent agreement, if pursued by Brigham and Women's Hospital, might result in the exclusive, royalty-free license of the technology to Brigham and Women's Hospital or other adverse consequences.

We have a license agreement with Daniel J. Drucker, MD, and his Canadian corporation 1149336 Ontario Inc. The license agreement grants to us an exclusive worldwide license under Dr. Drucker's patent portfolio for glucagon-like peptide-2, or GLP-2, and its therapeutic uses. Under the license agreement, we have agreed to ensure that reasonable commercial efforts are used to develop and commercialize any product covered by the licensed patents. The agreement requires us to pay annual non-refundable license maintenance fees, royalties on sales and licensing fees, and milestone payments. During the period commencing upon our acquisition of Allelix Biopharmaceuticals Inc., the original licensee under this agreement, on December 23, 1999 through December 31, 2012, we have paid license maintenance fees, milestone payments and sublicense fees totaling \$9.6 million under this license agreement. We have sublicensed our rights for certain territories to Takeda and under the terms of the license agreement, we are no longer obligated to make milestone payments, but instead are required to pay a share that represents a percentage in the twenties of our sublicense revenues (as defined in the license agreement) to 1149336 Ontario Inc. We are also obligated to pay a royalty to 1149336 Ontario Inc. that represents a percentage in the single digits of our sales of Gattex. The license agreement is perpetual but we may terminate the agreement at any time upon 60 days written notice. In addition, if we default on any of the material obligations under the agreement Dr. Drucker may terminate the license agreement and all rights granted under the agreement will revert to Dr. Drucker. In addition, if Dr. Drucker terminates the license agreement for our default, or if we terminate the license agreement for our convenience, we will be obligated to assign to Dr. Drucker all intellectual property relating to GLP-2 that is owned by us, and we will be prohibited from developing, making or selling a GLP-2 product for a period of 15 years.

### **Regulatory Matters**

#### *New Drug Development and Approval Process*

Regulation by governmental authorities in the U.S. and other countries is a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. All of our product candidates will require regulatory approval by governmental agencies prior to commercialization. In particular, all of our drug candidates are subject to rigorous preclinical testing, clinical trials, and other pre-marketing approval requirements by the FDA and regulatory authorities in other countries. In the U.S., various federal, and in some cases state statutes and regulations also govern or affect the manufacturing, safety, labeling, storage, record keeping and marketing of such products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. Regulatory approval, when and if obtained, will dictate the approved uses of the product for marketing purposes. Further, approved drugs, as well as their manufacturers, are subject to ongoing review and discovery of previously unknown problems with such products may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

The steps required by the FDA before our drug candidates may be marketed in the U.S. include, among other things:

- The performance of preclinical laboratory and animal tests and formulation studies;
- The submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials may commence;
- The completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug; and
- The submission and FDA approval of an application for marketing approval.

In addition to the above, the Food and Drug Administration Amendment Act (FDAAA) of 2007 requires new chemical entities to be evaluated by an FDA Advisory Committee, unless the FDA justifies differently in writing. The testing and approval process requires substantial time, effort and financial resources and we cannot be certain that any approvals for any of our proposed products will be granted on a timely basis, if at all.

Prior to commencing a clinical trial, we must submit an IND to the FDA. The IND becomes effective 30 days after receipt by the FDA, unless within the 30-day period, the FDA raises concerns or questions with respect to the conduct of the trial. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the study can begin. As a result, the submission of an IND may not necessarily result in FDA authorization to commence a clinical trial. Further, an independent institutional review board at the medical center or centers proposing to conduct the trial must review and approve the plan for any clinical trial before it commences.

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

- Phase 1: the drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- Phase 2: 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 optimal dosage.
- Phase 3: when Phase 2 evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase 3 trials are undertaken to further evaluate dosage and clinical efficacy and to further test for safety in an expanded patient population at geographically dispersed clinical study sites.

We cannot be certain that we, or any of our collaborative partners, will successfully complete Phase 1, Phase 2 or Phase 3 testing of any compound within any specific period, if at all. Furthermore, the FDA or the study sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a marketing authorization application (an NDA for new drugs or a BLA for new biologics). FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. If the NDA or BLA contains all pertinent information and data, the FDA will "file" the application and begin review. The FDA may "refuse to file" the NDA or BLA if it does not contain all pertinent information and data or if in the wrong format. In that case, the applicant may resubmit the NDA or BLA when it contains the missing information and data in the correct format. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Following a 60-day review period after the submission of an application, priority drug products are intended to be reviewed within 6 months and non-priority drug products are intended to be reviewed within 10 months or for a total of 8 and 12 months, respectively. The review process, however, may be substantially extended by FDA requests for additional information, preclinical or clinical studies and or clarification regarding information already provided in the submission, submission of a risk evaluation and mitigation strategy or proposed labeling. The submission of data after the initial submission may automatically trigger an additional 90-days to the assigned action date. The FDA may refer an application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved.

The FDA may withhold approval if the applicable regulatory criteria are not satisfied or may require additional testing or data. Even if such data are submitted, the FDA may ultimately decide that the application data do not satisfy the risk-to-benefit criteria for approval. The FDA may also limit the indications for use and/or require post-marketing testing and surveillance to monitor the safety and or efficacy of a product. If approved, 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 approved products even after they 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.

Satisfaction of the above 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 a product or indication.

Government regulation may delay or prevent marketing of potential products for a considerable period and impose costly procedures upon our or our partner's activities. The FDA or any other regulatory agency may not grant any approvals on a timely basis, if at all. 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 indications and dosages. Further, even if regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals may have a material adverse effect on our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Any products manufactured or distributed by us or our partners pursuant to Health Authority approvals are subject to pervasive and continuing regulation by that Health Authority, including record-keeping requirements and reporting of adverse experiences with the drug. In the U.S., drug manufacturers are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA for compliance with current Good Manufacturing Practice, or cGMP, regulations, which impose certain procedural and documentation requirements. We cannot be certain that we, or our present or future suppliers, will be able to comply with the cGMP regulations and other FDA regulatory requirements.

Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an institutional review board of a clinical hold on trials, the FDA's refusal to approve pending applications or supplements, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting a marketing authorization application. After the FDA grants orphan drug designation, the non-proprietary identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives FDA approval for the disease for which it has such designation, the product is entitled to orphan drug market exclusivity from the time of approval. For example, the FDA may not approve any other applications to market the same drug for the same disease, except in very limited circumstances, for seven years. We intend to file for orphan drug designation for those diseases that meet the criteria for orphan exclusivity. Although obtaining FDA approval to market a product with orphan drug exclusivity can be advantageous, there can be no assurance that it would provide us with a material commercial advantage.

Steps similar to those in the U.S. must be undertaken in virtually every other country comprising the market for our product candidates before any such product can be commercialized in those countries. The approval procedure and the time required for approval vary from country to country and may involve additional testing. There can be no assurance that approvals will be granted on a timely basis, or at all. In addition, regulated approval of prices is required in most countries other than the U.S. There can be no assurance that the resulting prices would be sufficient to generate an acceptable return to us.

#### *Patient Protection and Affordable Health Care Act*

In March 2010, the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA, was enacted, which includes measures that have or will

significantly change the way health care is financed by both governmental and private insurers. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, PPACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and biologic agents from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. PPACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization as of 2010 and by expanding the population potentially eligible for Medicaid drug benefits, to be phased in by 2014. The Centers for Medicare and Medicaid Services, or CMS, have proposed to expand Medicaid rebate liability to the territories of the United States as well. In addition, PPACA provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program. The implementation of this requirement by the CMS may also provide for the public availability of pharmacy acquisition cost data, which could negatively impact our sales.
- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. Effective in 2010, PPACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.
- Effective in 2011, PPACA imposed a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., "donut hole").
- Effective in 2011, PPACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.
- Effective in 2012, PPACA required pharmaceutical manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any "transfer of value" made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers will be required to report this information beginning in 2013.
- As of 2010, a new Patient-Centered Outcomes Research Institute was established pursuant to PPACA to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.
- PPACA created the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. Under certain circumstances, these recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings.
- PPACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Many of the details regarding the implementation of PPACA are yet to be determined, and at this time, it remains unclear the full effect that PPACA would have on our business.

#### *Biologics Price Competition and Innovation Act of 2009*

The PPACA included the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA amended the Public Health Service Act, the law pursuant to which the FDA regulates biologics, to create an abbreviated approval pathway for two types of “generic” biologics—biosimilars and interchangeable biologic products, and provides for a twelve-year exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however if pediatric studies are performed and accepted by the FDA, the twelve-year exclusivity period will be extended for an additional six months. A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved. The first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

In February 2012, the FDA issued three draft guidance documents on biosimilar product development. The draft guidance documents are: “Scientific Considerations in Demonstrating Biosimilarity to a Reference Product,” “Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product,” and “Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.” The guidance documents provide FDA’s current thinking on approaches to demonstrating that a proposed biological product is biosimilar to a reference product. The FDA received public comments on the draft documents and intends to issue final guidance documents in the future. Nevertheless, the absence of a final guidance document does not prevent a sponsor for seeking licensure of a biosimilar under the BPCIA.

#### **Patents and Other Proprietary Technology**

Our intellectual property portfolio includes patents, patent applications, trade secrets, know-how and trademarks. Our success will depend in part on our ability to obtain additional patents, maintain trade secrets and operate without infringing the proprietary rights of others, both in the U.S. and in other countries. We periodically file patent applications to protect the technology, inventions and improvements that may be important to the development of our business. We rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We file patent applications on our own behalf as assignee and, when appropriate, have filed and expect to continue to file, applications jointly with our collaborators. These patent applications cover compositions of matter, methods of treatment, methods of discovery, use of novel compounds and novel modes of action, as well as recombinantly expressed receptors and gene sequences that are important in our research and development activities. Some of our principal intellectual property rights related to processes, compounds, uses and techniques related to calcium receptor science are protected by issued U.S. patents. We intend to file additional patent applications relating to our technology and to specific products, as we think appropriate.

We hold patents directed to potential therapeutic products such as new chemical entities, pharmaceutical compositions and methods of treating diseases. We hold patents directed also to nucleic acid and amino acid sequences of novel cellular receptors and methods of screening for compounds active at such cellular receptors. We continue



actively to seek patent protection for these and related technologies in the U.S. and in foreign countries. Our intellectual property portfolio also includes patents in countries outside the U.S., which also cover the technology referenced above.

#### *Our Patent Portfolio*

The following is a description of patents we own or license from third parties which contain claims that cover our material products and product candidates.

*Gattex:* Twenty-three issued U.S. patents include claims that cover technology related to Gattex and GLP-2, certain of which we license from 1149336 Ontario Inc. These patents have expiration dates (not including any patent term extensions) ranging from 2015 to 2026. We have licensed foreign counterparts of these patents to Takeda for territories outside of North America. Our issued principal patents which contain claims that cover our product, Gattex, its formulation, and/or method of use, are summarized in the following table:

Territory	General Subject Matter	Expiration (not including term extension)
U.S.	Glucagon-like peptide-2 analogs	2015 <sup>1</sup>
U.S.	GLP-2 formulations	2022 <sup>1</sup>
Europe	Glucagon-like peptide-2 analogs	2017
Europe	GLP-2 formulations	2020
Japan	Glucagon-like peptide-2 analogs	2017
Japan	GLP-2 formulations	2020

<sup>1</sup> We are eligible for patent term extension of up to five years on one U.S. patent due to Gattex' marketing approval by the FDA.

*Natpara and Preotact:* Six issued U.S. patents include claims that cover technology related to parathyroid hormone. These patents have expiration dates ranging from 2013 to 2021. We have licensed foreign counterparts of these patents to Takeda for territories outside of North America, Israel, and Japan. Our issued principal patents which contain claims that cover formulations of Natpara and Preotact are summarized in the following table:

Territory	General Subject Matter	Expiration
U.S.	Parathyroid hormone formulation	2013 <sup>1</sup>
Europe	Parathyroid hormone formulation	2014
Europe	Protein formulations	2021 <sup>2</sup>
Japan	Parathyroid hormone formulation	2014 <sup>3</sup>
Japan	Protein formulations	2019 <sup>3</sup>

<sup>1</sup> Eligible for patent term extension of up to five years if Natpara is approved for marketing by the FDA.

<sup>2</sup> Includes approximately two years of supplementary protection, which varies by country. Applications for supplementary protection have been granted in most major European countries.

<sup>3</sup> Does not include any supplementary protection.

*Calcimimetics:* Sixteen issued U.S. patents cover calcimimetics and calcium receptor technology. These patents and their foreign counterparts have been licensed to Amgen, Inc. and cover their products Sensipar® (cinacalcet) and Mimpara® (cinacalcet) worldwide except for certain Asian countries. The patents in those territories have been licensed to Kyowa-Hakko Kirin and cover their product Regpara® (cinacalcet.) Our calcimimetics patents have expiration dates (including 449 days of patent term extension for U.S. Patent No. 6,011,068) ranging from 2013 to 2020. Our issued principal patents that cover cinacalcet, its formulation and/or method of use, are summarized in the following table:

Territory	General Subject Matter	Expiration
U.S.	Calcium receptor-active compounds	2015
U.S.	Calcium receptor-active molecules	2016
U.S.	Methods of use	2016
U.S.	Calcium receptor-active molecules	2018 <sup>1</sup>
Europe	Calcium receptor-active compounds	2019 <sup>2</sup>
Japan	Calcium receptor-active molecules	2017 <sup>3</sup>
Japan	Calcium receptor-active molecules	2017 <sup>3</sup>
Japan	Calcium receptor-active compounds	2020 <sup>3</sup>

<sup>1</sup> Includes 449 days of patent term extension.

<sup>2</sup> Includes approximately four years of supplementary protection, which varies by country. Applications for supplementary protection have been granted in most major European countries.

<sup>3</sup> Includes five years of supplementary protection

*Calcilytics:* Seven issued U.S. patents contain claims that cover technology related to calcilytic compounds we have under development and have licensed to GlaxoSmithKline LLC. These patents have expiration dates (not including any patent term extensions) ranging from 2016 to 2021. The products covered by these patents are in very early stages of development and the patents are not considered material at this time.

We do not believe that the expiration during the near term (2013 through 2015) of our principal patents relating to our material products will have a material adverse impact on our business, products or product candidates due to several factors. As noted above, one of the principal U.S. patents expiring in this time period that covers each of Gattex and Natpara will be eligible for up to five years of patent term extension as a result of the FDA’s marketing approval of Gattex in December 2012 and one of the principal U.S. patents expiring in this time period that covers Natpara will be eligible for up to five years of patent term extension if Natpara is approved by the FDA. In addition, each of Gattex and Natpara has been designated as an orphan drug and as a result, Gattex will receive seven years of marketing exclusivity in the U.S. based upon the FDA’s marketing approval of Gattex in December, 2012 and Natpara will receive seven years of marketing exclusivity in the U.S. in the event it is approved by the FDA. As a biologic product, Natpara is expected to receive 12 years of marketing exclusivity in the U.S. in the event it is approved by the FDA.

In connection with our research and development activities, we have sponsored research at various university and government laboratories. For example, we have executed license and research agreements regarding research in the area of calcium and other ion receptors with The Brigham and Women’s Hospital. We have also sponsored work at other government and academic laboratories for various evaluations, assays, screenings and other tests. Generally, under these agreements, we fund the work of investigators in exchange for the results of the specified work and the right or option to a license to any patentable inventions that may result in certain designated areas. If the sponsored work produces patentable subject matter, we generally have the first right to negotiate for license rights related to that subject matter. Any resulting license would be expected to require us to pay royalties on net sales of licensed products.

## Competition

Competition in the pharmaceutical industry is intense and is expected to continue to increase. Competition is based to a significant degree on technological and scientific factors, including, the availability of patent and other protection of products, product candidates, processes and other technologies, the ability to commercialize products and other technological developments, the ability to obtain governmental approval for testing, manufacturing and marketing of products, and the ability to enter into licensing and similar arrangements to facilitate the development of products and meet other business objectives. Many competitors, including biotechnology and pharmaceutical companies, are actively engaged in research and development in areas that we, or our partners, are also developing or commercializing products. These companies, as well as academic institutions, governmental entities and other organizations, also compete with us in recruiting and retaining highly qualified scientific management, personnel and consultants. Many of our competitors

are larger than we are and have substantially greater financial and management resources, superior intellectual property positions and greater manufacturing, marketing and sales capabilities.

We have focused our internal research and development on niche indications of significant unmet medical need where we believe a company of our size can successfully compete. For example, we have been granted orphan drug designation for Gattex in the treatment of SBS, where there are a limited number of competing therapies. Gattex is the first and only analog of GLP-2 proven to increase intestinal absorption and decrease or eliminate the need for parenteral support in adult SBS. Further, Gattex is the only pharmaceutical approved for long-term treatment of adult SBS. Other therapies for SBS include parenteral support and somatropin (rDNA origin) for injection, a human growth hormone marketed by Serono and L-glutamine in combination with somatropin (rDNA origin) for injection. Parenteral support does not address the issue of malabsorption for adult SBS. Further, a NIH publication reported that the annual mean costs of lifelong, complex home healthcare associated with PN/IV support ranged from \$185,000 to \$568,000, not including the indirect costs associated with disability and/or the dollar value that could be ascribed to the challenging daily living for these patients (Piamjariyakul 2010). In addition, parenteral support is associated with shortened life span, life-threatening complications including sepsis, blood clots or liver damage, and reduced quality-of-life due to the time required for and consequences of frequent access to an intravenous pump. Treatment with somatropin (rDNA origin) for injection is limited to 28 days and requires a specialized diet. Gattex will compete directly with somatropin (rDNA origin) for injection. Parental support-dependent pediatric SBS, pediatric feeding intolerance, and gastrointestinal mucositis or GIM are other specialty indications where few competitors exist. We are aware of two GLP-2 peptide analogs under development by Zealand Pharma, specifically ZP1846, which was licensed to Helsinn Healthcare, is in Phase 1 clinical development for chemotherapy-induced diarrhea and ZP1848 is in Phase 1 clinical development for inflammatory bowel diseases.

We have been granted orphan drug status for Natpara for the treatment of hypoparathyroidism. Presently, there is no approved treatment for hypoparathyroidism. It is currently managed with large doses of oral calcium and active vitamin D supplementation to raise the calcium levels in the body and reduce the severity of symptoms. Over time, calcium may build up in the body and result in serious health risks, including calcifications in the kidneys, heart or brain. Severe hypocalcemia can be life threatening and is treated with intravenous calcium. Natpara is a bioengineered replica of human parathyroid hormone that we believe has the potential to be the first hormone replacement therapy for hypoparathyroidism and that we believe will meet the unmet need of this chronic condition.

Many of our competitors have substantially greater financial, technical, marketing and personnel resources. In addition, some of them have considerable experience in preclinical testing, human clinical trials and other regulatory approval procedures. Moreover, certain academic institutions, governmental agencies and other research organizations are conducting research in the same areas in which we are working. These institutions are becoming increasingly aware of the commercial value of their findings and are more actively seeking patent protection and licensing arrangements to collect royalties for the technology that they have developed. These institutions may also market competitive commercial products on their own or through joint ventures and will compete with us in recruiting highly qualified personnel. Our ability to compete successfully will depend, in part, on our ability to:

- outsource activities critical to the advancement of our product candidates and manage those companies to whom such activities are outsourced;
- outsource manufacturing capabilities for our proprietary products;
- leverage our established collaborations and enter into new collaborations for the development of our products;
- identify new product candidates;
- develop products that reach the market first;
- develop products that are superior to other products in the market;
- develop products that are cost-effective and competitively priced;
- obtain and enforce patents covering our technology; and
- successfully market products we develop that receive regulatory approval or secure marketing partners who are successful in marketing our products.

## **Sales and Marketing**

We have established a small commercial organization to support sales of Gattex in the U.S. Our field force is comprised of 30 employees calling on a small prescriber base who are primarily gastrointestinal specialists. We believe the size of our sales force is appropriate to effectively market Gattex given the limited adult SBS population.

## **Customers**

Our customers are primarily specialty pharmacies who supply home infusion services to adult SBS patients. Gattex is shipped directly from our third-party warehouse to our limited distribution network. Our current network includes Accredo Health Group, Inc.; BioScrip; Inc.; Coram, LLC; ThriveRx; and Walgreens Infusion Services. In addition to dispensing Gattex, these contracted providers will provide clinical services to support the use of Gattex in reducing parenteral support for adult patients with SBS.

## **Manufacturing**

We rely on corporate collaborators and contract manufacturing organizations to supply drug product for our clinical trials and future commercial supply chain. We have established all of our commercial supply chain for Gattex and Natpara. We have agreements in place with Boehringer Ingelheim Austria GmbH (“Boehringer”) for Gattex and Boehringer and SynCo Bio Partners B.V. (“Synco”) for Natpara for the production of bulk supplies of the active pharmaceutical ingredients for our clinical and future commercial requirements. In addition, we have manufacturing agreements in place with Hospira Worldwide, Inc. (“Hospira”) and Vetter Pharma International GmbH (“Vetter”) for the production of our fill and finish clinical and commercial supplies of Gattex and Natpara, respectively. We have also established agreements with other third parties to perform additional steps in the manufacturing process, including packaging, testing and storage of our product candidates.

We have developed a prototype of an injection pen device for the delivery of Natpara and we have a manufacturing agreement in place. We are planning to file for market authorization as a drug-device combination, combining our proprietary product Natpara with an injection pen device delivery system. Due to a technical production issue, we are presently unable to have batches of Natpara finished product manufactured that are consistently within our specifications. The required manufacturing specifications related to the current problem are the same for Natpara as for Preotact (marketed in certain countries in the EU by our ex-US partner Takeda). Previously, 140 consecutive production runs for the finished product of this compound had been produced over a five year period for clinical trial and commercial supplies. We are working, and we understand that Takeda is working, with our suppliers to identify the cause of the out-of-specification production runs. We have met with FDA to discuss our Human Factors/Usability testing of the Natpara injection pen device. The final study will be initiated in March 2013 with results expected in the second quarter of 2013. We continue to work toward submitting our U.S. Biologics License Application (BLA) for Natpara. In order to finalize our submission, we need to resolve certain previously disclosed manufacturing issues. We expect to complete certain key root cause analyses during the second quarter of 2013. Subject to resolution of the manufacturing issue, we expect to submit our BLA in the second half of 2013. This issue only pertains to finished product for commercial supply; we currently have sufficient clinical supplies to support our ongoing studies into at least early 2014. It is our understanding that Takeda is no longer selling Preotact in their territories and we have not received any information as to when or if Takeda will re-introduce Preotact in the future.

We believe that our existing supplies of drug product, our contract manufacturing relationships, and potential contract manufacturers, who we are in discussions with, will be sufficient to accommodate our clinical trials and our commercial supply chain for Gattex and Natpara.

We are dependent on third parties for the manufacture of our product candidates and injection devices and in several instances we are sole sourced to these manufacturers, including Hospira and Vetter, who produce fill and finish supplies of Gattex and Natpara, respectively. If we are unable to contract for a sufficient supply of our product candidates or injection devices on acceptable terms, or encounter delays or difficulties in the manufacturing or supply process, we may not have sufficient product or injection devices to conduct or complete our clinical trials or support preparations for the commercial launch of our product candidates, if approved. Based on the highly-specialized and proprietary nature of the products provided to us by certain of our manufacturing partners, we could be subject to significant added costs and delays if we are required to replace our existing agreements or arrangements with those partners for any reason. For a more complete discussion of the various risks and uncertainties related to our manufacturing and supply relationships, see the discussion in Item 1A of this Annual Report under the heading “Risk Factors.” Under our existing manufacturing agreements we pay an agreed-upon fee to our suppliers based upon the amount of ingredients or product produced.

### *Boehringer Ingelheim Austria GmbH*

In October 2002 we entered into an agreement with Boehringer for the production of bulk supplies of the active pharmaceutical ingredient in Natpara. In March 2004, we entered into an amending agreement with Boehringer to provide for the production of the bulk supplies of the active pharmaceutical ingredient in Gattex. The initial term of the agreement expired on December 31, 2010 but was extended by the parties to December 31, 2018. Either party may terminate the agreement at any time upon twenty-four months' advance notice.

### *Hospira Worldwide, Inc.*

In March 2009 we entered into an agreement with Hospira for production of our fill and finish clinical and commercial supplies of Gattex. The agreement has a term of seven years following the first commercial sale of Gattex and automatically renews for subsequent three-year terms unless either party sends advanced notice of non-renewal. Hospira has the right to terminate the agreement if we do not order a specified amount of Gattex in any 12 month period following the first commercial sale.

### *SynCo Bio Partners B.V.*

In August 2009 we entered into an agreement with SynCo for the production of the bulk supplies of the active pharmaceutical ingredient in Gattex and Natpara. We are not currently obtaining the active pharmaceutical ingredient in Gattex from SynCo. The agreement may be terminated by either party after December 31, 2016 by providing at least 12 months' advanced notice.

### *Vetter Pharma International GmbH*

In December 2009 we entered into an agreement with Vetter for the production of our fill and finish clinical and commercial supplies of Natpara. The agreement has a term of five years and automatically renews for subsequent three-year terms unless either party provides advanced notice of non-renewal.

## **Employees**

As of February 14, 2013, we had approximately 149 employees. None of our employees is covered by a collective bargaining agreement and we believe that our relationship with our employees is good.

## **Trademarks**

"NPS", "NPS Pharmaceuticals", "Gattex", "Natpara", and "PREOS" are our trademarks. All other trademarks, trade names or service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

## **Available Information**

Our Internet address is [www.npsp.com](http://www.npsp.com). We make available free of charge on or through our Internet website 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 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These items also can be read and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington, DC 20549. Information on the operation of the Public Reference Room is available by calling the SEC at (800) SEC-0330. The SEC maintains a website ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements, and other information.

## **ITEM 1A. Risk Factors.**

*The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. If any of the following risks actually occur, our business, results of operation, prospects or financial condition could be harmed. These are not the only risks we face. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations.*

## Risks Related to Our Business

*We have a history of operating losses and we anticipate that we will incur substantial expenses in connection with our commercial launch of Gattex in the United States and further development and efforts to obtain regulatory approval for Natpara. If we do not generate significant revenues from the sale of Gattex, we will not be able to achieve and then maintain profitability.*

With the exception of 1996, we have not been profitable since our inception in 1986. As of December 31, 2012, we had an accumulated deficit of approximately \$1.0 billion. To date, our revenue has been primarily from royalty payments from Amgen on sales of Sensipar and Mimpara (cinacalcet HCl), royalty payments from Takeda on sales of Preotact, royalty payments from Kyowa Hakko Kirin on sales of REGPARA, milestone revenue from our collaborative agreements with Takeda and others, product sales to Takeda and royalty payments on sales of Nucynta by Janssen. In July 2007, we entered into an agreement with Takeda whereby they assumed sole responsibility for manufacturing Preotact. As described further herein, we have non-recourse debt that is secured by our royalty rights related to sales of Sensipar and Mimpara under our agreement with Amgen. In addition, we have sold to DRI and an affiliate of DRI our rights to receive royalty payments under our agreements with Takeda and Kyowa Hakko Kirin for Preotact and REGPARA, respectively. The right to receive the full royalty on Amgen's Sensipar and Mimpara sales will only be achieved if those royalties are sufficient to repay our non-recourse Sensipar Notes. The right to royalties on Takeda's Preotact sales and Kyowa Hakko Kirin's REGPARA sales will only be returned to us if the amount of royalties received by the purchasers exceeds two and a half times the amounts paid to us by DRI.

Our ability to achieve profitability in the future depends on the successful commercialization and further development of Gattex and Natpara. We expect to incur significant expenditures in connection with the commercialization of Gattex in the United States and further development and effort to seek regulatory approval for Natpara. If sales revenue from Gattex is insufficient, we may never achieve profitability. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Pursuant to the Company's license agreement with Amgen, so long as a patent infringement proceeding by a third party against Amgen continues for the manufacture, use or sale of a compound under the agreement in any country, Amgen may reserve up to 50% of the royalties otherwise payable by Amgen with respect to the affected compound in the country in question until the proceedings are concluded. If the third party's patent is finally determined to be un infringed, unenforceable or invalid, Amgen is required to promptly pay the reserved royalties to us. If the third party's patent is held to be valid and infringed or if Amgen enters into a settlement of such infringement claim, then Amgen may deduct any damages or settlement amount with respect to such claim from the reserved royalties prior to payment of any remaining amount. In the event any damages and/or settlement amounts exceed the amount of reserved royalties, Amgen could withhold such excess from its future royalty obligations in that country. If Amgen reserves or reduces the royalties paid on Sensipar sales as a result of a third party claim, our ability to repay the non-recourse Sensipar Notes on a timely basis could be adversely affected. In addition, if any such claim is successful or if Amgen settles the claim, the right to receive future royalty payments on the sales of Sensipar may never be returned to us.

### *We may require additional funds.*

Currently, we are not a self-sustaining business and certain economic, operational and strategic factors may require us to secure additional funds. If we are unable to obtain sufficient funding at any time in the future, we may not be able to develop or commercialize our products, take advantage of business opportunities or respond to competitive pressures.

