

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, 2014**

**Commission File Number 0-23272**

**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, NJ 07921**  
(Address of Principal Executive Offices including 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
Common Stock, \$.001 Par Value Per Share	The NASDAQ Stock Market LLC (NASDAQ Global Market)

**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  Smaller reporting company   
 (Do not check if a 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 \$3,543,284,815 as of June 30, 2014, based upon the closing price for the shares of common stock reported on The NASDAQ Global Market on such date.

As of February 11, 2015, there were 108,581,155 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 2015 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, or, in the event the Registrant does not prepare and file such Proxy Statement, will be provided instead by an amendment to this report containing the applicable disclosures within 120 days after the end of the fiscal year covered by this report. (With the exception of those portions which are specifically incorporated by reference in this report, any such Proxy Statement is not deemed to be filed or incorporated by reference as part of this report).

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#### TABLE OF CONTENTS

	Item	Page
<b>PART I</b>	1. <a href="#">Business</a>	3
	1A. <a href="#">Risk Factors</a>	26
	1B. <a href="#">Unresolved Staff Comments</a>	42
	2. <a href="#">Properties</a>	42
	3. <a href="#">Legal Proceedings</a>	42
	4. <a href="#">Mine Safety Disclosures</a>	45
<b>PART II</b>	5. <a href="#">Market for the Company's Common Equity, Related Stockholder Matters and Company Purchases of Equity Securities</a>	45
	6. <a href="#">Selected Financial Data</a>	47
	7. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	48
	7A. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	64

	8.	<a href="#">Financial Statements and Supplementary Data</a>	65
	9.	<a href="#">Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</a>	95
	9A.	<a href="#">Controls and Procedures</a>	95
	9B.	<a href="#">Other Information</a>	96
<b>PART III</b>	10.	<a href="#">Directors, Executive Officers and Corporate Governance</a>	96
	11.	<a href="#">Executive Compensation</a>	96
	12.	<a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a>	96
	13.	<a href="#">Certain Relationships and Related Transactions, and Director Independence</a>	96
	14.	<a href="#">Principal Accountant Fees and Services</a>	96
<b>PART IV</b>	15.	<a href="#">Exhibits and Financial Statement Schedules</a>	97

**[SIGNATURES](#)**

**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****Merger Agreement**

On January 11, 2015, we entered into an Agreement and Plan of Merger (Merger Agreement) with Shire Pharmaceutical Holdings Ireland Limited (Parent), a company incorporated in Ireland and a wholly owned subsidiary of Shire plc (Shire), a company incorporated in Jersey; Knight Newco 2, Inc. (Purchaser), a Delaware corporation and wholly owned subsidiary of Parent; and, solely for purposes of Section 12.14 of the Merger Agreement, Shire. Pursuant to the Merger Agreement, Purchaser has commenced a cash tender offer for all of the outstanding shares of the Company's common stock, upon the terms and subject to the conditions of the Merger Agreement. Consummation of the tender offer is subject to customary closing conditions, as set forth in the Merger Agreement. As soon as practicable following the consummation of the tender offer, and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Purchaser will merge with and into the Company pursuant to the provisions of section 251(h) of the Delaware General Corporation Law, with no stockholder vote required to consummate the merger, and the Company will survive as a wholly owned subsidiary of Parent.

The Merger Agreement contains representations, warranties and covenants of the parties customary for transactions of this type. Until the earlier of the termination of the Merger Agreement and the consummation of the merger, the Company has agreed to operate its business and the business of its subsidiaries in the ordinary course and has agreed to certain other operating covenants, as set forth more fully in the Merger Agreement. The Company has agreed not to solicit alternative acquisition proposals. However, the Company may, subject to the terms and conditions set forth in the Merger Agreement, furnish information to, and engage in discussions and negotiations with, a third party that makes an unsolicited acquisition proposal that the Board reasonably believes is or could reasonably be expected to lead to a superior proposal. Under certain circumstances and upon compliance with certain notice and other specified conditions set forth in the Merger Agreement, the Company may terminate the Merger Agreement to accept a superior proposal.

The Merger Agreement contains certain termination rights for both Parent and the Company and further provides that, upon termination of the Merger Agreement under certain circumstances relating to competing acquisition proposals, including if the Company terminates the Merger Agreement to accept a superior proposal, or where our Board of Directors changes its recommendation in favor of the transaction, the Company may be required to pay Parent a termination fee of \$155,939,696.

Shire has secured an \$850 million fully underwritten short-term bank facility, which in addition to Shire's cash and cash equivalents and its existing \$2.1 billion five-year revolving credit facility, is available to finance the transaction and pay related fees and expenses.

Additional information about the merger is set forth in our filings with the U.S. Securities and Exchange Commission (SEC).



## Overview

We are a global biopharmaceutical company pioneering and delivering first-in- or best-in disease therapies that transform the lives of patients with rare diseases. Our vision is a world where every person living with a rare disease has a treatment option. We incorporated in Utah in 1986 and reincorporated in Delaware in 1992. Our current therapeutic areas of focus are rare gastrointestinal and endocrine disorders. These include Short Bowel Syndrome, a potentially fatal gastrointestinal disorder in which patients may have to rely on parenteral support for their survival; Hypoparathyroidism, a complex endocrine disorder in which the parathyroid glands are either absent or damaged and the body produces insufficient or no parathyroid hormone; and Autosomal Dominant Hypocalcemia (ADH), an ultra-rare genetic disorder of calcium homeostasis caused by mutations of the calcium-sensing receptor gene.

Our first marketed 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. SBS is an ultra-rare potentially fatal disorder in which the body is unable to absorb enough nutrients and fluids through the gastrointestinal tract. In the European Union ("EU"), teduglutide (trade name: Revestive®) is approved for the treatment of adult patients with SBS; patients should be stable following a period of intestinal adaptation after surgery. We launched Revestive in Germany and Sweden in 2014 and plan to launch in other EU countries in 2015. We also have orphan drug designation in Japan and a small local study in Japanese SBS patients is underway. In addition, a global development program in pediatric SBS is advancing and we are currently evaluating the results from the first study.

Our second product, Natpara® (parathyroid hormone) for Injection was approved in January 2015 as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism, a rare endocrine disorder characterized by insufficient levels of parathyroid hormone or PTH. Natpara, a bioengineered replica of human PTH, is expected to be available in the second quarter of 2015.

Because of the potential risk of osteosarcoma, Natpara is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone. Natpara was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations or in patients with acute post-surgical hypoparathyroidism.

In the EU, the European Medicines Agency is currently reviewing our Marketing Authorization Application for Natpara® which is the European brand name for Natpara, in hypoparathyroidism.

We have collaborations or royalty agreements with a number of pharmaceutical companies. In 2014, we recorded \$122.9 million of royalty revenue that was driven by (i) Amgen's sales of Sensipar® and Mimpara® (cinacalcet HCl), (ii) Kyowa Hakko Kirin's sales of REGPARA® (cinacalcet HCl) in Japan, and (iii) Janssen's sales of Nucynta® (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 under our agreement with Kyowa Hakko Kirin.

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

### *Significant Developments*

- In January 2015, we entered into a merger agreement with Shire pursuant to which Shire will acquire all of our outstanding shares for \$46 per share.
- In January 2015, the FDA approved our BLA for Natpara.

## Product and Development Programs and Royalty-Based Agreements

The table below includes our proprietary product and development programs:

<b>Product</b>	<b>Indication</b>	<b>Status</b>	<b>Market</b>
Gattex <sup>®</sup> (teduglutide) for injection	Adult SBS	Commercial	U.S.
Revestive (teduglutide)	Adult SBS	Commercial	EU
Gattex/Revestive (teduglutide)	SBS (Registry)	Phase 4	Worldwide ex-Israel
Gattex/Revestive (teduglutide)	Pediatric SBS	Registration study	Worldwide ex-Israel
Natpara <sup>®</sup> (recombinant human parathyroid hormone 1-84)	Hypoparathyroidism	Commercial	U.S.
Natpar <sup>®</sup>	Hypoparathyroidism	MAA Accepted	Ex-U.S.
NPSP795	ADH	Phase 2	Worldwide

The table below includes certain of our royalty-based agreements:

<b>Product</b>	<b>Indication</b>	<b>Status</b>	<b>Market</b>	<b>Rights</b>
Sensipar <sup>®</sup> /Mimpara <sup>®</sup> (cinacalcet HCl) <sup>1</sup>	Primary and Secondary hyperparathyroidism	Commercial	Worldwide Ex-Asia	Amgen
Sensipar <sup>®</sup> (cinacalcet HCl) <sup>1</sup>	Hypercalcemia in parathyroid cancer	Commercial	Worldwide Ex-Asia	Amgen
REGPARA <sup>®</sup> (cinacalcet HCl) <sup>2</sup>	Secondary hyperparathyroidism	Commercial	Asia	Kyowa Hakko Kirin
NUCYNTA <sup>®</sup> (tapentadol) and Nucynta ER	Moderate to severe acute pain Moderate to severe chronic pain Neuropathic pain associated with diabetic peripheral neuropathy in adults	Commercial	U.S.	Janssen
Ronacaleret (calcilytic compound)	Stem cell mobilization	Phase 2	Worldwide	GlaxoSmith Kline

<sup>1</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>2</sup> We currently do not receive cash payments related to our REGPARA royalties as we have sold certain of our rights to receive these payments to service our non-recourse debt.

## Product and Development Programs

### *Gattex/Revestive (Teduglutide [rDNA] origin) for Injection*

Gattex is a novel recombinant analog of human glucagon-like peptide 2 (GLP-2), a protein involved in the rehabilitation of the intestinal lining. 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.

We launched Gattex in the U.S. in February 2013 and in certain ex-U.S. countries in late 2014. In December 2012, the FDA approved Gattex for the treatment of adult patients with SBS who are dependent on parenteral support. In August 2012, the European Commission approved Revestive® for the treatment of adult patients with SBS; patients should be stable following a period of intestinal adaptation after surgery.

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).

### *SBS Market Opportunity*

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/Revestive, 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 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/Revestive 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/Revestive 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 long-term 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/Revestive therapy.

### *Gattex/Revestive for adult SBS*

Gattex/Revestive 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/Revestive 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/Revestive. The U.S. and EU approvals of Gattex/Revestive were 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/Revestive achieved at least a 20 percent reduction in weekly parenteral support volume when compared to baseline, versus 30 percent of patients on placebo (p=0.002).

- After 24 weeks of treatment, parenteral support volume declined by 32 percent (4.4 L/week) in Gattex/Revestive-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/Revestive-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 ( $p = 0.005$ ).

Ninety-seven percent (76/78) of subjects who completed STEPS elected to enroll in STEPS 2 (37 received Gattex; 39 received Placebo). An additional 12 subjects entered STEPS 2, who had been optimized and stabilized but not randomized in STEPS because of closed enrollment.

### *30 months exposure*

Thirty Gattex subjects completed a total duration of 30 months (STEPS followed by STEPS 2 treatment). Of these, 28 subjects (93%) achieved a 20% or greater reduction of parenteral support. Of responders in STEPS who had completed 2 additional years of continuous treatment with Gattex, 96% (21/22) sustained their response to Gattex. The mean reduction in PN/I.V. (n=30) was 7.55 L/week (a 65.6% reduction from baseline). Ten subjects were weaned off their PN/I.V. support while on Gattex treatment for 30 months. Subjects were maintained on Gattex even if no longer requiring PN/I.V. support. These 10 subjects had required PN/I.V. support for 1.2 to 15.5 years, and prior to Gattex had required between 3.5 L/week and 13.4 L/week of PN/I.V. support. At the end of study, 21 (70%), 18 (60%) and 18 (60%) of the 30 completers achieved a reduction of 1, 2, or 3 days per week in PN/I.V. support, respectively.

### *24 month exposure*

Of the 39 placebo subjects from STEPS entering STEPS 2, 29 completed 24 months of treatment with Gattex. The mean reduction in PN/I.V. was 3.11 L/week (an additional 28.3% reduction) from the start of STEPS 2. Sixteen (55.2%) of the 29 completers achieved a 20% or greater reduction of parenteral support. At the end of study, 14 (48.3%), 7 (24.1%) and 5 (17.2%) achieved a reduction of 1, 2, or 3 days per week in PN/I.V. support, respectively. Two subjects were weaned off their PN/I.V. support while on Gattex. Of the 12 subjects entering STEPS 2 directly, 6 completed 24 months of treatment with Gattex. Similar effects were seen. One of the six subjects was weaned off their PN/I.V. support while on Gattex.

The most common adverse reactions ( $\geq 10$  percent) across all studies with Gattex/Revestive 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. Gattex may cause serious side effects, including: making abnormal cells grow faster, polyps in the colon (large intestine), blockage of the bowel (intestines), swelling (inflammation) or blockage of the gallbladder or pancreas, and fluid overload.

The FDA and European Commission have granted orphan drug status for Gattex and Revestive, respectively for the treatment of SBS.

### *Gattex/Revestive for pediatric SBS*

We are also evaluating the safety and efficacy of Gattex/Revestive in pediatric SBS. We recently completed an open-label 4-cohort study that enrolled 42 pediatric SBS patients between the ages of 1 and 17. Non-randomized patients received Gattex/Revestive in 3 active cohorts. We also enrolled additional patients into an observational fourth cohort who received standard of care. The three doses of Gattex/Revestive were investigated for 12 weeks. The patients were screened prior to the start of treatment to establish baseline characteristics including safety, eligibility and nutritional support. The primary outcome is safety, based on the number of reported adverse events after 12 weeks of teduglutide. In addition we will look at the pharmacodynamics based on the changes in parenteral and enteral support requirements after 12 weeks of treatment. We are currently analyzing the data from the study.

Pediatric SBS is a complex and highly morbid condition with significant mortality rates. Patients suffer from repeated episodes of sepsis, dehydration, and metabolic derangements. Pediatric SBS is also associated with diarrhea or stomal output that can be traumatizing and socially debilitating. Researchers from the University of Michigan reported in a publication that in the U.S., over a five-year period the mean cost of care for a child with SBS is \$1.6 million and over that same period pediatric SBS patients spend an average of 146 days in the hospital (Spencer et al. 2008). In December 2013, we initiated a global registration study of Gattex/Revestive in pediatric patients with SBS who are dependent on parenteral support.

### *Natpara® (parathyroid hormone) for Injection*

Natpara is our bioengineered replica of human parathyroid hormone that is approved as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism, a rare endocrine disorder in which the body produces insufficient levels of PTH, a principal regulator of the body's mineral homeostasis.

Natpara is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone. Natpara was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations or in patients with acute post-surgical hypoparathyroidism.

Hypoparathyroidism is a rare endocrine disorder in which the parathyroid glands fail to produce sufficient amounts of parathyroid hormone (PTH) or where the hormone lacks biologic activity. PTH plays a central role in a variety of critical physiological functions in the body. Insufficient levels of PTH lead to low levels of calcium and high levels of phosphate in the blood, and an inability to convert native vitamin D into its active state, which helps the body properly absorb oral calcium. Parathyroid hormone increases serum calcium by increasing renal tubular calcium reabsorption, increasing intestinal calcium absorption (i.e., by converting native vitamin D (25 OH) into its active form (1,25 OH<sub>2</sub> vitamin D)) and by increasing bone turnover which releases calcium into the circulation.

Acute symptoms of hypoparathyroidism are largely due to hypocalcemia and include fatigue, muscle spasms and cramps, tingling, tetany, seizures, brain fog/mental lethargy, anxiety, and depression. Prior to an approved parathyroid replacement therapy, treatment options were limited to calcium supplements and active vitamin D to increase calcium levels in the blood and reduce the severity of hypocalcemic symptoms. However, balancing the administration of supplements is challenging due to calcium fluctuations. In clinical trials, Natpara has been shown to reduce the amount of oral calcium and active vitamin D required to maintain serum calcium levels.

### *Hypoparathyroidism Market*

Epidemiological data on hypoparathyroidism are limited given its rarity and the variability in the severity of the symptoms associated with this disorder. 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 endocrine deficiency syndromes in which hormonal therapy is not clinically available. Treatment of hypoparathyroidism is further complicated by the lack of national or international consensus management guidelines.

As is the case for most rare diseases, the burden of illness for hypoparathyroidism has not been well described or studied. Considering the need to better understand the burden of illness associated with this condition, we conducted an extensive quantitative study known as PARADOX in conjunction with the Hypoparathyroidism Association and the Mayo Clinic. This study is the largest ever conducted in this condition and included 374 patients with hypoparathyroidism. Key findings from PARADOX suggest that patients with hypoparathyroidism have a high burden of illness, as 99% continue to experience multiple symptoms despite the use of calcium and vitamin D supplements and other medications. On average, patients reported experiencing a collection of 16 of the 38 symptoms reported in the analysis. The most common physical symptoms reported included fatigue (82%), muscle pain or cramping (78%), paresthesia (76%), tetany (70%), and joint or bone pain (67%), and pain/heaviness/weakness in extremities (53%). Cognitive and emotional symptoms were also prevalent. Brain fog/mental lethargy (72%), inability to focus or concentrate (65%), and memory loss or forgetfulness (61%), and sleep disturbances (57%) were common, while anxiety (59%) and depression (53%) were also reported. The findings also showed that symptoms persist for an average of 13 hours over the course of a day. While patients indicated that they were managing their symptoms with calcium and vitamin D, they continued to develop comorbidities of hypoparathyroidism and suffer from acute episodes requiring emergency care and/or hospitalization. Sixty-nine percent of patients experienced comorbidities since diagnosis. Common comorbid conditions that were most frequently reported by patients in PARADOX included heart arrhythmias (66%) and kidney stones (36%). Bone fractures (16%) were also reported. Seventy-nine percent of patients reported hospital stays or emergency department visits, with the annualized rate for patients who classified their condition as severe exceeding those of patients with mild or moderate condition. Patients exceeded the national average for the general population for emergency department visits and hospital stays.