Our current and anticipated operations require substantial capital. We expect that our existing cash, cash equivalents, and short-term investments will sufficiently fund our current and planned operations through at least 2013. However, our future capital needs will depend on many factors, including the extent to which we are able to generate sales of Gattex, enter into collaboration agreements, receive royalty and milestone payments from our collaborators and make progress in our development and commercialization activities. Our capital requirements will also depend on the magnitude and scope of these activities, our ability to maintain existing collaborations and establish new collaborations, the terms of those collaborations, the success of our collaborators in developing and marketing products under their respective collaborations with us, our ability to effectively out-source our clinical development, regulatory, data management, research, quality control and assurance, and other activities, the success of our contract manufacturers in producing clinical and commercial supplies of our product candidates and drug delivery devices on a timely basis and in sufficient quantities to meet our requirements, competing technological and market developments, the time and cost of obtaining regulatory approvals, the cost of preparing, filing, prosecuting, maintaining and enforcing patent and other rights and our success in acquiring and integrating complementary products, technologies or companies. We do not

have committed external sources of funding, and we cannot assure you that we will be able to obtain additional funds on acceptable terms, if at all. If adequate funds are not available, we may be required to:

- engage in equity financings that would be dilutive to current stockholders;
- delay or reduce the scope of our efforts to commercialize Gattex;
- delay, reduce the scope of or eliminate one or more of our development programs;
- obtain funds through arrangements with collaborators or others that may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves; or
- license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available.

In addition, the capital and credit markets have experienced extreme volatility and historical disruptions have led to uncertainty and liquidity issues for both companies seeking equity or debt refinancing and investors and lenders. In the future, we may not be able to obtain capital market financing on favorable terms, or at all, which could have a material adverse effect on our business and results of operations.

***Our ability to successfully commercialize Gattex is important to our future success.***

We developed Gattex as a treatment for SBS. In January 2011, we reported positive findings from a Phase 3 study, known as STEPS, for Gattex. Based in part on those results, in November 2011, we submitted a New Drug Application (NDA) to the FDA seeking marketing approval of Gattex for the treatment of adult short bowel syndrome (SBS). On January 30, 2012, the FDA accepted for review the NDA that we submitted for Gattex for the treatment of SBS in the United States, and on December 21, 2012, the FDA approved Gattex for the treatment of SBS. We intend to commercialize Gattex ourselves in the United States. Towards that end we have developed a small internal sales force that will call upon targeted physicians and have executed distribution agreements with five of the leading home infusion companies in the United States. We have no prior experience commercializing a pharmaceutical product and we may be unable to successfully commercialize Gattex. Gattex has been designated an “orphan drug” by the FDA and the number of patients who could benefit from treatment with Gattex is small. We will need to penetrate a significant portion of this potential patient population in order to successfully commercialize Gattex. If we are unable to successfully commercialize Gattex, our business and financial results and condition will be adversely affected.

***We have limited marketing and sales experience and have never distributed a product and may need to rely on third parties to successfully market and sell certain of our products and generate revenues.***

Other than the small internal sales force we have established for the commercialization of Gattex, we do not have commercial sales and related field operations. As a result, if and when we receive regulatory approval to market and sell one or more of our product candidates, we will have to either further build our internal commercial organization or enter into agreements with contract sales organizations to provide sales, marketing, market research and product planning services. Our ability to gain market acceptance and generate revenues will be substantially dependent upon our ability to build a commercial organization and/or enter into such agreements on favorable terms and to manage the efforts of those service providers successfully. We may also benefit from establishing a relationship with one or more companies with existing distribution systems and direct sales forces to market any or all of our product candidates; however, we cannot assure you that we will be able to enter into or maintain agreements with these companies on acceptable terms, if at all.

***If the market opportunities for any products we develop are smaller than we believe they are, then our revenues may be adversely affected and our business may suffer.***

Each of the diseases that Gattex has been developed to address, and that Natpara and our other product candidates are being developed to address, is relatively rare. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with Gattex, Natpara and our product candidates, are based on estimates.

Currently, most reported estimates of the prevalence of these diseases are based on studies of small numbers or small subsets of the population of specific geographic areas, which are then extrapolated to estimate the prevalence of the diseases in the broader world population. If our estimates of the prevalence of short bowel syndrome or hypoparathyroidism, or of the number of patients who may benefit from treatment with Gattex, Natpara and our product candidates prove to be incorrect, the market opportunities for Gattex, Natpara and our product candidates may be

smaller than we believe they are and our prospects for generating revenue may be adversely affected and our business may suffer.

***Adverse safety events involving Gattex or our product candidates can negatively affect our business and stock price.***

Adverse safety events involving Gattex or Natpara or any of our other product candidates which may receive marketing approval in the future may have a negative impact on our commercialization efforts. Later discovery of safety issues with Gattex, Natpara or our product candidates that were not known at the time of their approval by the FDA or comparable regulatory agencies in other countries could cause product liability events, additional regulatory scrutiny and requirements for additional labeling, withdrawal of products from the market and the imposition of fines or criminal penalties. Any of these actions could result in material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges and other adverse impacts on our results of operations. In addition, the reporting of adverse safety events involving our products and public rumors about such events could cause our stock price to decline or experience periods of volatility.

***If we do not receive regulatory approval to market our product candidates in a timely manner, or at all, or if we obtain regulatory approval to market those product candidates but the approved label is not competitive with then existing competitive products, our business will be materially harmed and our stock price may be adversely affected.***

Our future success is dependent on our ability to successfully develop additional product candidates. We are developing Natpara as a potential treatment for hypoparathyroidism and have two other product candidates in early stages of clinical development.

In November 2011, we reported positive top-line results from our Phase 3 registration study of Natpara, known as REPLACE, as the first hormone replacement therapy for hypoparathyroidism. Based on the REPLACE results, we plan to file for U.S. marketing approval of Natpara however, the timing of the filing will be dependent on when the manufacturing issue is resolved.

For more information on the development of our product candidates, see “Item 1 – Business – Proprietary Product Candidates.”

While we presently believe that we have the financial resources to fund the continued development of our product candidate, Natpara, in the U.S., we may need to obtain additional funding to continue development of our other product candidates. The FDA’s regulatory review and approval process is extensive, lengthy, expensive and inherently uncertain. To receive approval for a product candidate, we must, among other things, demonstrate to the FDA’s satisfaction with substantial evidence from well-controlled pre-clinical and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. We cannot predict if or when we might receive regulatory approvals for any of our product candidates currently under development.

If we submit a BLA for Natpara, there may be delays in the FDA review process. As part of PDUFA, the FDA has a goal to review and act on submissions in a given time frame. The FDA is not bound by, and has in the past missed, its PDUFA goals, and it is unknown whether the review of our future BLA filing for Natpara, or for any of our other drug candidates, will be completed within the FDA review goals or will be delayed.

Even if our product candidates receive regulatory approval from the FDA, any approvals that we obtain could contain significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use, or the requirement that we implement a risk evaluation and mitigation strategy. In such an event, our ability to generate revenues from such products could be greatly reduced and our business could be harmed.

The FDA has substantial discretion in the approval process and may either refuse to consider any applications we may file with respect to Natpara or any of our other product candidates for substantive review or may form the opinion after review of our data for Natpara or any of our other product candidates that our application is insufficient to allow approval of Natpara or our other product candidates. Even if we believe that data collected from our preclinical studies and clinical trials of our product candidates are promising, our data may not be sufficient to support marketing approval by the FDA, or regulatory interpretation of these data and procedures may be unfavorable. If the FDA does not accept or approve an application that we submit, it may require that we conduct additional clinical, pre-clinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and



completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our future applications for approval, which might significantly harm our business and prospects. As a result, we cannot predict when or whether regulatory approval will be obtained for any product candidate we develop.

Obtaining approval of a NDA or other submission by the FDA or a comparable foreign regulatory authority is inherently uncertain. Even after completing clinical trials and other studies, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- we may not be able to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any indication;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or other studies;
- the results of our clinical trials or other studies may not demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or other studies;
- the data collected from clinical trials and other studies of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical and other study data insufficient for approval; and
- the FDA or comparable foreign regulatory authorities may not approve the proposed manufacturing processes and facilities for a product candidate.

If we are ultimately unable to obtain regulatory approval to commercialize any one of our product candidates in a timely manner, or at all, or if the FDA approved indication, side effect and adverse events profile, and product distribution requirements are not competitive with existing competitor products or therapies:

- Our ability to generate revenues to sustain our operations will be substantially impaired, which would increase the likelihood that we would need to obtain additional financing for our other development efforts;
- Our reputation among investors might be harmed, which might make it more difficult for us to obtain equity capital on attractive terms or at all; and
- Our profitability would be delayed, our business will be materially harmed and our stock price may be adversely affected.

Biotechnology stock prices, including our stock price, have declined significantly in certain instances where companies have failed to meet expectations with respect to FDA approval or the timing for FDA approval.

***We may never develop any more commercial drugs or other products that generate revenues.***

To date, Sensipar (Mimpara in Europe), REGPARA in Japan, Preotact and Nucynta have been our only sources, to date, of commercial revenues. While we expect to commence generating revenues from the launch of our recently FDA-approved product Gattex in 2013, we cannot predict the amount of revenues we may receive from sales of Gattex. Our product candidates under development will require significant additional development, clinical trials, regulatory approvals and additional investment before their commercialization. Our product development efforts may not lead to commercial drugs for a number of reasons, including our inability to demonstrate that our product candidates are safe and effective in clinical trials or a lack of financial or other resources to pursue the programs through the clinical trial process. Even if we are able to successfully develop one or more of our product candidates, our ability to generate sales of any such products will depend on many factors, including the extent to which such product is accepted by the medical community. We cannot assure you that Gattex, Natpara or any other product candidate we may be able to develop will find acceptance in the medical community.

***Our dependence on contract research organizations could result in delays in and additional costs for our drug development efforts.***

We rely almost entirely on contract research organizations, or CROs, to perform preclinical testing and clinical trials for drug candidates that we choose to develop without a collaborator. If the CROs that we hire to perform our preclinical testing and clinical trials or our collaborators or licensees do not meet deadlines, do not follow proper procedures, or a conflict arises between us and our CROs, our preclinical testing and clinical trials may take longer than expected, may be delayed or may be terminated. If we were forced to find a replacement CRO to perform any of our preclinical testing or clinical trials, we may not be able to find a suitable replacement on favorable terms, if at all. Even if we were able to find another CRO to perform a preclinical test or clinical trial, any material delay in a test or clinical trial may result in significant additional expenditures that could adversely affect our operating results. Events such as these may also delay regulatory approval for our drug candidates or our ability to commercialize our products.

In addition, we may enter into agreements with collaborators or licensees to advance certain of our drug candidates through the later-stage, more expensive clinical trials, rather than invest our own resources to conduct these clinical trials. Depending on the terms of our agreements with these collaborators or licensees, we may have little or no control over the manner in which these clinical trials are conducted, and would be subject to other risks that are similar to those associated with our reliance on CROs, as described above.

***We depend exclusively on third parties, including a number of sole suppliers, for the manufacture, supply, testing, and storage of Gattex, our product candidates and drug delivery devices; if these third parties fail to supply us with sufficient quantities of products and devices on a timely basis, or if the products and devices they provide do not meet our specifications, our product sales may be reduced and our clinical trials and product introductions may be delayed or suspended***

We do not have the internal manufacturing capabilities to produce the supplies of Gattex that are needed to support the commercial launch of this product or the supplies of Natpara that are needed to support clinical trials or the commercial launch of this product, if it is approved. We also do not have internal manufacturing capabilities to produce supplies of the injection devices used to administer Gattex and Natpara. We are dependent on third parties for the manufacture, supply, testing, and storage of our product candidates and injection devices. If we are unable to contract for a sufficient supply of our product candidates or injection devices on acceptable terms, or if we encounter delays or difficulties in the manufacturing or supply process we may not have sufficient product or injection devices to support the commercial launch of our products which may receive marketing approval or conduct or complete clinical trials of our product candidates.

We depend on a number of contract manufacturers to supply key components of Gattex and Natpara. For a description of our agreements with these manufacturers, see “Item 1. – Business – Manufacturing.” The process for manufacturing biological products is complex and no assurances can be provided that our manufacturers will be able to produce the required quantities in a timely manner or at all.

We have experienced certain instances where our contract manufacturers have produced product and injection devices that have not met our required specifications and could not be used in clinical trials or for commercialization. Any extended disruption or termination of our relationship with any of our contract manufacturers could materially harm our business and financial condition and adversely affect our stock price.

Due to a technical production issue, we are presently unable to have batches of Natpara finished product manufactured that are consistently within our specifications. The required manufacturing specifications related to the current problem are the same for Natpara as for Preotact (marketed in certain countries in the EU by our ex-US partner Takeda). Previously, 140 consecutive production runs for the finished product of this compound had been produced over a five year period for clinical trial and commercial supplies. We are working, and we understand that Takeda is working, with our suppliers to identify the cause of the out-of-specification production runs. We have met with FDA to discuss our Human Factors/Usability testing of the Natpara injection pen device. The final study will be initiated in March 2013 with results expected in the second quarter of 2013. We continue to work toward submitting our U.S. Biologics License Application (BLA) for Natpara. In order to finalize our submission, we need to resolve certain previously disclosed manufacturing issues. We expect to complete certain key root cause analyses during the second quarter of 2013. Subject to resolution of manufacturing issue, we expect to submit our BLA in the second half of 2013. This issue only pertains to finished product for commercial supply; we currently have sufficient clinical supplies to support our ongoing studies into at least early 2014. It is our understanding that Takeda is no longer selling Preotact in their territory and we have not received any information as to when or if Takeda will re-introduce Preotact in the future.

Dependence on contract manufacturers for commercial production involves a number of additional risks, many of which are outside our control. These additional risks include:

- there may be delays as manufacturers scale-up to quantities needed for clinical trials and the commercial launch of our product candidates; manufacturers may be unable to manufacture such quantities to our specifications, or to deliver such quantities on the dates we require;
- our current and future manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and international regulatory authorities for compliance with strictly enforced cGMP regulations and similar foreign standards, and we are unable to ensure their compliance with these regulations and standards;
- our current and future manufacturers may not be able to comply with applicable regulatory requirements, which would prohibit them from manufacturing products or drug delivery devices for us;
- if we need to change to other commercial manufacturing contractors, the FDA and comparable foreign regulators must first approve these contractors, which would require new testing and compliance inspections, and the new manufacturers would have to be educated in, or themselves develop substantially equivalent processes necessary for, the production of our products and drug delivery devices;
- our manufacturers might not be able to fulfill our commercial needs, which would require us to seek new manufacturing arrangements that could result in substantial delays and higher costs; and
- we may not have intellectual property rights, or may have to share intellectual property rights, to any improvements in the manufacturing processes or new manufacturing processes for our products or drug delivery devices.

Any of these factors could cause us to delay or suspend commercialization of our approved products or the clinical trials, regulatory submission or required approvals of our products candidates under development, entail higher costs and result in our inability to commercialize our products effectively.

In addition, if we receive regulatory approval for Natpara for hypoparathyroidism there is no guarantee that we will be able to successfully complete the development of an injection device or that our supplier will be able to adequately supply our potential commercial needs.

***We are subject to extensive government regulations that may cause us to cancel or delay the introduction of our products to market.***

Our business is subject to extensive regulation by governmental authorities in the U.S. and other countries. Prior to marketing in the United States, a drug must undergo rigorous testing and an extensive regulatory approval process implemented by the FDA under federal law, including the Federal Food, Drug and Cosmetic Act. To receive approval, our collaborators or we must demonstrate, among other things, with substantial evidence from well-controlled clinical trials that the product is both safe and effective for each indication where approval is sought. Depending upon the type, complexity and novelty of the product and the nature of the disease or disorder to be treated, the approval process can take several years and require substantial expenditures. Data obtained from testing are susceptible to varying interpretations that could delay, limit or prevent regulatory approvals of our products. Drug testing is subject to complex FDA rules and regulations, including the requirement to conduct human testing on a large number of test subjects. Our collaborators, the FDA or we may suspend human trials at any time if a party believes that the test subjects are exposed to unacceptable health risks. We cannot assure you that any of our product candidates will be safe for human use. Other countries also have extensive requirements regarding clinical trials, market authorization and pricing. These regulatory requirements vary widely from country to country, but, in general, are subject to all of the risks associated with U.S. approvals.

With respect to any of our products that may receive regulatory approval, the approval will be limited to those disease states and conditions for which the product is safe and effective, as demonstrated through clinical trials and as defined by the regulatory agency. In addition, results of preclinical studies and clinical trials with respect to our products could subject us to adverse product labeling requirements that could harm the sale of such products. Even if regulatory approval is obtained, later discovery of previously unknown problems may result in restrictions of the product, including withdrawal of the product from the market. Further, governmental approval may subject us to ongoing requirements for post-marketing studies. Even if we obtain governmental approval, a marketed product, its respective manufacturer and its manufacturing facilities are subject to unannounced inspections by the FDA and must comply with the FDA's cGMP and other regulations. These regulations govern all areas of production, record keeping, personnel and quality control. If a manufacturer fails to comply with any of the manufacturing regulations, it may be

subject to, among other things, product seizures, recalls, fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecution. Other countries also impose similar manufacturing requirements. Our promotional materials and sales activities are governed by FDA regulation. The FDA may require us to withdraw promotional material, to issue corrected material, or to cease promotion resulting in loss of credibility with our customers, reduced sales revenue or increased costs.

Steps similar to those in the U.S. must be undertaken in virtually every other country comprising the market for our product candidates before any such product can be commercialized in those countries. The approval procedure and the time required for approval vary from country to country and may involve additional testing. There can be no assurance that approvals will be granted on a timely basis, or at all.

***Clinical trials are long, expensive and have uncertain outcomes; if the data collected from preclinical and clinical trials of our product candidates are not sufficient to support approval by the FDA, our future profitability and stock price could be adversely affected.***

Before we receive regulatory approval for the commercial sale of our product candidates, our product candidates are subject to extensive preclinical testing and clinical trials to demonstrate their safety and efficacy. Clinical trials are long, expensive and uncertain processes. Clinical trials may not be commenced or completed on schedule, and the FDA may not ultimately approve our product candidates for commercial sale.

Further, even if the results of our preclinical studies or clinical trials are initially positive, it is possible that we will obtain different results in the later stages of drug development or that results seen in clinical trials will not continue with longer-term treatment. Drugs in late stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. For example, positive results in early Phase 1 or Phase 2 clinical trials may not be repeated in larger Phase 2 or Phase 3 clinical trials. All of our potential drug candidates are prone to the risks of failure inherent in drug development. The clinical trials of any of our drug candidates, including Natpara, could be unsuccessful, which would prevent us from commercializing the drug. Our failure to develop safe, commercially viable drugs would substantially impair our ability to generate revenues and sustain our operations and would materially harm our business and adversely affect our stock price.

***If we fail to maintain our existing or establish new collaborative relationships, or if our existing collaborations fail, or if our collaborators do not devote adequate resources to the development and commercialization of our licensed drug candidates, we may have to reduce our rate of product development and may not see products brought to market or be able to achieve profitability.***

One of our strategies for developing, manufacturing and commercializing our products includes entering into various relationships with other pharmaceutical and biotechnology companies to advance many of our programs. We have granted development, commercialization and marketing rights to a number of our collaborators for some of our key product development programs, including cinacalcet HCl, Preotact, teduglutide and calcilytics. Our collaborators typically have full control over those efforts in their territories and the resources they commit to the programs. Accordingly, the success of the development and commercialization of product candidates in those programs depends on the efforts of our collaborators and is beyond our control. For us to receive any significant milestone or royalty payments from our collaborators, they must advance drugs through clinical trials, establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of those products. As a result, if a collaborator elects to terminate its agreement with us with respect to a research program, our ability to advance the program may be significantly impaired or we may elect to discontinue funding the program altogether. For example, in early 2002, Abbott terminated its agreement with respect to isovaleramide, and Forest Laboratories terminated its agreement with us with respect to ALX-0646. As a result, these programs were discontinued. As an additional example, in September 2008, we were notified by GSK that it had decided to terminate a Phase 2 dose-range finding study of ronacaleret in post-menopausal women with osteoporosis earlier than expected due to an observed lack of efficacy based on lumbar spine and hip bone mineral density. The counterparties to certain of our collaborative research, development or commercial agreements have the right to terminate those agreements prior to their expiration after providing us with the requisite notice. See the description of these agreements under “Item 1 – Business – Royalty-Based Products and Product Candidates.”

As part of our product development and commercialization strategy, we evaluate whether to seek collaborators for our product candidates. If we elect to collaborate, we may not be able to negotiate collaborative arrangements for our product candidates on acceptable terms, if at all. If we are unable to establish collaborative arrangements, we will

either need to increase our expenditures and undertake the development and commercialization activities at our own expense or delay further development of the affected product candidate.

Collaborative agreements, including our existing collaborative agreements, pose the following risks:

- our contracts with collaborators may be terminated and we may not be able to replace our collaborators;
- the terms of our contracts with our collaborators may not be favorable to us in the future;
- our collaborators may not pursue further development and commercialization of compounds resulting from their collaborations with us or may pursue the same on a different regulatory pathway from us;
- a collaborator with marketing and distribution rights to one or more of our product candidates may not commit enough resources to the marketing and distribution of such candidates;
- disputes with our collaborators may arise, leading to delays in or termination of the research, development or commercialization of our product candidates, or resulting in significant litigation or arbitration;
- contracts with our collaborators may fail to provide significant protection if one or more of them fail to perform;
- in some circumstances, if a collaborator terminates an agreement, or if we are found to be in breach of our obligations, we may be unable to secure all of the necessary intellectual property rights and regulatory approval to continue developing the same compound or product;
- our collaborators could independently develop, or develop with third parties, drugs that compete with our products; and
- we may be unable to meet our financial or other obligations under our collaborative agreements.

We cannot assure you that our current or future collaborative efforts will be successful. If our collaborative efforts fail, our business and financial condition would be materially harmed.

***Because of the uncertainty of pharmaceutical pricing, reimbursement and healthcare reform measures, we or our licensees may be unable to sell our products profitably.***

The availability of reimbursement by governmental and other third-party payers affects the market for any pharmaceutical product. These third-party payers continually attempt to contain or reduce the costs of healthcare. There have been a number of significant legislative and regulatory changes to the healthcare system enacted in recent years and further proposals and changes are likely. Medicare's policies may decrease the market for our products. Significant uncertainty exists with respect to the reimbursement status of newly approved healthcare products.

In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. We might not be able to sell our products profitably or recoup the value of our investment in product development if reimbursement is unavailable or limited in scope, particularly for product candidates addressing small patient populations, such as Gattex for the treatment of short bowel syndrome and Natpara for hypoparathyroidism. We have established a price for Gattex based upon its status as an orphan drug which could be viewed as excessive by third-party payers and could have a negative impact on our ability to sell Gattex. We cannot assure you concerning the level of reimbursement we will be able to obtain from third-party payers for Gattex.

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. We expect that there will continue to be a number of U.S. 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.

On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms to establish a bundled Medicare payment rate that includes services and drug/labs that are currently separately billed. A rule by the Centers for Medicare and Medicaid Services requires the inclusion of certain oral drugs such as Sensipar® (cinacalcet HCl) as part of the end stage renal disease Program of Medicare bundled payment. The implementation of this program is currently not expected to begin until at least 2016. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment. We cannot speculate on the sales impact to Sensipar based on the new rule.

Changes in government regulations or private third-party payers' reimbursement policies may reduce reimbursement for our products and adversely affect our future results. In addition, when a new medical product is approved, the availability of government and private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement for our product candidates.

In the U.S., federal and state legislatures, health agencies and third-party payers continue to focus on containing the cost of health care. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively PPACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. We will not know the full effects of PPACA until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of PPACA, the new law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, the Budget Control Act of 2011 mandates, among other things, reductions in Medicare payment rates if a sufficient deficit reduction plan is not approved and a reduction in funding for Medicare, Medicaid or similar government programs may adversely affect our future results. Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for our drugs. In recent years, some states have considered legislation that would control the prices of drugs. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

In the European Union and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries are reducing their public expenditures and we expect to see strong efforts to reduce healthcare costs in international markets, including patient access restrictions, suspensions on price increases, prospective and possibly retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases, and greater importation of drugs from lower-cost countries to higher-cost countries. These cost control measures could reduce our revenues. In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may not only limit the marketing of our products within that country, but may also adversely affect our ability to obtain acceptable prices in other markets. This may create the opportunity for third party cross border trade or influence our decision to sell or not to sell a product, thus adversely affecting our geographic expansion plans and revenues.

***Because of intense competition and technological change in the pharmaceutical industry, the marketplace may not accept our products, and we may not be able to compete successfully against other companies in our industry and achieve profitability.***

The pharmaceutical and biotechnology industries are intensely competitive, with many companies in our industry having substantially greater financial and management resources, superior intellectual property positions and greater manufacturing, marketing and sales capabilities, areas in which we have limited or no experience. In addition, many companies have significantly greater experience than we do in undertaking preclinical testing and clinical trials of new or improved pharmaceutical products and obtaining required regulatory approvals. Consequently, competitors may obtain FDA and other regulatory approvals for product candidates sooner and may be more successful in manufacturing and marketing their products than we or our collaborators, which could render our products and product candidates obsolete and non-competitive.

Existing and future products, therapies and technological approaches may compete directly or indirectly with any of the products we develop. Existing and prospective competing products or other therapies may provide greater therapeutic benefits for a specific problem, may offer easier delivery or may offer comparable performance at a lower cost. Products approved for other indications may be used "off-label" in competition with our products. Any product candidate that we develop and that obtains regulatory approval must then compete for market acceptance and market

share. Any products we develop may not gain market acceptance among physicians, patients, healthcare payers and the medical community. Further, any products we develop may become obsolete before we recover any expenses we incurred in connection with the development of these products. As a result, we may never achieve profitability.

***We may be unable to obtain patents to protect our technologies from other companies with competitive products, our patents may be challenged or circumvented by third parties, and patents of other companies could prevent us from manufacturing, developing or marketing our products.***

The patent positions of pharmaceutical and biotechnology firms are uncertain and involve complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents. If it allows broad claims, the number and cost of patent administrative proceedings in the U.S. and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. In addition, the scope of the claims in a patent application can be significantly modified during prosecution before the patent is issued. For example, third parties may submit prior art during prosecution of our patent applications that affects the scope of any allowed claims. Consequently, we cannot know whether our pending applications will result in the issuance of patents or, if any patents are issued, whether they will provide us with significant proprietary protection or will be circumvented, invalidated, or found to be unenforceable. Patent applications in the U.S. used to be maintained in secrecy until the patents were issued, and publication of discoveries in scientific or patent literature often lags behind discoveries. Patent applications filed in the U.S. after November 2000 generally will be published 18 months after the filing date unless the applicant certifies that the invention will not be the subject of a foreign patent application. We cannot assure you that, even if published, we will be aware of all such literature. Accordingly, we cannot be certain that the named inventors of our products and processes were the first to invent that product or process or that we were the first to pursue patent coverage for our inventions.

Our commercial success depends in part on our ability to maintain and enforce our proprietary rights. If third parties engage in activities that infringe our proprietary rights we may incur significant costs in asserting our rights. We may not be successful in asserting our proprietary rights, which could result in our patents being held invalid or a court holding that the third party is not infringing, either of which would harm our competitive position. In addition, we cannot assure you that others will not design around our patented technology.

Moreover, we may have to participate in derivation, reexamination, inter parties review, post grant review, or other U.S. Patent and Trademark Office administrative proceedings in other parts of the world to determine priority of invention and the validity of patent rights granted or applied for, which could result in substantial cost and delay, even if the eventual outcome is favorable to us. We cannot assure you that our pending patent applications, if issued, would be held valid or enforceable. Additionally, many of our foreign patent applications have been published as part of the patent prosecution process in such countries. Protection of the rights revealed in published patent applications can be complex, costly and uncertain.

Additionally, under the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act), a generic pharmaceutical manufacturer may file an Abbreviated New Drug Application, or ANDA, seeking permission to market a generic version of one of our products prior to the expiration of our relevant patents. For example, on June 15, 2008, we reported the receipt of Paragraph IV certification notification letters related to ANDAs submitted to the FDA by Barr Laboratories and Teva Pharmaceuticals USA, Inc. requesting approval to market and sell generic versions of cinacalcet HCl. Such a filing is an act of patent infringement and resulted in our filing patent infringement litigation to enforce our proprietary rights. Although we were ultimately successful in our patent infringement lawsuit against Barr Laboratories and Teva Pharmaceuticals USA, Inc., we could face additional challenges from generic pharmaceutical manufacturers seeking approval for generic versions of our products. Defending such challenges could be costly and the results uncertain.

Additionally the legislative implications of the Biologic Price Competition and Innovation Act of 2009 that became effective in March 2010 are still being defined and regulatory precedence is limited. Manufacturers of biosimilar or other competing products may seek FDA approval for such products, and the process for challenging such products is evolving and uncertain.

In order to protect goodwill associated with our company and product names, we rely on trademark protection for our marks. We have registered the "PREOS", "Gattex" and "Natpara" trademarks with the U.S. Patent and Trademark Office. A third party may assert a claim that one of those marks is confusingly similar to its mark, and such claims or

the failure to timely register a mark or objections by the FDA could force us to select a new name for our product candidates, which could cause us to incur additional expense or delay the introduction of a product candidate to market.

We also rely on trade secrets, know-how and confidentiality provisions in our agreements with our collaborators, employees and consultants to protect our intellectual property. However, these and other parties may not comply with the terms of their agreements with us, and we might be unable to adequately enforce our rights against these people or obtain adequate compensation for the damages caused by their unauthorized disclosure or use. Our trade secrets or those of our collaborators may also become known or may be independently discovered by others.

***We granted security interests in our intellectual property in connection with the agreements to monetize Preotact and REGPARA, and these security interests could be enforced against us if we default on these agreements.***

In connection with our July 2007 agreement with DRI Capital, or DRI (formerly Drug Royalty L.P.3) to monetize Preotact, we granted DRI a security interest in the our license agreement with Takeda for Preotact and certain of our patents related to Preotact and other intellectual property underlying that agreement. In the event of our default under the agreement with DRI, DRI would be entitled to enforce its security interest against us and the property described above. If DRI validly enforced its security interest, we could potentially lose rights to our Preotact intellectual property.

In addition, in connection with our February 2010 agreement with an affiliate of DRI or DRI, we granted DRI a security interest in our license agreement with Kyowa Hakkō Kirin and certain of our patents related to REGPARA and other intellectual property underlying that agreement. In the event of our default under the agreement with DRI, DRI would be entitled to enforce its security interest against us and the property described above. If DRI validly enforced its security interest, we could potentially lose rights to our REGPARA intellectual property.

***Our products and product candidates may infringe the intellectual property rights of others, which could increase our costs and negatively affect our profitability.***

Our success also depends on avoiding infringement of the proprietary technologies of others. In particular, there may be certain issued patents and patent applications claiming subject matter that our collaborators or we may be required to license in order to research, develop or commercialize at least some of our product candidates, including Gattex, Natpara and Preotact. In addition, third parties may assert infringement or other intellectual property claims against us based on our patents or other intellectual property rights. An adverse outcome in these proceedings could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease or modify our use of the technology. If we are required to license such technology, we cannot assure you that a license under such patents and patent applications will be available on acceptable terms or at all. Further, we may incur substantial costs defending ourselves in lawsuits against charges of patent infringement or other unlawful use of another's proprietary technology.

***If we fail to attract and retain key executives and employees, the development and commercialization of our products may be adversely affected.***

We depend heavily on our executive, managerial and clinical personnel. To the extent that we lose any of these key personnel, our ability to develop products and become profitable may suffer. The risk of being unable to retain key personnel may be increased by the fact that, other than with respect to our CEO, we have not entered into long-term employment contracts with our executives or employees. Our future success will also depend in large part on our ability to attract and retain qualified executives and employees in the future. We face competition for personnel from other companies, academic institutions, government entities and other organizations. In particular, we are highly dependent on members of our executive team to manage our business. Each member of our executive team is highly qualified, important to our business and would be difficult to replace. We are also dependent on several key employees who would also be difficult to replace. If we are unable to retain our executives and key employees, our ability to operate under the outsourcing business model we have adopted and compete in our industry may be hindered and our business may suffer. Each of our executives and key employees is an employee at will and, despite our retention efforts; we cannot assure you that they will remain with the company.



***If product liability claims are brought against us or we are unable to obtain or maintain product liability insurance, we may incur substantial liabilities that could reduce our financial resources.***

The clinical testing and commercial use of pharmaceutical products involves significant exposure to product liability claims. We have obtained product liability insurance coverage for commercial sales of Gattex we consider adequate and in conformance with industry standards and limited product liability insurance coverage for the clinical trials of our product candidates; however, our insurance coverage may be insufficient to protect us against all product liability damages. Further, liability insurance coverage is becoming increasingly expensive and we might not be able to obtain or maintain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us against product liability damages. Regardless of merit or eventual outcome, liability claims may result in decreased demand for a future product, injury to our reputation, withdrawal of clinical trial volunteers, loss of revenue, costs of litigation, distraction of management and substantial monetary awards to plaintiffs. Additionally, if we are required to pay a product liability claim, we may not have sufficient financial resources to complete development or commercialization of any of our product candidates and our business and results of operations will be adversely affected.

***Research and development involves hazardous materials and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.***

Research and development activities involve the controlled use of hazardous materials, radioactive compounds and other potentially dangerous chemicals and biological agents. We utilize contractors to dispose of the hazardous materials we use in our research and development activities and although we believe our contractors' safety procedures for these materials comply with governmental standards, we cannot eliminate the risk of accidental contamination or injury from these materials. We currently have insurance, in amounts and on terms typical for companies in businesses that are similarly situated, that could cover all or a portion of a damage claim arising from our use of hazardous and other materials. However, if an accident or environmental discharge occurs, and we are held liable for any resulting damages, the associated liability could exceed our insurance coverage and our financial resources.

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

***Our stock price has been and likely will continue to be volatile and an investment in our common stock could suffer a decline in value.***

You should consider an investment in our common stock as risky and invest only if you can withstand a significant loss and wide fluctuations in the market value of your investment. The market price of our common stock has been highly volatile and is likely to continue to be volatile. Factors affecting our common stock price include:

- fluctuations in our operating results;
- our ability to meet market expectations with respect to our sales of Gattex in the US;
- our ability to meet market expectations with respect to FDA approval or the timing for FDA approval for Natpara and our other product candidates;
- announcements of technological innovations or new commercial products by us, our collaborators or our competitors;
- published reports by securities analysts;
- the progress of our and our collaborators' clinical trials, including our and our collaborators' ability to produce clinical supplies of our product candidates on a timely basis and in sufficient quantities to meet our clinical trial requirements;
- governmental regulation and changes in medical and pharmaceutical product reimbursement policies;
- developments in patent or other intellectual property rights;
- publicity concerning the discovery and development activities by our licensees;
- public concern as to the safety and efficacy of drugs that we and our competitors develop and;
- general market conditions.

***Anti-takeover provisions in our Certificate of Incorporation, Bylaws and under Delaware law may discourage or prevent a change of control.***

Provisions of our Certificate of Incorporation and Bylaws and Section 203 of the Delaware General Corporation Law could delay or prevent a change of control of us. For example, our Board of Directors, without further stockholder approval, may issue preferred stock that could delay or prevent a change of control as well as reduce the voting power of the holders of common stock, even to the extent of losing control to others.

***Substantial future sales of our common stock by us or by our existing stockholders could cause our stock price to fall.***

Additional equity financings or other share issuances by us could adversely affect the market price of our common stock. From time to time we may issue our previously authorized and unissued securities, including shares of our common stock or securities convertible into or exchangeable for our common stock, resulting in the dilution of the ownership interests of our existing stockholders. We have an effective shelf registration statement from which additional shares of our common stock and other securities can be issued at any time. We may also issue additional shares of our common stock or securities convertible into or exchangeable for our common stock in connection with future strategic alliances or acquisitions, future private placements of our securities for capital raising purposes or for other business purposes. In addition, existing shareholders could sell a large number of our shares into the public market. Future issuances or sales of our common stock, or the perception that such issuances or sales could occur, could cause a decline in the price of our common stock.

***Royalty revenues received from Amgen on sales of cinacalcet HCl may not be sufficient to cover the interest and principal payments on our Sensipar Notes; we would have to either voluntarily make such payments out of available cash resources or risk forfeiture of certain royalty rights under the Amgen agreement.***

Our outstanding Sensipar Notes are non-recourse to us and are secured by our royalty and milestone payment rights under our agreement with Amgen. Until the Sensipar Notes are repaid, all royalties earned in excess of \$8.0 million per quarter from Amgen will go to the payment of interest and principal on the notes. If the royalties earned from Amgen are insufficient to cover the interest and other payments due under the notes, we would have to forfeit our rights to future royalties and other rights under the Amgen agreement, unless we make the payments due out of our available cash resources. If we make the payments, our cash resources would be significantly reduced and we may not have sufficient cash resources to fund our programs and operations.

***Our liquidity and future cash flow may not be sufficient to cover interest payments on our 5.75% Convertible Notes due 2014 or to repay the notes at maturity.***

Our ability to make interest payments on and to repay at maturity or refinance our 5.75% convertible notes due 2014 or the Convertible Notes, will depend on our ability to maintain sufficient cash and generate future cash flow. Other than in 2007, we have never generated positive annual cash flow from our operating activities, and we may not generate or sustain positive cash flows from operations in the future. Our ability to generate sufficient cash flow will depend on our ability to commercialize our proprietary products and product candidates in the U.S. and the ability of our partners to commercialize and successfully market our partnered products throughout the world. We cannot assure you that we, or our partners, will be successful in developing, commercializing and marketing our products or product candidates. Various factors such as general economic, financial, competitive, legislative and regulatory conditions may affect our and our partners' ability to successfully commercialize our product candidates and thereby limit our ability to generate future cash flow to repay our Convertible Notes.

Additionally, the Convertible Notes provide for certain events of default, including payment defaults, breaches of covenants and certain events of bankruptcy, insolvency and reorganization. If any event of default occurs and is continuing, the principal amount of the notes, plus accrued and unpaid interest, if any, may be declared immediately due and payable. The notes also provide that if a fundamental change occurs to our business, as defined in the note, at any time prior to the maturity of the note, then the holder shall have the right to require us to redeem the notes, or any portion thereof plus accrued interest and liquidated damages. There can be no assurance that, if any of the foregoing events were to occur, we would have the ability repay the principal amount and interest accrued under the notes and/or any additional monies owed in connection with the acceleration of the notes.

***Conversion of the Convertible Notes will dilute the ownership interest of our existing stockholders, including holders who had previously converted their notes.***

The conversion of some or all of our outstanding Convertible Notes will dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the notes may encourage short selling by market participants.

***Changes in interest rates can affect the fair value of our investment portfolio and the debt we have issued and its interest earnings.***

Our interest rate risk exposure results from our investment portfolio and our non-recourse notes. Our primary objectives in managing our investment portfolio are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. The securities we hold in our investment portfolio are subject to interest rate risk. At any time, sharp changes in interest rates can affect the fair value of the investment portfolio and its interest earnings. Currently, we do not hedge these interest rate exposures. We have established policies and procedures to manage exposure to fluctuations in interest rates. We place our investments with high quality issuers, limit the amount of credit exposure to any one issuer, and do not use derivative financial instruments in our investment portfolio.

The fair value of the Convertible Notes is affected by changes in the interest rates and by changes in the price of our common stock. The fair values of our Sensipar Notes are affected by changes in the interest rates and by historical and future rates of royalty revenues from cinacalcet HCl sales. The fair value of our DRI debt is affected by changes in the interest rates and by historical and future rates of royalty revenues from Preotact and REGPARA sales.

***If securities or industry analysts do not continue to publish research or reports or if they publish unfavorable research about our business, the price of our common stock and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If securities or industry analysts do not continue coverage of us the trading price for our common stock would be negatively affected. If one or more of the analysts who covers us downgrades our common stock, the price of our common stock would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our common stock could decrease, which could cause the price of our common stock or trading volume to decline.

#### **ITEM 1B. Unresolved Staff Comments.**

None.

#### **ITEM 2. Properties.**

We lease approximately 75,000 square feet of administrative space in Bedminster, New Jersey. The Bedminster lease will expire in August 2016.

#### **ITEM 3. Legal Proceedings.**

None.

#### **Executive Officers of the Registrant**

Listed below is information on our executive officers as of February 14, 2013. Executive officers are elected by the Board of Directors for an initial term, which continues until the first Board meeting following the next annual meeting of stockholders and thereafter are re-elected each year for a one-year term or until their successors have been elected. All executive officers serve at the pleasure of the Board of Directors.

**Francois Nader, MD, MBA**

President and Chief Executive Officer

Age: 56

Francois Nader has been President and Chief Executive Officer of NPS since March 2008. Dr. Nader joined NPS in June 2006 and served as Executive Vice President and Chief Operating Officer until March 2008. In that capacity, he was responsible for managing the Company's worldwide research and development, commercial operations, manufacturing and regulatory affairs. Before joining NPS, Dr. Nader was a venture partner at Care Capital, LLC from July 2005 to June 2006, during which time he served as Chief Medical Officer of its Clinical Development Capital unit. From 2000 to July 2005, Dr. Nader was with Aventis Pharmaceuticals where he served as Senior Vice President, Integrated Healthcare Markets and Senior Vice President, North America Medical and Regulatory Affairs. He was also Vice President, North America Medical and Regulatory Affairs and Vice President, U.S. Medical Affairs and Global Health Economics at Hoechst Marion Roussel from 1990 to 1999. Dr. Nader also served as Head of Global Commercial Operations at the Pasteur Vaccines division of Rhone-Poulenc from 1985 to 1990. Dr. Nader received a French State Doctorate in Medicine from St. Joseph University and a Physician Executive M.B.A. from the University of Tennessee.

**Luke M. Beshar, CPA**

Executive Vice President and Chief Financial Officer

Age: 54

Luke Beshar joined NPS in November 2007. He is a former Chief Financial Officer of various public and private companies and has more than 25 years of general and financial management experience. Prior to joining NPS, he served as Executive Vice President and Chief Financial Officer of Cambrex Corporation from December 2002 to November 2007, a global life sciences company, and Senior Vice President and Chief Financial Officer at Dendrite International from January 2002 to December 2002, a leading provider of services to the life sciences industry. Mr. Beshar began his career with Arthur Andersen & Co. in 1980 and is a Certified Public Accountant. Mr. Beshar obtained his B.S. degree in Accounting and Finance from Michigan State University and is a graduate of The Executive Program at the Darden Graduate School of Business at the University of Virginia.

**Roger J. Garceau, MD, FAAP**

Sr. Vice President and Chief Medical Officer

Age: 59

Roger Garceau, MD, joined NPS in December 2008 and brings over 20 years of broad pharmaceutical industry experience to his position. From 2002 to December 2008, Dr. Garceau served in a number of senior leadership positions at Sanofi-Aventis and most recently was vice president of the new products group. Previously, Dr. Garceau held various positions, including vice president of clinical operations, interim head of North American medical and regulatory affairs, and head of U.S. medical research, where he led a team of over 200 professionals and oversaw the design and execution of over 50 sponsored clinical trials in five different therapeutic areas. Prior to his tenure at Sanofi-Aventis, Dr. Garceau spent 16 years with Pharmacia Corporation in global development and medical affairs where he successfully contributed to a number of marketing applications. Dr. Garceau is a board-certified pediatrician. He received a bachelor of science in biology from Fairfield University in Fairfield, Connecticut and his doctorate of medicine from the University of Massachusetts Medical School. He is a Fellow of the American Academy of Pediatrics.

**Glenn Melrose**

Sr. Vice President, Human Resources

Age: 57

Glenn Melrose joined NPS in September 2012 as senior vice president, human resources. Mr. Melrose has more than 25 years of experience within the biomedical industry. He previously was vice president, human resources at Alexion Pharmaceuticals, Inc. from July 2007 to April 2011. Mr. Melrose began his career as a research scientist at the University of Maryland Cancer Center and Becton Dickinson Immunodiagnostics before joining Amersham Diagnostics in 1988. Over the course of 16 years at Amersham Mr. Melrose held several positions of increasing responsibility in sales and marketing before moving into human resources, rising to the position of vice president, human resources, North America, and ultimately leading the worldwide human resources function for Amersham Biosciences. Mr. Melrose received a B.S. in Biology from Washington and Lee University and an M.S. in Experimental Biology from the University of Maryland.

**Eric Pauwels**

Sr. Vice President and Chief Commercial Officer

Age: 51

Eric Pauwels joined NPS in September 2011 as senior vice president and chief commercial officer. Mr. Pauwels has more than 25 years of healthcare experience in biopharmaceuticals and medical devices. Most recently, from January 2011 to September 2011 Mr. Pauwels was senior vice president and chief marketing officer at Accuray Incorporated, a premier radiation oncology company. From 2005 to 2010, Mr. Pauwels served as chief commercial officer of Shire Human Genetic Therapies (Shire HGT), where he led all commercial functions and launched four orphan drugs. From 2000 to 2005, Mr. Pauwels held the position of vice president of global strategic marketing at Bayer Healthcare Pharmaceuticals. Previously, Mr. Pauwels held positions of increasing responsibility in the United States, China, France, and Belgium for Fournier Pharma and Johnson & Johnson. Mr. Pauwels also brings more than 15 years of alliance-management experience to NPS, having managed collaborations with companies such as Abbott, Centocor, Dianippon-Sumitomo, Genzyme, GlaxoSmithKline, Organon, and Takeda. Mr. Pauwels earned his Bachelor of Science degree from California State Polytechnic University in Pomona, California.

**Joseph J. Rogus, PE**

Vice President, Technical Operations and Supply Chain Management

Age: 66

Joseph Rogus joined NPS in April 2007. With over 35 years of pharmaceutical industry experience, Mr. Rogus has a wealth of knowledge of pharmaceutical and technology development through commercialization and marketed product support in the global environment. From 2006 to 2007, Mr. Rogus served as vice president of pharmaceutical development at Chugai Pharma USA. From 2004 to 2005, Mr. Rogus served as senior vice president of technical operations at Advancis Pharmaceutical Corporation. Before his tenure at Advancis, Mr. Rogus spent over 30 years with Schering-Plough Research Institute where he served in a number of key leadership roles, most recently as vice president of pharmaceutical product optimization and clinical supplies management. Mr. Rogus obtained his Bachelor of Science in Chemical Engineering from Newark College of Engineering and his Master of Science in Chemical Engineering from the New Jersey Institute of Technology and is a licensed professional engineer.

**Edward H. Stratemeier, JD, MBA**

Sr. Vice President and General Counsel

Age: 63

Edward Stratemeier joined NPS in October 2009. From 1982 to 2004, Mr. Stratemeier served in a number of senior leadership positions at Sanofi-Aventis and most recently served as general counsel and global senior vice president for Aventis Pharmaceuticals North America and was a member of the North American leadership team. From 2005 to 2009 Mr. Stratemeier was in private practice, counseling pharmaceutical and biotech companies on product life cycle management; patent, regulatory and litigation strategies; and product licensing. Mr. Stratemeier received a J.D. from the University of Missouri at Kansas City and an MBA from Rockhurst College.

**ITEM 4. Mine Safety Disclosures**

**Not applicable.**

## PART II

### ITEM 5. Market for Registrant's Common Equity and Related Stockholder Matters

#### Market Information

Our common stock is quoted on the NASDAQ Global Market under the symbol "NPSP." The following table sets forth, for the periods indicated, the high and low closing sales prices for our common stock, as reported on the NASDAQ Global Market.

	<u>High</u>	<u>Low</u>
<b>2011</b>		
First Quarter	\$ 10.01	\$ 7.16
Second Quarter	10.45	8.84
Third Quarter	10.18	6.11
Fourth Quarter	7.76	4.97
<b>2012</b>		
First Quarter	\$ 8.21	\$ 6.32
Second Quarter	8.61	6.37
Third Quarter	9.25	7.18
Fourth Quarter	10.86	8.89

#### Holders

As of February 14, 2013, there were approximately 150 holders of record of our common stock.

#### Dividends

We have never declared or paid cash dividends on capital stock. We intend to retain any future earnings to finance growth and development and therefore do not anticipate paying cash dividends in the foreseeable future.

Certain of the information required by this item will be contained in our definitive Proxy Statement with respect to our 2013 Annual Meeting of Stockholders under the caption "Equity Compensation Plan Information," and is incorporated into this section by reference.

## ITEM 6. Selected Financial Data.

The selected consolidated financial data presented below are for each fiscal year in the five-year period ended December 31, 2012. This data is derived from, and qualified by reference to, our audited consolidated financial statements and notes thereto appearing elsewhere in this Form 10-K.

### Consolidated Statements of Operations Data:

	Years Ended December 31,				
	2012	2011	2010	2009	2008
<b>(in thousands, except per share amounts)</b>					
Revenues:					
Royalties	\$ 105,587	\$ 96,502	\$ 86,181	\$ 79,339	\$ 70,217
Sale of royalty rights (1)	25,000	-	-	-	-
Product sales	-	99	551	66	4,544
Milestones and license fees	57	5,044	2,682	4,742	27,518
Total revenues	<u>130,644</u>	<u>101,645</u>	<u>89,414</u>	<u>84,147</u>	<u>102,279</u>
Operating expenses:					
Cost of royalties	-	500	-	500	5,831
Cost of goods sold	-	-	6	-	1,350
Cost of license fees	-	2,543	69	481	5,665
Research and development	94,839	73,831	60,814	35,339	18,965
General and administrative	36,929	24,226	18,951	20,101	22,563
Restructuring charges (credits)	-	-	-	26	(272)
Total operating expenses	<u>131,768</u>	<u>101,100</u>	<u>79,840</u>	<u>56,447</u>	<u>54,102</u>
Other operating gains:					
Gain on sale of fixed assets	-	-	-	-	(186)
Total other operating gains	-	-	-	-	(186)
Operating (loss) income	<u>(1,124)</u>	<u>545</u>	<u>9,574</u>	<u>27,700</u>	<u>48,363</u>
Other income (expense):					
Interest income	292	321	418	1,708	4,778
Interest expense	(18,198)	(37,736)	(45,128)	(52,627)	(65,373)
Loss on impairment of marketable investment securities	-	-	-	(2,206)	(20,898)
Gain (loss) on sale of marketable investment securities	4	-	3,751	1,326	(52)
Gain on sale of subsidiary	-	-	-	4,875	-
Other	291	621	1,035	(382)	1,277
Total other expense, net	<u>(17,611)</u>	<u>(36,794)</u>	<u>(39,924)</u>	<u>(47,306)</u>	<u>(80,268)</u>
Loss before income tax expense (benefit)	(18,735)	(36,249)	(30,350)	(19,606)	(31,905)
Income tax expense (benefit)	-	18	1,091	(1,744)	(179)
Net loss	<u>\$ (18,735)</u>	<u>\$ (36,267)</u>	<u>\$ (31,441)</u>	<u>\$ (17,862)</u>	<u>\$ (31,726)</u>
Basic and diluted net loss per share (2)	<u>\$ (0.22)</u>	<u>\$ (0.45)</u>	<u>\$ (0.54)</u>	<u>\$ (0.37)</u>	<u>\$ (0.67)</u>
Basic and diluted weighted average shares outstanding (2)	86,999	81,279	58,607	48,271	47,699

(1) In June 2012, we amended our agreement with Amgen and received a one-time non-refundable \$25.0 million payment in July 2012 in exchange for our rights to receive royalties under the license agreement that are earned after December 31, 2018.

(2) See note 1 to the consolidated financial statements for information concerning the computation of net loss per share.

## Consolidated Balance Sheets Data:

	Years Ended December 31,				
	2012	2011	2010	2009	2008
<b>(in thousands)</b>					
Cash, cash equivalents, and current marketable investment securities	\$ 100,715	\$ 162,233	\$ 133,771	\$ 74,928	\$ 97,380
Working capital	107,484	156,025	133,750	71,280	96,607
Total assets	151,109	213,980	228,905	159,592	203,606
Long-term portion of lease financing, convertible notes payable, non-recourse debt and other long-term liabilities	176,183	216,493	302,035	308,419	336,803
Accumulated deficit	(1,009,185)	(990,450)	(954,183)	(922,742)	(904,880)
Stockholders' deficit	(54,641)	(46,116)	(155,275)	(222,799)	(215,086)

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

### SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

The following discussion should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report.

This Annual Report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements represent our management's judgment regarding future events. In many cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "plan," "expect," "anticipate," "estimate," "predict," "intend," "potential" or "continue" or the negative of these terms or other words of similar import, although some forward-looking statements are expressed differently. All statements other than statements of historical fact included in this Annual Report on Form 10-K regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note that statements regarding potential drug candidates, their potential therapeutic effect, the possibility of obtaining regulatory approval, our ability or the ability of our collaborators to manufacture and sell any products, market acceptance, or our ability to earn a profit from sales or licenses of any drug candidate are all forward-looking in nature. We cannot guarantee the accuracy of the forward-looking statements, and you should be aware that results and events could differ materially from those described in the forward-looking statements due to a number of factors, including those described in Item 1A of this Annual Report under the heading "Risk Factors" which addresses factors that could cause results or events to differ materially from those set forth in the forward-looking statements. In addition, new risks emerge from time to time and it is not possible for management to predict all such risks or to assess the impact of such risks on our business. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. We undertake no obligation to update or revise these forward-looking statements to reflect subsequent events or circumstances.

### Overview

We are a biopharmaceutical company focused on pioneering and delivering therapies that transform the lives of patients with rare diseases worldwide. Our lead product, Gattex® 0.05 mg/kg/d (Teduglutide [rDNA origin]) for Injection, for subcutaneous use was approved by the U.S. Food and Drug Administration (FDA) in December 2012 for the treatment of adult patients with short bowel syndrome (SBS) who are dependent on parenteral support. We are also developing Natpara® (rhPTH[1-84]) for the treatment of adult hypoparathyroidism. We have met with FDA to discuss our Human Factors/Usability testing of the Natpara injection pen device. The final study will be initiated in March 2013 with results expected in the second quarter of 2013. We continue to work toward submitting our U.S. Biologics License Application (BLA) for Natpara. In order to finalize our submission, we need to resolve certain previously disclosed manufacturing issues. We expect to complete certain key root cause analyses during the second quarter of 2013. Subject to resolution of the manufacturing issue, we expect to submit our BLA in the second half of 2013. We also have two earlier stage calcilytic compounds with potential application in rare endocrine disorders, as well as a valuable royalty-based portfolio of marketed products and products in development.



Gattex is our novel recombinant analog of human glucagon-like peptide 2 (GLP-2), a protein involved in the rehabilitation of the intestinal lining. Gattex is used for the treatment of adults with short bowel syndrome or SBS, who are dependent on parenteral support. SBS is a highly disabling and potentially life-threatening chronic disorder. SBS results from surgical resection, congenital defect or disease-associated loss of absorption in the bowel in which patients are subsequently unable to maintain fluid, electrolyte, and nutrient balances on a conventional diet. Despite an adaptation that occurs generally in the two years after resection, many SBS patients require parenteral support to supplement and stabilize their nutritional and hydration needs. A National Institute of Health (NIH) publication reported that the annual mean costs of lifelong, complex home healthcare associated with PN/IV support ranged from \$185,000 to \$568,000, not including the indirect costs associated with disability and/or the dollar value that could be ascribed to the challenging daily living for these patients (Piamjariyakul 2010). In addition, parenteral support is associated with shortened life span, life-threatening complications including sepsis, blood clots or liver damage, and reduced quality-of-life due to the time required for and consequences of frequent access to an intravenous pump. Gattex is the first and only analog of GLP-2 proven to increase intestinal absorption and decrease or eliminate the need for parenteral support.

Natpara is our recombinant full-length human parathyroid hormone (rhPTH [1-84]) that we are developing as the first hormone replacement therapy for hypoparathyroidism, a rare hormone deficiency disorder in which patients are physiologically unable to regulate the levels of calcium and phosphates in their blood due to insufficient levels of endogenous parathyroid hormone (PTH). Endogenous PTH is the body's principal regulator of serum calcium and phosphate levels. Hypoparathyroidism is associated with hypocalcemia, hyperphosphatemia, hypercalciuria (excessive urinary calcium excretion), and increased bone mineral density. It typically results from permanent injury to the parathyroid gland(s) during thyroid or parathyroid surgery or other surgical procedures in the neck, radiation to the neck region, autoimmune destruction of the parathyroid glands, or their congenital absence. Although rare, hypoparathyroidism can also result from genetic mutations. Current therapy is limited to calcium supplementation and parenteral or metabolic forms of vitamin D. These palliative therapies are sometimes suboptimal and can also contribute to long-term health risks including kidney failure. Hypoparathyroidism is one of the few hormonal deficiency syndromes with no approved replacement therapy using the native hormone. If approved, Natpara could be the first treatment targeting the underlying cause of hypoparathyroidism by replacing the native hormone. In November 2011, we reported positive top-line results from our Phase 3 registration study of Natpara, known as REPLACE, which met the primary efficacy endpoint with a statistically higher responder rate versus placebo. A responder was defined as a 50 percent or greater reduction in oral calcium supplementation and active vitamin D therapy and a total serum calcium concentration that was maintained compared to baseline. Based on the REPLACE results, we plan to file for U.S. marketing approval of Natpara however, the timing of the filing will be dependent on when the manufacturing issue is resolved.

While SBS and hypoparathyroidism are relatively rare disorders, we believe these indications represent a substantial commercial opportunity to us due to the significant unmet need and lack of effective therapies, as well as the serious complications involved with and the chronic nature of these diseases.