Calcium supplementation is associated with several challenges, including renal function deterioration, renal stones, and soft tissue calcifications. In the long-term follow-up study of 120 patients with hypoparathyroidism (Mitchell et al. 2012) adverse renal effects were observed. The risk of renal complications in patients with hypoparathyroidism was also evaluated in a case study using the Danish National Patient Registry and a prescription database. Six hundred and eighty-eight (688) patients were identified who manifested symptoms of hypocalcemia and inappropriately low PTH levels following neck surgery that required oral calcium and/or active vitamin D. Compared with age- and sex-matched controls, patients with hypoparathyroidism had an increased risk of renal complications (hazard ratio: 3.67, 95% CI, 2.41 to 5.59) (Underbjerg et al. 2013). Experts recommend close monitoring of patients being treated for hypoparathyroidism with large amounts of calcium and vitamin D preparations (De Sanctis et al. 2012; Shoback 2008).

The direct and indirect health care costs for persons with hypoparathyroidism are substantial. In a study conducted by the Mayo Clinic, the mean and median costs for persons with hypoparathyroidism were approximately three-fold those for unaffected persons of similar age/sex.

The PARADOX study and other epidemiological research show that hypoparathyroidism has a significant impact on patients in many ways: physical, emotional, quality of life, social life, and productivity. Despite the currently available medical management, symptoms persist and occur frequently, even daily and, when experienced on a moderate or severe level, can negatively affect the patients' life. In addition to associated symptoms, patients report comorbidities that are directly related to their hypoparathyroidism. These concurrent conditions necessitate further medical treatment. Given the chronicity of hypoparathyroidism patients are faced with a lengthy affliction with chronic and debilitating symptoms and complications.

To help illustrate the fundamental aspects of hypoparathyroidism, we initiated enrollment in a global natural history registry for patients with hypoparathyroidism. The objective of the study, known as PARADIGHM, is to characterize the natural history of chronic hypoparathyroidism, including its treatment, clinical outcomes, comorbidities and mortality as observed in a typical clinical setting. The ultimate goal for compiling the PARADIGHM registry is to assist healthcare practitioners in optimizing clinical decision making for patients with hypoparathyroidism. The registry is designed to help healthcare practitioners better understand the variability, progression and natural history of the disorder. Patients will be enrolled and followed for at least 10 years to characterize this rare, complex endocrine disorder under conditions of normal clinical practice.

#### *Natpara for Hypoparathyroidism*

Natpara is a bioengineered replica of human parathyroid hormone. Natpara is identical in structure to the 84-amino acid single-chain polypeptide human parathyroid hormone and mimics the action of natural parathyroid hormone.

In January 2015, the FDA approved our BLA for Natpara and Natpara is expected to be available in the second quarter of 2015.

The company's clinical development program for Natpara includes 12 pharmacology studies, five efficacy and safety studies in hypoparathyroidism, and a supporting development program consisting of seven studies in osteoporosis. The pivotal Phase 3 study known as REPLACE, was a randomized, double-blind, placebo controlled study of 134 patients with hypoparathyroidism.

In REPLACE, patients with established hypoparathyroidism receiving calcium and active forms of vitamin D (vitamin D metabolite or analogs) were randomized (2:1) to NATPARA (n=84) or placebo (n=40). The mean age was 47 years (range, 19 to 74 years), 79.0% were females and 96.0% were Caucasian, 0.8% were Black, and 1.6% were Asian. Patients had hypoparathyroidism for on average 15 years and hypoparathyroidism was caused by post-surgical complications in 71% of cases, idiopathic hypoparathyroidism in 25%, DiGeorge Syndrome in 3%, and auto-immune hypoparathyroidism in 1%. Patients with hypoparathyroidism due to calcium-sensing receptor mutations were excluded from the trial. The mean eGFR at baseline was 97.4 mL/min/1.73 m<sup>2</sup> and 45%, 10% and 0% had mild, moderate and severe renal impairment, respectively, at baseline.

Before randomization, participants entered a 2-16 weeks run-in phase. In this phase calcium supplement and active vitamin D doses were adjusted to target an albumin-corrected serum calcium concentration between 8.0 and 9.0 mg/dL and 25-hydroxyvitamin D was replaced in patients with insufficient stores. At randomization, baseline serum calcium was 8.6 mg and participants were receiving a median (interquartile range) daily oral calcium dose of 2000 (1250, 3000) mg and a median daily oral active vitamin D dose equivalent to 0.75 mcg (0.5, 1) of calcitriol.





At randomization, active forms of vitamin D were reduced by 50% and patients were randomized to NATPARA 50 mcg daily or placebo. Randomization was followed by a 12-week NATPARA titration phase and a 12-week NATPARA dose maintenance phase. During the titration phase NATPARA was increased by 25 mcg increments every four weeks up to a maximum of 100 mcg. Titration was indicated for patients who could not achieve independence from active vitamin D and who could not reduce oral calcium to 500 mg or less per day. At end of treatment, 56% of subjects randomized to NATPARA were receiving 100 mcg of NATPARA per day, 26% were receiving 75 mcg of NATPARA per day, and 18% were receiving 50 mcg of NATPARA per day. Doses of co-administered active forms of vitamin D and calcium were adjusted (reduced or increased) to maintain albumin-corrected serum calcium within a desired target range throughout the trial in both arms.

For the efficacy analysis, subjects that fulfilled three components of a three-part response criterion were considered responders. A responder was defined as an individual who had: at least a 50% reduction from baseline in the dose of active vitamin D, at least a 50% reduction from baseline in the dose of oral calcium supplementation and an albumin-corrected total serum calcium concentration between 7.5 mg/dL and 10.6 mg/dL.

At the end of treatment, significantly (p-value <0.001) more subjects treated with NATPARA [46/84 (54.8%)] compared to placebo [1/40 (2.5%)] met the response criterion. Forty-two percent (35/84) of subjects randomized to NATPARA were independent of active forms of vitamin D and were on no more than 500 mg of oral calcium, compared with 2.5% (1/40) of subjects randomized to placebo (p<0.001). There were no differences in the proportion of patients with a calcium level between 7.5 mg and 10.6 mg at end of treatment between subjects randomized to NATPARA and placebo.

The most common adverse reactions associated with NATPARA and occurring in greater than 10% of individuals were: paresthesia, hypocalcemia, headache, hypercalcemia, nausea, hypoaesthesia, diarrhea, vomiting, arthralgia, hypercalciuria and pain in extremity. Because of the potential risk of osteosarcoma, Natpara is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone. Natpara was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations or in patients with acute post-surgical hypoparathyroidism. Natpara may cause serious side effects, including: possible bone cancer (osteosarcoma), high blood calcium (hypercalcemia), low blood calcium (hypocalcemia).

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 long-term, open-label study, known as RACE, which is investigating the long-term safety and tolerability of Natpara.

The FDA and European Commission have granted orphan drug status for Natpara for the treatment of hypoparathyroidism.

#### *NPSP795 in autosomal dominant hypocalcemia (ADH)*

Autosomal dominant hypocalcemia, or ADH, is a life-long genetic disorder related to the calcium-sensing receptor. It affects children and adults. Regardless of serum calcium or PTH levels, patients with ADH continuously excrete calcium through the renal system because their receptors are always sensing that serum calcium levels are too high. This results in hypocalcemia and hypercalciuria.

Symptoms of ADH can be severe and life-threatening and include tetany, convulsions, and renal impairment. There is no approved therapy for ADH and supportive approaches usually involve carefully adjusting calcium and active vitamin D. These efforts are not always effective and can worsen the condition by increasing calcium excretion and renal complications. For these reasons, physicians sometimes choose not to treat patients with ADH in order to avoid these complications.

NPSP795 is a calcilytic agent, which is a small molecule antagonist of the calcium-sensing receptors on the parathyroid glands. Calcilytics work by triggering a release of the body's stores of PTH. Initially developed to stimulate parathyroid hormone secretion and bone formation for the treatment of osteoporosis and other bone metabolism disorders, calcilytics have been shown to increase serum calcium and decrease urinary calcium excretion in a Phase 2 study of patients with osteoporosis.

We believe NPSP795 could be a novel treatment for disorders involving increased calcium receptor activity like ADH. We are conducting a Phase 2a proof-of-concept dose-ranging study and expect this study to conclude in the first half of 2015.

### **Royalty-Based Agreements**

We have agreements with Amgen, Janssen, GlaxoSmithKline and Kyowa Hakko Kirin. 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. 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 adult patients with chronic kidney disease (CKD) on dialysis, (ii) hypercalcemia in adult patients with parathyroid carcinoma, and (iii) hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but 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.

#### *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, 2014, 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. The outstanding principal balances on the Sensipar Notes, were \$26.2 million and \$54.4 million as of December 31, 2014 and 2013, respectively. 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, 2014, 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. 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. As of December 31, 2014 and 2013, the outstanding principal balances on REGPARA-secured debt were \$31.0 million and \$35.2 million, respectively. 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)) and Teduglutide, ex-North America Development*

On March 18, 2013, we entered into a Termination and Transition Agreement (the "Transition Agreement"), with Takeda GmbH ("Takeda GmbH"), and Takeda Pharma A/S ("Takeda Pharma" and, together with Takeda GmbH, "Takeda"). The Transition Agreement provides for the termination of the license agreement, dated as of July 2, 2007, as amended, which granted Takeda Pharma the exclusive license to sell, market and commercialize recombinant parathyroid hormone 1-84 [rDNA origin] ("PTH") worldwide, except for the U.S., Israel, and Japan, and a non-exclusive license to manufacture and develop PTH (the "PTH License Agreement"), and the license agreement, dated as of September 24, 2007, as amended, which granted Takeda GmbH the exclusive license to develop and commercialize teduglutide worldwide, except for North America and Israel (the "Revestive License Agreement," and together with the PTH License Agreement, the "License Agreements").

Preotact is the brand name that Takeda Pharma had used to market PTH for the treatment of osteoporosis in certain of its licensed territories. Takeda GmbH developed and obtained approval in the EU in August 2012 for teduglutide under the trade name Revestive for the treatment of short bowel syndrome ("SBS") in adults who are stable following a period of intestinal adaptation after surgery. We obtained FDA approval in the U.S. in December 2012 for teduglutide under the trade name Gattex for adult patients with SBS who are dependent on parenteral support. We obtained FDA approval for PTH under the trade name Natpara in January 2015. We are not marketing PTH for the treatment of osteoporosis in any territory.

As a result of the termination of the License Agreements, we have the exclusive rights worldwide, excluding Israel, to develop and commercialize teduglutide and PTH. In addition, under the Transition Agreement we acquired certain assets related to the products covered by the License Agreements, including, but not limited to, all of Takeda's inventory, patents, and regulatory approvals related to such products. We were also assigned Takeda's rights and assumed Takeda's obligations under certain contracts related to such assets.

Pursuant to the Transition Agreement, we issued 6,067,961 shares of our common stock to Takeda in a private placement transaction, which approximated \$50 million based upon the 30-day volume weighted average share price of our common stock as calculated pursuant to the Transition Agreement. We will be obligated to make an additional \$30 million milestone payment to Takeda in the event world-wide net sales of the products covered by the License Agreements exceed \$750 million in a single calendar year; provided that such milestone payment will become due upon a change in control of the Company. Such milestone payment may be made at our discretion in the form of either cash, shares of our common stock or a combination of both, subject to certain restrictions, including a limit on the maximum number of shares that may be offered under the Transition Agreement.

On December 20, 2013, we entered into an amendment and restatement (the "Amendment and Restatement") to our Agreement for the Sale and Assignment of Rights (the "2007 Agreement"), dated as of July 16, 2007, between NPS Allelix Corp., Drug Royalty L.P. 3 ("DRLP3"), an investment fund managed by DRI Capital Inc. ("DRI"), and NPS.

Under the 2007 Agreement, we sold to DRLP3 our rights to receive future royalty payments arising from the sale of recombinant human parathyroid hormone 1-84 [rDNA origin] ("PTH") under the PTH License Agreement.

Pursuant to the Amendment and Restatement, (i) DRLP3 has consented to the commercialization of PTH by NPS, (ii) the terms of the 2007 Agreement are tolled, and (iii) the parties' rights and obligations regarding PTH and related technology are governed by the Amendment and Restatement. We will be required to pay royalties in the mid-single digits to DRLP3 based upon sales of PTH by us and our licensees (if any) worldwide, excluding Israel. We have agreed to undertake certain efforts to commercialize PTH.

Our obligation to pay royalties to DRLP3 under the Amendment and Restatement shall expire on a country-by-country basis upon the later of (i) the last to expire patent controlled by us with claims covering PTH in such country or (ii) the expiration of any period of regulatory exclusivity applicable to PTH in such country. Our obligation to pay royalties to DRLP3 under the Amendment and Restatement shall terminate in its entirety once cumulative royalty payments made to DRLP3 by Takeda and us total \$125 million. As of December 31, 2014, \$45.5 million in royalties had been paid to DRLP3.

DRLP3 continues to maintain a security interest in NPS patents that contain claims covering PTH and certain other NPS intellectual property related to PTH. In the event of a default by us under the Amendment and Restatement, DRLP3 would be entitled to enforce its security interest against us and such intellectual property.

#### *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.

*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 FDA 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. In August 2012, the label for Nucynta ER was amended to provide for the use of the product for the management of neuropathic pain associated with diabetic peripheral neuropathy in adults. Tapentadol is a centrally acting oral analgesic.

*Hoffman-La Roche Inc. and F. Hoffmann-La Roche Ltd.*

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. We are required to pay royalties on the sales of cinacalcet HC1 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 HC1, of which \$10.4 million has been paid. Annual payments due are limited to a maximum of \$1.0 million. Brigham and Women's Hospital may terminate the patent license agreement if we breach the terms of the 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, 2014, we have paid license maintenance fees, milestone payments and sublicense fees totaling \$16.7 million under this license agreement. We are obligated to pay a royalty that represents a percentage in the single digits of our sales of Gattex and Revestive. 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.

## Government Regulation

### *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 (i) 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; (ii) expanding Medicaid drug rebates to cover drugs provided through managed Medicaid plans; and (iii) changing the rebate rates for line extensions (i.e., new formulations, such as extended release formulations) or new formulations of solid oral dosage form drugs.
- 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. In early 2012, the Centers for Medicare and Medicaid Services, or CMS, proposed to expand Medicaid rebate liability to the territories of the United States (Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa) as well. Though not yet finalized, CMS' proposed rule would extend Medicaid drug rebates to the territories and include applicable sales in AMP and best price calculations. 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.

- PPACA made some important changes to the Medicare drug benefit, including phasing out the Medicare coverage gap by 2020. Prior to PPACA, beneficiaries who reached a certain level of spending on prescription medications (the Medicare Part D coverage gap or "doughnut hole") had to pay 100% of the cost of their drugs until personal out-of-pocket spending reached a level qualifying them for catastrophic coverage. The Medicare Part D Coverage Gap Discount Program uses public and private funding to relieve the financial burden facing beneficiaries who fall into this coverage gap. Beginning in 2011, branded pharmaceutical companies paid 50% of the cost of the branded drugs in the gap and the government paid 7% of the cost of the generic drugs in the gap. As a result, rather than paying 100% of the total cost of their drugs when they reached the coverage gap, enrollees paid 50% of the total cost of branded drugs and 93% of the total cost of generic drugs. In addition, starting in 2013, the 50% discount from branded pharmaceutical companies was supplemented by a contribution from the government, which will also grow steadily over time until reaching 25% in 2020. That means that by 2020, enrollees will pay only 25% of the cost of their branded drugs in the gap.
- 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.
- Starting in August 2013, PPACA required pharmaceutical and medical device manufacturers to record any transfers of value made to licensed physicians and teaching hospitals and to disclose such data to HHS on an annual basis. In addition to civil penalties for failure to report transfers of value to physicians or teaching hospitals, there will be criminal penalties if a manufacturer intentionally makes false statements or excludes information in such reports. The payment data across pharmaceutical and medical device companies is posted by HHS on a publicly available website. Increased access to such data by fraud and abuse investigators, industry critics and media will draw attention to our collaborations with reported entities and will importantly provide opportunities to underscore the critical nature of our collaborations for developing new medicines and exchanging scientific information. This national payment transparency effort, coupled with industry commitment to uphold voluntary codes of conduct and rigorous internal training and compliance efforts, will complement existing laws and regulations to help ensure ethical collaboration and truthful product communications.
- PPACA established the Patient Centered Outcomes Research Institute (PCORI), a federally funded, private, non-profit corporation empowered to fund and disseminate comparative effectiveness research and build infrastructure for improved outcomes analysis. PCORI has no authority to impose formulary changes directly in government-funded health programs. In 2013, PCORI announced that it will issue a new type of funding for pragmatic, head-to-head comparison studies, as well as plans to develop a national clinical research data network. Both developments are expected to increase the availability of medical evidence related to health care interventions. Overseeing and managing the PCORI is an advisory board drawn from multiple and varied stakeholder organizations, including the pharmaceutical industry. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.

PPACA also created the Independent Payment Advisory Board (IPAB), a 15-member panel to be appointed by the President. The IPAB is charged with developing proposals to "reduce the per capita rate of growth in Medicare spending" in the event that the actual Medicare per capita growth rate exceeds a specified target. Due to slow growth in health care spending that did not exceed the target per capita growth rate, the IPAB will not be required to act until 2016, at the earliest. To date, the IPAB's members have not been named or appointed. If asked to act in 2016 or beyond, the IPAB could potentially limit access to certain treatments or mandate price controls for our products.

- 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*

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.

*Sales and Marketing Regulation*

In February 2013, we launched and initiated commercial sales of Gattex, the first NPS product to be commercialized and sold directly by NPS. In the past, we entered into agreements with third parties who have been responsible for commercialization of our products. As an organization that sells and markets its products directly, we are now subject to additional sales and marketing regulation and will be subject to similar regulations as we expand internationally into new markets.

The FDA regulates all advertising and promotion activities for products under its jurisdiction, including Gattex and Natpara. Broadly speaking, a company may not commercially promote a product prior to its approval, and after approval can make only those claims relating to safety and efficacy that are consistent with the labeling approved by the FDA. Physicians may, on their own choice and responsibility, prescribe drugs for uses that are not described in the drug's labeling and that differ from those tested by the product's manufacturer and approved by the FDA. Such "off-label" uses are common across medical specialties and may reflect a physician's belief that the "off-label" use is the best treatment for the patients. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations do impose stringent restrictions on manufacturers' promotion and communications regarding such "off-label" uses. Generally speaking, a manufacturer may not promote a drug for "off-label" use, but may engage in non-promotional, balanced communication regarding "off-label" use under certain conditions. If a company is found to have promoted "off-label" uses, it may become subject to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. Such actions could subject a company to a range of penalties that could result in a significant commercial impact, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA and other government agencies, including those related to false claims, any one of which could materially restrict the manner in which a company promotes or distributes drug products.

Several states have also enacted legislation requiring pharmaceutical companies operating within the state to establish marketing and promotional compliance programs or codes of conduct and/or file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities. Similar legislation is being considered by additional states and by Congress. We will also be required to publicly report certain payments and gifts, including those made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are not always clear.

We also are subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws.

Similar restrictions are imposed on the promotion and marketing of medicinal products in the EU and other countries. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. The specific regulations for sales and marketing vary from country to country, and compliance with such regulations may impose additional costs and time delays with respect to international commercialization of our products. Even in those countries where we are not directly responsible for the promotion and marketing of our products, inappropriate activity by our international distribution partners can have implications for us.

### **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/Revestive*: Twenty 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 been issued foreign counterparts of these patents. 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
U.S.	Glucagon-like peptide-2 analogs	2015 <sup>1,2</sup>
U.S.	GLP-2 formulations	2022 <sup>1,2</sup>
Europe	Glucagon-like peptide-2 analogs	2017 <sup>3</sup>
Europe	GLP-2 formulations	2020
Japan	Glucagon-like peptide-2 analogs	2017 <sup>4</sup>
Japan	GLP-2 formulations	2020 <sup>4</sup>

<sup>1</sup> A request for interim extension of patent term has been filed for this patent.

<sup>2</sup> We are eligible for patent term extension of up to five years on one U.S. patent due to marketing approval of Gattex by the FDA.

<sup>3</sup> Does not include any supplementary protection. Applications for supplementary protection have been filed in most major European countries. In countries that have granted our applications, we have received approximately five years of supplementary protection.

<sup>4</sup> Does not include any supplementary protection.

*Natpara*: Seven issued U.S. patents include claims that cover technology related to parathyroid hormone. These patents have expiration dates ranging from 2015 to 2018. We have been issued foreign counterparts of these patents. 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	2015 <sup>1</sup>
Europe	Protein formulations	2021 <sup>2</sup>
Japan	Protein formulations	2019 <sup>3</sup>

<sup>1</sup> Includes two years of interim patent term extension. We are eligible for up to three additional years of patent term extension.

<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*: Ten 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 2015 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, including NPSP795*: Five issued U.S. patents contain claims that cover technology related to calcilytic compounds we have under development or 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 (2015 through 2016) 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 Gattex is 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 was granted a second year of interim patent term extension and is eligible for up to three additional years of patent term extension. In addition, each of Gattex and Natpara has been designated as an orphan drug by the FDA and, as a result, both Gattex and Natpara 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 in January 2015. As a biologic product, Natpara is expected to receive 12 years of marketing exclusivity in the U.S. In Europe, Revestive and Natpar have each been granted orphan designation. Market exclusivity for orphan drugs is generally granted for a period of ten years.

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 rare 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 and Revestive in the treatment of SBS, where there are a limited number of competing therapies. Gattex/Revestive 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.



Natpara® (parathyroid hormone) has received FDA approval as an adjunct to calcium supplements and active vitamin D to control hypocalcemia in patients with hypoparathyroidism. We have also been granted orphan drug status for Natpara for the treatment of hypoparathyroidism. Natpara is a bioengineered replica of human parathyroid hormone and the only parathyroid hormone approved for chronic use in hypoparathyroidism.

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:

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## 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/Revestive and Natpara. We have agreements in place with Boehringer Ingelheim Austria GmbH ("Boehringer") for Gattex/Revestive 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 Patheon, Inc. ("Patheon") for the production of our fill and finish clinical and commercial supplies of Gattex/Revestive and Vetter Pharma International GmbH ("Vetter") for the production of our fill and finish clinical and commercial supplies of Natpara. We have also established agreements with other third parties to perform additional steps in the manufacturing process, including sterile water for injection, packaging, testing and storage of our product candidates.

We have developed an injection pen device for the delivery of Natpara and we have a manufacturing agreement in place. We received U.S. market authorization as a drug-device combination in January 2015, combining our proprietary product Natpara with an injection pen device delivery system. Due to a technical production issue during parts of 2012 and 2013 we were unable to have batches of Natpara finished product manufactured that were consistently within our specifications. These manufacturing problems caused a delay in the filing of our BLA for Natpara. Although we were able to resolve this manufacturing issue and submit our BLA in October 2013, we cannot assure you that we will not encounter manufacturing problems with respect to Natpara or any of our products or product candidates 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, Revestive and Natpara.

We are dependent on third parties for the manufacture of our products, product candidates and injection devices and in several instances we are sole sourced to these manufacturers, including Hospira, Patheon and Vetter, who produce fill and finish supplies of Gattex, Revestive and Natpara, respectively. If we are unable to contract for a sufficient supply of our products, 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 be able to continue to sell our products or 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.

*Patheon UK Limited*

In September 2013 we were assigned an agreement with Patheon from Takeda for production of our fill and finish clinical and commercial supplies of Gattex and Revestive. This agreement, which was originally entered into in February 2010, has a term of ten years and automatically renews for subsequent two-year terms unless either party sends advanced notice of non-renewal. Either party may terminate the agreement at any time upon twenty-four months' advance notice.

*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 commercial 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 11, 2015, we had approximately 365 employees. Our U.S. and European employees are not represented by a collective bargaining agreement and we believe that our relationship with our employees is good.

**Trademarks**

"NPS", the "NPS Logo", "NPS Pharmaceuticals", "NPS Pharma", "Gattex", "Revestive", "Natpara", "Preotact" 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*. 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*) 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, operating results and financial condition.*

## **Risks Related to the Merger Agreement**

***The conditions under the Merger Agreement to Shire's consummation of the tender offer and our subsequent merger with a subsidiary of Shire may not be satisfied at all or in the anticipated timeframe.***

Under the terms of the Merger Agreement, the consummation of Shire's pending tender offer and subsequent merger is subject to customary conditions. Satisfaction of certain of the conditions is not within our control, and difficulties in otherwise satisfying the conditions may prevent, delay or otherwise materially adversely affect the consummation of the tender offer and subsequent merger. These conditions include, among other things, there being validly tendered and not validly withdrawn, subject to certain conditions, a number of shares of our common stock that, together with the shares then owned by Shire and its subsidiaries, represents at least a majority of the outstanding shares of our common stock immediately prior to the expiration of the tender offer. It also is possible that an event, occurrence, revelation or development of a state of circumstances or facts since the date of the Merger Agreement may have or reasonably be expected to have a material adverse effect (as defined in the Merger Agreement) on NPS, the non-occurrence of which is a condition to the consummation of the tender offer. We cannot predict with certainty whether and when any of the required conditions will be satisfied. If the acquisition does not receive, or timely receive, the required regulatory approvals and clearances, or if another event occurs delaying or preventing the acquisition, such delay or failure to complete the acquisition may create uncertainty or otherwise have negative consequences that may materially and adversely affect our sales, financial condition and results of operations, as well as the price per share for our common stock.

***While Shire's tender offer and the proposed merger are pending, we are subject to business uncertainties and contractual restrictions that could disrupt our business.***

Whether or not Shire's pending tender offer and subsequent proposed merger are consummated, the proposed acquisition may disrupt our current plans and operations, which could have an adverse effect on our business and financial results. The pendency of the acquisition may also divert management's attention and our resources from ongoing business and operations and our employees and other key personnel may have uncertainties about the effect of the pending acquisition, and the uncertainties may impact our ability to retain, recruit and hire key personnel while the acquisition is pending or if it fails to close. We may incur unexpected costs, charges or expenses resulting from the acquisition. Furthermore, we cannot predict how our suppliers, customers and other business partners will view or react to the acquisition upon consummation. If we are unable to reassure our customers, suppliers and other business partners to continue transacting business with us, our sales, financial condition and results of operations may be adversely affected.

The preparations for integration between Shire and NPS have placed and we expect will continue to place a significant burden on many of our employees and on our internal resources. If, despite our efforts, key personnel depart because of these uncertainties and burdens, or because they do not wish to remain with the combined company, our business and results of operations may be adversely affected. In addition, whether or not the merger is consummated, while it is pending we will continue to incur costs, fees, expenses and charges related to the proposed merger, which may materially and adversely affect our financial condition and results of operations.

In addition, the Merger Agreement generally requires NPS to operate its business in the ordinary course of business consistent with past practice pending consummation of the merger and also restricts us from taking certain actions with respect to our business and financial affairs without Shire's consent. Such restrictions will be in place until either the merger is consummated or the Merger Agreement is terminated. For these and other reasons, the pendency of the tender offer and merger could adversely affect our business and results of operations.

***In the event that our proposed merger with a wholly owned subsidiary of Shire is not consummated, the trading price of our common stock and our future business and results of operations may be negatively affected.***

The conditions to the consummation of the proposed acquisition may not be satisfied as noted above. If the acquisition is not consummated, we would remain liable for significant transaction costs, and the focus of our management would have been diverted from seeking other potential strategic opportunities, in each case without realizing any benefits of the proposed acquisition. For these and other reasons, not consummating the acquisition could adversely affect our business and results of operations. Furthermore, if we do not consummate the acquisition, the price of our common stock may decline significantly from the current market price, which we believe reflects a market assumption that the tender offer and the merger will be consummated. Certain costs associated with the acquisition have already been incurred or may be payable even if the acquisition is not consummated. Further, a failed transaction may result in negative publicity and a negative impression of us in the investment community. Finally, any disruptions to our





business resulting from the announcement and pendency of the tender offer and merger, including any adverse changes in our relationships with our customers, vendors and employees or recruiting and retention efforts, could continue or accelerate in the event of a failed acquisition.

***If the Merger Agreement is terminated, we may, under certain circumstances, be obligated to pay a termination fee to Shire. These costs could require us to use available cash that would have otherwise been available for other uses.***

If the proposed acquisition is not completed, in certain circumstances, we could be required to pay a termination fee of \$155,939,696 to Shire. If the Merger Agreement is terminated, the termination fee we may be required to pay, if any, under the Merger Agreement may require us to use available cash that would have otherwise been available for general corporate purposes or other uses. For these and other reasons, termination of the Merger Agreement could materially and adversely affect our business, results of operations or financial condition, which in turn would materially and adversely affect the price per share of our common stock.

***We are involved in litigation relating to the Merger Agreement that could divert management's attention and adversely affect our business.***

The Company and the individual members of our Board of Directors have been named as defendants in litigation related to the Merger Agreement and the transactions contemplated thereby. The plaintiffs, purported stockholders of the Company, generally allege that the members of our Board of Directors breached their fiduciary duties to the Company's stockholders by approving the Merger Agreement because the merger consideration is unfair, certain terms of the Merger Agreement are unfair, the individual defendants are financially interested in the Merger and certain disclosures in the Company's Solicitation/Recommendation Statement on Schedule 14D-9 concerning the transactions contemplated by the Merger Agreement are materially misleading or incomplete. They further allege that the Company aided and abetted these alleged breaches of fiduciary duty. Although we believe that these suits are without merit, the defense of these suits may be expensive and may divert management's attention and resources, which could adversely affect our business.

## **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 Revestive in countries outside of the United States, our launch initiatives for Natpara, the build-out of our infrastructure and core competencies to support our continued growth as a global organization, and the further development of our product candidates and potential in-licensing or product acquisitions. If we do not generate significant revenues from the sale of Gattex/Revestive and Natpara, 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, 2014, we had an accumulated deficit of approximately \$1.0 billion. To date, our revenue has been primarily from royalty payments from our collaborators on sales of Sensipar and Mimpara (cinacalcet HCl), Preotact (rhPTH[1-84]), REGPARA and Nucynta, sales of Gattex which was launched in the United States in February of 2013, sales of Revestive which was launched in the EU in the second half of 2014, and milestone revenue under our collaborative agreements. 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 our rights to receive royalty payments under our agreements with Kyowa Hakko Kirin for REGPARA. 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 the royalty advance and a 9 percent per annum discount on the balance of the advance. The right to royalties on Kyowa Hakko Kirin's REGPARA sales will only be returned to us if the amount of royalties received by DRI exceeds two and a half times the amounts paid to us by DRI. We received no royalties from sales of Preotact (rhPTH[1-84]) by Takeda in 2013, and in March 2013, Takeda's rights to rhPTH[1-84] were returned to us and we are now developing as Natpara in the United States for the treatment of hypoparathyroidism.

Our ability to achieve profitability in the future depends on the successful commercialization and further development of Gattex/Revestive and Natpara/Natpar. We expect to incur significant expenditures in connection with the commercialization of Revestive outside of the United States, the commercial launch of Natpara in the United States and the further development and effort to seek regulatory approval for Natpar outside of the United States. If sales revenue from Gattex/Revestive and Natpara are 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 unenfringed, 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.***

Historically, we have not been 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, including in-licensing or acquisition 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 and anticipated cash flow will sufficiently fund our current and planned operations through at least January 1, 2016. However, our future capital needs will depend on many factors, including the extent to which we are able to grow sales of Gattex and Revestive, receive royalty and milestone payments from our collaborators, make progress in our development and commercialization activities and find and execute on our business development initiatives to build our pipeline. Our capital requirements will also depend on the magnitude and scope of these activities and our expansion as a global company, our ability to maintain existing collaborations, the success of our collaborators in developing and marketing products under their respective collaborations with us, the success of our contract manufacturers in producing commercial and clinical supplies of our products, drug delivery devices and product candidates 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/Revestive and or Natpara;
- delay or reduce the scope of our efforts to obtain regulatory approvals of Natpar and Revestive outside the U.S and EU and, if and when such regulatory approvals are obtained, delay or reduce the scope of our efforts to commercialize Natpar or Revestive;
- delay, reduce the scope of or eliminate one or more of our development programs and/or business development initiatives, including potential in-licensing or acquisition opportunities;
- 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.

***We have limited marketing and sales experience and our ability to successfully commercialize Gattex/Revestive and other products is important to our future success.***

We are commercializing Gattex/Revestive ourselves in the United States and in certain countries outside 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 and plan to build a small internal sales force in select countries outside the United States. Prior to 2013, we had no prior experience commercializing a pharmaceutical product and we may be unable to continue to successfully commercialize Gattex/Revestive or to commercialize Natpara. Gattex and Natpara have each been designated an "orphan drug" in the United States by the FDA, Revestive and Natpar has been designated an "orphan drug" in the European Union by the European Commission and we may seek additional "orphan drug" or similar designations for our products in the future. Accordingly, the number of patients who could benefit from treatment with Gattex/Revestive and Natpara/Natpar is small. We will need to penetrate a significant portion of this potential patient population in order to successfully commercialize Gattex/Revestive and Natpara/Natpar. If we are unable to successfully commercialize Gattex/Revestive and Natpara, our business and financial results and condition will be adversely affected.

***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/Revestive and Natpara have been developed to address, 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/Revestive, Natpara and our other 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/Revestive, Natpara and our other product candidates prove to be incorrect, the market opportunities for Gattex/Revestive, 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/Revestive or Natpara or our other product candidates can negatively affect our business and stock price.***

Adverse safety events involving Gattex/Revestive 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/Revestive, Natpara or our other 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 Natpar as a potential treatment for hypoparathyroidism outside the U.S. and have one other product candidate in early stages of clinical development.

For more information on the development of our product candidates, see "Item 1 - Business - Product and Development Programs and Royalty-Based Agreements."

The regulatory review and approval process conducted by the FDA and comparable regulatory agencies in foreign countries is extensive, lengthy, expensive and inherently uncertain. To receive approval for a product candidate, we must, among other things, demonstrate to the satisfaction of the FDA and comparable regulatory agencies in foreign countries 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.

Even if our product candidates receive regulatory approval from the FDA and comparable regulatory agencies in foreign countries, 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 and comparable regulatory agencies in foreign countries have substantial discretion in the approval process and may either refuse to consider any applications we may file any of our other product candidates for substantive review or may form the opinion after review of any of our other product candidates that our application is insufficient to allow approval of 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 and comparable regulatory agencies in foreign countries, or regulatory interpretation of these data and procedures may be unfavorable. If the FDA and comparable regulatory agencies in foreign countries do not accept or approve an application that we submit, they may require that we conduct additional clinical, pre-clinical or manufacturing validation studies and submit that data before they 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 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 BLA 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 our product candidates in a timely manner, or at all, or if the 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, royalties on sales of Sensipar (Mimpara in Europe), REGPARA in Japan, Preotact and Nucynta, and our sales of Gattex/Revestive have been our only sources of commercial revenues. 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 acceptance of Gattex/Revestive and or Natpara in the medical community will increase or continue or that 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/Revestive, Natpara/Natpar, our other product candidates and our 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/Revestive that are needed to support the commercialization of this product or the supplies of Natpara that are needed to support the commercial launch of this product candidate. We also do not have internal manufacturing capabilities to produce supplies of the injection devices used to administer Gattex/Revestive and Natpara/Natpar. We are dependent on third parties for the manufacture, supply, testing, and storage of our products, product candidates and injection devices. If we are unable to contract for a sufficient supply of our products, 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/Revestive and Natpara/Natpar. 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, during parts of 2012 and 2013 we were unable to have batches of Natpara finished product manufactured that were consistently within our specifications. These manufacturing problems caused a delay in the filing of our BLA for Natpara. Although we were able to resolve this manufacturing issue and submit our BLA for Natpara in October 2013, we cannot assure you that we will not encounter manufacturing problems with respect to Natpara or any of our products or product candidates 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.

***We are subject to extensive government regulations that may cause us to cancel or delay the introduction of our products to market or which could have a material negative impact on our ability to sell our products.***

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, we or our collaborators 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. We, our collaborators, or the FDA 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. Other countries also regulate our promotional materials and sales activities.