We have incurred cumulative losses from inception through December 31, 2012 of approximately \$1.0 billion. We expect to continue to incur operating losses over the next several years as we launch Gattex and incur sales and marketing costs, incur pre-launch and launch costs for Natpara in the U.S., invest in the development of our pipeline and pursue in-licensing opportunities.

During the years ended December 31, 2012, 2011 and 2010, we incurred expenses of \$48.3 million, \$32.8 million and \$24.4 million, respectively, in the research and development of teduglutide, including costs associated with the manufacture of clinical and pre-launch commercial supplies of teduglutide. We have incurred expenses of approximately \$258.5 million since we assumed development obligations of this product candidate upon our acquisition of Allelix Biopharmaceuticals Inc. in December 1999. During the years ended December 31, 2012, 2011 and 2010, we incurred expenses of \$32.0 million, \$27.4 million and \$25.4 million, respectively, in the research and development of Natpara, including costs associated with the manufacture of clinical and commercial supplies of Natpara. We have incurred expenses of approximately \$448.2 million since we assumed development obligations for Natpara, upon our acquisition of Allelix Biopharmaceuticals Inc. in December 1999. Our development administration overhead costs are included in total research and development expense for each period, but are not allocated among our various projects. See "Item 1 – Business – Proprietary Product Candidates." Our ability to complete our research and development efforts and commercialize our product candidates is subject to various risks and uncertainties. See "Item 1A – Risk Factors."

As a result of the marketing approval for Gattex in the United States by the FDA on December 21, 2012, we will no longer expense manufacturing costs relating to Gattex as research and development expense. Instead, we will capitalize these costs as inventory as they are incurred. There will be no cost of goods sold associated with the sale of Gattex inventory that was on hand at the time of the FDA's approval of the NDA for Gattex. We expect that this will result in higher gross margins during the period that we sell off this supply than we will achieve once we begin selling Gattex that is manufactured after the date of the FDA's approval of our NDA for Gattex. Based on our current plans and assumptions, we believe that by the end of 2015, we will have sold off this supply of product on hand at the time of the FDA's approval of the NDA for Gattex. We also expect to incur increased sales and marketing expenses relating to commercialization of Gattex in the United States beginning in the first half of 2013 and we expect to begin to recognize product revenue from the sale of Gattex in the U.S. beginning in the first half of 2013.

## Results of Operations

The following table summarizes selected operating statement data for the years ended December 31, 2012, 2011 and 2010 (dollars in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Revenues:			
Royalties	\$ 105,587	\$ 96,502	\$ 86,181
Sale of royalty rights	25,000	-	-
Product sales	-	99	551
Milestones and license fees	57	5,044	2,682
Total Revenues	<u>\$ 130,644</u>	<u>\$ 101,645</u>	<u>\$ 89,414</u>
Operating expenses:			
Cost of royalties	\$ -	\$ 500	\$ -
Cost of goods sold	\$ -	\$ -	\$ 6
Cost of license fees	\$ -	\$ 2,543	\$ 69
Research and development	\$ 94,839	\$ 73,831	\$ 60,814
% of revenues	73 %	73 %	68 %
General and administrative	\$ 36,929	\$ 24,226	\$ 18,951
% of revenues	28 %	24 %	21 %

## Years ended December 31, 2012 and 2011

**Revenues.** Substantially all our revenues relate to royalty payments, license fees, milestone payments and product sales from our licensees and collaborators. These revenues fluctuate from year to year. Our revenues were \$130.6 million in 2012 compared to \$101.6 million in 2011. We recognized revenue under our research and license agreements as follows (amounts in thousands):

	<u>2012</u>	<u>2011</u>
Royalties:		
Sensipar and Mimpara (cinacalcet HCl)	\$ 89,271	\$ 77,554
Regpara (cinacalcet HCl)	8,693	7,645
Preotact (parathyroid hormone (PTH 1-84))	4,786	9,116
Nucynta (tapentadol)	2,837	2,185
Other	-	2
Total royalties	<u>105,587</u>	<u>96,502</u>
Sale of royalty rights - Sensipar	25,000	-
Product sales - Teduglutide	-	99
Milestones and license fees:		
Teduglutide	-	5,000
Other	57	44
Total milestones and license fees	<u>57</u>	<u>5,044</u>
Total revenues	<u>\$ 130,644</u>	<u>\$ 101,645</u>

For the years ended December 31, 2012 and 2011, our revenues related to our agreement with Amgen for Sensipar and Mimpara were comprised of \$89.3 million and \$77.6 million in royalty revenue, respectively. The increase in royalty revenue earned from Amgen is due to the sales growth of Sensipar and Mimpara (cinacalcet HCl). We amended our agreement with Amgen, effective September 30, 2011, and Amgen began withholding the royalties on sales of Sensipar and Mimpara and credited them, net of the discount, to the Sensipar Notes issued pursuant to the amended agreement. In June 2012, we amended our agreement with Amgen and received a one-time non-refundable \$25.0 million payment in July 2012 in exchange for our rights to receive royalties under the license agreement that are earned after December 31, 2018. The amendment also limits the royalty offset of the royalty advance that we received from Amgen up to \$8.0 million per quarter with royalties in excess of \$8.0 million paid to us for the respective quarter, thereby extending the royalty advance repayment period. After the repayment of the royalty advance and a 9% per annum discount factor on the outstanding balance, Amgen will resume paying us all royalties earned through December 31, 2018.

For the years ended December 31, 2012 and 2011, we recognized \$8.7 million and \$7.6 million, respectively, in royalty revenue under our agreement with Kyowa Hakko Kirin for sales of REGPARA, which was launched in the first quarter of 2008. The increase is primarily due to increased demand of REGPARA. In February 2010, we sold our rights to receive certain future royalty payments from Kyowa Hakko Kirin's sale of REGPARA to an affiliate of DRI. The agreement provides DRI with the right to receive payments related to sales of REGPARA occurring on or after July 1, 2009.

For the years ended December 31, 2012 and 2011, our revenues related to our agreement with Takeda for Preotact were comprised of \$4.8 million and \$9.1 million in royalty revenue, respectively. In July 2007, we sold our rights to receive certain future royalty payments from Takeda's sale of Preotact in Europe to DRI Capital (DRI) and we therefore do not receive any such royalty payments until the Preotact-secured debt is repaid. The decrease in royalty revenue was primarily due to a technical production issue whereby, Takeda is presently unable to have batches of finished product manufactured that are consistently within specification and we have been informed that as a result Takeda is no longer selling Preotact in their territories. We understand that Takeda has taken a number of actions to resolve the manufacturing issue and to accelerate a return to normal supply situation. We have not received any information as to when or if Takeda will re-introduce Preotact in the future. Because we previously monetized our Preotact royalty rights as non-recourse debt, declines in Preotact sales will impact our royalty revenues but will have no material impact on our short-term liquidity.

For the years ended December 31, 2012 and 2011, our revenues related to our agreement with Takeda for teduglutide were \$0 million and \$5.0 million, respectively. In September 2007, we entered into an agreement with Takeda for the rights to develop and commercialize teduglutide in territories outside of North America for gastrointestinal disorders. In 2011, in connection with this agreement, we earned a \$5.0 million milestone payment for Takeda's submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for clearance to market teduglutide (Revestive®) as a once-daily subcutaneous treatment for short bowel syndrome (SBS).

For the years ended December 31, 2012 and 2011, we recognized royalty revenue of \$2.8 million and \$2.2 million respectively, from Janssen for sales of Nucynta, which was launched in the second quarter of 2009. The increase in royalty revenue earned from Nucynta was primarily due to increased demand for Nucynta.

See “Liquidity and Capital Resources” below for further discussion of payments that we may earn in the future under these agreements.

**Cost of Royalties.** We recorded cost of royalties of \$0 and \$500,000, respectively, during the years ended December 31, 2012 and 2011. Our cost of royalties consists of royalties owed under our agreement with a third party based on achieving a threshold for cumulative sales of Preotact during 2011.

**Cost of License Fees.** Our cost of license fees primarily relate to fees owed to a third party upon the licensing of teduglutide to Takeda in September 2007. We recorded cost of license fees of \$0 and \$2.5 million during the years ended December 31, 2012 and 2011, respectively.

**Research and Development.** Our research and development expenses are primarily comprised of personnel and third-party costs to conduct preclinical and clinical trials and to manufacture drugs needed for clinical studies and commercial production prior to FDA approval.

We group our research and development expenses into two major categories: clinical development costs and product development costs.

Clinical development costs were \$26.9 million and \$32.3 million for the years ended December 31, 2012 and 2011, respectively. Clinical development costs are primarily comprised of costs paid to outside parties to conduct and manage clinical trials related to Gattex and Natpara as well as costs associated with regulatory functions. Product development costs were \$43.7 million and \$24.2 million for the years ended December 31, 2012 and 2011, respectively. Product development costs are costs related to the drug needed for our clinical studies and commercial production of pre-launch inventory.

Unallocated research and development costs were \$24.2 million and \$17.3 million for the years ended December 31, 2012 and 2011, respectively. Unallocated research and development costs consist primarily of personnel, personnel related costs and overhead costs that relate to medical affairs and product development activities which have not been allocated directly to each program.

For the year ended December 31, 2012, our research and development expenses increased to \$94.8 million from \$73.8 million for the year ended December 31, 2011. The increase in research and development expenses primarily related to an increase of \$19.5 million of costs for the commercial production of pre-launch Gattex and Natpara inventory and an increase of \$6.9 million which mainly consists of regulatory costs as well as personnel and personnel related costs. These increases were partially offset by a \$5.4 million reduction in costs associated with clinical development activities.

**General and Administrative.** Our general and administrative expenses consist primarily of compensation for employees in executive, finance, legal and sales and marketing functions as well as facility costs and professional fees for accounting and legal services. Our general and administrative expenses increased to \$36.9 million for the year ended December 31, 2012 from \$24.2 million in 2011. The increase in general and administrative expenses primarily relate to an increase in personnel and external costs related to commercial-readiness activities for Gattex.

**Interest Income.** Interest income decreased to \$292,000 for the year ended December 31, 2012 from \$321,000 from the comparative period in 2011.

**Interest Expense.** Our interest expense decreased to \$18.2 million for the year ended December 31, 2012 from \$37.7 million for the comparable period in 2011. Our long-term royalty forecasts for Preotact and REGPARA are used to calculate the implicit interest rate and the related interest expense for our non-recourse debt. Interest expense decreased due primarily to (i) the final principal payments of \$46.2 million and \$150.3 million on the Class A and B Notes, respectively, during 2011 (\$18.8 million), (ii) a lower effective interest rate due to a decrease in the forecast of Preotact royalties related to the non-recourse debt associated with the sale of certain of our Preotact royalty rights (\$5.7 million) and (iii) a reduction in the principal outstanding due to the conversion of \$33.5 million of our 5.75% convertible notes during 2011 (\$528,000). These decreases were partially offset by increased interest expense on the non-recourse debt associated with the Amgen advance of our Sensipar royalty rights in September 2011 (\$5.6 million).

**Income Taxes.** We reported an income tax expense of \$0 and \$18,000 in 2012 and 2011, respectively.

As of December 31, 2012, we had United States federal and New Jersey state income tax net operating loss carryforwards of approximately \$382.3 million and \$368.4 million, respectively, federal and New Jersey capital loss carryforwards of approximately \$10.6 million and \$18.0 million, respectively, and a United States federal research credit carryforwards of approximately \$50.0 million. Our ability to utilize the United States operating loss, capital loss carryforwards and credit carryforwards against future taxable income may be subject to annual limitations in future periods pursuant to the “change in ownership rules” under Section 382 of the Internal Revenue Code of 1986. We recently completed a Section 382 study through December 31, 2011. The study concluded that we experienced an ownership change in 2010. As a result of the ownership change we will not be able to utilize a portion of our pre-change United States net operating loss and all of its pre-change United States research credits and capital losses. Losses and credits that are recognized after the change are not affected by the 2010 ownership change but may be affected by future ownership changes.

### Years ended December 31, 2011 and 2010

**Revenues.** Our revenues were \$101.6 million in 2011 compared to \$89.4 million in 2010. We recognized revenue under our research and license agreements as follows (amounts in thousands):

	<u>2011</u>	<u>2010</u>
Royalties:		
Sensipar and Mimpara (cinacalcet HCl)	\$ 77,554	\$ 69,833
Regpara (cinacalcet HCl)	7,645	5,643
Preotact (parathyroid hormone (PTH 1-84))	9,116	9,467
Nucynta (tapentadol)	2,185	1,237
Other	<u>2</u>	<u>1</u>
Total royalties	96,502	86,181
Product sales:		
Preotact	-	452
Teduglutide	<u>99</u>	<u>99</u>
Total product sales	99	551
Milestones and license fees:		
Sensipar	-	2,000
Teduglutide	5,000	-
Other	<u>44</u>	<u>682</u>
Total milestones and license fees	5,044	2,682
Total revenues	<u>\$ 101,645</u>	<u>\$ 89,414</u>

The increase in royalty revenue earned from Amgen is due to the sales growth of Sensipar and Mimpara. We amended our agreement with Amgen, effective September 30, 2011, and Amgen began withholding the royalties on sales of Sensipar and Mimpara and credited them, net of the discount, to the Sensipar Notes issued pursuant to the amended agreement. The \$2.0 million milestone revenue earned from Amgen during the year ended December 31, 2010 was for their initiation of a Phase 3 study of Sensipar in primary hyperparathyroidism in March 2010.

For the years ended December 31, 2011 and 2010, we recognized \$7.6 million and \$5.6 million, respectively, in royalty revenue under our agreement with Kyowa Hakko Kirin for sales of REGPARA, which was launched in the first quarter of 2008. The increase is primarily due to increased demand of REGPARA. In February 2010, we sold our rights to receive certain future royalty payments from Kyowa Hakko Kirin’s sale of REGPARA to an affiliate of DRI.

The agreement provides DRI with the right to receive payments related to sales of REGPARA occurring on or after July 1, 2009.

For the years ended December 31, 2011 and 2010, our revenues related to our agreement with Takeda for Preotact were comprised of \$9.1 million and \$9.5 million in royalty revenue, respectively. The decrease in royalty revenue was primarily due to a decrease in demand, changes in foreign exchange that negatively impacted royalties and reductions in the reimbursement rates of Preotact in certain European countries. In April 2006, the European Medicines Agency or EMA approved Preotact for the treatment of postmenopausal women with osteoporosis at high risk for fractures. In July 2007, we sold our right to receive certain future royalty payments from Takeda's sale of Preotact in Europe to DRI, therefore, all royalty payments due since the second half of 2007 were paid to DRI. Under our agreement with Takeda for Preotact, Takeda assumed the responsibility for manufacturing Preotact in the first quarter of 2008. Therefore, we will no longer recognize product sale revenue in the future under this arrangement.

For the years ended December 31, 2011 and 2010, our revenues related to our agreement with Takeda for teduglutide were \$5.0 million and \$0, respectively. In September 2007, we entered into an agreement with Takeda for the rights to develop and commercialize teduglutide in territories outside of North America for gastrointestinal disorders. In 2011, in connection with this agreement, we earned a \$5.0 million milestone payment for Takeda's submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for clearance to market teduglutide (Revestive®) as a once-daily subcutaneous treatment for short bowel syndrome (SBS).

For the years ended December 31, 2011 and 2010, we recognized royalty revenue of \$2.2 million and \$1.2 million respectively, from Janssen for sales of Nucynta, which was launched in the second quarter of 2009. The increase in royalty revenue earned from Nucynta was primarily due to increased demand for Nucynta.

**Cost of Royalties.** We recorded cost of royalties of \$500,000 and \$0, respectively, during the years ended December 31, 2011 and 2010. Our cost of royalties consists of royalties owed under our agreement with a third party based on achieving a threshold for cumulative sales of Preotact during 2011.

**Cost of License Fees.** Our cost of license fees primarily relate to fees owed to a third party resulting from the licensing of teduglutide to Takeda in September 2007. We recorded cost of license fees of \$2.5 million and \$69,000 during the years ended December 31, 2011 and 2010, respectively.

**Research and Development.** Our research and development expenses are primarily comprised of the fees paid and costs reimbursed to outside professionals to conduct research, preclinical and clinical trials, and to manufacture drug compounds and related supplies prior to FDA approval, as well as personnel-related costs for our employees who are dedicated to development activities. For the year ended December 31, 2011, our research and development expenses increased to \$73.8 million from \$60.8 million for the year ended December 31, 2010. The increase in research and development expenses primarily related to a \$8.0 million increase in outside services principally due to higher levels of activity in our ongoing clinical studies and a \$3.7 million increase in personnel and related costs primarily due to the advancement of our registration programs for Gattex and Natpara.

**General and Administrative.** Our general and administrative expenses consist primarily of professional fees, the costs of our management and administrative staff and administrative expenses. Our general and administrative expenses increased to \$24.2 million for the year ended December 31, 2011 from \$19.0 million in 2010. The increase in general and administrative expenses primarily related to a \$2.0 million increase in personnel and related costs and a \$1.4 million increase in market research.

**Interest Income.** Interest income decreased to \$321,000 for the year ended December 31, 2011 from \$418,000 from the comparative period in 2010, primarily due to lower interest rates on our investments.

**Interest Expense.** Our interest expense decreased to \$37.7 million for the year ended December 31, 2011 from \$45.1 million for the comparable period in 2010. Our long-term royalty forecasts for Sensipar and Mimpara, Preotact and REGPARA are used to calculate the implicit interest rate and the related interest expense for our non-recourse debt. Interest expense decreased due primarily to (i) the final principal payment of \$46.2 million on March 30, 2011 on the Class A Notes (\$4.8 million), (ii) the final principal payment of \$150.3 million on September 30, 2011 for the Class B Notes (\$4.8 million), (iii) a reduction in the principal outstanding due to the conversion of \$33.5 million of our 5.75% convertible notes (\$1.5 million) and a lower effective interest rate due to a decrease in the forecast of Preotact royalties related to the non-recourse debt associated with the sale of certain of our Preotact royalty rights (\$1.1 million). These decreases were partially offset by increased interest expense on the (i) non-recourse debt associated with the advance of our Sensipar royalty rights in September 2011 (\$3.0 million) and (ii) an increase in interest expense on the non-recourse

debt associated with our REGPARA royalties due to an increase in the sales forecast of REGPARA and the favorable impact of foreign exchange associated with the non-recourse debt (\$1.8 million).

**Gain on Sale of Marketable Investment Securities.** We recorded a gain on sale of marketable investment securities of \$0 and \$3.8 million for the years ended December 31, 2011 and 2010, respectively, related primarily to the sale of certain auction rate securities, or ARS during 2010.

**Income Taxes.** We reported an income tax expense of \$18,000 and \$1.1 million in 2011 and 2010, respectively. The \$1.1 million income tax expense in 2010, primarily related to the Canadian province of Quebec.

## Liquidity and Capital Resources

The following table summarizes selected financial data (amounts in the thousands):

	<u>December 31, 2012</u>	<u>December 31, 2011</u>
Cash, cash equivalents, and marketable investment securities	\$ 100,715	\$ 162,233
Total assets	151,109	213,980
Current debt	6,278	19,267
Non-current debt	169,569	208,630
Stockholders' deficit	\$ (54,641)	\$ (46,116)

Currently, we are not a self-sustaining business and certain economic, operational and strategic factors may require us to secure additional funds. If we are unable to obtain sufficient funding at any time in the future, we may not be able to develop or commercialize our products, take advantage of business opportunities or respond to competitive pressures. Our current and anticipated operations require substantial capital. We expect that our existing capital resources including interest earned thereon, will be sufficient to fund our current and planned operations through at least January 1, 2014. However, our actual needs will depend on numerous factors, including the progress and scope of our internally funded development and commercialization activities related to the launch of Gattex and the pre-launch of Natpara; our ability to comply with the terms of our research funding agreements; our ability to maintain existing collaborations; our decision to seek additional collaborators; the success of our collaborators in developing and marketing products under their respective collaborations with us; our success in producing clinical and commercial supplies of our product candidates on a timely basis sufficient to meet the needs of our clinical trials and commercial launch; the costs we incur in obtaining and enforcing patent and other proprietary rights or gaining the freedom to operate under the patents of others; and our success in acquiring and integrating complementary products, technologies or businesses. Our clinical trials may be modified or terminated for several reasons including the risk that our product candidates will demonstrate safety concerns; the risk that regulatory authorities may not approve our product candidates for further development or may require additional or expanded clinical trials to be performed; and the risk that our manufacturers may not be able to supply sufficient quantities of our drug candidates to support our clinical trials or commercial launch, which could lead to a disruption or cessation of the clinical trials or commercial activities. We may also be required to conduct unanticipated preclinical or clinical trials to obtain regulatory approval of our product candidate Natpara. If any of the events that pose these risks comes to fruition, our actual capital needs may substantially exceed our anticipated capital needs and we may have to substantially modify or terminate current and planned clinical trials or postpone conducting future clinical trials. As a result, our business may be materially harmed, our stock price may be adversely affected, and our ability to raise additional capital may be impaired.

We will need to raise additional funds to support our long-term research, product development, and commercialization programs. We regularly consider various fund raising alternatives, including, for example, debt or

equity financing, partnering of existing programs, monetizing of potential revenue streams and merger and acquisition alternatives. We may also seek additional funding through strategic alliances, collaborations, or license agreements and other financing mechanisms. There can be no assurance that additional financing will be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay or reduce the scope of our efforts to commercialize Gattex, delay, reduce the scope of, or eliminate one or more of our research and development programs, or obtain funds through arrangements with licensees or others that may require us to relinquish rights to certain of our technologies or product candidates that we may otherwise seek to develop or commercialize on our own.

We require cash to fund our operating expenses, to make capital expenditures, acquisitions and investments and to service our debt. We have financed operations since inception primarily through payments received under collaborative research and license agreements, the private and public issuance and sale of equity securities, and the issuance and sale of secured debt, convertible debt and lease financing. Through December 31, 2012, we have recognized \$755.4 million of cumulative revenues from payments for research support, license fees, product sales, milestone and royalty payments, \$777.2 million from the sale of equity securities for cash and \$738.6 million from the sale of secured debt and convertible debt for cash.

Our principal sources of liquidity are cash, cash equivalents, and marketable investment securities, which totaled \$100.7 million at December 31, 2012. We expect that our existing cash, cash equivalents and short-term investments will sufficiently fund our current and planned operations through at least 2013. The primary objectives for our marketable investment security portfolio are liquidity and safety of principal. Investments are intended to achieve the highest rate of return to us, consistent with these two objectives. Our investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

In August 2011, we amended our agreement with Amgen that became effective after the retirement of our Class B Notes. Under the Amgen agreement, Amgen advanced \$145.0 million of Sensipar and Mimpara royalties to us. In June 2012, we amended our agreement with Amgen and received a one-time non-refundable \$25.0 million payment in July 2012 in exchange for our rights to receive royalties under the license agreement that are earned after December 31, 2018. The amendment also limits the royalty offset of the royalty advance that we received from Amgen up to \$8.0 million per quarter with royalties in excess of \$8.0 million paid to us for the respective quarter, thereby extending the royalty advance repayment period. After the payment of the royalty advance and a 9% per annum discount on the balance of the advance, Amgen will resume paying royalties to us.

In January 2011 and April 2011, certain holders of the 5.75% Convertible Notes converted portions of the outstanding notes at a conversion price of \$5.44 per share. We issued 529,282 and 5,620,445 shares of common stock pursuant to this conversion and retired \$2.9 million and \$30.6 million, respectively, of the outstanding 5.75% Convertible Notes. We have \$16.5 million of the 5.75% Convertible Notes outstanding as of December 31, 2012.

The following table summarizes our cash flow activity for the years ended December 31, 2012, 2011 and 2010 (amounts in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Net cash used in operating activities	\$ (60,992)	\$ (56,658)	\$ (17,732)
Net cash used in investing activities	(6,489)	(28,119)	(729)
Net cash provided by financing activities	\$ 2,561	\$ 90,003	\$ 77,370

Net cash used in operating activities was \$61.0 million, \$56.7 million and \$17.7 million in 2012, 2011 and 2010, respectively. The net cash used was primarily related to the increased spending in research and development due to the advancement of our registration programs for Gattex and Natpara and due to the non-cash components of accounts receivable and interest expense related to the issuance of non-recourse Sensipar Notes to Amgen. The Preotact and REGPARA royalty revenues are pledged to service the principal and interest on our non-recourse notes and are not available to fund operations.

Net cash used in investing activities was \$6.5 million, \$28.1 million and \$729,000 in 2012, 2011 and 2010, respectively. Net cash used in investing activities during 2012, 2011 and 2010 was primarily the result of investing excess cash not currently required to fund operations. Additionally, capital expenditures for 2012, 2011 and 2010 were \$1.2 million, \$3.4 million and \$862,000, respectively.



Net cash provided by financing activities was \$2.6 million, \$90.0 million and \$77.4 million during 2012, 2011 and 2010, respectively. Cash provided by financing activities during 2012 consisted of \$2.6 million received from the exercise of employee stock options and the sale of shares for the employee stock purchase plan. Cash provided by financing activities during 2011 primarily consisted of the \$145.0 million received from Amgen for the issuance of the non-recourse Sensipar Notes, \$106.8 million received from the public sale of common shares in April 2011 and approximately \$1.3 million received from the exercise of employee stock options and the sale of shares for the employee stock purchase plan. The decrease in our restricted cash balance of \$50.8 million was due to making principal and cash sweep premium payments on our Class A Notes and our Class B Notes net of increases from cash received for royalty payments. These were offset by making principal and cash sweep premium payments on our Class A Notes and Class B Notes totaling \$213.8 million. Cash provided by financing activities during 2010 primarily consisted of \$44.4 million and \$53.2 million received from the public sale of common shares in September 2010 and April 2010, respectively, and \$38.4 million received from the sale of REGPARA royalty rights to DRI Capital. These were offset by principal payments of \$50.7 million on our Class A Notes, DRI REGPARA Notes and capital lease obligation during 2010 and an increase in our restricted cash balance of \$9.0 million related to making principal and cash sweep premium payments on our Class A Notes net of increases from cash received for royalties earned. Employee stock option exercises and proceeds from the sale of stock by us pursuant to the employee stock purchase plan provided approximately \$2.6 million, \$1.1 million, and \$1.2 million of cash during 2012, 2011 and 2010, respectively. Proceeds from the exercise of employee stock options vary from period to period based upon, among other factors, fluctuations in the market price of our common stock relative to the exercise price of such options and the availability of stock under the employee stock purchase plan.

We could receive future milestone payments from all our agreements of up to \$206.2 million in the aggregate if each of our current licensees accomplishes the specified research and/or development milestones provided in the respective agreements. In addition, all of the agreements require the licensees to make royalty payments to us if they sell products covered by the terms of our license agreements. However, we do not control the subject matter, timing or resources applied by our licensees to their development programs. Thus, potential receipt of milestone and royalty payments from these licensees is largely beyond our control. Further, each of these agreements may be terminated before its scheduled expiration date by the respective licensee either for any reason or under certain conditions.

Depending on the commercial success of certain of our products, we may be required to pay license fees or royalties. For example, we are required to make royalty payments to certain licensors on teduglutide net sales and cinacalcet HCl royalty revenues. We expect to enter into additional sponsored research and license agreements in the future.

We have entered into long-term agreements with certain manufacturers and suppliers that require us to make contractual payment to these organizations. We expect to enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require up-front payments and long-term commitments of cash.

The following represents our contractual obligations as of December 31, 2012 (in millions):

<b>Contractual Obligations</b>	<b>Total</b>	<b>Less than</b>			<b>More than</b>
		<b>1 year</b>	<b>2-3 years</b>	<b>4-5 years</b>	<b>5 years</b>
Operating leases	\$ 7.0	\$ 1.9	\$ 3.8	\$ 1.3	\$ -
Purchase commitments (1)	53.5	45.1	7.8	0.6	-
Convertible notes payable	16.5	-	16.5	-	-
Interest on convertible notes payable	1.6	0.7	0.8	-	-
Non-recourse debt (2)	159.3	25.9	62.1	9.8	61.6
Interest on non-recourse debt (2)	44.8	14.8	17.0	8.2	4.9
Royalty payment obligation	6.6	1.0	2.0	2.0	1.6

(1) Purchase obligations primarily represent commitments for manufacturing agreements (\$23.3 million), services (\$16.1 million) and market research agreements (\$14.1 million). Commitments for services primarily represent agreements with external service providers, under which we will continue to incur expenses relating to clinical trials of Natpara and other clinical candidates. These agreements are cancellable on notice of up to six months.

(2) Amounts shown as contractual commitments under our non-recourse debt represent our estimate of expected principal repayment based on anticipated cinacalcet HCl, Preotact and REGPARA royalty income. Amounts

shown in interest on non-recourse debt include our premium redemption payment and estimated interest payments based on estimated cinacalcet HCl, Preotact and REGPARA royalty income levels. Due to the current out-of-stock situation with Takeda for Preotact, we have classified all the principal remaining for the Preotact debt as having an expected maturity of longer than 5 years.

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our consolidated financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue and research and development costs. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect the significant judgments and estimates used in the preparation of our consolidated financial statements:

- revenue recognition;
- accrual of research and development expenses;
- share based payments;
- valuation of marketable investment securities;
- effective interest computation and;
- valuation of long-lived and intangible assets and goodwill.

**Revenue Recognition.** We earn our revenue from product sales, license fees, milestone payments, research and development support payments and royalty payments. As described below, significant management judgment and estimates must be made and used in connection with the revenue recognized in any accounting period. Material differences may result in the amount and timing of our revenue for any period if our management made different judgments or utilized different estimates.

We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured and we have no further performance obligations. All revenues from product sales are recorded net of the applicable provision for returns in the same period the related sales are recorded. We recognize revenue from milestone payments as agreed upon events representing the achievement of substantive steps in the development process are achieved and where the amount of the milestone payment approximates the fair value of achieving the milestone. We defer and recognize revenue from up-front nonrefundable license fees on a straight-line basis, unless another pattern is apparent, over the period we have continuing involvement in the research and development project. Royalties from licensees are based on third-party sales of licensed products and are recorded in accordance with the contract terms when third-party results are reliably measurable and collectability is reasonably assured.

We analyze our arrangements entered into to determine whether the elements can be separated and accounted for individually or as a single unit of accounting. Allocation of revenue to individual elements which qualify for separate accounting is based on the estimated fair value of the respective elements.

**Accrual of Research and Development Expenses.** Research and development costs are expensed as incurred and include salaries and benefits; costs paid to third-party contractors to perform research, conduct clinical trials, develop and manufacture drug materials and delivery devices; and associated overhead expenses and facilities costs. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. Invoicing from third-party contractors for services performed can lag several months. We accrue the costs of services rendered in connection with third-party contractor activities based on our estimate of

management fees, site management and monitoring costs and data management costs. Differences between actual clinical trial costs from estimated clinical trial costs have not been material and are adjusted for in the period in which they become known.

**Share-Based Payments.** We grant options to purchase our common stock to our employees and directors under our stock option plans. For options awards with market conditions we use the Monte Carlo simulation to value the awards. For other option awards which vest based on passage of time, we estimate the fair value on the date of grant using a Black-Scholes pricing model (Black-Scholes model). The determination of the fair value of share-based payment awards on the date of grant using the Black-Scholes model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. If factors change and we employ different assumptions in future periods, the compensation expense that we record may differ significantly from what we have recorded in the current period.

Estimates of share-based compensation expenses are significant to our financial statements, but these expenses are based on option valuation models and will never result in the payment of cash by us.

There are significant differences among valuation models, and there is a possibility that we will adopt different valuation models in the future. This may result in a lack of consistency in future periods and materially affect the fair value estimate of share-based payments. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

For purposes of estimating the fair value of stock options granted during 2012 using the Black-Scholes model, we have made an estimate regarding our stock price volatility. We consider the historical volatility and the implied volatility of market-traded options in our stock for the expected volatility assumption input to the Black-Scholes model. The risk-free interest rate is based on the yield curve of U.S. Treasury strip securities for a period consistent with the expected term of the option in effect at the time of grant. The dividend yield assumption is based on our history and expectation of dividend payouts. The expected term is estimated considering historical option information.

**Valuation of Marketable Investment Securities.** We classify our marketable investment securities as available for sale or trading securities. Available for sale securities are recorded at fair value. Unrealized holding gains and losses, net of the related tax effect, are excluded from earnings and are reported as a separate component of stockholders' deficit until realized. A decline in the market value below cost that is deemed other than temporary is charged to results of operations, resulting in the establishment of a new cost basis for the security. Trading securities are also recorded at fair value, however, holding gains and losses are charged to results of operations when incurred. Our marketable securities consist primarily of U.S. dollar denominated corporate or government debt securities. Debt securities generally are long-term securities with coupons that may or may not reset periodically against a benchmark interest rate.

We conduct periodic reviews to identify and evaluate each investment that has an unrealized loss. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income.

For available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether it would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or where it may be more likely than not be required to sell the security before the expected recovery of the amortized cost basis, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded in results of operations as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

**Effective Interest Computation.** In July 2007, we entered into an agreement with DRI Capital, or DRI, in which we sold to DRI our right to receive future royalty payments arising from sales of Preotact under our licensing agreement with Takeda. We received an up-front purchase price of \$50.0 million in 2007. If and when DRI receives two and a half times the payment we received, the agreement will terminate and the remainder of the royalties, if any, will revert back to us. We have determined that we should classify the up-front purchase price as debt and amortize this using the effective interest rate method over the estimated period to recover two and a half times the initial principal advanced. We estimate future net sales of Preotact by Takeda and then calculate the effective interest rate on the DRI debt. Changes to the future Preotact net sales forecast may have a material impact on interest expense. Management evaluates its future Preotact net sales estimates on a quarterly basis and adjusts the effective interest rate when information indicates that the estimate is materially above or below the prior estimate. Due to the current out-of-stock situation with Takeda for Preotact, we have classified all the principal remaining for the Preotact debt as having an expected maturity of longer than 5 years and we could potentially earn royalties that are less than the remaining non-recourse principle amount owed.

In February 2010, we entered into an agreement with DRI in which we sold to DRI our right to receive future royalty payments arising from sales of REGPARA under our licensing agreement with Kyowa Hakko Kirin. We received an up-front purchase price of \$38.4 million in 2010. If and when DRI receives two and a half times the payment we received, the agreement will terminate and the remainder of the royalties, if any, will revert back to us. We have determined that we should classify the up-front purchase price as debt and amortize this using the effective interest rate method over the estimated period to recover two and a half times the principal advanced. We estimate future net sales of REGPARA by Kyowa Hakko Kirin and then calculate the effective interest rate on the DRI debt. Changes to the future REGPARA net sales forecast may have a material impact on interest expense. Management evaluates its future REGPARA net sales estimates on a quarterly basis and adjusts the effective interest rate when information indicates that the estimate is materially above or below the prior estimate.

**Valuation of Long-lived Assets and Goodwill.** We assess the impairment of long-lived assets and goodwill whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important which could trigger an impairment review include the following:

- significant underperformance relative to expected historical or projected future operating results;
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends;
- significant decline in our stock price for a sustained period; and
- our market capitalization relative to net book value.

When we determine that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we measure any impairment based on a probability weighted projected discounted cash flow method using a discount rate determined to be commensurate with the risk inherent in our current business model.

Goodwill represents the excess of costs over fair value of net assets of businesses acquired. Goodwill acquired in a purchase business combination is not amortized, but instead tested for impairment at least annually, or sooner if circumstances indicate that an impairment might have occurred.

## **Recent Accounting Pronouncements**

See note 13 to the consolidated financial statements for a full description of recent accounting pronouncements including the respective expected dates of adoption and expected effects on results of operations and financial condition.

## **ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk.**

**Interest Rate Risk.** Our interest rate risk exposure results from our investment portfolio, our convertible notes, and our non-recourse notes. Our primary objectives in managing our investment portfolio are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. The securities we hold in our investment portfolio are subject to interest rate risk. At any time, sharp changes in interest rates can affect the fair value of the investment portfolio and its interest earnings. After a review of our marketable investment securities, we believe that in the event of a hypothetical ten percent increase in interest rates, the resulting decrease in fair value of our marketable

investment securities would be insignificant to the consolidated financial statements. Currently, we do not hedge these interest rate exposures. We have established policies and procedures to manage exposure to fluctuations in interest rates. We place our investments with high quality issuers and limit the amount of credit exposure to any one issuer and do not use derivative financial instruments in our investment portfolio. We invest in highly liquid, investment-grade securities and money market funds of various issues, types and maturities. These securities are classified as available for sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as accumulated other comprehensive income as a separate component in stockholders' deficit unless a loss is deemed other than temporary, in which case the loss is recognized in earnings. Our 5.75% Convertible Notes due 2014 and our 9% Sensipar Notes, each have a fixed interest rate. As of December 31, 2012, our Convertible Notes and Sensipar Notes had \$16.5 million and \$80.2 million, respectively, in aggregate principal amount outstanding. The fair value of the Convertible Notes is affected by changes in the interest rates and by changes in the price of our common stock. The fair value of the Sensipar Notes is affected by changes in interest rates and by historical and projected rates of royalty revenues from cinacalcet HCl sales.

***Foreign Currency Risk.*** We have significant clinical and commercial manufacturing agreements which are denominated in euros and Canadian Dollars. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar and the Canadian dollar or euro, or by weak economic conditions in Canada or Europe. When the U.S. dollar strengthens against the Canadian dollar or euros, the cost of expenses in Canada or Europe decreases. When the U.S. dollar weakens against the Canadian dollar or euro, the cost of expenses in Canada or Europe increases. The monetary assets and liabilities in our foreign subsidiary which are impacted by the foreign currency fluctuations are cash, accounts payable, and certain accrued liabilities. A hypothetical ten percent increase or decrease in the exchange rate between the U.S. dollar and the Canadian dollar or euro from the December 31, 2012 rate would cause the fair value of such monetary assets and liabilities in our foreign subsidiary to change by an insignificant amount. We are not currently engaged in any foreign currency hedging activities.

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

**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**

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## Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
NPS Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheets of NPS Pharmaceuticals, Inc. and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, stockholders' deficit, and cash flows for each of the years in the three-year period ended December 31, 2012. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of NPS Pharmaceuticals, Inc. and subsidiaries as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), NPS Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 21, 2013, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Short Hills, New Jersey  
February 21, 2013

## Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
NPS Pharmaceuticals, Inc.:

We have audited NPS Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). NPS Pharmaceuticals, 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, included in the accompanying Management's Report on Internal Control over Financial Reporting appearing under Item 9A(b). Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included 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, NPS Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of NPS Pharmaceuticals, Inc. and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, stockholders' deficit, and cash flows for each of the years in the three-year period ended December 31, 2012, and our report dated February 21, 2013 expressed an unqualified opinion on these consolidated financial statements.

/s/ KPMG LLP

Short Hills, New Jersey  
February 21, 2013



**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**Consolidated Balance Sheets**

**December 31, 2012 and 2011**

(In thousands, except share data)

	<u>2012</u>	<u>2011</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 17,471	\$ 82,401
Marketable investment securities	83,244	79,832
Accounts receivable	30,276	29,532
Prepaid expenses	4,317	6,174
Other current assets	1,743	1,689
Total current assets	<u>137,051</u>	<u>199,628</u>
Property and Equipment, net	4,193	4,346
Goodwill	9,429	9,429
Debt issuance costs, net of accumulated amortization of \$618 and \$477, respectively	436	577
Total assets	<u>\$ 151,109</u>	<u>\$ 213,980</u>
<b>Liabilities and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 4,373	\$ 5,337
Accrued expenses and other current liabilities	9,297	6,047
Accrued research and development expenses	5,636	6,860
Accrued interest expense	3,983	6,092
Current portion of non-recourse debt	6,278	19,267
Total current liabilities	<u>29,567</u>	<u>43,603</u>
Non-recourse debt, less current portion	153,024	192,085
Convertible notes payable	16,545	16,545
Other liabilities	6,614	7,863
Total liabilities	<u>205,750</u>	<u>260,096</u>
Commitments and contingencies (notes 7, 8 and 14)		
Stockholders' deficit:		
Preferred stock, \$0.001 par value. Authorized 5,000,000 shares; issued and outstanding no shares	-	-
Common stock, \$0.001 par value. Authorized 175,000,000 shares; issued and outstanding 86,779,049 shares and 86,081,167 shares, respectively	87	86
Additional paid-in capital	954,452	944,344
Accumulated other comprehensive income (loss)	5	(96)
Accumulated deficit	<u>(1,009,185)</u>	<u>(990,450)</u>
Total stockholders' deficit	<u>(54,641)</u>	<u>(46,116)</u>
Total liabilities and stockholders' deficit	<u>\$ 151,109</u>	<u>\$ 213,980</u>

See accompanying notes to consolidated financial statements.

**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**Consolidated Statements of Operations**  
**Years ended December 31, 2012, 2011, and 2010**  
(In thousands, except per share data)

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Revenues:			
Royalties	\$ 105,587	\$ 96,502	\$ 86,181
Sale of royalty rights	25,000	-	-
Product sales	-	99	551
Milestones and license fees	57	5,044	2,682
Total revenues	<u>130,644</u>	<u>101,645</u>	<u>89,414</u>
Operating expenses:			
Cost of royalties	-	500	-
Cost of goods sold	-	-	6
Cost of license fees	-	2,543	69
Research and development	94,839	73,831	60,814
General and administrative	36,929	24,226	18,951
Total operating expenses	<u>131,768</u>	<u>101,100</u>	<u>79,840</u>
Operating (loss) income	<u>(1,124)</u>	<u>545</u>	<u>9,574</u>
Other income (expense):			
Interest income, net	292	321	418
Interest expense	(18,198)	(37,736)	(45,128)
Gain on sale of marketable investment securities, net	4	-	3,751
Foreign currency transaction gain	54	318	448
Other	237	303	587
Total other expense, net	<u>(17,611)</u>	<u>(36,794)</u>	<u>(39,924)</u>
Loss before income tax expense	<u>(18,735)</u>	<u>(36,249)</u>	<u>(30,350)</u>
Income tax expense	-	18	1,091
Net loss	<u>\$ (18,735)</u>	<u>\$ (36,267)</u>	<u>\$ (31,441)</u>
Basic and diluted net loss per common and potential common share	<u>\$ (0.22)</u>	<u>\$ (0.45)</u>	<u>\$ (0.54)</u>
Weighted average common and potential common shares outstanding—basic and diluted	<u>86,999</u>	<u>81,279</u>	<u>58,607</u>

See accompanying notes to consolidated financial statements.

**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**Consolidated Statements of Comprehensive Loss**

**Years ended December 31, 2012, 2011 and 2010**

**(In thousands)**

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Net loss	\$ (18,735)	\$ (36,267)	\$ (31,441)
Other comprehensive income:			
Unrealized gains (losses) on securities:			
Unrealized holding gains (losses) arising during period	107	(102)	(31)
Reclassification for recognized gain (loss) on marketable securities during the period	<u>4</u>	<u>-</u>	<u>(2,846)</u>
Net unrealized gain (loss) on marketable investment securities	111	(102)	(2,877)
Foreign currency translation (loss) gain	<u>(10)</u>	<u>5</u>	<u>(15)</u>
Other comprehensive income (loss)	<u>101</u>	<u>(97)</u>	<u>(2,892)</u>
Comprehensive loss	<u>\$ (18,634)</u>	<u>\$ (36,364)</u>	<u>\$ (34,333)</u>

See accompanying notes to consolidated financial statements.

**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**Consolidated Statements of Stockholders' Deficit**

**Years ended December 31, 2012, 2011 and 2010**

**(In thousands, except share data)**

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balances, December 31, 2009	-	\$ -	48,427,880	\$ 48	\$ 697,002	\$ 2,893	\$ (922,742)	\$ (222,799)
Stock options exercised	-	-	251,319	-	1,106	-	-	1,106
Shares issued for services rendered	-	-	30,881	-	112	-	-	112
Compensation expense on share-based awards	-	-	-	-	2,984	-	-	2,984
Net proceeds from sale of shares	-	-	18,276,860	19	97,636	-	-	97,655
Other comprehensive loss	-	-	-	-	-	(2,892)	-	(2,892)
Net loss	-	-	-	-	-	-	(31,441)	(31,441)
Balances, December 31, 2010	-	-	66,986,940	67	798,840	1	(954,183)	(155,275)
Stock options exercised	-	-	257,435	-	1,130	-	-	1,130
Compensation expense on share-based awards	-	-	-	-	4,100	-	-	4,100
Net proceeds from sale of shares	-	-	12,687,065	13	107,020	-	-	107,033
Conversion of 5.75% convertible notes	-	-	6,149,727	6	33,254	-	-	33,260
Other comprehensive loss	-	-	-	-	-	(97)	-	(97)
Net loss	-	-	-	-	-	-	(36,267)	(36,267)
Balances, December 31, 2011	-	-	86,081,167	86	944,344	(96)	(990,450)	(46,116)
Stock options exercised	-	-	481,058	1	2,407	-	-	2,408
Shares issued for services rendered	-	-	171,271	-	149	-	-	149
Compensation expense on share-based awards	-	-	-	-	7,298	-	-	7,298
Net proceeds from sale of shares	-	-	45,553	-	254	-	-	254
Other comprehensive income	-	-	-	-	-	101	-	101
Net loss	-	-	-	-	-	-	(18,735)	(18,735)
Balances, December 31, 2012	-	\$ -	86,779,049	\$ 87	\$ 954,452	\$ 5	\$ (1,009,185)	\$ (54,641)

See accompanying notes to consolidated financial statements.

**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Cash Flows**  
**Years ended December 31, 2012, 2011 and 2010**  
**(In thousands)**

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Cash flows from operating activities:			
Net loss	\$ (18,735)	\$ (36,267)	\$ (31,441)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,083	462	137
Accretion of premium on marketable investment securities	2,005	1,379	856
Non-cash interest expense	17,239	18,115	38,811
Non-cash royalties	(55,993)	(57,467)	(15,208)
Realized gain on marketable investment securities	(4)	-	(3,751)
Loss on extinguishment of debt	-	646	-
Compensation expense on share based awards	7,548	4,100	3,096
Decrease (increase) in operating assets:			
Accounts receivable	(16,010)	18,663	(2,266)
Prepaid expenses, other current assets and other assets	1,803	(2,948)	617
Increase (decrease) in operating liabilities:			
Accounts payable and accrued expenses	1,321	(3,425)	1,863
Other liabilities	(1,249)	84	(10,446)
Net cash used in operating activities	<u>(60,992)</u>	<u>(56,658)</u>	<u>(17,732)</u>
Cash flows from investing activities:			
Sales of marketable investment securities	7,628	240	9,621
Maturities of marketable investment securities	111,879	86,428	109,708
Purchases of marketable investment securities	(124,809)	(111,380)	(119,196)
Acquisitions of property and equipment	(1,187)	(3,407)	(862)
Net cash used in investing activities	<u>(6,489)</u>	<u>(28,119)</u>	<u>(729)</u>
Cash flows from financing activities:			
Proceeds from issuance of non-recourse debt	-	145,000	38,400
Principal payments on debt and capital lease obligation	-	(213,848)	(50,662)
Payment of debt issuance costs	-	(96)	(166)
Net proceeds from the sale of common stock and exercise of stock options	2,561	108,163	98,761
Decrease (increase) in restricted cash and cash equivalents	-	50,784	(8,963)
Net cash provided by financing activities	<u>2,561</u>	<u>90,003</u>	<u>77,370</u>
Effect of exchange rate changes on cash	<u>(10)</u>	<u>5</u>	<u>(15)</u>
Net (decrease) increase in cash and cash equivalents	<u>(64,930)</u>	<u>5,231</u>	<u>58,894</u>
Cash and cash equivalents at beginning of year	82,401	77,170	18,276
Cash and cash equivalents at end of year	<u>\$ 17,471</u>	<u>\$ 82,401</u>	<u>\$ 77,170</u>

*Supplemental Disclosures of Cash Flow Information:*

Cash paid for interest	\$ 954	\$ 27,109	\$ 16,096
Cash paid for income taxes	-	-	594

*Supplemental Disclosures of Non-Cash Investing and Financing Activities:*

Unrealized gains (losses) on marketable investment securities	\$ 111	\$ (102)	\$ (2,877)
Accrued acquisition of equipment	96	353	94
Debt issued in lieu of interest	-	-	23,653
Noncash principal payments	52,050	19,899	-
Conversion of 5.75% convertible notes	-	33,260	-

See accompanying notes to consolidated financial statements.

## NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements December 31, 2012, 2011, and 2010

#### **(1) Organization and Summary of Significant Accounting Policies**

The consolidated financial statements are comprised of the financial statements of NPS Pharmaceuticals, Inc. and its subsidiaries (NPS), collectively referred to as the Company or NPS. NPS is a biopharmaceutical company focused on pioneering and delivering therapies that transform the lives of patients with rare diseases worldwide. The Company's lead product, Gattex® 0.05 mg/kg/d (Teduglutide [rDNA origin]) for Injection, for subcutaneous use was approved by the U.S. Food and Drug Administration (FDA) in December 2012 for the treatment of adult patients with short bowel syndrome (SBS) who are dependent on parenteral support. The Company is also developing Natpara® (rhPTH[1-84]) for the treatment of adult hypoparathyroidism. The Company has met with FDA to discuss its Human Factors/Usability testing of the Natpara injection pen device. The final study will be initiated in March 2013 with results expected in the second quarter of 2013. The Company continues to work toward submitting its U.S. Biologics License Application (BLA) for Natpara. In order to finalize its submission, the Company needs to resolve certain previously disclosed manufacturing issues. The Company expects to complete certain key root cause analyses during the second quarter of 2013. Subject to resolution of the manufacturing issue, the company expects to submit its BLA in the second half of 2013.

In addition to the Company's proprietary clinical portfolio, it has a number of royalty-based clinical and commercial stage programs.

Since inception, the Company's principal activities have been performing research and development, raising capital and establishing research and license agreements. All monetary amounts are reported in U.S. dollars unless specified otherwise.

#### ***Liquidity***

The Company has a history of losses and has been incurring negative cash flow from operations, and has expended, and expects to continue to expend substantial funds to implement its planned product development efforts and commercialization programs. The Company believes its existing capital resources at December 31, 2012 should be sufficient to fund its current and planned operations through at least January 1, 2014. The Company will need to raise additional funds to support its long-term research, product development, and commercialization programs. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce spending, including modifying or terminating current clinical trials or commercialization programs, to provide the required liquidity.

#### ***Subsequent Events***

The Company has evaluated all events and transactions since December 31, 2012. The Company did not have any material recognized or non-recognized subsequent events.

#### ***Significant Accounting Policies***

The following significant accounting policies are followed by the Company in preparing its consolidated financial statements:

##### ***(a) Cash Equivalents***

The Company considers all highly liquid investments with maturities at the date of purchase of three months or less to be cash equivalents. Cash equivalents at December 31, 2012 and 2011 are carried at cost and consist of commercial paper, money market funds, debt securities and other highly liquid instruments of approximately \$16.2 million and \$80.4 million, respectively. At December 31, 2012 and 2011, the book value of cash equivalents approximates fair value.

##### ***(b) Marketable Investment Securities***

The Company classifies its marketable investment securities as available-for-sale or as trading securities. Available-for-sale and trading securities are recorded at fair value. Unrealized holding gains and losses on available-

for-sale securities, net of the related tax effect, are excluded from earnings and are reported as a separate component of stockholders' deficit until realized. A decline in the fair value below cost of available-for-sale securities that is deemed other than temporary is charged to results of operations, resulting in the establishment of a new cost basis for the security. Premiums and discounts are amortized or accreted into the cost basis over the life of the related security as adjustments to the yield using the effective-interest method. Unrealized holding gains and losses on trading securities are included in earnings in each period. Interest income is recognized when earned. Realized gains and losses from the sale of marketable investment securities are based on the specific identification method and are included in results of operations and are determined on the specific-identification basis.

The Company conducts periodic reviews to identify and evaluate each investment that has an unrealized loss. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income.

For available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether the Company intends to sell or whether it would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where the Company intends to sell a security, or where it may be more likely than not be required to sell the security before the expected recovery of the amortized cost basis, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded within earnings as an impairment loss.

Regardless of the Company's intent to sell a security, the Company performs additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where the Company does not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

#### ***(c) Trade Accounts Receivable***

Trade accounts receivable are recorded for research and development support performed, for license fees, milestone payments and royalty income earned, and for product sales, and do not bear interest. The Company determines an allowance for doubtful accounts based on assessed customers' ability to pay, historical write-off experience, and economic trends. Such allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing accounts receivable. The Company reviews its allowance for doubtful accounts monthly. The Company did not record any bad debt expense for the years ended December 31, 2012, 2011 and 2010. At December 31, 2012 and 2011 the allowance for bad debts was zero.

#### ***(d) Property and Equipment***

Property and equipment is stated at cost. Depreciation and amortization of property and equipment is calculated on the straight-line method over estimated useful lives of 3 to 5 years. Leasehold improvements are amortized using the straight-line method over the shorter of the life of the asset or remainder of the lease term.

#### ***(e) Goodwill***

Goodwill represents the excess of costs over fair value of assets of businesses acquired. Goodwill and intangible assets acquired in a purchase business combination and determined to have an indefinite useful life are not amortized, but instead tested for impairment at least annually or sooner if circumstances indicate that impairment might have occurred. As a result of the annual impairment test performed by management at year-end, it was noted that fair value significantly exceeded the carrying value of the reporting unit. The company considers itself a single reportable segment and reporting unit.

#### ***(f) Income Taxes***

The Company accounts for income taxes using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating loss, and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company evaluates the need for a valuation allowance based on historical and projected income and whether the realizability of a deferred tax asset is deemed to be more likely than not.

### ***(g) Revenue Recognition***

The Company analyzes its revenue arrangements to determine whether the elements should be separated and accounted for individually or as a single unit of accounting. Allocation of revenue to individual elements which qualify for separate accounting is based on the estimated fair value of the respective elements.

The Company earns revenue from license fees, milestone payments, royalty payments and product sales. The Company defers and recognizes revenue from up-front nonrefundable license fees on a straight-line basis, unless another pattern is apparent, over the period wherein the Company has continuing involvement in the research and development project. The Company recognizes revenue from up-front nonrefundable license fees upon receipt when there is no continuing involvement in the research and development project. The Company recognizes revenue from its milestone payments as agreed-upon events representing the achievement of substantive steps in the development process are achieved and where the amount of the milestone payment approximates the fair value of achieving the milestone. Royalties from licensees are based on third-party sales of licensed products and are recorded in accordance with contract terms when sales results are reliably measurable and collectability is reasonably assured. The Company recognizes revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured and the Company has no further performance obligations. All revenues from product sales are recorded net of the applicable provision for returns in the same period the related sales are recorded.

### ***(h) Research and Development Expenses***

Research and development expenses, are expensed as incurred and are primarily comprised of the following types of costs incurred in performing research and development activities: clinical trial and related clinical manufacturing costs, contract services, outside costs, salaries and benefits, overhead and occupancy costs.

The Company analyzes how to characterize payments under collaborative agreements based on the relevant facts and circumstances related to each agreement.

### ***(i) Income (Loss) per Common Share***

Basic income (loss) per common share is the amount of income (loss) for the period divided by the sum of the weighted average shares of common stock outstanding during the reporting period. Diluted income (loss) per common share is the amount of income (loss) for the period plus interest expense on convertible debt divided by the sum of weighted average shares of common stock outstanding during the reporting period and weighted average share that would have been outstanding assuming the issuance of common shares for all dilutive potential common shares.

### ***(j) Share-Based Compensation***

The Company accounts for share-based compensation in accordance with Financial Accounting Standards Board's Accounting Standards Codification ("ASC") 718, "*Compensation – Stock Compensation*" (ASC 718). Compensation cost is recorded based on the grant date fair value estimated using the Black-Scholes option-pricing for awards which vest based on a service or performance condition or the Monte Carlo simulation model for awards with market conditions. The Company recognizes compensation cost for awards on a straight-line basis over the requisite service period for the entire award.

### ***(k) Use of Estimates***

Management of the Company has made estimates and assumptions relating to reporting of assets and liabilities and the disclosure of contingent assets and liabilities to prepare these consolidated financial statements in conformity with U.S. generally accepted accounting principles (U.S. GAAP). Actual results could differ from those estimates.

### ***(l) Principles of Consolidation***

The consolidated financial statements include the accounts of the Company, all subsidiaries in which it owns a majority voting interest including a variable interest entity in which the Company is the primary beneficiary. The Company eliminates all intercompany accounts and transactions in consolidation.



***(m) Accounting for Impairment of Long-Lived Assets***

As described in (e), goodwill is tested for impairment at least annually. The Company reviews all other long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets held and used is measured by a comparison of the carrying amount of an asset to future net cash flows (undiscounted) expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets held for sale are reported at the lower of the carrying amount, or fair value, less costs to sell.

***(n) Foreign Currency Translation***

Assets and liabilities of foreign operations with non-U.S. dollar functional currencies are translated into U.S. dollars at the period end exchange rates. Income, expenses and cash flows are translated at the average exchange rates prevailing during the period. Adjustments resulting from translation are reported as a separate component of accumulated other comprehensive loss in stockholders' deficit. Certain transactions are denominated in currencies other than the functional currency. Transaction gains and losses are included in other income (expense) for the period in which the transaction occurs.

***(o) Comprehensive Income (Loss)***

Comprehensive income (loss) consists of net income (loss) and other gains and losses affecting stockholders' equity (deficit) that, under U.S. GAAP, are excluded from net income (loss). For the Company, these consist of net unrealized gains or losses on marketable investment securities and foreign currency translation gains and losses. Accumulated other comprehensive income (loss) as of December 31, 2012 and 2011 consists of accumulated net unrealized losses on marketable investment securities of \$22,000 and \$133,000, respectively, and foreign currency translation gains of \$27,000 and \$37,000, respectively.