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 to FDA and related regulatory requirements in the U.S. and abroad, we are subject to extensive additional federal, state and foreign healthcare regulation, which includes but is not limited to, the Federal False Claims Act, the Federal Anti-Kickback Statute, the FCPA and similar laws in countries outside of the U.S. Similar laws and regulations exist in many other countries throughout the world in which we commercialize and intend to commercialize our products, including Revestive. We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry, but cannot guarantee that we, our employees, our consultants or our third-party contractors are or will be in compliance with all federal, state and foreign regulations. If we, our representatives or our partners fail to comply with any of these laws or regulations, a range of fines, penalties and/or other sanctions could be imposed on us and/or our partners, including, but not limited to, restrictions on how we and/or our partners market and sell our products, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation or other sanctions. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations.

***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 and comparable foreign regulatory authorities, 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 and comparable regulatory authorities in foreign countries 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 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 collaborative relationships, or if our existing collaborations fail, or if our collaborators do not devote adequate resources to the 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.***

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 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. 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."

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.

***Changes in our effective income tax rate could adversely affect our results of operations.***

We are subject to income taxes in the United States and various foreign jurisdictions, and our domestic and foreign tax liabilities are largely dependent upon the distribution of pre-tax earnings among these different jurisdictions. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, the accounting for stock options and other share-based compensation, changes in accounting standards, future levels of research and development spending, changes in the mix and level of pre-tax earnings by taxing jurisdiction, the outcome of examinations by the U.S. Internal Revenue Service and other jurisdictions, the accuracy of our estimates for unrecognized tax benefits, the realization of deferred tax assets, or by changes to our ownership or capital structure. The impact on our income tax provision resulting from the above-mentioned factors and others may be significant and could adversely affect our results of operations.



***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/Revestive for the treatment of short bowel syndrome and Natpara for hypoparathyroidism. We have established a price for Gattex in the U.S. based upon its status as an orphan drug which has generally been accepted to date but could be viewed as excessive by third-party payers in the future 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 Revestive in markets outside the U.S.

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. Also, we cannot predict whether we will be able to secure reimbursement in certain ex-US markets within an acceptable range.

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 and registered the "Revestive" trademark in the European Union and other jurisdictions. 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 PTH 1-84 and REGPARA, and these security interests could be enforced against us if we default on these agreements.***

In connection with our July 2007 agreement, as amended in December 2013, with DRI Capital, or DRI (formerly Drug Royalty L.P.3) to monetize PTH 1-84, we granted DRI a security interest in certain of our patents related to PTH 1-84 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 PTH 1-84 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 Hakko 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 we or our collaborators may be required to license in order to research, develop or commercialize at least some of our products or product candidates, including Gattex/Revestive and Natpara/Natpar. 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, commercial 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. We are seeking to hire executives to manage our operations in certain countries outside of the United States and employees of those respective operations. We face additional challenges in our hiring efforts outside the United States due to the fact that we have limited operations and resources and are not well-known outside of the United States.

***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/Revestive 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.

***We have limited experience operating internationally, are subject to a number of risks associated with our international activities and operations and may not be successful in our efforts to expand internationally.***

We have manufacturing, collaboration, clinical trial and other relationships outside the United States but we currently have very limited operations outside of the United States. In order to meet our long-term goals, we will need to grow our international operations significantly over the next several years. Consequently, we are and will continue to be subject to additional risks related to operating in foreign countries, including:

- the fact that we have limited experience operating our business internationally;
- we may not achieve the optimal pricing and reimbursement for Revestive;
- it may take longer than expected to process prescriptions for named patient sales of Revestive;
- there may be fewer addressable SBS patients than were originally forecasted;
- unexpected adverse events related to Gattex/Revestive, Natpara/Natpar or our other products that occur in foreign markets that we have not experienced in the United States;
- local, economic and political conditions, including geopolitical events, such as war and terrorism, foreign currency fluctuations, which could result in increased or unpredictable operating expenses and reduced revenues and other obligations incident to doing business in, or with a company located in, another country;
- unexpected changes in reimbursement and pricing requirements, tariffs, trade barriers and regulatory requirements;
- economic weakness, including foreign currency exchange risks, inflation or political instability in particular foreign economies and markets; and
- compliance with foreign or U.S. laws, rules and regulations, including data privacy requirements, labor relations laws, tax laws, anti-competition regulations, import, export and trade restrictions, anti-bribery/anti-corruption laws, regulations or rules, which could lead to actions by us or our licensees, distributors, manufacturers, other third parties who act on our behalf or with whom we do business in foreign countries or our employees who are working abroad that could subject us to investigation or prosecution under such foreign or U.S. laws.

These and other risks associated with our international operations may materially adversely affect our business and results of operations.

### **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 and Revestive outside of the U.S.;
- our ability to meet market expectations with respect to FDA approval or the timing for FDA approval for 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.

***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 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 Natpara/Natpar 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.

***If certain transactions occur with respect to our capital stock, limitations may be imposed on our ability to utilize net operating loss and tax credit carryforwards to reduce our income taxes.***

We have accumulated net operating loss and tax credit carryforwards available to offset taxable income in future tax periods. If certain transactions occur with respect to our capital stock that result in a cumulative change of more than 50% of the ownership of capital stock over a three-year period (as determined under rules prescribed by Section 382 of the U.S. Internal Revenue Code and applicable Treasury regulations), an annual limitation would be imposed with respect to the ability to utilize our net operating loss and tax credit carryforwards that existed at the time of the ownership change.

We experienced an ownership change in 2010. As a result of this ownership change, we are subject to an annual limitation imposed on our use net operating loss and tax credit carryforwards existing at the time of the ownership change to offset current and future taxable income.

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

None.

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

We lease approximately 95,000 square feet of administrative space in Bedminster, New Jersey. The Bedminster leases will expire in August 2016. In addition to the Bedminster location, we also lease space in other ex-U.S. countries to support our operations as a global organization.

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

In connection with the transactions contemplated by the Merger Agreement, purported stockholders of the Company have filed putative class action lawsuits in the Court of Chancery of the State of Delaware against various combinations of the Company, the members of the Board, Shire, Parent and Purchaser, captioned *Bragger v. NPS Pharmaceuticals, Inc., et al.*, C.A. No. 10553-VCN, *Grimaldi v. NPS Pharmaceuticals, Inc., et al.*, C.A. No. 10563-VCN, *Goldstein v. NPS Pharmaceuticals, Inc., et al.*, C.A. No. 10577-VCN, *Mantler v. NPS Pharmaceuticals, Inc., et al.*, C.A. No. 10580-VCN, and *Lyons v. Tombros, et al.*, C.A. No. 10590-VCN (Actions). Pursuant to an order granted on February 2, 2015 by the Court of Chancery of the State of Delaware (Consolidation Order), the Actions were consolidated into one action captioned *In Re NPS Pharmaceuticals Stockholders Litigation*, C.A. No. 10553-VCN (Consolidated Action). The Consolidation Order applies to any future-filed actions relating to the subject matter of the Consolidated Action. On February 2, 2015, the plaintiffs in the Consolidated Action filed a consolidated class action complaint (Consolidated Complaint), naming as defendants the Company, members of the Board, SPHIL and Purchaser. The Consolidated Complaint generally alleges that the individual director defendants breached their fiduciary duties to the Company's stockholders by approving the Merger Agreement because the merger consideration is unfair, certain terms of the Merger Agreement are unfair, the individual defendants are financially interested in the Merger and certain disclosures in the Company's Solicitation/Recommendation Statement on Schedule 14D-9 filed with the SEC on January 23, 2015 (as amended and supplemented from time to time, the Schedule 14D-9) concerning the transactions contemplated by the Merger Agreement are materially misleading or incomplete. The Consolidated Complaint further alleges that the corporate defendants aided and abetted these alleged breaches of fiduciary duty. The Consolidated Action seeks, among other remedies, to enjoin the transactions contemplated by the Merger Agreement, or in the event that an injunction is not awarded, unspecified money damages, costs and attorney's fees.

On February 6, 2015, the parties to the Consolidated Action entered into a memorandum of understanding (MOU) setting forth the terms of a settlement of the Consolidated Action. Pursuant to the terms of the MOU, and without agreeing that any of the claims in the Consolidated Action have merit or that such supplemental disclosures were required under any applicable statute, rule, regulation or law, the Company issued supplemental disclosures contained in Amendment No. 4 to the Schedule 14D-9, filed with the SEC on February 6, 2015. Also pursuant to the terms of the MOU, the parties expect to execute a stipulation of settlement, which will be subject to approval by the Court of Chancery of the State of Delaware following notice to the Company's stockholders. There can be no assurance that the settlement will be finalized or that the Court of Chancery of the State of Delaware will approve the settlement.



The settlement terms provide that the Consolidated Action will be dismissed with prejudice as to all defendants, and that all defendants will be released of any and all claims relating to, among other things, the Merger Agreement and the merger contemplated thereby, if and when the Court of Chancery of the State of Delaware approves the settlement.

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

Listed below is information on our executive officers as of February 11, 2015. 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: 58

Dr. 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. Before joining NPS, Dr. Nader was a venture partner at Care Capital, LLC, where he served as Chief Medical Officer of its Clinical Development Capital unit from July 2005 to June 2006. From 2000 to 2004, he served as Senior Vice President, Integrated Healthcare Markets and Senior Vice President, North America Medical and Regulatory Affairs with Aventis Pharmaceuticals. He also held similar positions at Hoechst Marion Roussel and served as Head of Global Commercial Operations at the Pasteur Vaccines division of Rhone- Poulenc. Dr. Nader is the Chairman of the Board of BioNJ, a trade association representing the biotechnology industry in New Jersey. Dr. Nader is a Board member of the Biotechnology Industry Organization (BIO) and the New Jersey Chamber of Commerce. He is also a Director of Trevena, Inc. and Chair of its Compensation Committee, and a Director of Clementia Pharmaceuticals, Inc. and Acceleron Pharma, Inc. Dr. Nader received a French State Doctorate in Medicine from St. Joseph University (Lebanon) and a Physician Executive MBA from the University of Tennessee.

#### **Luke M. Beshar, CPA**

Executive Vice President and Chief Financial Officer

Age: 56

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 is a Director of Trillium Therapeutics, Inc. and Chair of its Audit Committee. 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.

#### **Paul Firuta, MBA**

President, U.S. Commercial Operations

Age: 49

Paul Firuta joined NPS in March 2014 with twenty-three years of industry experience launching and commercializing biologics and pharmaceutical products. Previously, Mr. Firuta served at ViroPharma, Inc. from 2008 to 2014 as Vice President and General Manager, Americas. Prior to his term at ViroPharma, he was in several leadership roles with Johnson and Johnson for 6 years and Lev Pharmaceutical for 2 years. His responsibilities included National Accounts, Managed Care, and Managed Markets. He also served SmithKline Beecham for nine years in multiple leadership roles in the Managed Care Division. Mr. Firuta began his career in finance and accounting as an Asset/Liabilities Management Analyst for a large national bank and Internal Auditor for a large national conglomerate, both affording him opportunity to gain early international experience. Mr. Firuta received his bachelor's degree from King's College and Masters of Business Administration from St. Joseph's University.

**Robin D. Friedman, MS**

Sr. Vice President, Human Resources

Age: 54

Robin Friedman joined NPS in March 2014 with more than 20 years of human resource management experience at leading multi-national pharmaceutical companies. From 2010 to 2014, Ms. Friedman was senior vice president of human resources and communications at LifeCell Corporation, a manufacturer and distributor of tissue repair products. Prior to her tenure at LifeCell, Ms. Friedman was director of human resources at Johnson & Johnson Pharmaceutical Services for nearly 3 years, where she helped manage a number of important organizational transitions. Ms. Friedman has also held human resources and organizational development positions of increasing responsibility with Biovail and Bristol Myers Squibb and was an external human resources consultant to several organizations including Pharmacia, Novartis, and Columbia Labs. Ms. Friedman received her undergraduate degree from Monmouth College and her master's degree in counseling and personnel services from The College of New Jersey.

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

Executive Vice President and Chief Medical Officer

Age: 61

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.

**Susan E. Graf, RPh, MBA**

Vice President, Corporate Development and Strategy

Age: 42

Susan Graf joined NPS in May 2013 with nearly 20 years of broad industry experience in global business development and commercial operations. Before she joined NPS, Ms. Graf spent 17 years at Roche, most recently as global head, commercial assessment and due diligence for Roche Partnering. She began her career at Roche in technical operations and then moved to the commercial side taking on roles in sales and marketing research. Ms. Graf later served as director of global business development, director of U.S. marketing and global head of strategic evaluation where she was responsible for product licensing and acquisition during the integration of Genentech into the Roche organization. Ms. Graf is a licensed pharmacist and received her Bachelor of Science degree in Pharmacy from Purdue University and her Master of Business Administration degree from the Leonard N. Stern School of Business at New York University.

**Christine Mikail, JD**

Sr. Vice President, Legal Affairs, General Counsel and Secretary

Age: 37

Christine Mikail joined NPS in March 2014 with over 11 years of experience in public company representation, business development and pharmaceutical law. From February 2012 to March 2014, Ms. Mikail was executive vice president, corporate development, general counsel, chief compliance officer and corporate secretary at Dendreon Corporation. While at Dendreon, she built and led a bi-coastal legal and compliance team, as well as a business development team. Prior to Dendreon, Ms. Mikail held senior corporate development and legal positions with Savient Pharmaceuticals from February 2011 to February 2012, ImClone Systems and Eli Lilly from March 2008 to February 2011. Ms. Mikail began her legal career working at several prominent law firms where she counseled on corporate and securities law, regulatory, licensing, financings and M&A activities on behalf of public and private companies. She received her bachelor's degree from Rutgers University and her Juris Doctor degree from Fordham University School of Law.





**Eric Pauwels**

President, NPS Pharma International

Age: 53

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: 68

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.

**ITEM 4. Mine Safety Disclosures****Not applicable.****PART II****ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Company Purchases of Equity Securities****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>2013</b>		
First Quarter	\$ 10.21	\$ 7.54
Second Quarter	16.18	9.94
Third Quarter	32.97	15.78
Fourth Quarter	34.98	22.64
<b>2014</b>		
First Quarter	\$ 39.06	\$ 27.55
Second Quarter	35.37	23.38

Third Quarter  
Fourth Quarter

33.42  
36.96

25.77  
23.03

45

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**Holders**

As of February 11, 2015, there were approximately 102 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 2015 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, 2014. 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:**

	<b>Years Ended December 31,</b>				
	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
<b>(in thousands, except per share amounts)</b>					
Revenues:					
Product sales, net	\$ 101,195	\$ 31,752	\$ -	\$ 99	\$ 551
Royalties	122,867	123,804	105,587	96,502	86,181
Sale of royalty rights (1)	-	-	25,000	-	-
Milestones and license fees	-	36	57	5,044	2,682
Total revenues	<u>224,062</u>	<u>155,592</u>	<u>130,644</u>	<u>101,645</u>	<u>89,414</u>
Cost of sales (2)	14,648	3,587	-	-	6
Cost of royalties	-	-	-	500	-
Cost of license fees	-	9	-	2,543	69
Operating expenses:					
Research and development	90,109	85,421	94,839	73,831	60,814
Selling, general and administrative	114,255	68,070	36,929	24,226	18,951
Total operating expenses	<u>204,364</u>	<u>153,491</u>	<u>131,768</u>	<u>98,057</u>	<u>79,765</u>
Operating (loss) income	<u>5,050</u>	<u>(1,495)</u>	<u>(1,124)</u>	<u>545</u>	<u>9,574</u>
Other income (expense):					
Interest income	406	340	292	321	418
Interest expense	(13,728)	(11,938)	(18,198)	(37,736)	(45,128)
Gain on sale of marketable investment securities	12	4	4	-	3,751
Other	321	(233)	291	621	1,035
Total other expense, net	<u>(12,989)</u>	<u>(11,827)</u>	<u>(17,611)</u>	<u>(36,794)</u>	<u>(39,924)</u>
Loss before income tax expense	<u>(7,939)</u>	<u>(13,322)</u>	<u>(18,735)</u>	<u>(36,249)</u>	<u>(30,350)</u>
Income tax expense	766	182	-	18	1,091
Net loss	<u>\$ (8,705)</u>	<u>\$ (13,504)</u>	<u>\$ (18,735)</u>	<u>\$ (36,267)</u>	<u>\$ (31,441)</u>
Basic and diluted net loss per share (3)	<u>\$ (0.08)</u>	<u>\$ (0.14)</u>	<u>\$ (0.22)</u>	<u>\$ (0.45)</u>	<u>\$ (0.54)</u>
Basic and diluted weighted average shares outstanding (3)	106,341	97,750	86,999	81,279	58,607

(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) As a result of the marketing approvals for our products, we will no longer expense manufacturing costs relating to these products as research and development expenses. Instead, we will capitalize these costs as inventory as they are incurred. There will be no cost of sales associated with the sale of our product inventory that was on hand at the time of the FDA's approval of our products. 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 product that is manufactured after the date of the FDA's approval. Based on our current plans and assumptions, we believe that by the end of 2015 for Gattex and the middle of 2018 for Natpara, we will have sold off this supply of product on hand at the time of the FDA's approval. We expect that the higher gross margins will be partially off-set by the full cost of sales sold for Revestive, which did not have any inventory expensed prior to approval.

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

share.

**Consolidated Balance Sheets Data:**

	<b>Years Ended December 31,</b>				
	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
<b>(in thousands)</b>					
Cash, cash equivalents, and marketable investment securities	\$ 164,191	\$ 180,474	\$ 100,715	\$ 162,233	\$ 133,771
Working capital	200,812	200,338	107,484	156,025	133,750
Total assets	289,617	292,222	151,109	213,980	228,905
Long-term portion of convertible, notes payable, non-recourse debt and other long-term liabilities	100,159	128,918	176,183	216,493	302,035
Accumulated deficit	(1,031,394)	(1,022,689)	(1,009,185)	(990,450)	(954,183)
Stockholders' equity (deficit)	133,825	104,890	(54,641)	(46,116)	(155,275)

**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 global biopharmaceutical company pioneering and delivering first-in- or best-in- disease therapies that transform the lives of patients with rare diseases. Our vision is creating a world where every person living with a rare disease has a treatment option. We incorporated in Utah in 1986 and reincorporated in Delaware in 1992. Our current therapeutic areas of focus are rare gastrointestinal and endocrine disorders. These include Short Bowel Syndrome, a potentially fatal gastrointestinal disorder in which patients may have to rely on parenteral support for their survival; Hypoparathyroidism, a complex endocrine disorder in which the parathyroid glands are either absent or damaged and the body produces insufficient or no parathyroid hormone; and Autosomal Dominant Hypocalcemia ("ADH"), an ultra-rare genetic disorder of calcium homeostasis caused by mutations of the calcium-sensing receptor gene.

Our marketed 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. SBS is an ultra-rare potentially fatal disorder in which the body is unable to absorb enough nutrients and fluids through the gastrointestinal tract. In the European Union ("EU"), teduglutide (trade name: Revestive®) is approved for the treatment of adult patients with SBS; patients should be stable following a period of intestinal adaptation after surgery. We launched Revestive in Germany and Sweden in 2014 and plan to launch in other EU countries in 2015. We are also implementing our regulatory strategy for Japan, which included filing for orphan drug status. In addition, a global development program in pediatric SBS is advancing and we expect reporting top-line results from the first study in early 2015.

On January 23, 2015, we received U.S. FDA approval for our second product, Natpara® (parathyroid hormone) for Injection as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. Natpara is a bioengineered replica of human PTH. Natpara is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone. Natpara was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations or in patients with acute post-surgical hypoparathyroidism.

Hypoparathyroidism is a rare endocrine disorder in which the parathyroid glands fail to produce sufficient amounts of parathyroid hormone (PTH) or where the hormone lacks biologic activity. PTH plays a central role in a variety of critical physiological functions in the body. Insufficient levels of PTH lead to low levels of calcium and high levels of phosphate in the blood, and an inability to convert native vitamin D into its active state, which helps the body properly absorb oral calcium. Parathyroid hormone increases serum calcium by increasing renal tubular calcium reabsorption, increasing intestinal calcium absorption (i.e., by converting native vitamin D (25 OH) into its active form (1,25 OH<sub>2</sub> vitamin D)) and by increasing bone turnover which releases calcium into the circulation.

In the EU, the European Medicine Agency is reviewing our Marketing Authorization Application for Natpar®, which is the European brand name for Natpara.

We are also developing NPSP795 for ADH and we are completing a Phase 2a proof-of-concept study. ADH is caused by mutations of the calcium-sensing receptor (CaSR) gene that increase the sensitivity of the receptor to serum calcium. NPSP795 is a selective calcium receptor antagonist (termed calcilytic), which binds to the CaSR and decreases its sensitivity to serum calcium. NPSP795's mechanism of action is believed to restore the normal physiological action of the CaSR and address the underlying molecular defect in ADH to return normal calcium homeostasis.

While SBS, Hypoparathyroidism, and ADH 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 the chronic nature of these diseases.

We have collaborations or royalty agreements with a number of pharmaceutical companies. In 2014, we recorded \$122.9 million of royalty revenue that was driven by (i) Amgen's sales of Sensipar® and Mimpara® (cinacalcet HCl), (ii) Kyowa Hakko Kirin's sales of REGPARA® (cinacalcet HCl) in Japan, and (iii) Janssen's sales of Nucynta® (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 under our agreement with Kyowa Hakko Kirin.

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

### ***Significant Developments***

- In January 2015, we entered into a merger agreement with Shire pursuant to which Shire will acquire all of our outstanding shares for \$46 per share.
- In January 2015, the FDA approved our BLA for Natpara.



## Merger Agreement

On January 11, 2015, we entered into the Merger Agreement with Parent, Purchaser and, solely for purposes of Section 12.14 of the Merger Agreement, Shire. Pursuant to the Merger Agreement, Purchaser has commenced a cash tender offer for all of the outstanding shares of the Company's common stock, upon the terms and subject to the conditions of the Merger Agreement. Consummation of the tender offer is subject to customary closing conditions, as set forth in the Merger Agreement. As soon as practicable following the consummation of the tender offer, and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Purchaser will merge with and into the Company pursuant to the provisions of section 251(h) of the Delaware General Corporation Law, with no stockholder vote required to consummate the merger, and the Company will survive as a wholly owned subsidiary of Parent.

The Merger Agreement contains representations, warranties and covenants of the parties customary for transactions of this type. Until the earlier of the termination of the Merger Agreement and the consummation of the merger, the Company has agreed to operate its business and the business of its subsidiaries in the ordinary course and has agreed to certain other operating covenants, as set forth more fully in the Merger Agreement. The Company has agreed not to solicit alternative acquisition proposals. However, the Company may, subject to the terms and conditions set forth in the Merger Agreement, furnish information to, and engage in discussions and negotiations with, a third party that makes an unsolicited acquisition proposal that the Board reasonably believes is or could reasonably be expected to lead to a superior proposal. Under certain circumstances and upon compliance with certain notice and other specified conditions set forth in the Merger Agreement, the Company may terminate the Merger Agreement to accept a superior proposal.

The Merger Agreement contains certain termination rights for both Parent and the Company and further provides that, upon termination of the Merger Agreement under certain circumstances relating to competing acquisition proposals, including if the Company terminates the Merger Agreement to accept a superior proposal, or where our Board of Directors changes its recommendation in favor of the transaction, the Company may be required to pay Parent a termination fee of \$155,939,696. Shire has secured an \$850 million fully underwritten short-term bank facility, which in addition to Shire's cash and cash equivalents and its existing \$2.1 billion five-year revolving credit facility, is available to finance the transaction and pay related fees and expenses.

Additional information about the merger agreement is set forth in our filings with the U.S. Securities and Exchange Commission (SEC).

We have incurred cumulative losses from inception through December 31, 2014 of approximately \$1.0 billion. We expect our operating expenses to continue to increase over the next several years as we launch Revestive in certain ex-U.S. countries and incur pre-launch and launch costs for Natpara, invest in the development of our pipeline and pursue in-licensing opportunities.

During the years ended December 31, 2014, 2013 and 2012, we incurred expenses of \$16.2 million, \$8.9 million and \$48.3 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 \$283.6 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, 2014, 2013 and 2012, we incurred expenses of \$29.1 million, \$46.2 million and \$32.0 million, respectively, in the research and development of PTH 1-84 (Natpara in the U.S.), including costs associated with the manufacture of clinical and commercial supplies of PTH 1-84. We have incurred expenses of approximately \$523.6 million since we assumed development obligations for PTH 1-84, upon our acquisition of Allelix Biopharmaceuticals Inc. in December 1999. During the years ended December 31, 2014, 2013 and 2012, we incurred expenses of \$2.6 million, \$2.8 million and \$323,000, respectively, in the research and development of NPSP795, including costs associated with the manufacture of clinical supplies of NPSP795. We have incurred expenses of approximately \$5.7 million since we assumed development obligations for NPSP795, under the agreement with GSK in August 2011. 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 approvals for our products, we will no longer expense manufacturing costs relating to these products as research and development expenses. Instead, we will capitalize these costs as inventory as they are incurred. There will be no cost of sales associated with the sale of our approved products that were on hand at the time of our marketing approval. 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 the approved products that are manufactured after the date of approval. 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 approval for Gattex and by the middle of 2018 for Natpara. We expect that the higher gross margins for Gattex will be partially off-set by the full cost of sales for Revestive, which did not have any inventory expensed prior to approval. We also expect to record increased sales and incur additional marketing costs related to the commercialization of Gattex, Revestive and Natpara, pre-launch costs for Natpara and higher operating costs to support our expansion into the international market.

## Results of Operations

The following table summarizes selected operating statement data for the years ended December 31, 2014, 2013 and 2012 (dollars in thousands):

	<u>2014</u>	<u>2013</u>	<u>2012</u>
Revenues:			
Product sales, net	\$ 101,195	\$ 31,752	\$ -
Royalties	122,867	123,804	105,587
Sale of royalty rights	-	-	25,000
Milestones and license fees	-	36	57
Total Revenues	<u>\$ 224,062</u>	<u>\$ 155,592</u>	<u>\$ 130,644</u>
Cost of sales	\$ 14,648	\$ 3,587	\$ -
Cost of license fees	\$ -	\$ 9	\$ -
Operating expenses:			
Research and development	\$ 90,109	\$ 85,421	\$ 94,839
% of revenues	40 %	55 %	73 %
Selling, general and administrative	\$ 114,255	\$ 68,070	\$ 36,929
% of revenues	51 %	44 %	28 %

## Years ended December 31, 2014 and 2013

**Revenues.** All our revenues relate to product sales of Gattex, which was launched in the U.S. in February 2013 and royalties and milestones from our licensees. Our revenues were \$224.1 million in 2014 compared to \$155.6 million in 2013. We recognized revenue under our research and license agreements and product sales as follows (amounts in thousands):

	<u>2014</u>	<u>2013</u>
Product sales, net	\$ 101,195	\$ 31,752
Royalties:		
Sensipar and Mimpara (cinacalcet HCl)	111,857	112,876
Regpara (cinacalcet HCl)	8,450	8,033
Nucynta (tapentadol)	<u>2,560</u>	<u>2,895</u>
Total royalties	122,867	123,804
Other	<u>-</u>	<u>36</u>
Total revenues	<u>\$ 224,062</u>	<u>\$ 155,592</u>

**Product Sales, net.** For the years ended December 31, 2014 and 2013, we recognized net product sales revenue of \$101.2 million and \$31.8 million, respectively, for the sales of Gattex and Revestive. We received approval from the FDA in December 2012 and subsequently launched Gattex in February 2013. Also, pursuant to the Termination and Transition Agreement with Takeda, we received back the rights to market Revestive in certain territories outside of the U.S. Revestive was approved in the EU in 2012 and we launched in certain countries in the EU in the second half of 2014. Product sales for the years ended December 31, 2014 and 2013 are not necessarily indicative of the results that may be expected for any future period. We expect that product sales of Gattex and Revestive will vary from period to period given the limited size of the patient population.

We record product sales net of allowances and accruals for prompt pay discounts, rebates and chargebacks under governmental programs (including Medicaid), product returns, and distribution-related fees. These allowances and accruals will continue to grow in relation to an increase in the sales of Gattex and Revestive. The following table summarizes the provisions, and credits/payments, for government rebates and chargebacks, distribution-related fees, and returns and other sales-related deductions (in thousands):

	<b>Rebates and</b>	<b>Distribution-</b>	<b>Returns and</b>	
	<b>Chargebacks</b>	<b>Related Fees</b>	<b>Other Sales-</b>	
	<b>Chargebacks</b>	<b>Related Fees</b>	<b>Deductions</b>	<b>Total</b>
Balance as of December 31, 2012	\$ -	\$ -	\$ -	\$ -
Provision related to current period sales	1,375	332	1,098	2,805
Credits/payments	(262)	(185)	(857)	(1,304)
Balance as of December 31, 2013	1,113	147	241	1,501
Provision related to current period sales	3,929	461	2,217	6,607
Credits/payments	(3,398)	(514)	(2,208)	(6,120)
Balance as of December 31, 2014	<u>\$ 1,644</u>	<u>\$ 94</u>	<u>\$ 250</u>	<u>\$ 1,988</u>

**Royalties.** For the years ended December 31, 2014 and 2013, our revenues related to our agreement with Amgen for Sensipar and Mimpara were comprised of \$111.9 million and \$112.9 million in royalty revenue, respectively. The decrease in royalty revenue earned from Amgen is due to a non-recurring favorable adjustment in 2013 which was partially offset by the sales growth of Sensipar and Mimpara (cinacalcet HC1). 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, 2014 and 2013, we recognized \$8.5 million and \$8.0 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 higher sales demand of REGPARA which were partially offset by unfavorable fluctuations in foreign exchange rates. 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, 2014 and 2013, we recognized royalty revenue of \$2.6 million and \$2.9 million respectively, from Janssen for sales of Nucynta, which was launched in the second quarter of 2009. The decrease in royalty revenue earned from Nucynta was primarily due to decreased net sales 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 Sales.** Upon marketing approval from the FDA in December 2012, we began capitalizing inventory costs associated with commercial supplies of Gattex. Costs for manufacturing supplies of Gattex prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not being included in cost of sales when revenue is recognized from the sale of those supplies of Gattex. Based on our current projections, we anticipate that by the end of 2015 we will have sold off the supply of Gattex on-hand at the time of the FDA's approval of the NDA for Gattex. Cost of sales for the years ended December 31, 2014 and 2013 was \$14.6 million and \$3.6 million, respectively, and consisted primarily of royalty costs related to sales of Gattex and costs incurred for certain batches of Revestive that did not pass our quality control specifications. We purchased Revestive inventory from Takeda when we completed the Takeda Transition Agreement and therefore, the cost of sales for Revestive is expected to be higher in relation to the cost of sales for Gattex until the end of 2015 (when we anticipate to have sold off the supply of Gattex on hand at the time of the FDA's approval of the NDA for Gattex). Accordingly, we expect our current product gross margins to decrease from approximately 90% to the 80% to 85% range as we begin sales of product that has been capitalized to inventory.

**Research and Development.** Our research and development expenses are categorized into three areas: clinical development costs, product development costs and other research and development costs.

Clinical development costs were \$22.8 million and \$16.9 million for the years ended December 31, 2014 and 2013, respectively. Clinical development costs are primarily comprised of costs paid to outside parties to conduct and manage clinical trials related to Gattex, Natpara and NPSP795 as well as costs associated with regulatory functions.

Product development costs were \$25.1 million and \$41.1 million for the years ended December 31, 2014 and 2013, respectively. Product development costs are costs related to the drug needed for our clinical studies and pre-approval inventory.

Other research and development costs were \$42.2 million and \$27.5 million for the years ended December 31, 2014 and 2013, respectively. Other research and development costs consist primarily of personnel, personnel-related costs and overhead costs that relate to clinical and product development activities.

For the year ended December 31, 2014, our research and development expenses increased to \$90.1 million from \$85.4 million for the year ended December 31, 2013. The increase in research and development expenses is primarily related to a \$14.7 million increase in other research and development costs which mainly consists of regulatory costs as well as personnel and personnel-related costs and a \$9.6 million increase in costs associated with clinical development activities related to the completion of certain clinical trials for Gattex. These increases were partially offset by a \$16.9 million decrease for the cost of preapproval PTH 1-84, which included certain lots of inventory that were purchased from Takeda in 2013 and designated for use in research and development during 2013. .

**Selling, General and Administrative.** Our selling, general and administrative expenses consist primarily of compensation for employees in executive, finance, legal, medical science liaisons and sales and marketing functions as well as facility costs and professional fees for accounting and legal services. Our selling, general and administrative expenses increased to \$114.3 million for the year ended December 31, 2014 from \$68.1 million for the year ended December 31, 2013. The increase in our selling, general and administrative expenses were primarily due to a \$23.4 million increase in personnel and personnel related costs and a \$9.6 million increase in external costs and a \$3.5 million increase in marketing costs related to launch and pre-launch activities for Gattex and Natpara, respectively. As we continue our international expansion and begin our launch of Natpara, we expect that these costs would continue to increase.

**Interest Income.** Interest income increased to \$406,000 for the year ended December 31, 2014 from \$340,000 from the comparative period in 2013.

**Interest Expense.** Our interest expense increased to \$13.7 million for the year ended December 31, 2014 from \$11.9 million for the comparable period in 2013. Our long-term sales forecasts for Natpara and royalty forecast for REGPARA are used to calculate the implicit interest rate and the related interest expense for our non-recourse debt. Interest expense increased due primarily to a higher effective interest rate related to the non-recourse debt due to an increase in the forecast of Natpara sales (\$6.2 million). This increase was partially offset by decreases in interest expense for (i) the lower principal balance on our Sensipar Notes (\$2.4 million), (ii) a lower effective interest rate due to a decrease in the forecast of REGPARA royalties related to the non-recourse debt associated with the sale of certain of our REGPARA royalty rights (\$1.3 million) and (iii) lower interest expense due to the conversion of our remaining outstanding convertible notes during the year ended December 31, 2014 (\$718,000).



**Income Taxes.** We reported an income tax expense of \$766,000 and \$182,000 in 2014 and 2013, respectively. The increase in income tax expense was primarily related to state and non-U.S. income tax expense.

Our deferred tax assets are comprised primarily of net operating loss and tax credit carryforwards. We maintain a full valuation allowance on our deferred tax assets because we have a history of cumulative losses in these jurisdictions. We will continue to evaluate the need for a valuation allowance in the future. If we determine that the reversal of all or a portion of the valuation allowance is appropriate, a one-time non-cash benefit will be recognized in the period of the reversal. At such time, we will also commence recognizing an income tax provision at our blended effective tax rate. However, these net operating loss and tax credit carryforwards may be used to offset taxable income in future periods, reducing the amount of taxes we might otherwise be required to pay.

For further information, refer to Note 13, *Income Taxes*, in "Notes to Consolidated Financial Statements."

### Years ended December 31, 2013 and 2012

**Revenues.** Substantially all our revenues relate to royalty payments, license fees, milestone payments and product sales from our licensees and collaborators. Our revenues were \$155.6 million in 2013 compared to \$130.6 million in 2012. We recognized revenue under our research and license agreements as follows (amounts in thousands):

	<u>2013</u>	<u>2012</u>
Product sales, net	\$ 31,752	\$ -
Royalties:		
Sensipar and Mimpara (cinacalcet HCl)	112,876	89,271
Regpara (cinacalcet HCl)	8,033	8,693
Nucynta (tapentadol)	2,895	2,837
Preatact (parathyroid hormone (PTH 1-84))	-	4,786
Total royalties	<u>123,804</u>	<u>105,587</u>
Sale of royalty rights - Sensipar	-	25,000
Other	<u>36</u>	<u>57</u>
Total revenues	<u>\$ 155,592</u>	<u>\$ 130,644</u>

**Product Sales, net.** For the year ended December 31, 2013, we recognized net product sales revenue of \$31.8 million for the sales of Gattex. We received approval from the FDA in December 2012 and subsequently launched Gattex in February 2013. We expect that product sales of Gattex and Revestive will vary from period to period given the limited size of the patient population.