***(p) Concentration of Suppliers***

The Company has entered into agreements with contract manufacturers to manufacture clinical and commercial supplies of its product candidates. In some instances, the Company is dependent upon a single supplier. The loss of one of these suppliers could have a material adverse effect upon the Company's operations.

***(q) Leases***

The Company leases its facility under terms of a lease agreement which provides for rent holidays and escalating payments. Rent under operating leases is recognized on a straight-line basis beginning with lease commencement through the end of the lease term. The Company records deferred lease payments in other long-term liabilities.

***(r) Deferred Financing Costs***

Costs incurred in issuing the 5.75% convertible notes are amortized using the straight-line method over the shorter of the term of the related instrument or the initial date on which the holders can require repurchase of the notes. The amortization of deferred financing costs is included in Interest expense in the Consolidated Statements of Operations.

Costs incurred in connection with the issuance of the Sensipar Notes and under the agreements with DRI, in which the Company sold to DRI its right to receive future royalty payments arising from sales of Preotact and REGPARA under its license agreements with Takeda and Kyowa Hakko Kirin, respectively, are amortized using the effective-interest method over the same period and in the same manner as the related debt. The amortization of deferred financing costs is included in Interest expense in the Consolidated Statements of Operations.

***(s) Deferred License Fees***

Cost of license fees are deferred if they are a direct cost of a revenue generating activity and that revenue is being deferred. These deferred costs are amortized over the same period and in the same manner as the related deferred revenue. The amortization of deferred license fees is included in Cost of license fees in the Consolidated Statements of Operations.

## **(2) Collaborative and License Agreements**

The Company is pursuing product development both on an independent basis and in collaboration with others. Because the Company has granted exclusive development, commercialization, and marketing rights under certain of the below-described collaborative research, development, and license agreements, the success of each program is dependent upon the efforts of the licensees. Each of the respective agreements may be terminated early. If any of the licensees terminates an agreement, such termination may have a material adverse effect on the Company's operations.

Following is a description of significant collaborations and license agreements:

### ***(a) Amgen Inc.***

In 1996, the Company licensed worldwide rights (with the exception of China, Japan, North and South Korea, and Taiwan) to Amgen, Inc. to develop and commercialize cinacalcet HCl for the treatment of hyperparathyroidism and indications other than osteoporosis and related bone metabolism disorders. Amgen is incurring all costs of developing and commercializing these products. Amgen paid the Company a \$10.0 million nonrefundable license fee and agreed to pay up to \$400,000 per year through 2000 in development support, potential additional development milestone payments totaling \$26.0 million, and royalties on any future product sales. Such \$26.0 million of potential additional milestone payments includes the Company's potential to earn a \$5.0 million milestone payment upon the FDA approval to sell a compound under the license agreement having a different structural formula from cinacalcet HCl. The future milestone is tied to future events outside the Company's control. The Company believes these are substantive in nature and there is no assurance that they will be achieved. Through December 31, 2012, Amgen has paid the Company \$21.0 million in milestone payments, of which \$0, \$0 and \$2.0 million were recognized during 2012, 2011, and 2010, respectively. The Company recognized royalties from product sales of \$89.3 million, \$77.6 million and \$69.8 million in 2012, 2011 and 2010, respectively, under the contract.

The Company receives a royalty from Amgen that represents a percentage in the high single digits to low double digits of Amgen's sales of cinacalcet HCl. In June 2012, we amended our agreement with Amgen and received a one-time non-refundable \$25.0 million payment in July 2012 in exchange for our rights to receive royalties under the license agreement that are earned after December 31, 2018. Amgen has a right to terminate upon 90 days written notice to the Company, and either party may terminate upon material default by the other party subject to a right to cure such default.

### ***(b) GlaxoSmithKline***

In 1993, the Company entered into an agreement with GlaxoSmithKline (GSK) to collaborate on the research, development and commercialization of calcium receptor active compounds to treat osteoporosis and other bone metabolism disorders, excluding hyperparathyroidism. GSK also acquired an equity investment in the Company in 1993. Under the terms of the agreement, the Company may receive milestone payments and royalties from any product sales under the license and a share of the profits from co-promoted products. To date, GSK has paid the Company \$12.0 million in milestone payments, of which none were recognized during 2012, 2011 or 2010. The Company granted GSK the exclusive license to develop and market worldwide compounds described under the GSK agreement, subject to the Company's right to co-promote in the United States. Once compounds have been selected for development, GSK has agreed to conduct and fund all development of such products, including all human clinical trials and regulatory submissions. In December 2006, the Company entered into an amendment to the agreement with GSK that permits GSK to develop additional compounds. In consideration for this amendment, the Company received a \$3.0 million fee during 2006. The Company recognized no revenue related to its agreement with GSK in 2012, 2011 or 2010.

The Company is entitled to receive a royalty from GSK that represents a percentage in the high single digits or low double digits, depending on sales, of such compounds should GSK commercialize any such compounds. The license agreement with GSK is effective for the longer of ten years from first marketing in the last country in the territory or the expiration of the last patent. GSK may terminate the agreement on 30-day written notice on a country-by-country basis if it reasonably determines that any compound developed under the agreement is not worth continued development. NPS may terminate the agreement on 90-day written notice if no compound is under development or commercialization for a period of twelve consecutive months, subject to GSK showing that it has a compound under development or commercialization or that it intends to enter development within six months. Either party may terminate upon material default by the other party subject to a right to cure such default. Upon termination, the rights and licenses the Company granted GSK revert to the Company.

In August 2011, the Company formed a new agreement with GSK which terminated and replaced the 1993 agreement. Under the agreement, GSK assigned to NPS the investigational new drug filings for two Phase 1 calcilytic compounds, NPSP790 and NPSP795. The Company believes calcilytics may have clinical application in treating rare disorders involving increased calcium receptor activity, such as autosomal dominant hypocalcemia with hypercalciuria (ADHH). The new agreement also expands GSK's licensed field of research for Ronacaleret to include stem cell transplants, in addition to osteoporosis and other bone disorders. Under the terms of the agreement, the Company has the potential to earn up to \$11.5 million in future milestone payments upon the achievement of certain pre-specified product development and sales-based milestones plus royalties on product sales. The Company has the potential to earn the next product development milestone of \$1.0 million upon the decision by GSK to continue development in the first indication following the proof of concept trial. The remaining milestones vary by additional indications, with \$7.5 million relating to successful proof of concept studies and acceptance of regulatory filings, and \$4.0 million relating to the first commercial sale of each indication. The future milestones are tied to future events outside the Company's control. The Company believes these are substantive in nature and there is no assurance that they will be achieved.

***(c) Kyowa Hakko Kirin***

In 1995, the Company entered into an agreement with the pharmaceutical division of Kyowa Hakko Kirin Co. Ltd, formerly Kirin Brewery Company Limited, to develop and commercialize compounds for the treatment of hyperparathyroidism in Japan, China, North Korea, South Korea and Taiwan. Kyowa Hakko Kirin paid the Company a \$5.0 million license fee during 2005 and agreed to pay up to \$7.0 million in research support, potential additional milestone payments totaling \$13.0 million and royalties on product sales. Kyowa Hakko Kirin is incurring all costs of developing and commercializing products. Any payments subsequent to June 2000 represent milestone and royalty payments. Through December 31, 2012, Kyowa Hakko Kirin has paid the Company \$7.0 million in research support and \$13.0 million in milestone payments none of which were recognized during 2012, 2011 or 2010. In October 2007, Kyowa Hakko Kirin received approval from the Japanese Pharmaceuticals and Medical Devices Agency to market cinacalcet HCl in Japan for the treatment of patients with secondary hyperparathyroidism during maintenance dialysis. The parties participate in a collaborative research program utilizing the Company's parathyroid calcium receptor technology. Under the Company's agreement with Kyowa Hakko Kirin, the Company recognized no milestone and license fee revenue in 2012, 2011 and 2010, respectively, and royalty revenue of \$8.7 million in 2012, \$7.6 million in 2011 and \$5.6 million in 2010.

The Company receives a royalty from Kyowa Hakko Kirin that represents a percentage in the single digits of sales. The agreement with Kyowa Hakko Kirin is effective until expiration of the last patent. Kyowa Hakko Kirin has a right to terminate upon 90 days written notice to the Company, and either party may terminate upon material default by the other party subject to a right to cure such default. Kyowa Hakko Kirin also has the right to terminate the agreement with respect to individual countries based upon a reasonable determination by if that continued development or marketing of a compound is not justified in such country, subject to providing 60 days notice and the Company's right to delay termination for up to 90 days. Certain agreements between the Company and DRI Capital Inc., or DRI (formerly Drug Royalty L.P.3) limit the Company's right to terminate this license (see note 8).

***(d) Takeda GmbH***

***Teduglutide***

In September 2007 the Company entered into a license agreement with Takeda GmbH, formerly known as Nycomed (Takeda) in which the Company granted Takeda the right to develop and commercialize teduglutide, outside the United States, Canada and Mexico for the treatment of gastrointestinal disorders. Teduglutide, (planned brand name Gattex®) is our novel recombinant analog of GLP-2, a peptide involved in the regeneration and repair of the intestinal lining. The Company has been developing teduglutide for the treatment of adults with short bowel syndrome (SBS). A positive opinion was issued in June 2012 by the Committee for Medicinal Products for Human Use, followed by the European Commission granting European market authorization on August 30, 2012 for the medicinal product teduglutide (trade name in Europe: Revestive®) as a once-daily treatment for adult patients with SBS.

The Company received \$35.0 million in up-front fees under the agreement during 2007. Takeda paid the Company \$10.0 million upon signing the license agreement and paid the Company an additional \$25.0 million in up-front license fees in the fourth quarter of 2007. Under the terms of the agreement, the Company was responsible to complete the first Phase 3 clinical trial in SBS and Takeda may elect to share equally the future development costs with NPS to advance and broaden the indications for teduglutide. Additionally, under a previously existing licensing agreement with a third party, the Company paid \$6.6 million in 2007 to the licensor and will be required to make future payments based on teduglutide royalties and milestone payments earned. Due to the Company's continuing

involvement, the Company recognized revenue associated with the upfront fees over the estimated performance period and for the years ended December 31, 2012, 2011 and 2010, the Company recognized no license fee revenue.

During 2011, Takeda paid the Company \$5.0 million for Takeda's submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for clearance to market teduglutide (Revestive®) as a once-daily subcutaneous treatment for SBS. Additionally, under a previously existing licensing agreement with a third party, the Company paid \$2.4 million in 2011 to the licensor and will be required to make future payments based on teduglutide royalties and milestone payments earned. The Company recognized revenue from this milestone payment due to the achievement of an as agreed-upon event of a substantive step in the development process and due to the amount of the milestone payment approximated the fair value of achieving the milestone.

Under the terms of the agreement, the Company has the potential to earn up to \$170.0 million in total future milestone payments, of which \$150.0 million is payable upon the achievement of certain pre-specified product development milestones and \$20.0 million is payable upon the achievement of certain sales-based milestones, plus royalties on product sales. The Company has the potential to earn the next product development milestone of \$5.0 million upon the launch of Revestive for adult SBS in the first major EU country. The remaining product development milestones relate to, and the amount of the milestone payments vary by, additional indications and pertain to successful proof of concept studies, acceptance of regulatory filings, and launch of product in the first major EU country. It is the Company's understanding that no clinical trials have commenced for any such additional indications. The future milestones are tied to future events outside the Company's control. The Company believes these are substantive in nature and there is no assurance that they will be achieved. Cumulatively through December 31, 2012, the Company has received \$40.0 million in license fees and milestone payments from Takeda under the license agreement of which none was received during the years ended December 31, 2012 and 2010 and \$5.0 million during the year ended December 31, 2011.

The Company is entitled to receive a royalty from Takeda, net of related payments to the licensor of certain intellectual property, that represents a percentage (i) in the teens of the Takeda net sales of teduglutide during the longer of the first ten years of sales in a particular country or the expiration of certain patents in such country, and (ii) in the single-digits thereafter until twenty years of sales in a particular country. The royalties for a particular country may be reduced to zero percent if aggregate sales of any other product containing GLP-2 exceeds a certain percentage during the longer of the first ten years of sales in such country or the expiration of certain patents in such country. The license agreement with Takeda is effective on a country by country basis for the longer of twenty years from first commercial sale or the expiration of the last patent. Prior to the first commercial sale, Takeda may terminate upon 180 days written notice to the Company. Following the first commercial sale, Takeda must provide 365-day written notice in order to terminate. If the Company receives such a termination notice, the Company may terminate the agreement at any time prior to the expiration of Takeda's requisite notice period. Either party may terminate upon material breach by the other party subject to a right to cure such breach.

In December 2008, Takeda and the Company agreed to share equally in certain external clinical costs incurred by both companies, including those related to a second Phase 3 study of teduglutide in SBS. Reimbursements from Takeda for their portion of the research and development activities are characterized as a reduction of the Company's research and development costs because performing contract research and development services is not central to the Company's operations.

### ***Preotact® (parathyroid hormone 1-84)***

In 2004, the Company signed a distribution and license agreement with Takeda in which the Company granted Takeda the right to develop and market Preotact® (recombinant parathyroid hormone 1-84) in Europe. During 2004, Takeda also made an equity investment in the Company of \$40.0 million through the purchase of 1.33 million shares of the Company's common stock. The agreement requires Takeda to pay the Company up to 22.0 million euros in milestone payments upon regulatory approvals and achievement of certain sales targets. The Company is also entitled to royalties on product sales. In July 2007, the Company entered into a new license agreement with Takeda which superseded the 2004 agreement, pursuant to which the Company granted to Takeda the right to commercialize Preotact in all non-U.S. territories, excluding Japan and Israel; however, Takeda's licensed rights in Canada and Mexico, revert back to the Company if the Company receives regulatory approval for the compound in the U.S. The 2007 license agreement contains milestone and royalty payment obligations which are similar to those under the 2004 distribution and license agreement. Takeda is required to pay the Company royalties on sales of Preotact only in the European Union, European countries outside the European Union, the Commonwealth of Independent States and Turkey. Pursuant to the Company's 2007 license agreement with Takeda, as described below, Takeda assumed NPS' manufacturing and supply obligations and patent prosecution and maintenance obligations under the 2004 license

agreement, which occurred in 2008. As part of the manufacturing and supply transfer, Takeda paid the Company \$11.0 million during 2007, for a significant portion of the Company's existing bulk drug inventory. Cumulatively through December 31, 2012, the Company has received 7.1 million euros in milestone payments from Takeda under the 2004 and 2007 agreements, all of which have been recognized as revenue. Under the terms of the agreement, the Company has the potential to earn a product development milestone of 311,000 euros upon the approval of Preotact in France. The remaining sales milestone of 14.5 million euros pertains to reaching a certain sales threshold for Preotact. The future milestones are tied to future events outside the Company's control. The Company believes these are substantive in nature and there is no assurance that they will be achieved.

The Company receives a royalty from Takeda that represents a percentage, depending on the amount of sales of Preotact, in the teens to low twenties of the Takeda net sales of Preotact in the European Union, European countries outside the European Union, the Commonwealth of Independent States and Turkey. The 2007 license agreement with Takeda is effective on a country by country basis for the longer of fifteen years from first commercial sale or the expiration of the last patent. If Takeda reasonably determines that it has no prospects for making a reasonable profit under the 2007 Agreement, and it is unable to agree to terms on a renegotiated agreement with the Company within eight weeks, Takeda may terminate the agreement by providing the Company with six months prior written notice; provided, however, that, upon any such termination the ownership of all rights to the Preotact trademark previously transferred by the Company to Takeda will revert to the Company and Takeda will allow certain regulatory authorizations to be transferred to the Company. Either party may terminate upon material breach by the other party subject to a right to cure such breach. Certain agreements with DRI Capital Inc., (DRI) limit the Company's right to terminate this license (see note 8). Due to a technical production issue, Takeda is presently unable to have batches of finished product manufactured that are consistently with specification and the Company has been informed that as a result Takeda is no longer selling Preotact in their territories. The Company understands that Takeda has taken a number of actions to resolve the manufacturing issue and to accelerate a return to normal supply situation. The Company has not received any information as to when or if Takeda will re-introduce Preotact in the future. Because the Company previously monetized its Preotact royalty rights as non-recourse debt, declines in Preotact sales will impact the Company's royalty revenues but will have no material impact on its short-term liquidity.

Revenues from Takeda related to the Preotact agreement, for the years ended December 31, are as follows (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Royalties	\$ 4,786	\$ 9,116	\$ 9,467
Product sales	-	-	452
Total revenues	<u>\$ 4,786</u>	<u>\$ 9,116</u>	<u>\$ 9,919</u>

***(e) Janssen Pharmaceuticals, Inc.***

In December 2006, the Company entered into an agreement with Janssen Pharmaceuticals, Inc. formerly known as Ortho-McNeil Pharmaceutical (Janssen) pertaining to certain NPS patents. Janssen paid the Company an \$8.0 million fee and agreed to pay royalties on sales of licensed products. NPS will not incur any development or commercialization costs for these products. The Company is responsible for patent prosecution and maintenance of the related patents. The Company may terminate the agreement if Janssen fails to make a payment and does not cure that default within 30 days, or if it does not cure any other default within sixty days of notice. Janssen may terminate the agreement on 60 days written notice for material breach if NPS has not cured the breach by that time or on 60 days written notice. Termination does not affect any previously-matured payment obligations. In November 2008, the U.S. Food and Drug Administration (FDA) approved Nucynta (tapentadol) hydrochloride immediate release (IR) tablets for the relief of moderate to severe acute pain. This compound is covered under our agreement and Janssen is required to pay the Company a royalty on the product's sales. Nucynta is a novel investigational, centrally acting oral analgesic, which was launched in the second quarter of 2009. The Company recognized revenue of \$2.8 million, \$2.2 million and \$1.2 million in 2012, 2011 and 2010, respectively.

***(f) Hoffman-La Roche Inc. and F. Hoffmann-La Roche Ltd.***

In December 2008, the Company entered into an agreement with Hoffman-La Roche Inc. and F. Hoffmann-La Roche Ltd. (Roche), under which the Company granted the Roche entities a non-exclusive license (with the right to grant sublicenses) to develop, make, import, use of for sale or sell products covered by patents relating to modulation of NMDA receptor activity using glycine uptake antagonists. In return Roche paid the Company an upfront licensing fee

of \$2.0 million, and agreed to make additional payments for the achievement of certain regulatory milestones. Through December 31, 2012, Roche has paid the Company \$250,000 in milestone payments. Further, Roche agreed to pay royalties on sales of licensed products, if any. Either party may terminate the agreement on 30 days written notice due to a material breach by the other, or in the case of the other party's insolvency. Amounts due prior to termination will remain due thereafter. NPS will not incur any development or commercialization costs for these products. The Company recognized revenue of \$0, \$0, and \$250,000 in 2012, 2011 and 2010, respectively, as the Company had no continuing involvement in the arrangement.

### ***(g) In-License and Purchase Agreements***

Depending on the commercial success of certain products, the Company may be required to pay license fees or royalties. Additionally, the Company is required to pay royalties on sales of cinacalcet HCl up to a cumulative maximum of \$15.0 million. To date, \$15.0 million has been accrued for related royalties payable on sales of cinacalcet HCl, of which, \$8.4 million has been paid. Annual payments due are limited to a maximum of \$1.0 million. Accruals of \$5.6 million and \$1.0 million at December 31, 2012 are recorded in other liabilities and accrued expenses and other current liabilities, respectively.

### **(3) Income (loss) Per Common Share**

Basic income (loss) per common share is the amount of income (loss) for the period divided by the weighted average shares of common stock outstanding during the reporting period. Diluted income (loss) per common share is the amount of income (loss) for the period plus interest expense on convertible debt divided by the sum of weighted average shares of common stock outstanding during the reporting period and weighted average shares that would have been outstanding assuming the issuance of common shares for all dilutive potential common shares.

Potential common shares of approximately 8.0 million, 8.3 million and 12.7 million during the years ended December 31, 2012, 2011, and 2010, respectively, that could potentially dilute basic income (loss) per common share in the future were not included in the computation of diluted income (loss) per share because to do so would have been anti-dilutive for the periods presented. Potential dilutive common shares for the years ended December 31, 2012, 2011 and 2010 include approximately 3.0 million, 4.7 million and 9.2 million common shares related to convertible debentures, respectively, and 5.0 million, 3.6 million, and 3.5 million shares, respectively, related to stock options, restricted stock, and restricted stock units.

### **(4) Fair Value Measurement**

#### ***Summary of Assets Recorded at Fair Value***

The Company's financial assets and liabilities are measured using inputs from the three levels of the fair value hierarchy. The three levels are as follows:

Level 1- Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2- Inputs are other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3- Inputs are unobservable and reflect the Company's assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available.

In accordance with the fair value hierarchy described above, the following table shows the fair value of the Company's financial assets (all marketable investment securities) that are required to be measured at fair value as of December 31, 2012 and December 31, 2011 (in thousands):

<i>As of December 31, 2012:</i>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Marketable investment securities	\$ 67,723	\$ 15,521	\$ -	\$ 83,244

<i>As of December 31, 2011:</i>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Marketable investment securities	\$ 50,824	\$ 29,008	\$ -	\$ 79,832

As of December 31, 2012 and December 31, 2011, the fair values of the Company's Level 2 securities were \$15.5 million and \$29.0 million, respectively. These securities are certificates of deposit or commercial paper issued by domestic companies with an original maturity of greater than ninety days. These securities are currently rated A-1 or higher. The Company's cash equivalents are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices or broker or dealer quotations for similar assets. These investments are initially valued at the transaction price and subsequently valued utilizing third party pricing providers or other market observable data. Data used in the analysis include reportable trades, broker/dealer quotes, bids and offers, benchmark yields and credit spreads. The Company validates the prices provided by its third party pricing providers by reviewing their pricing methods, analyzing pricing inputs and confirming that the securities have traded in normally functioning markets. The Company did not adjust or override any fair value measurements provided by its pricing providers as of December 31, 2012 or 2011.

As of December 31, 2012 and 2011, the Company did not have any investments in Level 3 securities.

There were no transfers of assets or liabilities between Level 1 and Level 2 during the years ended December 31, 2012 and 2011.

The carrying amounts reflected in the consolidated balance sheets for certain short-term financial instruments including cash and cash equivalents, restricted cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and other liabilities approximate fair value due to their short-term nature except that the estimated fair value and carrying value of the Brigham and Women's Hospital royalty liability using a discounted cash flow model is approximately \$4.8 million and \$6.6 million, respectively, at December 31, 2012 and \$4.9 million and \$7.6 million, respectively, at December 31, 2011.

#### ***Summary of Liabilities Recorded at Carrying Value***

The fair and carrying value of our debt instruments are detailed as follows (in thousands):

	<u>As of December 31, 2012</u>		<u>As of December 31, 2011</u>	
	<u>Fair Value</u>	<u>Carrying Value</u>	<u>Fair Value</u>	<u>Carrying Value</u>
5.75% Convertible Notes	\$ 28,131	\$ 16,545	\$ 22,925	\$ 16,545
Sensipar Notes	79,129	80,234	123,655	126,799
Preotact-Secured Debt	28,605	42,816	46,750	48,302
Regpara-Secured Debt	48,887	36,252	50,244	36,252
Total	<u>\$ 184,752</u>	<u>\$ 175,847</u>	<u>\$ 243,574</u>	<u>\$ 227,898</u>

The fair values of the Company's convertible notes were estimated using the (i) terms of the convertible notes; (ii) rights, preferences, privileges, and restrictions of the underlying security; (iii) time until any restriction(s) are released; (iv) fundamental financial and other characteristics of the Company; (v) trading characteristics of the underlying security (exchange, volume, price, and volatility); and (vi) precedent sale transactions. The fair values of the Company's non-recourse Sensipar notes, Preotact-secured debt and REGPARA-secured debt were estimated using a discounted cash flow model. Within the hierarchy of fair value measurements, these are Level 3 fair values.

## (5) Financial Instruments

Financial instruments that potentially subject the Company to concentrations of credit risk are accounts receivable and marketable investment securities. The majority of the Company's accounts receivable are payable by large pharmaceutical companies and collateral is generally not required from these large customers. Substantially all of the Company's revenues for the years ended December 31, 2012 and 2011 were from four licensees of the Company. At December 31, 2012 and 2011, substantially all of the Company's accounts receivable balances were from four licensees. The Company's portfolio of marketable investment securities is subject to concentration limits set within the Company's investment policy that help to mitigate its credit exposure.

The following is a summary of the Company's marketable investment securities (in thousands):

	<u>Amortized cost</u>	<u>Gross unrealized holding gains</u>	<u>Gross unrealized holding losses</u>	<u>Fair value</u>
<i>As of December 31, 2012:</i>				
Debt securities:				
Corporate	\$ 50,822	\$ 3	\$ (31)	\$ 50,794
Government agency	32,444	10	(4)	32,450
Total marketable investment securities	<u>\$ 83,266</u>	<u>\$ 13</u>	<u>\$ (35)</u>	<u>\$ 83,244</u>

	<u>Amortized cost</u>	<u>Gross unrealized holding gains</u>	<u>Gross unrealized holding losses</u>	<u>Fair value</u>
<i>As of December 31, 2011:</i>				
Debt securities:				
Corporate	\$ 49,296	\$ 1	\$ (124)	\$ 49,173
Government agency	30,668	3	(12)	30,659
Total marketable investment securities	<u>\$ 79,964</u>	<u>\$ 4</u>	<u>\$ (136)</u>	<u>\$ 79,832</u>

Marketable investment securities available for sale in an unrealized loss position as of December 31, 2012 and 2011 are summarized as follows (in thousands):

	<u>Held for less than 12 months</u>		<u>Held for more than 12 months</u>		<u>Total</u>	
	<u>Fair value</u>	<u>Unrealized losses</u>	<u>Fair value</u>	<u>Unrealized losses</u>	<u>Fair value</u>	<u>Unrealized losses</u>
<b>December 31, 2012</b>						
<b>Available for Sale:</b>						
Debt securities:						
Corporate	\$ 37,974	\$ 31	\$ -	\$ -	\$ 37,974	\$ 31
Government agency	7,110	4	-	-	7,110	4
	<u>\$ 45,084</u>	<u>\$ 35</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 45,084</u>	<u>\$ 35</u>
<b>December 31, 2011</b>						
<b>Available for Sale:</b>						
Debt securities:						
Corporate	\$ 38,276	\$ 124	\$ -	\$ -	\$ 38,276	\$ 124
Government agency	23,425	12	-	-	23,425	12
	<u>\$ 61,701</u>	<u>\$ 136</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 61,701</u>	<u>\$ 136</u>



### *Summary of Contractual Maturities*

Maturities of marketable investment securities are as follows at December 31, 2012 and December 31, 2011 (in thousands):

	<u>As of December 31, 2012</u>		<u>As of December 31, 2011</u>	
	<u>Amortized</u>		<u>Amortized</u>	
	<u>cost</u>	<u>Fair value</u>	<u>cost</u>	<u>Fair value</u>
Due within one year	\$ 65,637	\$ 65,632	\$ 70,902	\$ 70,794
Due after one year through five years	17,629	17,612	9,062	9,038
Due after five years through ten years	-	-	-	-
Due after ten years	-	-	-	-
Total debt securities	<u>\$ 83,266</u>	<u>\$ 83,244</u>	<u>\$ 79,964</u>	<u>\$ 79,832</u>

### *Impairments*

No impairment losses were recognized through earnings related to available for sale securities during the years ended December 31, 2012 or 2011.

### *Proceeds from Available for Sale Securities*

The proceeds from maturities and sales of available for sale securities and resulting realized gains and losses, were as follows (in thousands):

	<u>For the Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Proceeds from sales and maturities	\$ 119,507	\$ 86,668	\$ 117,929
Realized gains	4	-	3,589
Realized losses	-	-	-

The realized gains for the year ended December 31, 2010, primarily related to the sale of ARS.

### **(6) Property and Equipment, Net**

Property and equipment is recorded at cost and consists of the following (in thousands):

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
Office Equipment	\$ 4,379	\$ 3,826
Laboratory Equipment	216	168
Leasehold Improvements	1,795	1,466
Total property and equipment	6,390	5,460
Less accumulated depreciation	(2,197)	(1,114)
Total equipment, net	<u>\$ 4,193</u>	<u>\$ 4,346</u>

## (7) Leases

The Company has a non-cancelable operating lease for its office space in Bedminster, New Jersey that expires in 2016. The Company also has non-cancelable operating leases for certain equipment that expire between 2013 and 2014. Rent-free periods and other incentives granted under the leases and scheduled rent increases are charged to rent expense on a straight-line basis over the related terms of the lease. Rental expense for operating leases was approximately \$1.6 million, \$1.3 million, and \$728,000 for 2012, 2011, and 2010, respectively. The future lease payments under non-cancelable operating leases as of December 31, 2012 are as follows (in thousands):

	<u>Operating leases</u>
Year ending December 31:	
2013	\$ 1,881
2014	1,892
2015	1,908
2016	1,287
2017	-
Total minimum lease payments	<u>\$ 6,968</u>

## (8) Long-term Debt

The following table reflects the carrying value of our long-term debt under various financing arrangements as of December 31, 2012 and 2011 (in thousands):

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
Convertible notes	\$ 16,545	\$ 16,545
Non-recourse debt	159,302	211,352
Total debt	175,847	227,897
Less current portion	6,278	19,267
Total long-term debt	<u>\$ 169,569</u>	<u>\$ 208,630</u>

### (a) Convertible Notes

In August 2007, the Company completed a private placement of \$50.0 million in 5.75% Convertible Notes due August 7, 2014 (5.75% Convertible Notes). The Company received net proceeds from the 5.75% Convertible Notes of approximately \$49.4 million, after deducting costs associated with the offering. The 5.75% Convertible Notes accrue interest at an annual rate of 5.75% payable quarterly in arrears on the first day of the succeeding calendar quarter commencing January 1, 2008. Accrued interest on the 5.75% Convertible Notes was \$0 as of December 31, 2012 and 2011, respectively. The holders may convert all or a portion of the 5.75% Convertible Notes into common stock at any time, subject to certain limitations, on or before August 7, 2014. The 5.75% Convertible Notes are convertible into common stock at a conversion price of \$5.44 per share (see below), subject to adjustments in certain events. The 5.75% Convertible Notes are unsecured debt obligations and rank equally in right of payment with all existing and future unsecured senior indebtedness. On or after August 7, 2012, the Company may redeem any or all of the 5.75% Convertible Notes at a redemption price of 100% of their principal amount, plus accrued and unpaid interest to the day preceding the redemption date. The 5.75% Convertible Notes provide for certain events of default, including payment defaults, breaches of covenants and certain events of bankruptcy, insolvency and reorganization. The 5.75% Convertible Notes also provide that if there shall occur a fundamental change, as defined, at any time prior to the maturity of the Note, then the holder shall have the right, at the Holder's option, to require the Company to redeem the notes, or any portion thereof plus accrued interest and liquidated damages, if any. If a change of control, as defined, occurs and if the holder converts notes in connection with any such transaction, the Company will pay a make whole premium by increasing the conversion rate applicable to the notes. If any event of default occurs and is continuing, the principal amount of the 5.75% Convertible Notes, plus accrued and unpaid interest, if any, may be declared immediately due and payable. The Company incurred debt issuance costs of approximately \$600,000, which have been deferred and which are being amortized over a seven-year period. The effective interest rate on the 5.75% Convertible Notes, including debt issuance costs, is 5.9%.

On January 31, 2011 and April 14, 2011, certain holders of the 5.75% Convertible Notes converted portions of the outstanding notes at a conversion price of \$5.44 per share. The Company issued 529,282 and 5,620,445 shares on January 31, 2011 and April 14, 2011, respectively, pursuant to this conversion and retired \$2.9 million and \$30.6 million, respectively, of the outstanding 5.75% Convertible Notes. The Company has \$16.5 million of the 5.75% Convertible Notes outstanding as of December 31, 2012.

Pursuant to the Registration Rights Agreement, the Company has filed a shelf registration statement with the SEC, covering resales of the common stock issuable upon conversion of the 5.75% Convertible Notes. The registration statement has been declared effective. The Company agreed to use its reasonable best efforts to keep the registration statement effective until the earlier of (i) the date as of which holders may sell all of the securities covered by the registration statement without restriction pursuant to Rule 144(k) promulgated under the Securities Act of 1933 or (ii) the date on which holders shall have sold all of the securities covered by the registration statement. If the Company fails to comply with these covenants or suspends use of the registration statement for periods of time that exceed what is permitted under the Registration Rights Agreement, the Company is required to pay liquidated damages in an amount equivalent to 1% per annum of (a) the principal amount of the notes outstanding, or (b) the conversion price of each underlying share of common stock that has been issued upon conversion of a note, in each case, until the Company is in compliance with these covenants. The Company believes the likelihood of such an event occurring is remote and, as such, the Company has not recorded a liability as of December 31, 2012.

### ***(b) Non-recourse Debt***

#### **Sensipar and Mimpara-secured Non-recourse Debt**

As of December 31, 2012 and 2011, the outstanding principal balances on Sensipar and Mimpara- secured debt were \$80.2 million and \$126.8 million, respectively. The Sensipar and Mimpara-secured debt is non-recourse to the Company and solely secured and serviced by its Sensipar and Mimpara (cinacalcet HCl) royalty revenues and milestone payments. The Sensipar and Mimpara- secured non-recourse debt relates to the following royalty monetization transactions: (i) the private placement of \$175.0 million in non-recourse 8.0% Notes due March 30, 2017 (Class A Notes), (ii) the private placement of \$100.0 million in non-recourse 15.5% Notes due March 30, 2017 (Class B Notes), and (iii) the amendment of the Company's agreement with Amgen in August 2011. These three transactions are summarized below.

As of December 31, 2011 and 2010, the outstanding principal balances on the Class A Notes were \$0 and \$46.2 million, respectively. In December 2004, the Company completed a private placement of the Class A Notes. The Company received net proceeds from the issuance of the Class A Notes of approximately \$169.3 million, after deducting costs associated with the offering. The Class A Notes accrued interest at an annual rate of 8.0%. Additionally, the only source for interest payments and principal repayment of the Class A Notes was royalty and milestone payments received from Amgen. The Class A Notes were paid in full on March 30, 2011.

The outstanding principal balances on the Class B Notes, were \$0 and \$167.7 million, which included PIK Notes which have been issued, as of December 31, 2011 and 2010, respectively. In August 2007, the Company completed a private placement of \$100.0 million in Class B Notes. The Company received net proceeds from the issuance of the Class B Notes of approximately \$97.0 million, after deducting costs associated with the offering. The Class B Notes accrued interest at an annual rate of 15.5% payable quarterly in arrears on March 30, June 30, September 30 and December 30 of each year. The Class B Notes were secured by certain royalty and related rights of the Company under its agreement with Amgen for Sensipar and Mimpara (cinacalcet HCl). Additionally, the only source for interest payments and principal repayment of the Class B Notes was royalty and milestone payments received from Amgen and only after the Class A Notes were paid in full. Prior to repayment in full of the Class A Notes, interest on the Class B Notes was paid in kind through the issuance of notes (the PIK Notes) which were part of the same class and had the same terms and rights as the Class B Notes, except that interest on the PIK Notes began to accrue from the date that such PIK Notes were issued. The Class B Notes were paid in full on September 30, 2011 when they were redeemable at their par value.

The Company amended its agreement with Amgen effective September 30, 2011 whereby Amgen advanced \$145.0 million of Sensipar and Mimpara royalties to the Company. The Sensipar Notes accrue interest at an annual rate of 9%, compounded quarterly and payable forty-five days after the close of each quarter. The payment of the royalty advance and discount shall be satisfied solely by Amgen's withholding of royalties and except in the event of a breach of certain customary representations and warranties under the agreement, the Company will have no obligation to repay any unsettled amount. The Company further amended the agreement with Amgen effective June 29, 2012, limiting the

royalty offset of the royalty advance up to \$8.0 million per quarter with royalties in excess of \$8.0 million paid to the Company for the respective quarter, thereby extending the royalty advance repayment period. After the payment of the royalty advance and a 9 percent per annum discount on the balance of the advance, Amgen will resume paying NPS all royalties earned through December 31, 2018. As of December 31, 2012, the Company classified \$6.3 million of the Sensipar Notes as current based on royalty payments accrued as of December 31, 2012. The Sensipar Notes are non-recourse to the Company. The outstanding principal balance on the Sensipar Notes, were \$80.2 million and \$126.8 million as of December 31, 2012 and 2011, respectively. Accrued interest on the Sensipar Notes was approximately \$874,000 and \$1.4 million as of December 31, 2012 and 2011, respectively. The Company incurred debt issuance costs of \$96,000, which are being amortized using the effective interest method. The effective interest rate on the Sensipar Notes, including debt issuance costs, is approximately 9%.

Under the Company's agreement for the Sensipar Notes, the Company would potentially be liable for its breaches or defaults, if any.

#### **Preotact-secured Non-recourse Debt**

As of December 31, 2012 and 2011, the outstanding principal balances on Preotact-secured debt were \$42.8 million and \$48.3 million, respectively. In July 2007, the Company entered into an agreement with DRI Capital, or DRI, formerly Drug Royalty L.P.3, in which the Company sold to DRI its right to receive future royalty payments arising from sales of Preotact under its license agreement with Takeda. Under the agreement, DRI paid the Company an up-front purchase price of \$50.0 million. If and when DRI receives two and a half times the amount paid to the Company, the agreement will terminate and the remainder of the royalties, if any, will revert back to the Company. In connection with the Company's July 2007 agreement with DRI, the Company granted DRI a security interest in its license agreement with Takeda for Preotact and certain of its patents and other intellectual property underlying that agreement. In the event of a default by NPS under the agreement with DRI, DRI would be entitled to enforce its security interest against NPS and the property described above. The Company determined the initial up-front purchase price is debt and is being amortized into earnings using the effective interest method over the estimated life of approximately 14 years. Accrued interest under the DRI agreement was \$0 and \$716,000 as of December 31, 2012 and 2011, respectively. As of December 31, 2012, \$45.5 million has been paid to DRI. The repayment of the remaining \$42.8 million is secured solely by future royalty payments arising from sales of Preotact by Takeda. The Preotact-secured debt is non-recourse to the Company. Due to a technical production issue, Takeda is presently unable to have batches of finished product manufactured that are consistently within specification and the Company has been informed that as a result, Takeda is no longer selling Preotact in their territories. The Company understands that Takeda has taken a number of actions to resolve the manufacturing issue and to accelerate a return to normal supply situation. The Company has not received any information as to when or if Takeda will re-introduce Preotact in the future and therefore, the Company could potentially earn royalties that are less than the remaining non-recourse principle amount owed.

#### **REGPARA-secured Non-recourse Debt**

As of December 31, 2012 and 2011, the outstanding principal balances on REGPARA-secured debt were \$36.3 million, respectively. In February 2010, the Company entered into an agreement with an affiliate of DRI, in which the Company sold to DRI its right to receive future royalty payments arising from sales of REGPARA<sup>®</sup> (cinacalcet HC1) under its license agreement with Kyowa Hakko Kirin. Under the agreement, DRI paid the Company an up-front purchase price of \$38.4 million. If and when DRI receives two and a half times the amount paid to the Company, the agreement will terminate and the remainder of the royalties, if any, will revert back to the Company. In connection with the Company's February 2010 agreement with DRI, the Company granted DRI a security interest in its license agreement with Kyowa Hakko Kirin for REGPARA and certain of its patents and other intellectual property underlying that agreement. In the event of a default by NPS under the agreement with DRI, DRI would be entitled to enforce its security interest against NPS and the property described above. The Company determined the initial up-front purchase price is debt and is being amortized into earnings using the effective interest method over the estimated life of approximately 11 years. In accordance with the agreement, on March 1, 2010, DRI received the \$2.1 million royalty owed to NPS for REGPARA sales during the six months ended December 31, 2009, which reduced the liability recorded for the DRI transaction to \$36.3 million. Accrued interest under the DRI agreement was \$3.1 million and \$4.0 million as of December 31, 2012 and 2011, respectively. Through December 31, 2012, \$19.7 million has been paid to DRI. The repayment of the remaining \$36.3 million is secured solely by future royalty payments arising from sales of REGPARA by Kyowa Hakko Kirin. The effective interest rate under the agreement, including issuance costs, is approximately 18.2%. The REGPARA-secured debt is non-recourse to the Company.

### ***(c) Contractual maturities of long-term debt***

The aggregate contractual maturities of long-term debt, including estimated maturities of the Non-recourse Debt, due subsequent to December 31, 2012 are as follows (in thousands):

Year ending December 31:	
2013	\$ 25,865
2014	47,452
2015	31,160
2016	5,005
2017	4,780
Thereafter	61,585
Total long-term debt	<u>\$ 175,847</u>

## **(9) Capital Stock**

### ***Stockholder Rights Plan***

In December 1996, the Company's board of directors approved the adoption of a Stockholder Rights Plan (the Rights Plan). The Rights Plan provided for the distribution of a preferred stock purchase right (Right) as a dividend for each outstanding share of the Company's common stock. This Right entitled stockholders to acquire stock in the Company or in an acquirer of the Company at a discounted price in the event that a person or group acquired 20% or more of the Company's outstanding voting stock or announces a tender or exchange offer that would result in ownership of 20% or more of the Company's stock. The Rights expired on December 31, 2011.

### ***Equity Financing***

In April 2011, the Company completed a public sale of 12,650,000 shares of its common stock at a per share price of \$9.00. Net proceeds to the Company from the sale totaled approximately \$106.8 million, after deducting expenses and the commission in connection with the offering paid by the Company.

In September 2010, the Company completed a public sale of 7,912,000 shares of its common stock at a per share price of \$6.00. Net proceeds to the Company from the sale totaled approximately \$44.4 million, after deducting expenses and the commission in connection with the offering paid by the Company.

In April 2010, the Company completed a public sale of 10,350,000 shares of its common stock at a per share price of \$5.50. Net proceeds to the Company from the sale totaled approximately \$53.2 million, after deducting expenses and the commission in connection with the offering paid by the Company.

On August 5, 2009, the Company entered into an equity line of credit arrangement (the "Agreement") with Azimuth Opportunity Ltd. ("Azimuth"), which provided that, upon the terms and subject to the conditions set forth therein, Azimuth was committed to purchase up to \$40,000,000 of the Company's common stock, or the number of shares which is one share less than twenty percent (20%) of the issued and outstanding shares of the Company's common stock as of August 5, 2009 (subject to automatic reduction in certain circumstances), at varying price discounts of up to 5% as defined, over the 18-month term of the Purchase Agreement. The Company was not obligated to utilize this facility but if it elected to make a draw under this facility, the timing, dollar amount, and floor price per share were at the sole discretion of the Company, subject to certain limits as to the price per share and the draw down amounts. Azimuth was permitted to terminate this agreement under certain circumstances. NPS did not pay a commitment fee or issue any warrants to secure this facility. On September 29, 2009, Azimuth purchased 842,511 shares of the Company's common stock under the Agreement at an aggregate purchase price of \$3.5 million. In connection with the September 2010 offering, the Company delivered a notice to Azimuth for the purpose of reducing the aggregate limit by \$36.5 million of the Company's common stock. The Company had the right to further amend this agreement at a later date to increase the aggregate limit by \$36.5 million, subject to the terms and conditions of the purchase agreement. This Agreement expired in January 2011.

## Convertible Debt

As of December 31, 2012, the Company had outstanding \$16.5 million in aggregate principal amount of its 5.75% Convertible Notes. The holders of the 5.75% Convertible Notes may convert all or a portion of their notes into common stock at any time, subject to certain limitations, on or before August 7, 2014 at a conversion price equal to approximately \$5.44 per share, subject to adjustment in certain events. The Company has reserved 3,041,451 shares of its common stock for issuance upon conversion of the 5.75% Convertible Notes.

## (10) Share-Based Compensation Plans

As of December 31, 2012, the Company has four equity incentive plans: the 1994 Nonemployee Directors' Stock Option Plan (the Directors' Plan), the 1998 Stock Option Plan (the 1998 Plan), the 2005 Omnibus Incentive Plan (the 2005 Plan), and the Employee Stock Purchase Plan ("ESPP"). These plans provide that in the event of certain change in control transactions, including a merger or consolidation in which the Company is not the surviving corporation or a reorganization in which more than fifty-percent (50%) of the shares of the Company's common stock entitled to vote are exchanged, all outstanding, unvested equity awards under these plans will vest, and in the case of stock options, will become immediately exercisable.

As of December 31, 2012, there are no shares reserved for future grant under the Directors' Plan and the 1998 Plan. As of December 31, 2012, there are 3,248,782 shares reserved for future grant under the 2005 Plan. The Company's 2005 Plan provides for the grant of nonqualified stock options, incentive stock options, stock appreciation rights, restricted stock, restricted stock units, deferred stock units, performance shares, cash-based awards and other stock-based awards. Under the Company's 2005 Plan, the exercise price of stock options, the grant price of stock appreciation rights and the initial value of performance awards, must be equal to at least 100% of the fair market value of the Company's common stock on the date of grant. Stock options generally vest 28% after year one and 2% per month thereafter or 25% after year one and 6.25% every three months thereafter. Under the Company's 1998 Plan, the exercise price of options is generally not less than the fair market value of the Company's common stock on the date of grant. The number of shares, terms, and exercise period are determined by the board of directors on a grant-by-grant basis, and the exercise period does not extend beyond ten years from the date of the grant. Stock options generally vest 28% after one year and 2% or 3% per month thereafter or 25% after year one and 6.25% every three months thereafter.

During the year ended December 31, 2009, the Company's Board of Directors awarded a total of 378,000 options to certain of the Company's executive officers. Vesting of these options is subject to the Company achieving certain performance criteria established at the beginning of each of the two and three year performance periods, beginning January 20, 2009. Vesting percentages are calculated based on the Total Shareholder Return (TSR) of the Company's common stock as compared to the TSR of the NASDAQ Biotechnology Index. The vesting schedule, as seen below, can produce vesting percentages of 0%, 50%, 115% and 125% of the options granted, half of which relate to each performance period. TSR is determined as the change in stock prices from January 20, 2009 to the end of each performance period using a 20 day average of the adjusted closing price. The first performance period ended on January 20, 2011 with 50% of the target award vesting. The second performance period ended on January 20, 2012 with 50% of the target award vesting.

Vesting Schedule	
Performance of Company Stock Price Relative to the NASDAQ Biotechnology Index	Vesting (% of Target Award for Performance Period)
Top Quartile	125%
Second Quartile	115%
Third Quartile	50%
Bottom Quartile	0%

The Company utilized a Monte Carlo simulation to determine the grant date fair value of the awards. Compensation expense is recognized over the performance period of each tranche. For the years ended December 31, 2012, 2011 and 2010, the Company recorded \$99,000, \$215,000 and \$357,000, respectively, of share-based compensation expense related to these options. The assumptions used in this model were as follows:

Fair value of the Company's common stock	\$ 5.71
Expected volatility	70.0%
Risk-free interest rate	1.1%
Dividend yield	0%

The Monte Carlo simulation model also assumed correlations of returns of the stock prices of the Company's common stock and the common stock of a peer group of companies and historical stock price volatilities of the peer group of companies. The valuation model also used terms based on the length of the performance period and compound annual growth rate goals for total stockholder return based on the provisions of the award.

During the year ended December 31, 2010, the Company's Board of Directors awarded a total of 1,130,700 performance condition options to certain of the Company's employees. Vesting of these options are subject to the Company achieving certain performance criteria established at the grant date and the individuals fulfilling a service condition (continued employment). As of December 31, 2012, the performance criteria of 825,340 of these options had been satisfied and these options will become exercisable based on the following vesting schedule: 25% on each of the first four anniversaries of the date of grant, which was February 20, 2010 (the date of grant). The Company recognized \$1.1 million and \$153,000 of compensation expense during the years ended December 31, 2012 and 2011, respectively, related to these options.

The Company utilized the Black-Scholes option pricing model to determine the grant date fair value of the awards. As of December 31, 2012, except for the 825,340 options discussed above, the Company does not believe that the achievement of the performance criteria is probable and therefore has not recognized any compensation expense related to these options during the years ended December 31, 2012, 2011 and 2010, respectively. Compensation expense will be recognized only once the performance condition is probable of being achieved and then only the cumulative amount related to the service condition that has been fulfilled.

On May 19, 2010, the shareholders approved an ESPP whereby qualified employees are allowed to purchase limited amounts of the Company's common stock at the lesser of 85% of the market price at the beginning or end of the offering period. The shareholders have authorized 500,000 shares for purchase by employees. During the years ended December 31, 2012, 2011 and 2010, employees purchased 45,553, 37,065 and 14,860 shares, respectively, under the Employee Stock Purchase Plan. The Company has 402,522 shares available for future purchase as of December 31, 2012.

The Company estimates expected volatility considering implied volatility based on market-traded options on the Company's common stock and historical volatility of the Company's common stock over the expected life of the options. In estimating volatility for the years ended December 31, 2012, 2011 and 2010 the Company weighted implied volatility at zero percent and historical volatility at 100%. The Company recognizes compensation cost for awards on a straight-line basis over the requisite service period for the entire award. Additionally, the Company's policy is to issue new shares of common stock to satisfy stock option exercises, ESPP purchases or grants of restricted shares or deferred stock units.

The compensation expense related to stock options, ESPP purchases, restricted shares and deferred stock units are recorded in expense categories based on where other compensation cost is recorded for employees receiving the awards.

The following table summarizes the effect of compensation cost arising from share-based payment arrangements in the Company's Statements of Operations for the years ended December 31, 2012, 2011 and 2010 for the Company's stock option plans, the ESPP and other share-based awards (in thousands):

	<b>Years ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Research and development	\$ 3,343	\$ 1,544	\$ 820
General and administrative	4,205	2,556	2,276
Amounts charged against income, before income tax expense (benefit)	<u>\$ 7,548</u>	<u>\$ 4,100</u>	<u>\$ 3,096</u>

Excluding the 378,000 options awarded in 2009 discussed above, the fair value of each option award is estimated, on the date of grant using the Black-Scholes option-pricing valuation model, which incorporates ranges of assumptions for inputs as shown in the following table. The assumptions are as follows:

- The expected volatility is a blend of implied volatility based on market-traded options on the Company's common stock and historical volatility of the Company's stock over the expected term of the options.
- The Company uses historical data to estimate the expected term of the option; separate groups of employees that have similar historical exercise behavior are considered separately for valuation purposes. The expected term of options granted represents the period of time the options are expected to be outstanding.
- The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods within the expected term of the option.
- The expected dividend yield is based on the Company's current dividend yield as the best estimate of projected dividend yield for periods within the expected term of the option.

	Years ended December 31,		
	2012	2011	2010
Dividend yield	—	—	—
Expected volatility	61.22% – 67.58%	60.5% – 67.8%	62.9% – 68.1%
Risk-free interest rate	0.6% – 1.1%	0.9% – 3.0%	1.1% – 3.2%
Expected term (in years)	5.1 – 5.9	4.8 – 5.9	4.8 – 6.0

A summary of activity related to aggregate stock options under all plans is indicated in the following table (in thousands, except per share amounts):

	Year ended December 31, 2012			
	Number of options (in thousands)	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Options outstanding at beginning of year	6,627	\$ 6.62		
Options granted	1,721	8.06		
Options exercised	481	5.00		
Options forfeited/expired	477	11.32		
Options outstanding at end of year	<u>7,390</u>	6.75	6.97	\$ 22,564
Vested and expected to vest	<u>7,035</u>	6.71	6.88	\$ 21,988
Options exercisable at end of year	<u>4,097</u>	\$ 6.76	5.71	\$ 14,686

The weighted-average grant-date fair value of options granted during the years ended December 31, 2012, 2011 and 2010 was \$4.46, \$4.57 and \$2.25, respectively. The intrinsic value for stock options is defined as the difference between the current market value and the grant price. The total intrinsic value of stock options exercised during the years ended December 31, 2012, 2011 and 2010 was \$2.0 million, \$1.0 million and \$499,000, respectively.



Restricted stock, restricted stock units and deferred stock unit grants consist of the Company's common stock. The fair value of each restricted stock grant, restricted stock unit and deferred stock unit is equal to the market price of the Company's stock at the date of grant. Restricted stock and restricted stock unit grants are time vested. During the years ended December 31, 2012, 2011 and 2010, the Company granted 20,334, 64,792 and 89,745 deferred stock units, respectively, to directors for services, which did not contain any vesting restrictions. During the years ended December 31, 2012, 2011 and 2010, the Company granted 106,575, 0 and 0 restricted stock units, respectively, to directors for services, which vest over one year. At December 31, 2012, there are 607,409 deferred stock units outstanding. During the years ended December 31, 2012, 2011 and 2010 the Company granted to employees 307,720, 10,000 and 126,500 shares of restricted stock, respectively, which will vest over a period of one to three years. A summary of activity related to aggregate restricted stock, restricted stock units and deferred stock units as of December 31, 2012, is indicated in the following table (shares in thousands):

	<u>Number of shares</u>	<u>Weighted-average grant date fair value</u>
Nonvested at beginning of year	137	\$ 3.57
Granted	435	8.17
Vested	(67)	7.92
Forfeited	-	-
Nonvested at December 31, 2012	<u>505</u>	\$ 6.96

As of December 31, 2012, there was \$9.7 million of total unrecognized compensation cost related to all unvested share-based compensation arrangements that is expected to be recognized over a weighted-average period of 2.67 years.

#### (11) Income Taxes

The Company has recorded income tax expense for the years ended December 31, 2012, 2011 and 2010 of \$0, \$18,000 and \$1.1 million, respectively, related primarily to the Company's Canadian subsidiary based in the Canadian province of Quebec. All of the Company's pre-tax losses are from domestic sources.

Income tax differed from the amounts computed by applying the U.S. federal income tax rate of 34% to loss before income tax expense (benefit) as a result of the following (in thousands):

	<u>Years ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Computed "expected" tax benefit	\$ (6,370)	\$ (12,325)	\$ (10,319)
Expiration of tax attributes	-	360	4,270
IRC §382 adjustment	59,822	94,442	-
Change in the valuation allowance for deferred tax assets attributable to operations and other adjustments	(42,124)	(70,514)	18,457
U.S. and foreign credits	(10,231)	(11,732)	(12,292)
State income taxes, net of federal tax effect	-	-	1
Equity based compensation expense	513	578	397
Quebec income tax expense (credits)	-	-	1,118
Other	(1,610)	(791)	(541)
	<u>\$ -</u>	<u>\$ 18</u>	<u>\$ 1,091</u>

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets at December 31, 2012 and 2011 are presented below (in thousands):

	<u>2012</u>	<u>2011</u>
Deferred tax assets:		
Stock compensation expense	\$ 5,631	\$ 3,906
Accrued compensation	2,105	1,398
Capital loss carryforward	4,169	12,582
Net operating loss carryforward	140,416	191,238
Research credit carryforward	49,960	46,383
Non-recourse debt	32,619	35,881
Acquired intellectual property	29,287	31,312
Capitalization of inventory	13,146	3,884
Other	273	127
Total gross deferred tax assets	<u>277,606</u>	<u>326,711</u>
Less valuation allowance	<u>(277,606)</u>	<u>(326,711)</u>
Deferred tax assets	-	-
Deferred tax liabilities	-	-
Net deferred tax asset (liability)	<u>\$ -</u>	<u>\$ -</u>

The Company has a cumulative loss and projects losses into the future. Accordingly, as of December 31, 2012, the Company believes that it is not more likely than not that results of future operations will generate sufficient income to realize any of the gross deferred tax assets and accordingly, has recorded a 100% valuation allowance. The net change in the Company's total valuation allowance for the years ended December 31, 2012, 2011, and 2010 were decreases of \$49.1 million and \$101.4 million, and an increase of \$37.4 million, respectively. The valuation allowance includes the benefit for stock option exercises which increased the domestic net operating loss carryforwards. Future reductions to the domestic valuation allowance will be allocated \$267.5 million to operations and \$10.1 million to paid-in capital.

At December 31, 2012, the Company had U.S. federal net operating losses of \$382.3 million which begin to expire in 2018 available to offset future income for tax purposes. The Company also had U.S. federal capital loss carryforwards of \$10.6 million which begins to expire in 2013. At December 31, 2012, the Company also had U.S. federal research credit carryforwards of \$50.0 million which begin to expire in 2030. The Company's domestic tax loss carryforwards for alternative minimum tax purposes is approximately the same as the Company's regular tax loss carryforwards.

The Company also has New Jersey state net operating loss and capital loss carryforwards of approximately \$368.4 million and \$18.0 million, respectively, which begin to expire in 2013, and other domestic state net operating loss carryforwards and tax credit carryforwards in varying amounts depending on the different state laws.

The Company recently updated its Section 382 study to assess whether the Company has undergone certain greater than 50% changes of ownership as defined in Section 382 of the Internal Revenue Code. This study concluded that the Company had an ownership change in 2010. Section 382 can potentially limit a company's ability to use net operating losses, capital losses, tax credits and other tax attributes in periods subsequent to a change in ownership. The maximum amount of carry-forwards available in a given year is limited to the product of the Company's fair market value on the date of ownership change and the federal long-term tax-exempt rate, plus any limited carry-forward not utilized in prior years. Based upon a Section 382 study that was performed, the Company determined that certain NOLs, capital losses and tax credit carry-forwards will expire prior to their utilization due to the expected annual Section 382 limitations, and accordingly the NOL carry-forwards, capital losses and tax credits on the above table have been reduced accordingly. The Company maintains a full valuation allowance against the NOLs and credit carryforwards, as the Company believes it is more likely than not that the benefits will not be realized.

The Company applies the provisions of ASC 740, "Income Taxes", which prescribe a comprehensive model for how a company should recognize, measure, present, and disclose in its consolidated financial statements uncertain tax positions that the Company has taken or expects to take on a tax return. The Company regularly evaluates, assesses and adjusts the related assets and liabilities in light of changing facts and circumstances.