We record product sales net of allowances and accruals for prompt pay discounts, rebates and chargebacks under U.S. federal and state governmental programs (including Medicaid), product returns, and distribution-related fees. These allowances and accruals will continue to grow in relation to an increase in the sales of Gattex. The following table summarizes the provisions, and credits/payments, for government rebates and chargebacks, distribution-related fees, and returns and other sales-related deductions (in thousands):

	<u>Rebates and</u> <u>Chargebacks</u>	<u>Distribution-</u> <u>Related Fees</u>	<u>Returns and</u> <u>Other Sales-</u> <u>Related</u> <u>Deductions</u>	<u>Total</u>
Balance as of December 31, 2012	\$ -	\$ -	\$ -	\$ -
Provision related to current period sales	1,375	332	1,098	2,805
Credits/payments	(262)	(185)	(857)	(1,304)
Balance as of December 31, 2013	<u>\$ 1,113</u>	<u>\$ 147</u>	<u>\$ 241</u>	<u>\$ 1,501</u>

**Royalties.** For the years ended December 31, 2013 and 2012, our revenues related to our agreement with Amgen for Sensipar and Mimpara were comprised of \$112.9 million and \$89.3 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) and a non-recurring favorable adjustment. 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, 2013 and 2012, we recognized \$8.0 million and \$8.7 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 decrease is primarily due to unfavorable fluctuations in foreign exchange rates which were partially offset by 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, 2013 and 2012, we recognized royalty revenue of \$2.9 million and \$2.8 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.

For the years ended December 31, 2013 and 2012, our revenues related to our agreement with Takeda for Preotact (parathyroid hormone (PTH 1-84)) were \$0 and \$4.8 million in royalty revenue, respectively. The decrease in royalty revenue was primarily due to the Termination and Transition agreement with Takeda. On March 18, 2013, Takeda terminated this license agreement and returned the rights to NPS. In July 2007, we sold our rights to receive certain future royalty payments from Takeda's sale of PTH 1-84 in Europe, CIS and Turkey to DRI Capital (DRI) and we therefore we were not entitled to receive any such royalty payments until the PTH 1-84-secured debt was repaid. Because we previously monetized our PTH 1-84 royalty rights as non-recourse debt, declines in PTH 1-84 sales would impact our royalty revenues but would have no material impact on our short-term liquidity.

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

**Cost of Sales.** For the year ended December 31, 2013, we began recognizing revenue and cost of sales from product sales of Gattex. Upon marketing approval from the FDA in December 2012, we began capitalizing inventory costs associated with commercial supplies of Gattex subsequent to receipt of marketing approval from the FDA. Costs for manufacturing supplies of Gattex prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not being included in cost of sales when revenue is recognized from the sale of those supplies of Gattex. Cost of sales for the year ended December 31, 2013 was \$3.6 million and consisted primarily of royalty costs related to sales of Gattex. Accordingly, we expect our current product gross margins to decrease from approximately 90% to the 80% to 85% range as we begin sales of product that has been capitalized to inventory. 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.

**Research and Development.** Our research and development are categorized into three areas: clinical development costs, product development costs and other research and development costs.

Clinical development costs were \$16.9 million and \$26.9 million for the years ended December 31, 2013 and 2012, 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 \$41.1 million and \$43.7 million for the years ended December 31, 2013 and 2012, respectively. Product development costs are costs related to the drug needed for our clinical studies and pre-approval inventory.

Other research and development costs were \$27.5 million and \$24.2 million for the years ended December 31, 2013 and 2012, respectively. Other research and development costs consist primarily of personnel, personnel related costs and overhead costs that relate to clinical and product development activities which have not been allocated directly to each program.

For the year ended December 31, 2013, our research and development expenses decreased to \$85.4 million from \$94.8 million for the year ended December 31, 2012. The decrease in research and development expenses is primarily related to a \$10.0 million reduction in costs associated with clinical development activities and adjustments related to the completion of certain clinical trials for both Gattex and Natpara. Additionally, we no longer expense, as research and development, inventory production for Gattex given its approval in the fourth quarter of 2012, the impact of which was \$25.2 million, in 2012. These decreases were partially offset by a \$21.2 million increase for the cost of preapproval PTH 1-84, which includes certain lots of inventory that were purchased from Takeda and designated for use in research and development during the year and a \$3.3 million increase in other research and development which mainly consists of regulatory costs as well as personnel and personnel-related costs.

**Selling, General and Administrative.** Our selling, general and administrative expenses consist primarily of compensation for employees in executive, finance, legal, medical science liaisons and sales and marketing functions as well as facility costs and professional fees for accounting and legal services. Our selling, general and administrative expenses increased to \$68.1 million for the year ended December 31, 2013 from \$36.9 million for the year ended December 31, 2012. The increase in our selling, general and administrative expenses were primarily due to a \$16.4 million increase in personnel and personnel related costs and a \$7.0 million increase in external costs and a \$3.3 million increase in marketing costs related to launch and pre-launch activities for Gattex and Natpara, respectively. As we continue our international expansion and begin our pre-launch Natpara plan, we expect that these costs would continue to increase.

**Interest Income.** Interest income increased to \$340,000 for the year ended December 31, 2013 from \$292,000 from the comparative period in 2012.

**Interest Expense.** Our interest expense decreased to \$11.9 million for the year ended December 31, 2013 from \$18.2 million for the comparable period in 2012. Our long-term royalty forecasts for PTH 1-84 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 lower principal balance on our Sensipar Notes (\$2.7 million), (ii) a lower effective interest rate due to a decrease in the forecast of REGPARA royalties related to the non-recourse debt associated with the sale of certain of our REGPARA royalty rights (\$2.5 million) and (iii) a lower effective interest rate due to a decrease in the forecast of PTH 1-84 royalties related to the non-recourse debt associated with the sale of certain of our PTH 1-84 royalty rights (\$1.1 million).

**Income Taxes.** We reported an income tax expense of \$182,000 and \$0 in 2013 and 2012, respectively. The increase in income tax expense was primarily related to a non-cash charge for state income taxes.

## Liquidity and Capital Resources

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

	<u>December 31,</u> <u>2014</u>	<u>December 31,</u> <u>2013</u>
Cash, cash equivalents, and marketable investment securities	\$ 164,191	\$ 180,474
Total current assets	256,445	258,752
Current debt	10,252	8,752
Non-current debt	89,754	123,635
Stockholders' equity	\$ 133,825	\$ 104,890

Historically, we have not been a self-sustaining business and certain economic, operational and strategic factors may require us to secure additional funds. If we are unable to generate sufficient cash flows from operations or 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. Our actual needs will depend on numerous factors, including, without limitation, the progress and scope of our internally funded commercialization and development activities related to the launch of Gattex and Revestive and the commercial



readiness activities for Natpara; the success of our collaborators in developing and

marketing products under their respective collaborations with us; our success in producing commercial and clinical supplies of our products and product candidates generally, and on a timely basis sufficient to meet the needs of our commercial activities and clinical trials; our ability to successfully execute our strategic plans, including international expansion; 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 commercial activities may not be successful for many reasons, including, without limitation, our inability to effectively market and distribute our products in the United States and other territories; our patients' ability to obtain sufficient coverage or reimbursement by third-party payers for our products at the prices we set, if at all; the risk that safety concerns may develop with respect to our products; the risk that our manufacturers may not be able to supply sufficient quantities of our products to support our commercialization activities or that other manufacturing problems may occur; and the risk that our products may face competition from new products or technologies that may be developed. Our clinical trials may be modified, disrupted or terminated and our commercial activities and clinical filings could be delayed 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, our regulatory filing or commercial launches, or that other manufacturing problems may occur. We may also be required to conduct unanticipated preclinical or clinical trials to obtain regulatory approval of our product candidates, Natpar and NPSP795. 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 may need to raise additional funds to support our long-term research, product development, business development activities, and commercialization programs. We regularly consider various fund raising alternatives, including, for example, debt or equity financing and 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, reduce the scope of our efforts to commercialize Gattex/Revestive or Natpara and Natpar, if it receives regulatory approval, delay, reduce the scope of, or eliminate one or more of our research and development programs, including NPSP795, or to 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. 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; the issuance and sale of non-recourse debt, convertible debt and lease financing; and sales of Gattex/Revestive. Through December 31, 2014, we have recognized \$1.0 billion of cumulative revenues from payments for research support, license fees, product sales, milestone and royalty payments; \$893.2 million from the sale of equity securities for cash; \$738.6 million from the sale of non-recourse debt and convertible debt for cash; and \$133.0 million from sales of Gattex and Revestive, since its launch in February 2013 and September 2014, respectively.

Our principal sources of liquidity are cash, cash equivalents, and marketable investment securities, which totaled \$164.2 million at December 31, 2014. 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.

The following table summarizes our cash flow activity for the years ended December 31, 2014, 2013 and 2012 (amounts in thousands):

	<u>2014</u>	<u>2013</u>	<u>2012</u>
Net cash used in operating activities	\$ (16,710)	\$ (24,316)	\$ (60,992)
Net cash provided by (used in) investing activities	24,298	(50,113)	(6,489)
Net cash provided by financing activities	\$ 8,430	\$ 108,118	\$ 2,561

Net cash used in operating activities was \$16.7 million, \$24.3 million and \$61.0 million in 2014, 2013 and 2012, respectively. The decrease in net cash used in 2014 was primarily due to the decrease in interest expense and non-cash royalty receivable related to the issuance of non-recourse Sensipar Notes to Amgen in the second quarter of 2012. The REGPARA royalty revenue is pledged to service the principal and interest on our non-recourse notes and is not available to fund operations. The decrease in net cash used in 2014, was also related to the increased cash received from revenues earned from the sales of Gattex during the year ended December 31, 2014. The above decreases in net cash used in 2014 were partially offset by increased spending related to the launch of Gattex in the year ended December 31, 2014. The decrease in net cash used in 2013 was primarily due to the decrease in interest expense and non-cash royalty receivable related to the issuance of non-recourse Sensipar Notes to Amgen in the second quarter of 2012. The REGPARA royalty revenue is pledged to service the principal and interest on our non-recourse notes and is not available to fund operations. The decrease in net cash used in 2013, was also related to the increased cash received from revenues earned from the sales of Gattex during the year ended December 31, 2013 and also due to the reduction in research and development costs associated with clinical development activities. The above decreases in net cash used in 2013 were partially offset by increased spending related to the launch of Gattex in the year ended December 31, 2013. The net cash used in the year ended December 31, 2012 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 PTH 1-84 royalty revenues earned during the year ended December 31, 2012 were pledged to service the principal and interest on our non-recourse notes and were not available to fund operations.

Net cash provided by investing activities was \$24.3 million in 2014 compared to cash used in investing activities of \$50.1 million, and \$6.5 million in 2013 and 2012, respectively. Net cash provided by investing activities during 2014 was primarily the result of selling marketable investment securities to fund current operations. Net cash used in investing activities during 2013 and 2012 was primarily the result of investing excess cash not currently required to fund operations. Additionally, capital expenditures for 2014, 2013 and 2012 were \$3.1 million, \$1.1 million and \$1.2 million, respectively.

Net cash provided by financing activities was \$8.4 million, \$108.1 million and \$2.6 million during 2014, 2013 and 2012, respectively. Cash provided by financing activities during 2014 primarily consisted of approximately \$10.3 million received from the exercise of employee stock options and the sale of shares under the employee stock purchase plan. This provision of net cash from financing activities was partially offset by using \$2.2 million to pay taxes that were due from the withholding of shares upon the vesting of certain restricted stock units. Cash provided by financing activities during 2013 primarily consisted of the \$93.5 million received from the public sale of 6.9 million common shares in May 2013 and approximately \$14.5 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 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. Employee stock option exercises and proceeds from the sale of stock by us pursuant to the employee stock purchase plan provided approximately \$10.3 million, \$14.5 million, and \$2.6 million of cash during 2014, 2013 and 2012, 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 \$16.8 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.

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, 2014 (in millions):

<b>Contractual Obligations</b>	<b>Total</b>	<b>Less than 1 year</b>	<b>2-3 years</b>	<b>4-5 years</b>	<b>More than 5 years</b>
Operating leases	\$ 5.0	\$ 3.2	\$ 1.8	\$ -	\$ -
Purchase commitments (1)	134.4	119.0	10.5	4.9	-
Non-recourse debt (2)	100.0	32.0	10.0	32.1	25.9
Interest on non-recourse debt (2)	45.1	3.7	16.8	23.1	1.4
Royalty payment obligation	4.6	1.0	2.0	1.6	-

- (1) Purchase obligations primarily represent commitments for manufacturing agreements (\$73.7 million), services (\$43.2 million) and commercial readiness, market access and market research agreements (\$17.4 million). Commitments for services primarily represent agreements with external service providers, under which we will continue to incur expenses relating to clinical trials of Gattex/Revestive in pediatrics 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, PTH 1-84 and REGPARA royalty income. Amounts shown in interest on non-recourse debt include our estimated interest payments based on estimated cinacalcet HCl, PTH 1-84 and REGPARA royalty income levels.

### 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;
- inventory valuation;
- 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.

**Product Sales.** 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, we have no further performance obligations, and returns can be reasonably estimated. Currently, product sales represent U.S. sales of Gattex and international sales of Revestive.

Our customers are primarily comprised of specialty pharmacies, distributors and other health care providers. In some cases, we may also sell Gattex or Revestive to governments and government agencies.

Because of factors such as the pricing of Gattex and Revestive, the limited number of patients and the lack of contractual return rights, Gattex and Revestive customers often carry limited inventory. We also monitor inventory within our sales channels to determine whether deferrals are appropriate based on factors such as inventory levels compared to demand, contractual terms and financial strength of distributors.

In addition to sales in countries where Gattex and Revestive are commercially available, we have also recorded revenue on sales for patients receiving Gattex or Revestive through named-patient programs. The relevant authorities or institutions in those countries have agreed to reimburse for product sold on a named-patient basis where Gattex or Revestive have not received final approval for commercial sale.

We record estimated rebates payable under governmental programs, including Medicaid in the U.S. and other programs outside the U.S., as a reduction of revenue at the time of product sale. Our calculations related to these rebate accruals require analysis of historical claim patterns and estimates of customer mix to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any necessary adjustments, which may have an impact on revenue in the period in which the adjustment is made. Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months.

All U.S. prescriptions for Gattex, received directly by us from the patient's physician, are handled through NPS Advantage, our data management and patient support program, which investigates and determines the patient's insurance coverage for Gattex. Once coverage is confirmed, we forward the prescription to the specialty pharmacy (SP) who then re-confirms the coverage and dispenses Gattex to the patient. We sell Gattex directly to a limited number of SPs and a specialty distributor (SD) who dispense product to patients, hospitals or U.S. government entities. We invoice and record revenue upon the SPs' or SD's receipt of Gattex from our third-party logistics warehouse. Our SPs order product to fill prescriptions that have been approved for reimbursement by payers.

Specific considerations for Gattex sold in the U.S. are as follows:

- **Rebates:** Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector (e.g. Medicaid) benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. Our estimate for expected utilization for rebates is based in part on actual and pending prescriptions for which we have validated the insurance benefits.
- **Chargebacks:** Chargebacks are discounts that occur when contracted customers purchase from our SPs or SD. Contracted customers, which currently consist primarily of Public Health Service institutions and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. Our SPs or SD, in turn, charge back the difference between the price initially paid by the SP or SD and the discounted price paid to the SP or SD by the customer. The allowance for chargebacks is based on actual and expected sales to the SPs and SD.
- **SP and SD Fees and Deductions:** Our SPs and our SD are offered prompt payment discounts and are paid fees for their services and data.

- **Product returns:** We will accept product that is damaged or defective when shipped directly to the SP or SD from our third-party logistics provider or for product that is returned with more than two (2) months remaining until the expiration date from our SP or SD only. We will not provide any credit for product that has been labeled for or sent to a patient. Product returned is generally not resalable as the product must be temperature-controlled throughout the supply chain and such control is difficult to confirm. We make a reasonable estimate of future potential product returns based on the number of prescriptions that have been approved for reimbursement and sent to an SP with each corresponding shipment of Gattex that has been sent to each respective SP. We also have the visibility to see current inventory levels and the current shelf life at the SPs and SD and have the ability to control the amount of product that is sold to the SPs and SD. At the end of each reporting period, we determine a product returns reserve by evaluating the units held in our distribution channel, the underlying demand for such units and the risk of potential product returns. At December 31, 2014 and 2013 we have a product returns reserve of \$0 and approximately \$119,000, respectively.

Product sales are recorded net of accruals for estimated rebates, chargebacks, discounts, and other deductions (collectively, sales deductions) and returns. With the exception of allowances for prompt payment, allowances for sales deductions and returns are included in accounts payable and accrued expenses in the accompanying consolidated balance sheets.

**Milestone Revenue.** 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.

**Royalty Revenue.** 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 that qualify for separate accounting is based on the estimated fair value of the respective elements.

**Inventory valuation.** Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of inventory using the first-in, first-out, or FIFO, method. We capitalize inventory costs associated with our products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. We periodically analyze our inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and writes-down such inventories as appropriate. In addition, our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, we record a charge to cost of sales to write down such unmarketable inventory to its estimated realizable value.

**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 pre-approval 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 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. 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. 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 (PTH1-84) 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.

In December 2013, we entered into an amendment and restatement (the "Amendment and Restatement") to our agreement with DRI for PTH 1-84. Pursuant to the previously disclosed Termination and Transition Agreement between NPS and Takeda (See note 10 to the consolidated financial statements), our license agreement with Takeda was terminated and NPS re-acquired exclusive rights worldwide to develop and commercialize PTH. Preotact is the brand name that Takeda had used to market PTH for the treatment of osteoporosis in certain of its licensed territories. NPS is developing PTH in the U.S. under the trade name Natpara for the treatment of hypoparathyroidism. In January 2015, the FDA approved Natpara. Pursuant to the Amendment and Restatement, (i) DRI has consented to the commercialization of PTH by the Company, (ii) the terms of the 2007 Agreement are tolled, and (iii) the parties' rights and obligations regarding PTH and related technology are governed by the Amendment and Restatement. We will be required to repay the outstanding non-recourse debt based upon a mid-single digit percentage of worldwide Natpara sales, excluding Israel.