A reconciliation of the unrecognized tax benefits for the years ended December 31, 2012 and 2011 is as follows (in thousands):

	<u>Unrecognized Tax Benefits</u>
Balance as of January 1, 2011	\$ 4,614
Additions for current year tax positions	-
Reductions for prior year tax positions	-
Balance as of December 31, 2011	<u>4,614</u>
Additions for current year tax positions	-
Reductions for prior year tax positions	-
Balance as of December 31, 2012	<u>\$ 4,614</u>

Unrecognized tax benefits amounted to \$4.6 million at December 31, 2012, and did not include any accrued potential penalties or interest. The total amount of unrecognized tax benefits relating to the Company's tax positions is subject to change based on future events including, but not limited to, the settlements of ongoing audits and/or the expiration of applicable statutes of limitations. Although the outcomes and timing of such events are highly uncertain, it is not reasonably possible that the balance of gross unrecognized tax benefits will change during the next 12 months. However, changes in the occurrence, expected outcomes and timing of those events could cause the Company's current estimate to change materially in the future.

The Company accounts for penalties or interest related to uncertain tax positions as part of its provision for income taxes. Due to the Company's net operating loss carryforwards, any adjustment related to a liability would not be expected to result in a cash tax liability. Accordingly, the Company has not accrued for penalties or interest for the U.S. (both Federal and State) as of December 31, 2012 and 2011. Assuming the continued existence of a full valuation allowance on the Company's net deferred tax assets, future recognition of any of the Company's unrecognized tax benefits would not impact the effective tax rate.

The Company files income tax returns in various jurisdictions with varying statutes of limitations. The statute of limitations for assessing tax in the U.S. remains open for the tax years ended on or after December 31, 2009. In August 2012, the IRS completed its examination of the Company's U.S. federal income tax returns for the year ended December 31, 2009. There were no adjustments as a result of the examination. The Company is currently under audit by the State of New Jersey for the years 2007 to 2010. The Company does not expect any significant adjustments to its filed income tax returns.

## **(12) Employee Benefit Plans**

The Company maintains a tax-qualified employee savings and retirement plan (401(k) Plan) covering all of the Company's employees in the United States. Pursuant to the 401(k) Plan, employees may elect to reduce their current compensation up to the maximum percent allowable, not to exceed the limits of code section 401(k), 403(b), 404 and 415, of eligible compensation or the prescribed IRS annual limit and have the amount of such reduction contributed to the 401(k) Plan. The 401(k) Plan permits, but does not require, additional matching contributions to the 401(k) Plan by the Company on behalf of all participants. During the years ended December 31, 2012, 2011 and 2010, the Company matched 100% of employee contributions up to 3% of employee pre-tax contributions and 50% of employee contribution on the next 3% of employee pre-tax contributions. The Company recorded an expense associated with these matching contributions for the years ended December 31, 2012, 2011, and 2010 of \$620,000, \$432,000 and \$357,000, respectively.

## **(13) Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In September 2011, the FASB issued ASU 2011-08, *Intangibles — Goodwill and Other* (ASU 2011-08). The update allows companies to waive comparing the fair value of a reporting unit to its carrying amount in assessing the recoverability of goodwill if, based on qualitative factors, it is not more likely than not that the fair value of a reporting

unit is less than its carrying amount. ASU 2011-08 will be effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this ASU did not have a material impact on the Company's financial position or results of operations.

In June 2011, the FASB issued ASU 2011-05, *Presentation of Comprehensive Income* (ASU 2011-05), an amendment to Accounting Standards Codification (ASC) Topic 220, *Comprehensive Income*. The update gives companies the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The amendments in the update do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. This ASU is effective for the Company for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of this ASU did not have a material impact on the Company's financial position or results of operations.

In May 2011, the FASB issued FASB ASU 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU 2011-04), an amendment to FASB ASC Topic 820, *Fair Value Measurement*. The update revises the application of the valuation premise of highest and best use of an asset, the application of premiums and discounts for fair value determination, as well as the required disclosures for transfers between Level 1 and Level 2 fair value measures and the highest and best use of nonfinancial assets. The update provides additional disclosures regarding Level 3 fair value measurements and clarifies certain other existing disclosure requirements. This ASU is effective for the Company for interim and annual periods beginning after December 15, 2011. The adoption of this ASU did not have a material impact on the Company's financial position or results of operations.

#### **(14) Commitments and Contingencies**

The Company has agreed to indemnify, under certain circumstances, certain manufacturers and service providers from and against any and all losses, claims, damages or liabilities arising from services provided by such manufacturers and service providers or from any use, including clinical trials, or sale by the Company or any Company agent of any product supplied by the manufacturers.

The Company has contractual commitments of \$14.1 million with external marketing and commercial readiness organizations relating to pre-launch activities for Gattex. These agreements are cancellable on notice of up to six months. The Company also has approximately \$16.1 million in contractual commitments for other service agreements with varying terms and conditions.

The Company has entered into long-term agreements with various third-party contract manufacturers for the production and packaging of drug substance and drug product. Under the terms of these various contracts, the Company will be required to purchase certain minimum quantities of drug product each year.

The Company has contractual commitments of \$23.3 million for drug substance, drug product and other manufacturing processes as of December 31, 2012 for the manufacture of clinical and commercial supplies of Gattex and Natpara. Amounts owed to third-party contract manufacturers are based on firm commitments for the purchase of drug product. Amounts purchased under contractual inventory commitments from third-party contract manufacturers for the years ended December 31, 2012, 2011 and 2010 were \$25.9 million, \$14.5 million and \$20.8 million, respectively.

In December 2009, the Company sold a majority interest in its subsidiary, Allelix, to a group of investors ("Investors"). NPS received \$5.6 million in connection with the transactions in 2009. NPS is entitled to receive an additional Cnd. \$4.8 million, which would only be paid upon further investment in Allelix by the Investors, which would be expected to occur upon the successful completion of certain Canadian court proceedings. In connection with the transaction, the Company has indemnified the Investors for various items including product liabilities arising from the past operations of Allelix and has guaranteed that certain tax attributes exist as of the closing date. The maximum potential future payments related to these indemnifications or guarantees shall not exceed the amounts the Company has received in connection with the transaction (\$5.9 million at December 31, 2012).

## (15) Selected Quarterly Financial Data (Unaudited)

The following is a summary of the quarterly results of operations for the years ended December 31, 2012 and 2011 (in thousands, except for per share amounts):

	Quarters Ended			
	March 31	June 30	September 30	December 31
<b>(in thousands, except per share amounts)</b>				
<b>2012</b>				
Revenues	\$ 22,924	\$ 53,517	\$ 27,019	\$ 27,184
Operating (loss) income	(5,045)	11,206	733	(8,018)
Net (loss) income	(10,563)	7,355	(3,324)	(12,203)
Basic (loss) income per common share	\$ (0.12)	\$ 0.08	\$ (0.04)	\$ (0.14)
Diluted (loss) income per common and potential common share	\$ (0.12)	\$ 0.08	\$ (0.04)	\$ (0.14)
<b>2011</b>				
Revenues	\$ 23,576	\$ 27,210	\$ 24,601	\$ 26,258
Operating income (loss)	1,057	4,036	(2,041)	(2,507)
Net loss	(9,150)	(6,132)	(12,349)	(8,636)
Basic loss per common share	\$ (0.13)	\$ (0.07)	\$ (0.14)	\$ (0.10)
Diluted loss per common and potential common share	\$ (0.13)	\$ (0.07)	\$ (0.14)	\$ (0.10)

### ITEM 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable

#### ITEM 9A. Controls and Procedures.

##### a) *Evaluation of Disclosure Controls and Procedures*

We maintain “disclosure controls and procedures” within the meaning of Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures, or Disclosure Controls, are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission’s rules and forms. Our Disclosure Controls include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

As of the end of the period covered by this Annual Report on Form 10-K, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures, which was done under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the date of their evaluation, our disclosure controls and procedures were effective as of December 31, 2012.

##### b) *Management’s Report on Internal Control over Financial Reporting.*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide our management and board of directors reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with GAAP. Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by

collusion or improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management has assessed the effectiveness of internal control over financial reporting as of December 31, 2012. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*. Based on our assessment we believe that, as of December 31, 2012, our internal control over financial reporting is effective based on those criteria.

KPMG LLP, our independent registered public accounting firm that audited the financial statements included in this Annual Report on Form 10-K has issued an audit report on our internal control over financial reporting as of December 31, 2012. This report appears on page 57 of this report.

**(c) *Change in Internal Control over Financial Reporting.***

There have been no changes in our internal control over financial reporting that occurred during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. Other Information.**

None.

**PART III**

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

Certain of the information required by this item will be contained in our definitive Proxy Statement with respect to our 2013 Annual Meeting of Stockholders, under the captions “Election of Directors,” and “Compliance with Section 16(a) of the Exchange Act.” Such information is incorporated into this item by reference. For information regarding our executive officers see Part I of this Form 10-K under the caption “Executive Officers of the Registrant.”

**ITEM 11. Executive Compensation.**

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2013 Annual Meeting of Stockholders, under the captions “Executive Compensation,” “Compensation Committee Interlocks and Insider Participation,” and “Compensation Committee Report” and is incorporated into this item by reference.

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

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2013 Annual Meeting of Stockholders, under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” and is incorporated into this item by reference.

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

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2013 Annual Meeting of Stockholders under the captions “Certain Relationships and Related Transactions” and “Independence of the Board” and is incorporated into this item by reference.

**ITEM 14. Principal Accountant Fees and Services.**

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2013 Annual Meeting of Stockholders, under the caption “Principal Accountant Fees and Services” and is incorporated into this item by reference.

## PART IV

### ITEM 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K.

1. *Financial Statements.* The financial statements listed on the accompanying Index to Consolidated Financial Statements are filed as part of this report.

2. *Financial statement schedules.* There are no financial statements schedules included because they are either not applicable or the required information is shown in the consolidated financial statements or the notes thereto.

3. *Exhibits.* The following exhibits are filed or incorporated by reference as part of this Form 10-K.

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1A	Amended and Restated Certificate of Incorporation of the Registrant (1)
3.1B	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated December 16, 1999 (2)
3.1C	Certificate of Designation of Series A Junior Participating Preferred Stock of the Registrant, dated December 18, 1996 (3)
3.1D	Amendment to Certificate of Designation of Series A Junior Participating Preferred Stock of the Registrant, dated September 5, 2000 (2)
3.1E	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated September 30, 2003 (8)
3.1F	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated May 19, 2011 (24)
3.2	Amended and Restated Bylaws of the Registrant (19)
4.1	Specimen Common Stock Certificate (1)
10.1A**	1994 Non-Employee Directors' Stock Option Plan (1)
10.1B**	1994 Non-Employee Directors' Stock Option Plan, as amended December 1996 (28)
10.1C**	1994 Non-Employee Directors' Stock Option Plan, as amended December 2002 (7)
10.2A**	1998 Stock Option Plan (reflects all amendments by the Board of Directors through May 2008) (18)
10.2B**	Form of Performance-Based Stock Option Agreement under the NPS Pharmaceutical, Inc. 1998 Stock Option Plan (20)
10.3**	Form of Indemnity Agreement entered into between the Registrant and each of its officers and directors (1)
10.4A**	Change in Control Severance Pay Plan, as amended (10)
10.4B**	Form of Agreement Providing Specified Benefits Following Termination of Employment Incident to a Merger, Acquisition or Other Change of Control or to Some Other Strategic Corporate Event, between the Registrant and each of its executive officers (8)

- 10.5A Collaborative Research and License Agreement between the Registrant and SmithKline Beecham Corporation (now GlaxoSmithKline), dated November 1, 1993 (1)
- 10.5B Amendment Agreement to Collaborative Research and License Agreement between GlaxoSmithKline, effective June 29, 1995 (4)
- 10.5C Amendment Agreement between the Registrant and GlaxoSmithKline, dated October 28, 1996 (3)
- 10.5D Amendment Agreement between the Registrant and GlaxoSmithKline, dated October 27, 1997 (5)
- 10.5E Amendment to Collaborative Research and License Agreement between the Registrant and GlaxoSmithKline, dated November 26, 1997 (5)
- 10.5F Letter, dated January 24, 2000, from SmithKline Beecham to NPS Re: Amendment Agreement to Amend the November 26, 1997 Amendment Agreement (7)
- 10.5G Letter, dated May 15, 2000, from SmithKline Beecham to NPS Re: Amendment Agreement (7)
- 10.5H Letter, dated August 1, 2001, from GlaxoSmithKline to NPS Re: Amendment Agreement to Amend the January 24, 2000 Amendment Agreement (7)
- 10.5I Amendment Agreement between the Registrant and SmithKline Beecham Corporation, dba GlaxoSmithKline dated December 14, 2006 (14)
- 10.5J\* Exclusive Patent License Agreement between the Registrant and GlaxoSmithKline LLC dated July 29, 2011 (26)
- 10.6A Patent Agreement between the Registrant and The Brigham and Women's Hospital, Inc., dated February 19, 1993 (1)
- 10.6B Letter dated March 15, 1993 from the Registrant to The Brigham and Women's Hospital, Inc. regarding Patent Agreement between the Registrant and The Brigham and Women's Hospital, Inc. (7)
- 10.6C Amendment to Patent Agreement between the Registrant and The Brigham and Women's Hospital, Inc., effective February 7, 1996 (6)
- 10.6D 1999 Patent Agreement Amendment between the Registrant and The Brigham and Women's Hospital, Inc., effective February 18, 1999 (7)
- 10.7 Collaborative Research and License Agreement between the Registrant and Kirin Brewery Company, Ltd. dated June 29, 1995 (6)
- 10.8A\* Development and License Agreement between the Registrant and Amgen Inc. effective as of December 27, 1995 (4)
- 10.8B First Amendment dated November 19, 2004 to the Development and License Agreement between the Registrant and Amgen Inc. (26)
- 10.8C\* Second Amendment dated November 19, 2004 to the Development and License Agreement between the Registrant and Amgen Inc. (26)
- 10.8D Third Amendment dated March 4, 2008 to the Development and License Agreement between the Registrant and Amgen Inc. (26)
- 10.8E\* Fourth Amendment dated August 10, 2011 to the Development and License Agreement between the Registrant and Amgen Inc. (27)
- 10.8F Fifth Amendment dated June 29, 2012 to the Development and License Agreement between the Registrant and Amgen Inc. (29)



- 10.9A\* Distribution and License Agreement between Registrant and Takeda GmbH, dated April 26, 2004 (9)
- 10.9B\* First Amendment to Distribution and License Agreement between the Registrant and Takeda GmbH, dated July 1, 2004 (9)
- 10.9C\* License Agreement, dated July 2, 2007, between NPS Allelix Corp. and Takeda GmbH (15)
- 10.10A\*\* 2005 Omnibus Incentive Plan, as amended through May 18, 2011 (24)
- 10.10B\*\* 2005 Omnibus Incentive Plan, as amended through February 13, 2013 (31)
- 10.10C\*\* Form of Stock Option Grant Agreement (31)
- 10.10D\*\* Form of Restricted Stock Unit Agreement for Non-Employee Directors (31)
- 10.10E\*\* Form of Restricted Stock Unit Agreement for Employees (31)
- 10.10F\*\* Form of Restricted Stock Unit Agreement for Employees (31)
- 10.10G\*\* Form of Restricted Stock Unit Agreement for Employees (31)
- 10.10H\*\* Non-Employee Director Compensation Program (30)
- 10.11A\*\* Non-Employee Director Deferred Compensation Program (11)
- 10.11B\*\* Form of Deferred Stock Unit Award Agreement (11)
- 10.12A Securities Purchase Agreement dated as of August 7, 2007 among the Registrant and Visium Balanced Fund, LP, Visium Balanced Offshore Fund, Ltd., Visium Long Bias Fund, LP, Visium Long Bias Offshore Fund, Ltd. and Atlas Master Fund (13)
- 10.12B Form of Note issued pursuant to the Securities Purchase Agreement referred to in Exhibit 10.12A above (13)
- 10.12C Registration Rights Agreement dated as of August 7, 2007 among the Registrant and the Investors (13)
- 10.13\* Agreement for Sale and Assignment of Rights, dated July 16, 2007, among the Registrant, NPS Allelix Corp. and DRI (15)
- 10.14\* Distribution and License Agreement, dated September 24, 2007, among the Registrant, NPS Allelix Corp. and Takeda GmbH (15)
- 10.15\* Amendment Agreement to the Distribution and License Agreement, dated October 29, 2007, among the Registrant, NPS Allelix Corp. and Takeda GmbH (15)
- 10.16\* License Agreement, dated September 28, 1995, between 1149336 Ontario Inc., Daniel J. Drucker, and Allelix Biopharmaceuticals Inc. (15)
- 10.17 Asset Purchase Agreement, dated October 9, 2007, between AstraZeneca AB and the Registrant (16)
- 10.18A\* Commercial Manufacturing Agreement, dated October 18, 2002, by and between NPS Allelix Corp. and Boehringer Ingelheim Austria GmbH (16)
- 10.18B\* Amending Agreement, dated March 15, 2004, by and between NPS Allelix Corp. and Boehringer Ingelheim Austria GmbH (16)
- 10.18C\* Amendment Number One to Amending Agreement, dated December 22, 2005, by and between NPS Allelix Corp. and Boehringer Ingelheim Austria GmbH (16)

- 10.18D\* Amendment Number Two to Amending Agreement, dated August 28, 2007, by and between NPS Allelix Corp. and Boehringer Ingelheim Austria GmbH (25)
- 10.18E\* Letter Agreement dated January 19, 2009, by and between the Registrant and Boehringer Ingelheim Austria GmbH (25)
- 10.18F\* Amendment Number Three to Amending Agreement, dated February 1, 2011, by and between the Registrant and Boehringer Ingelheim Austria GmbH (25)
- 10.19A\*\* Employment Agreement with Francois Nader (17)
- 10.19B\*\* First Amendment to the Employment Agreement with Francois Nader (20)
- 10.19C\*\* Second Amendment to the Employment Agreement with Francois Nader (20)
- 10.20\*\* First Amendment to Restrictive Covenant Agreement with Francois Nader (17)
- 10.21\*\* Employment Agreement with Roger Garceau (20)
- 10.22 Common Stock Purchase Agreement between the Registrant and Azimuth Opportunity Ltd., dated as of August 5, 2009 (21)
- 10.23\* Agreement for Sale and Assignment of Rights, dated February 26, 2010, between the Registrant and LSRC II S.À.R.L. (22)
- 10.24\*\* NPS Pharmaceuticals, Inc. 2010 Employee Stock Purchase Plan (23)
- 10.25\* Development and Supply Agreement between the Registrant and Hospira Worldwide, Inc. dated March 25, 2009 (25)
- 10.26\*\* Employment Agreement with Eric Pauwels (26)
- 10.27\* Manufacturing Agreement between the Registrant and SynCo Bio Partners B.V. dated August 1, 2009 (26)
- 10.28\*\* Employment Agreement with Glenn Melrose (10)
- 10.29\* Commercial Manufacturing Agreement between the Registrant and Vetter Pharma International GmbH dated December 21, 2009 (10)
- 10.30 Covenant Not to Sue Agreement between the Registrant and Ortho-McNeil Pharmaceutical dated December 21, 2006.
- 12.1† Computation Ratio of Earnings Available to Cover Fixed Charges
- 21.1† List of Subsidiaries
- 23.1† Consent of Independent Registered Public Accounting Firm
- 31.1† Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2† Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32† Certification of Annual Financial Report by the Chief Executive Officer and Chief Financial Officer furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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† Filed herewith.

\* Confidential information was omitted from this exhibit pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

\*\* Management contract, compensatory plan or arrangement.

- (1) Incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-74318, filing date January 21, 1994).
- (2) Incorporated herein by reference to the Registrant's Registration Statement on Form S-3 (SEC File No. 333-45274, filing date September 6, 2000).
- (3) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated December 19, 1996 (SEC File No. 000-23272).
- (4) Incorporated herein by reference to Amendment No. 1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995 (SEC File No. 000-23272, filing date March 29, 1996).
- (5) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated January 27, 1998 (SEC File No. 000-23272).
- (6) Incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995 (SEC File No. 000-23272).
- (7) Incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002 (SEC File No. 000-23272, filing date March 21, 2003).
- (8) Incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003 (SEC File No. 000-23272, filing date February 10, 2004).
- (9) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2004 (SEC File No. 000-23272, filing date August 9, 2004).
- (10) Incorporated herein by reference to the Registrant's Quarterly Report on Form 8-Q for the quarterly period ended September 30, 2012 (SEC File No. 000-23272, filing date November 9, 2012).
- (11) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated July 1, 2005 (SEC File No. 000-23272, filing date July 1, 2005).
- (12) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2005 (SEC File No. 000-23272, filing date July 26, 2005).
- (13) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated August 31, 2007 (SEC File No. 000-23272, filing date August 31, 2007).
- (14) Incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 (SEC File No. 000-23272, filing date March 14, 2007).
- (15) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2007 (SEC File No. 000-23272, filing date November 9, 2007).
- (16) Incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (SEC File No. 000-23272, filing date March 17, 2008).
- (17) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2008 (SEC File No. 000-23272, filing date May 19, 2008).
- (18) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated May 22, 2008 (SEC File No. 000-23272, filing date May 28, 2008).
- (19) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated December 21, 2012 (SEC File No. 000-23272, filing date December 21, 2012).
- (20) Incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (SEC File No. 000-23272, filing date March 16, 2009).
- (21) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated August 5, 2009 (SEC File No. 000-23272, filing date August 6, 2009).
- (22) Incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended

- December 31, 2009 (SEC File No. 000-23272, filing date March 11, 2010).
- (23) Incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272, filing date May 24, 2010).
  - (24) Incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272, filing date May 24, 2011).
  - (25) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2011 (SEC File No. 000-23272, filing date May 3, 2011).
  - (26) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2011 (SEC File No. 000-23272, filing date November 3, 2011).
  - (27) Incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272, filing date August 15, 2011).
  - (28) Incorporated herein by reference to the Registrant's Registration Statement on Form S-8 (SEC File No. 333-17521, Film No. 96677983, filing date December 9, 1996).
  - (29) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012 (SEC File No. 333-17521, filing date August 1, 2012).
  - (30) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 (SEC File No. 333-17521, filing date May 3, 2012).
  - (31) Incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272, filing date February 13, 2013).

## SIGNATURES

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

### NPS PHARMACEUTICALS, INC.

Date: February 21, 2013

By: /s/ FRANCOIS NADER  
**Francois Nader**  
**President and Chief Executive Officer (Principal Executive Officer)**

Date: February 21, 2013

By: /s/ LUKE M. BESHAR  
**Luke M. Beshar**  
**Chief Financial Officer (Principal Financial and Accounting Officer)**

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ FRANCOIS NADER</u> Francois Nader	President and Chief Executive Officer (principal executive officer) and Director	February 21, 2013
<u>/s/ LUKE M. BESHAR</u> Luke M. Beshar	Executive Vice President and Chief Financial Officer (principal financial and accounting officer)	February 21, 2013
<u>/s/ Michael W. Bonney</u> Michael W. Bonney	Director	February 21, 2013
<u>/s/ Colin Broom</u> Colin Broom	Director	February 21, 2013
<u>/s/ Georges Gemayel</u> Georges Gemayel	Director	February 21, 2013
<u>/s/ Pedro Granadillo</u> Pedro Granadillo	Director	February 21, 2013
<u>/s/ James G. Groninger</u> James G. Groninger	Director	February 21, 2013
<u>/s/ Rachel R. Selisker</u> Rachel R. Selisker	Director	February 21, 2013
<u>/s/ Peter G. Tombros</u> Peter G. Tombros	Chairman of the Board of Directors	February 21, 2013

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# CORPORATE INFORMATION

## Corporate Headquarters

NPS Pharmaceuticals, Inc.  
550 Hills Drive, 3rd Floor  
Bedminster, NJ 07921  
908.450.5300

## Common Stock

The common stock of NPS is traded on the Nasdaq Global Market under the symbol NPSP.

## Key Executives

### Francois Nader, MD

President and Chief Executive Officer

### Luke M. Beshar, CPA

Executive Vice President and Chief Financial Officer

### Roger J. Garceau, MD, FAAP

Executive Vice President and Chief Medical Officer

### Glenn R. Melrose

Senior Vice President, Human Resources

### Eric Pauwels

Senior Vice President and Chief Commercial Officer

### Joseph J. Rogus, PE

Vice President, Technical Operations and Supply Chain Management

### Edward H. Stratemeier, JD, MBA

Senior Vice President and General Counsel

## Board of Directors

### Peter G. Tombros (chairman)

Professor and Executive in Residence in the Eberly College of Science BS/MBA Program at Pennsylvania State University

### Michael W. Bonney

President and Chief Executive Officer, Cubist Pharmaceuticals, Inc.

### Colin Broom, MD

Vice President and Chief Scientific Officer, ViroPharma Inc.

### Georges Gemayel, PhD

Chairman, Syndexa Pharmaceuticals Corporation and Vascular Magnetics, Inc.

### Pedro Granadillo

Director, Dendreon Corporation, Haemonetics Corporation, and Nile Therapeutics

### James G. Groninger

Chief Financial Officer of Fluorinov Pharmaceuticals, Inc.

### Francois Nader, MD

President and Chief Executive Officer, NPS Pharmaceuticals, Inc.

### Rachel R. Selisker, CPA

President, Seamark Advisors LLC

## Independent Registered Public Accounting Firm

KPMG LLP

Short Hills, NJ

## Investor Relations

Information about NPS is available by accessing the company's website at [www.npsp.com](http://www.npsp.com). NPS' website includes press releases and filings with the U.S. Securities and Exchange Commission. Interested parties may also subscribe to email alerts through the investor relations section. Email alerts are delivered to subscribers when new and relevant company information is posted to the site. Copies of current press releases and SEC filings can also be obtained by calling NPS investor relations at 908.450.5335.

## Annual Meeting of Stockholders

The annual stockholders' meeting will be held at 9:00 AM ET on May 7, 2013 at The Bernards Inn, 27 Mine Brook Road, Bernardsville, NJ 07924.

## Transfer Agent and Registrar

The transfer agent is responsible for handling inquiries relating to stock transfer or lost certificates and notifications of changes in address. These requests may be directed to the transfer agent using the following information:

Registrar and Transfer Company

10 Commerce Drive

Cranford, NJ 07016

800-866-1340

## Code of Ethics

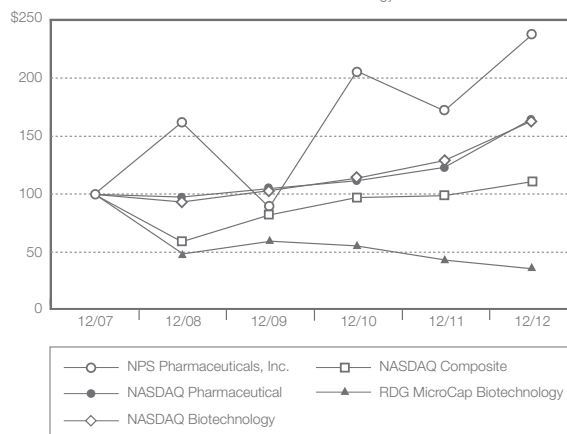
NPS has adopted a corporate Code of Business Conduct and Ethics that applies to all of its directors, officers (including our chief executive officer and chief financial and accounting officers), employees and agents. The company requires that all of its directors, officers, employees and agents certify compliance with the code on an annual basis. A copy of the Code of Business Conduct and Ethics is accessible through the corporate governance section of the NPS website at [www.npsp.com](http://www.npsp.com).

## Stock Performance Graph

The graph depicted below shows a comparison of cumulative total shareholder returns among NPS common stock, the NASDAQ Composite Index, the RDG MicroCap Biotechnology Index, the NASDAQ Pharmaceutical Index, and the NASDAQ Biotechnology Index. The Stock Performance Graph is not "soliciting material," is not deemed filed with the SEC, and is not incorporated by reference in any filing of NPS under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in such filing. You are cautioned not to draw any conclusions from this information as past results are not indicative of future performance. This graph in no way reflects a forecast of future financial performance or value.

### Comparison of 5-Year Cumulative Total Return\*

Among NPS Pharmaceuticals, Inc., the NASDAQ Composite Index, the NASDAQ Pharmaceutical Index, the RDG MicroCap Biotechnology Index, and the NASDAQ Biotechnology Index



\*\$100 invested on 12/31/07 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

## Safe Harbor Statement

This annual report contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Reference is made in particular to statements regarding the description of the plans, objectives, and other forward-looking statements included in the Letter to Stockholders and Annual Report on Form 10-K for the fiscal year ended December 31, 2012, which is included herein. Such statements are based on management's current expectations and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. In particular, careful consideration should be given to cautionary statements made in the company's filings with the SEC, specifically those statements found in its Annual Report on Form 10-K under the caption "Risk Factors" in Item 1A.

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