Our obligation to pay royalties to DRI under the Amendment and Restatement shall expire on a country-by-country basis upon the later of (i) the last to expire patent controlled by us with claims covering PTH in such country or (ii) the expiration of any period of regulatory exclusivity applicable to PTH in such country. Our obligation to pay royalties to DRI under the Amendment and Restatement shall terminate in its entirety once cumulative royalty payments made to DRI by Takeda and us total \$125 million. As of December 31, 2014, \$45.5 million in royalties had been paid to DRI. We determined the initial up-front purchase price is debt and is being amortized into earnings using the effective interest method over the estimated life.

We estimate future net sales of PTH and then calculate the effective interest rate on the DRI debt. Changes to the future PTH net sales forecast may have a material impact on interest expense. Management evaluates its future PTH 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.

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, Intangibles and Goodwill.*** We assess the impairment of long-lived assets, intangibles 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.

Intangibles represent the fair value of product rights purchased. Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events occur.

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 15 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 9% non-recourse Sensipar Notes have a fixed interest rate. As of December 31, 2014, our Sensipar Notes had \$26.2 million in aggregate principal amount outstanding. 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-scale manufacturing agreements as well as foreign subsidiaries which are denominated in other foreign currencies. 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 other foreign currencies, or by weak economic conditions in other countries. When the U.S. dollar strengthens against the foreign currencies, the cost of expenses outside the U.S. decrease. When the U.S. dollar weakens against other foreign currencies, the cost of expenses in other countries increase. The monetary assets and liabilities in our foreign subsidiaries which are impacted by the foreign currency fluctuations are cash, inventory, accounts payable, and certain accrued liabilities. A hypothetical ten percent increase or decrease in the exchange rate between the U.S. dollar and other foreign currencies from the December 31, 2014 rate would cause the fair value of such monetary assets and liabilities in our foreign subsidiaries 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**  
**Table of Contents**

	<b>Page</b>
<a href="#">Reports of Independent Registered Public Accounting Firm</a>	66
<a href="#">Consolidated Balance Sheets</a>	67
<a href="#">Consolidated Statements of Operations</a>	68
<a href="#">Consolidated Statements of Comprehensive Loss</a>	69
<a href="#">Consolidated Statements of Stockholders' Equity (Deficit)</a>	70
<a href="#">Consolidated Statements of Cash Flows</a>	71
<a href="#">Notes to Consolidated Financial Statements</a>	72

*All other schedules are omitted, as the required information is presented in the consolidated financial statements or related notes.*

**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, 2014 and 2013, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2014. 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, 2014 and 2013, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2014, 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, 2014, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 18, 2015 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Short Hills, New Jersey  
February 18, 2015

**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, 2014, based on criteria established in *Internal Control - Integrated Framework (2013)* 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, 2014, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

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, 2014 and 2013, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2014, and our report dated February 18, 2015 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Short Hills, New Jersey  
February 18, 2015

## NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES

**Consolidated Balance Sheets**  
**December 31, 2014 and 2013**  
(In thousands, except share data)

	<b>2014</b>	<b>2013</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 65,565	\$ 51,204
Marketable investment securities	98,626	129,270
Accounts receivable	48,854	41,242
Inventory	36,815	30,035
Prepaid expenses	5,225	5,621
Other current assets	1,360	1,380
Total current assets	256,445	258,752
Property and equipment, net	5,786	4,402
Goodwill	9,429	9,429
Intangibles, net	17,505	19,301
Debt issuance costs, net of accumulated amortization of \$601 and \$716, respectively	251	338
Other long-term assets	201	-
Total assets	\$ 289,617	\$ 292,222
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 21,810	\$ 10,919
Accrued expenses and other current liabilities	19,301	17,037
Accrued research and development expenses	3,408	3,541
Accrued interest expense	862	1,620
Convertible notes payable	-	16,545
Current portion of non-recourse debt	10,252	8,752
Total current liabilities	55,633	58,414
Non-recourse debt, less current portion	89,754	123,635
Other liabilities	10,405	5,283
Total liabilities	155,792	187,332
Commitments and contingencies (notes 8, 9 and 16)		
Stockholders' equity (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 107,103,262 shares and 102,613,780 shares, respectively	107	103
Additional paid-in capital	1,167,385	1,127,420
Accumulated other comprehensive (loss) income	(2,273)	56
Accumulated deficit	(1,031,394)	(1,022,689)
Total stockholders' equity	133,825	104,890
Total liabilities and stockholders' equity	\$ 289,617	\$ 292,222

See accompanying notes to consolidated financial statements.

## NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES

**Consolidated Statements of Operations**  
**Years ended December 31, 2014, 2013, and 2012**  
(In thousands, except per share data)

	<u>2014</u>	<u>2013</u>	<u>2012</u>
Revenues:			
Product sales, net	\$ 101,195	\$ 31,752	\$ -
Royalties	122,867	123,804	105,587
Sale of royalty rights	-	-	25,000
Milestones and license fees	-	36	57
Total revenues	<u>224,062</u>	<u>155,592</u>	<u>130,644</u>
Cost of sales	14,648	3,587	-
Cost of license fees	-	9	-
Operating expenses:			
Research and development	90,109	85,421	94,839
Selling, general and administrative	114,255	68,070	36,929
Total operating expenses	<u>204,364</u>	<u>153,491</u>	<u>131,768</u>
Operating income (loss)	<u>5,050</u>	<u>(1,495)</u>	<u>(1,124)</u>
Other income (expense):			
Interest income, net	406	340	292
Interest expense	(13,728)	(11,938)	(18,198)
Gain on sale of marketable investment securities, net	12	4	4
Foreign currency transaction (loss) gain	22	(233)	54
Other	299	-	237
Total other expense, net	<u>(12,989)</u>	<u>(11,827)</u>	<u>(17,611)</u>
Loss before income tax expense	(7,939)	(13,322)	(18,735)
Income tax expense	766	182	-
Net loss	<u>\$ (8,705)</u>	<u>\$ (13,504)</u>	<u>\$ (18,735)</u>
Basic and diluted net loss per common and potential common share	<u>\$ (0.08)</u>	<u>\$ (0.14)</u>	<u>\$ (0.22)</u>
Weighted average common and potential common shares outstanding - basic and diluted	<u>106,341</u>	<u>97,750</u>	<u>86,999</u>

See accompanying notes to consolidated financial statements.

## NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES

**Consolidated Statements of Comprehensive Loss**  
**Years ended December 31, 2014, 2013, and 2012**  
(In thousands)

	<u>2014</u>	<u>2013</u>	<u>2012</u>
Net loss	\$ (8,705)	\$ (13,504)	\$ (18,735)
Other comprehensive income:			
Unrealized gains (losses) on securities:			
Unrealized holding gains (losses) arising during period	(71)	3	107
Reclassification for recognized gain on marketable securities during the period	<u>12</u>	<u>4</u>	<u>4</u>
Net unrealized gain (loss) on marketable investment securities	(59)	7	111
Foreign currency translation gain (loss)	<u>(2,270)</u>	<u>44</u>	<u>(10)</u>
Other comprehensive income (loss)	<u>(2,329)</u>	<u>51</u>	<u>101</u>
Comprehensive loss	<u>\$ (11,034)</u>	<u>\$ (13,453)</u>	<u>\$ (18,634)</u>

See accompanying notes to consolidated financial statements.



## NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES

**Consolidated Statements of Stockholders' Equity (Deficit)**  
**Years ended December 31, 2014, 2013, and 2012**  
(In thousands, except share data)

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Other</u>	<u>Deficit</u>	<u>Stockholders'</u>
					<u>Capital</u>	<u>Income (Loss)</u>		<u>Equity</u>
								<u>(Deficit)</u>
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
Restricted stock vesting	-	-	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)
Stock options exercised	-	-	2,521,764	3	14,528	-	-	14,531
Restricted stock vesting	-	-	211,389	-	339	-	-	339
Compensation expense on share-based awards	-	-	-	-	8,480	-	-	8,480
Excess tax benefit from stock options	-	-	-	-	178	-	-	178
Stock issued in connection with the Takeda Termination and Transition agreement	-	-	6,128,641	6	55,397	-	-	55,403
Net proceeds from sale of shares	-	-	6,972,937	7	94,046	-	-	94,053
Other comprehensive income	-	-	-	-	-	51	-	51
Net loss	-	-	-	-	-	-	(13,504)	(13,504)

Balances, December 31, 2013	-	-	102,613,780	103	1,127,420	56	(1,022,689)	104,890
Stock options exercised	-	-	1,245,034	1	9,317	-	-	9,318
Restricted stock vesting	-	-	162,877	-	3,109	-	-	3,109
Compensation expense on share-based awards	-	-	-	-	9,740	-	-	9,740
Excess tax benefit from stock options	-	-	-	-	312	-	-	312
Conversion of 5.75% convertible notes	-	-	3,041,451	3	16,532	-	-	16,535
Net proceeds from sale of shares	-	-	40,120	-	955	-	-	955
Other comprehensive income	-	-	-	-	-	(2,329)	-	(2,329)
Net loss	-	-	-	-	-	-	(8,705)	(8,705)
Balances, December 31, 2014	-	\$ -	107,103,262	\$ 107	\$1,167,385	\$ (2,273)	\$ (1,031,394)	\$ 133,825

See accompanying notes to consolidated financial statements.

## NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES

**Consolidated Statements of Cash Flows**  
**Years ended December 31, 2014, 2013, and 2012**  
(In thousands)

	<u>2014</u>	<u>2013</u>	<u>2012</u>
Cash flows from operating activities:			
Net loss	\$ (8,705)	\$ (13,504)	\$ (18,735)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,335	2,630	1,083
Accretion of premium on marketable investment securities	3,206	2,956	2,005
Shares issued for payment of services	-	549	-
Non-cash interest expense	7,278	10,982	17,239
Non-cash royalties	(40,304)	(39,804)	(55,993)
Realized gain on marketable investment securities	(12)	(4)	(4)
Loss on disposal of equipment	-	41	-
Compensation expense on share-based awards	15,003	9,437	7,548
Decrease (increase) in operating assets:			
Accounts receivable	(7,713)	(11,324)	(16,010)
Inventory	(898)	4,265	-
Prepaid expenses, other current assets and other assets	138	(466)	1,803
Increase (decrease) in operating liabilities:			
Accounts payable and accrued expenses	6,839	11,257	1,321
Other liabilities	5,123	(1,331)	(1,249)
Net cash used in operating activities	<u>(16,710)</u>	<u>(24,316)</u>	<u>(60,992)</u>
Cash flows from investing activities:			
Sales of marketable investment securities	11,209	11,850	7,628
Maturities of marketable investment securities	123,458	96,021	111,879
Purchases of marketable investment securities	(107,276)	(156,842)	(124,809)
Acquisitions of property and equipment	(3,093)	(1,142)	(1,187)
Net cash provided by (used in) investing activities	<u>24,298</u>	<u>(50,113)</u>	<u>(6,489)</u>
Cash flows from financing activities:			
Excess tax benefit from stock options	312	178	-
Net proceeds from the sale of common stock and exercise of stock options	<u>8,118</u>	<u>107,940</u>	<u>2,561</u>
Net cash provided by financing activities	<u>8,430</u>	<u>108,118</u>	<u>2,561</u>
Effect of exchange rate changes on cash	<u>(1,657)</u>	<u>44</u>	<u>(10)</u>
Net increase (decrease) in cash and cash equivalents	14,361	33,733	(64,930)
Cash and cash equivalents at beginning of year	<u>51,204</u>	<u>17,471</u>	<u>82,401</u>
Cash and cash equivalents at end of year	<u>\$ 65,565</u>	<u>\$ 51,204</u>	<u>\$ 17,471</u>
<i>Supplemental Disclosures of Cash Flow Information:</i>			
Cash paid for interest	\$ 256	\$ 952	\$ 954
Cash paid for income taxes	270	4	-
<i>Supplemental Disclosures of Non-Cash Investing and Financing Activities:</i>			
6.1 million shares of NPS common stock issued in connection with the Takeda Termination and Transition agreement, see note 10	\$ -	\$ 55,403	\$ -
Unrealized gains (losses) on marketable investment securities	(59)	7	111
Accrued acquisition of equipment	293	428	96
Accrued acquisition of inventory	7,279	602	-
Noncash principal payments	32,381	26,915	52,050
Conversion of 5.75% convertible notes	16,535	-	-

See accompanying notes to consolidated financial statements.



**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**Notes to Consolidated Financial Statements**  
**December 31, 2014, 2013, and 2012**

**(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, collectively referred to as the Company or NPS Pharma. NPS Pharma is a global biopharmaceutical company pioneering and delivering first-in or best-in disease therapies that transform the lives of patients with rare diseases. The Company's marketed 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 and was approved by the European Union ("EU"), in August 2012, for the treatment of adult patients with SBS; patients should be stable following a period of intestinal adaptation after surgery. The Company launched Revestive in Germany and Sweden in 2014 and plans to launch in other EU countries in early 2015. In January 2015, the FDA approved the Company's second product, Natpara® (parathyroid hormone) for Injection as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism, a rare endocrine disorder characterized by insufficient levels of parathyroid hormone or PTH. Natpara, a bioengineered replica of human PTH, is expected to be available in the U.S. in the second quarter of 2015.

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, establishing research and license agreements and effecting the commercial launch of Gattex in the U.S. All monetary amounts are reported in U.S. dollars unless specified otherwise.

***Subsequent Events***

The Company has evaluated all events and transactions since December 31, 2014. The Company did not have any material recognized subsequent events but did have the following non-recognized subsequent event:

**Merger Agreement**

On January 11, 2015, the Company entered into an Agreement and Plan of Merger (Merger Agreement) with Shire Pharmaceutical Holdings Ireland Limited (Parent), a company incorporated in Ireland and a wholly owned subsidiary of Shire plc (Shire), a company incorporated in Jersey; Knight Newco 2, Inc. (Purchaser), a Delaware corporation and wholly owned subsidiary of Parent; and, solely for purposes of Section 12.14 of the Merger Agreement, Shire. Pursuant to the Merger Agreement, Purchaser has commenced a cash tender offer for all of the outstanding shares of the Company's common stock, upon the terms and subject to the conditions of the Merger Agreement. Consummation of the tender offer is subject to customary closing conditions, as set forth in the Merger Agreement. As soon as practicable following the consummation of the tender offer, and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Purchaser will merge with and into the Company pursuant to the provisions of section 251(h) of the Delaware General Corporation Law, with no stockholder vote required to consummate the merger, and the Company will survive as a wholly owned subsidiary of Parent.

The Merger Agreement contains representations, warranties and covenants of the parties customary for transactions of this type. Until the earlier of the termination of the Merger Agreement and the consummation of the merger, the Company has agreed to operate its business and the business of its subsidiaries in the ordinary course and has agreed to certain other operating covenants, as set forth more fully in the Merger Agreement. The Company has agreed not to solicit alternative acquisition proposals. However, the Company may, subject to the terms and conditions set forth in the Merger Agreement, furnish information to, and engage in discussions and negotiations with, a third party that makes an unsolicited acquisition proposal that the Board reasonably believes is or could reasonably be expected to lead to a superior proposal. Under certain circumstances and upon compliance with certain notice and other specified conditions set forth in the Merger Agreement, the Company may terminate the Merger Agreement to accept a superior proposal.

The Merger Agreement contains certain termination rights for both Parent and the Company and further provides that, upon termination of the Merger Agreement under certain circumstances relating to competing acquisition proposals, including if the Company terminates the Merger Agreement to accept a superior proposal, or where our Board of Directors changes its recommendation in favor of the transaction, the Company may be required to pay Parent a termination fee of \$155,939,696.

Additional information about the merger is set forth in the Company's filings with the U.S. Securities and Exchange Commission (SEC).

### ***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, 2014 and 2013 are carried at cost and consist of commercial paper, money market funds, debt securities and other highly liquid instruments of approximately \$42.3 million and \$40.6 million, respectively. At December 31, 2014 and 2013, the book value of cash equivalents approximates fair value.

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

The Company classifies its marketable investment securities as available-for-sale and 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. 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, 2014 2013 and 2012. At December 31, 2014 and 2013 the allowance for bad debts was zero.

**(d) Inventory**

Inventories are stated at the lower of cost or estimated realizable value. The Company determines the cost of inventory using the first-in, first-out, or FIFO, method. The Company capitalizes inventory costs associated with the Company's products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and writes-down such inventories as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company records a charge to cost of sales sold to write down such unmarketable inventory to zero.

**(e) 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.

**(f) Goodwill and Intangibles**

Goodwill represents the excess of costs over fair value of assets of businesses acquired. Intangibles represents acquired assets and are measured at fair value as of the date of acquisition. Goodwill and indefinite lived intangible assets acquired in a purchase or 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. Intangible assets with finite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events occur. 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.

**(g) Income Taxes**

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. The Company establishes a valuation allowance when it believes it is more likely than not that deferred tax assets will not be realized.

The Company determines the need for a valuation allowance by assessing the probability of realizing deferred tax assets, taking into consideration all available positive and negative evidence, including historical operating results, expectations of future taxable income, carryforward periods available to the Company for tax reporting purposes, various income tax strategies and other relevant factors. Significant judgment is required in making this assessment and to the extent future expectations change, the Company would have to assess the recoverability of its deferred tax assets at that time. At December 31, 2014 and 2013, the Company maintained a full valuation allowance on its deferred tax assets.

At any one time the Company's tax returns for numerous tax years are subject to examination by U.S. federal, state and foreign taxing jurisdictions. The impact of an uncertain tax position taken or expected to be taken on an income tax return must be recognized in the financial statements at the largest amount that is more likely than not to be sustained. An uncertain income tax position will not be recognized in the financial statements unless it is more likely than not to be sustained. The Company adjusts these tax liabilities, as well as the related interest and penalties, based on the latest facts and circumstances, including recently enacted tax law changes, published rulings, court cases, and outcomes of tax audits. While the Company does not expect material changes, it is possible that its actual tax liability will differ from its established tax liabilities for unrecognized tax benefits, and the Company's effective tax rate may be materially impacted. The Company accounts for interest and penalties related to uncertain tax positions as a component of Income tax expense.

For further information, refer to Note 13, *Income Taxes*.



**(h) 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.

**License fees.** 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.

**Milestone payments.** 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.** 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.

**Product sales.** 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, the Company has no further performance obligations, and returns can be reasonably estimated. Currently, product sales represent U.S. sales of Gattex, which was approved by the FDA in December 2012 and European sales of Revestive, which was approved in the EU in August 2012.

The Company's customers are primarily comprised of specialty pharmacies, distributors and other health care providers. In some cases, the Company may also sell Gattex or Revestive to governments and government agencies.

Because of factors such as the pricing of Gattex and Revestive, the limited number of patients and the lack of contractual return rights, Gattex and Revestive customers often carry limited inventory. The Company also monitors inventory within its sales channels to determine whether deferrals are appropriate based on factors such as inventory levels compared to demand, contractual terms and financial strength of distributors.

In addition to sales in countries where Gattex and Revestive are commercially available, the Company has also recorded revenue on sales for patients receiving Gattex or Revestive through named-patient programs. The relevant authorities or institutions in those countries have agreed to reimburse for product sold on a named-patient basis where Gattex or Revestive have not received final approval for commercial sale.

The Company records estimated rebates payable under governmental programs, including Medicaid in the U.S. and other programs outside the U.S., as a reduction of revenue at the time of product sale. The Company's calculations related to these rebate accruals require analysis of historical claim patterns and estimates of customer mix to determine which sales will be subject to rebates and the amount of such rebates. The Company updates its estimates and assumptions each period and record any necessary adjustments, which may have an impact on revenue in the period in which the adjustment is made. Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months.

All U.S. prescriptions for Gattex, received directly by NPS from the patient's physician, are handled through NPS Advantage, the Company's data management and patient support program, which investigates and determines the patient's insurance coverage for Gattex. Once coverage is confirmed, NPS forwards the prescription to the specialty pharmacy (SP) who then re-confirms the coverage and dispenses Gattex to the patient. The Company sells Gattex directly to a limited number of SPs and a specialty distributor (SD) who dispense product to patients, hospitals or U.S. government entities. The Company invoices and records revenue when the SPs or SD receives Gattex from the Company's third-party logistics warehouse. The Company's SPs order product to fill prescriptions that have been approved for reimbursement by payers.

Specific considerations for Gattex sold in the U.S. are as follows:

- *Rebates:* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector (e.g. Medicaid) benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. The Company's estimate for expected utilization for rebates is based in part on actual and pending prescriptions for which it has validated the insurance benefits.
- *Chargebacks:* Chargebacks are discounts that occur when contracted customers purchase from the Company's SPs or SD. Contracted customers, which currently consist primarily of Public Health Service institutions and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The Company's SPs or SD, in turn, charge back the difference between the price initially paid by the SP or SD and the discounted price paid to the SP or SD by the customer. The allowance for chargebacks is based on actual and expected sales to the SPs and SD.
- *SP and SD Fees and Deductions:* The Company's SPs and its SD are offered prompt payment discounts and are paid fees for their services and data.
- *Product returns:* The Company will accept product that is damaged or defective when shipped directly to the SP or SD from the Company's third-party logistics provider or for product that is returned with more than two (2) months remaining until the expiration date from its SP or SD only. The Company will not provide any credit for product that has been labeled for or sent to a patient. Product returned is generally not resalable as the product must be temperature-controlled throughout the supply chain and such control is difficult to confirm. The Company makes a reasonable estimate of future potential product returns based on the number of prescriptions that have been approved for reimbursement and sent to an SP with each corresponding shipment of Gattex that has been sent to each respective SP. The Company also has the visibility to see current inventory levels and the current shelf life at the SPs and SD and has the ability to control the amount of product that is sold to the SPs and SD. At the end of each reporting period, the Company determines a product returns reserve by evaluating the units held in its distribution channel, the underlying demand for such units and the risk of potential product returns.

The following table summarizes the provisions, and credits/payments, for government rebates and chargebacks, distribution-related fees, and returns and other sales-related deductions (in thousands):

	<b>Rebates and Chargebacks</b>	<b>Distribution- Related Fees</b>	<b>Returns and Other Sales- Related Deductions</b>	<b>Total</b>
Balance as of December 31, 2012	\$ -	\$ -	\$ -	\$ -
Provision related to current period sales	1,375	332	1,098	2,805
Credits/payments	<u>(262)</u>	<u>(185)</u>	<u>(857)</u>	<u>(1,304)</u>
Balance as of December 31, 2013	1,113	147	241	1,501
Provision related to current period sales	3,929	461	2,217	6,607
Credits/payments	<u>(3,398)</u>	<u>(514)</u>	<u>(2,208)</u>	<u>(6,120)</u>
Balance as of December 31, 2014	<u>\$ 1,644</u>	<u>\$ 94</u>	<u>\$ 250</u>	<u>\$ 1,988</u>

Product sales are recorded net of accruals for estimated rebates, chargebacks, discounts, and other deductions (collectively, sales deductions) and returns. With the exception of allowances for prompt payment, allowances for sales deductions and returns are included in accounts payable and accrued expenses in the accompanying consolidated balance sheets.

#### **(i) 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.



***(j) 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.

***(k) 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, except for performance condition options where vesting is subject to the Company achieving certain performance criteria. Compensation costs for performance condition options will be recognized when the achievement of the performance criteria is probable.

***(l) 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.

***(m) 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.

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

As described in (f), goodwill and indefinite lived intangible assets are 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.

***(o) 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.

***(p) 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, 2014 and 2013 consists of accumulated net unrealized gains on marketable investment securities of \$74,000 and unrealized losses of \$15,000, respectively, and unrealized foreign currency translation losses of \$2.2 million and unrealized gains of \$71,000, respectively.



***(q) 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.

***(r) Leases***

The Company leases its facilities under terms of individual lease agreements 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 accrued expenses and other current liabilities and in other long-term liabilities.

***(s) Deferred Financing Costs***

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 REGPARA under its license agreement with Kyowa Hakko Kirin and a future royalty in the mid-single digits from the sales of PTH, 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.

***(t) 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 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, 2014, Amgen has paid the Company \$21.0 million in milestone payments, of which none were recognized during 2014, 2013, and 2012, respectively. The Company recognized royalties from product sales of \$111.9 million, \$112.9 million and \$89.3 million in 2014, 2013 and 2012, 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. 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 2014, 2013 or 2012. 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 2014, 2013 or 2012.

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, 2014, 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 2014, 2013 or 2012. 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 2014, 2013 and 2012, respectively, and royalty revenue of \$8.5 million in 2014, \$8.0 million in 2013 and \$8.7 million in 2012.

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**

On March 18, 2013, the Company entered into a Termination and Transition Agreement, with Takeda GmbH, whereby the 2007 teduglutide and 2004 Preotact agreements were terminated. (see note 10)

Revenues from Takeda related to the Preotact agreement, were \$0, \$0 and \$4.8 million for the years ended December 31, 2014, 2013 and 2012, respectively.

**(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 \$2.6 million, \$2.9 million and \$2.8 million in 2014, 2013 and 2012, 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, 2014, 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 has not recognized revenue in 2014, 2013 and 2012, 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, \$10.4 million has been paid. Annual payments due are limited to a maximum of \$1.0 million. Accruals of \$3.6 million and \$1.0 million at December 31, 2014 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 5.6 million, 7.2 million and 8.0 million during the years ended December 31, 2014, 2013, and 2012, 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, 2014, 2013 and 2012 include approximately 817,000, 3.0 million and 3.0 million common shares related to convertible debentures, respectively, and 4.8 million, 4.1 million, and 5.0 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, 2014 and December 31, 2013 (in thousands):

<i>As of December 31, 2014:</i>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Certificate of deposits	\$ -	\$ 6,615	\$ -	\$ 6,615
Corporate debt	-	88,733	-	88,733
Government agency debt	-	3,278	-	3,278
Money market funds	42,349	-	-	42,349
Total assets at fair value	<u>\$ 42,349</u>	<u>\$ 98,626</u>	<u>\$ -</u>	<u>\$ 140,975</u>

<i>As of December 31, 2013:</i>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Certificate of deposits	\$ -	\$ 13,020	\$ -	\$ 13,020
Corporate debt	-	91,887	-	91,887
Government agency debt	-	27,131	-	27,131
Money market funds	23,043	-	-	23,043
Total assets at fair value	<u>\$ 23,043</u>	<u>\$ 132,038</u>	<u>\$ -</u>	<u>\$ 155,081</u>

As of December 31, 2014 and December 31, 2013, the fair values of the Company's Level 2 securities were \$98.6 million and \$132.0 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, 2014 or 2013.

As of December 31, 2014 and 2013, 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, 2014 and 2013.

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 \$3.7 million and \$4.6 million, respectively, at December 31, 2014 and \$4.3 million and \$5.6 million, respectively, at December 31, 2013.

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

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

	<b>As of December 31, 2014</b>		<b>As of December 31, 2013</b>	
	<b>Fair Value</b>	<b>Carrying Value</b>	<b>Fair Value</b>	<b>Carrying Value</b>
5.75% Convertible Notes	\$ -	\$ -	\$ 92,338	\$ 16,545
Sensipar Notes	26,312	26,230	54,097	54,395
PTH 1-84-Secured Debt	54,730	42,790	50,058	42,790
Regpara-Secured Debt	29,249	30,986	37,348	35,202
Total	<u>\$ 110,291</u>	<u>\$ 100,006</u>	<u>\$ 233,841</u>	<u>\$ 148,932</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, PTH 1-84-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 specialty pharmacies and collateral is generally not required from these companies. Substantially all of the Company's royalty revenues and the related accounts receivable balances for the years ended December 31, 2014 and 2013 were from three licensees of the Company. Substantially all of the Company's product sales revenues for the year ended December 31, 2014 and 2013, and substantially all of the Company's trade accounts receivable balances at December 31, 2014 and 2013 were from six specialty pharmacies. 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>
<b>As of December 31, 2014:</b>				
Debt securities:				
Corporate	\$ 95,423	\$ 3	\$ (78)	\$ 95,348
Government agency	3,277	1	-	3,278
Total marketable investment securities	<u>\$ 98,700</u>	<u>\$ 4</u>	<u>\$ (78)</u>	<u>\$ 98,626</u>

	<u>Amortized cost</u>	<u>Gross unrealized holding gains</u>	<u>Gross unrealized holding losses</u>	<u>Fair value</u>
<b>As of December 31, 2013:</b>				
Debt securities:				
Corporate	\$ 103,175	\$ 23	\$ (60)	\$ 103,138
Government agency	26,110	22	-	26,132
Total marketable investment securities	<u>\$ 129,285</u>	<u>\$ 45</u>	<u>\$ (60)</u>	<u>\$ 129,270</u>

Marketable investment securities available for sale in an unrealized loss position as of December 31, 2014 and 2013 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, 2014</b>						
<b>Available for Sale:</b>						
Debt securities:						
Corporate	\$ 90,327	\$ 78	\$ -	\$ -	\$ 90,327	\$ 78
Government agency	-	-	-	-	-	-
	<u>\$ 90,327</u>	<u>\$ 78</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 90,327</u>	<u>\$ 78</u>
<b>December 31, 2013</b>						
<b>Available for Sale:</b>						
Debt securities:						
Corporate	\$ 74,407	\$ 56	\$ 5,732	\$ 4	\$ 80,139	\$ 60
Government agency	-	-	-	-	-	-
	<u>\$ 74,407</u>	<u>\$ 56</u>	<u>\$ 5,732</u>	<u>\$ 4</u>	<u>\$ 80,139</u>	<u>\$ 60</u>

### **Summary of Contractual Maturities**

Maturities of marketable investment securities are as follows at December 31, 2014 and December 31, 2013 (in thousands):

	<u>As of December 31, 2014</u>		<u>As of December 31, 2013</u>	
	<u>Amortized cost</u>	<u>Fair value</u>	<u>Amortized cost</u>	<u>Fair value</u>
Due within one year	\$ 95,499	\$ 95,430	\$ 103,280	\$ 103,266
Due after one year through five years	3,201	3,196	26,005	26,004
Due after five years through ten years	-	-	-	-
Due after ten years	-	-	-	-
Total debt securities	<u>\$ 98,700</u>	<u>\$ 98,626</u>	<u>\$ 129,285</u>	<u>\$ 129,270</u>



**Impairments**

No impairment losses were recognized through earnings related to available for sale securities during the years ended December 31, 2014 or 2013.

**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):

	<b>For the Years Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Proceeds from sales and maturities	\$ 134,667	\$ 107,871	\$ 119,507
Realized gains	12	4	4
Realized losses	-	-	-

**(6) Inventory**

Inventories are stated at the lower of cost or market. Inventory is as follows at December 31, 2014 and 2013 (in thousands):

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Raw materials	\$ 34,020	\$ 29,330
Finished goods	2,795	705
Total inventory	<u>\$ 36,815</u>	<u>\$ 30,035</u>

Inventory acquired prior to receipt of marketing approval of a product candidate is expensed as research and development as incurred. The Company begins to capitalize the costs associated with the production of the inventory upon marketing approval of a product candidate.

**(7) Property and Equipment, Net**

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

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Office Equipment	\$ 8,346	\$ 5,519
Laboratory Equipment	223	216
Leasehold Improvements	2,109	2,023
Total property and equipment	<u>10,678</u>	<u>7,758</u>
Less accumulated depreciation	<u>(4,892)</u>	<u>(3,356)</u>
Total equipment, net	<u>\$ 5,786</u>	<u>\$ 4,402</u>

**(8) Leases**

The Company has non-cancelable operating leases for its office space in Bedminster, New Jersey that expire in 2016. The Company also has non-cancelable operating leases for office space in Europe for the expansion of the Company's global business and certain equipment that expire between 2015 and 2016. 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 \$2.6 million, \$1.7 million, and \$1.6 million for 2014, 2013, and 2012, respectively. The future lease payments under non-cancelable operating leases as of December 31, 2014 are as follows (in thousands):

	<b>Operating leases</b>
Year ending December 31:	
2015	\$ 3,154
2016	1,835
2017	4
2018	-
2019	-
Total minimum lease payments	<u>\$ 4,993</u>

**(9) Long-term Debt**

The following table reflects the carrying value of our long-term debt under various financing arrangements as of December 31, 2014 and 2013 (in thousands):

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Convertible notes	\$ -	\$ 16,545
Non-recourse debt	100,006	132,387
Total debt	<u>100,006</u>	<u>148,932</u>
Less current portion	10,252	25,297
Total long-term debt	<u>\$ 89,754</u>	<u>\$ 123,635</u>

**(a) Convertible Notes**

On April 8, 2014, the holders of the 5.75% Convertible Notes converted the remaining outstanding notes at a conversion price of \$5.44 per share. The Company issued 3.0 million shares pursuant to this conversion and retired the remaining \$16.5 million of the outstanding 5.75% Convertible Notes.

**(b) Non-recourse Debt****Sensipar and Mimpara-secured Non-recourse Debt**

As of December 31, 2014 and 2013, the outstanding principal balances on Sensipar and Mimpara-secured debt were \$26.2 million and \$54.4 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.

The Class A Notes were paid in full on March 30, 2011 and 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, 2014, the Company classified \$7.4 million of the Sensipar Notes as current based on royalty payments accrued as of December 31, 2014. The Sensipar Notes are non-recourse to the Company. Accrued interest on the Sensipar Notes was approximately \$286,000 and \$592,000 as of December 31, 2014 and 2013, 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.

#### **PTH 1-84-secured Non-recourse Debt**

As of December 31, 2014 and 2013, the outstanding principal balances on the PTH 1-84-secured debt were \$42.8 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 recombinant human parathyroid hormone 1-84 [rDNA origin] ("PTH") 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.

In December 2013, the Company entered into an amendment and restatement (the "Amendment and Restatement") to its agreement with DRI. Pursuant to the Termination and Transition Agreement between NPS and Takeda (See note 10), NPS' license agreement with Takeda was terminated and NPS re-acquired exclusive rights worldwide, excluding Israel, to develop and commercialize PTH. Preotact is the brand name that Takeda had used to market PTH for the treatment of osteoporosis in certain of its licensed territories. NPS is developing PTH in the U.S. under the trade name Natpara for the treatment of hypoparathyroidism. NPS filed a BLA for Natpara with the FDA in October 2013.

Pursuant to the Amendment and Restatement, (i) DRI has consented to the commercialization of PTH by the Company, (ii) the terms of the 2007 Agreement are tolled, and (iii) the parties' rights and obligations regarding PTH and related technology are governed by the Amendment and Restatement.

The Company will be required to pay royalties in the mid-single digits to DRI based upon sales of PTH by the Company and its licensees (if any) worldwide, excluding Israel. The Company has agreed to undertake certain efforts to commercialize PTH. If the Company does not submit a Marketing Authorization Application to the European Medicines Agency for PTH in the European Union by an agreed upon date, DRI will have the right to revoke the consent granted in the Amendment and Restatement, reinstate the 2007 Agreement, and either cause the Company to enter into a new license agreement with a third party with respect to PTH on terms that are substantially similar and no more extensive (when taken as a whole) than the terms contained in the terminated Takeda License Agreement, or negotiate such an agreement on NPS' behalf.

The Company's obligation to pay royalties to DRI under the Amendment and Restatement shall expire on a country-by-country basis upon the later of (i) the last to expire patent controlled by the Company with claims covering PTH in such country or (ii) the expiration of any period of regulatory exclusivity applicable to PTH in such country. The Company's obligation to pay royalties to DRI under the Amendment and Restatement shall terminate in its entirety once cumulative royalty payments made to DRI by Takeda and the Company total \$125.0 million. As of December 31, 2014, \$45.5 million in royalties had been paid to DRI.

DRI continues to maintain a security interest in NPS patents that contain claims covering PTH and certain other NPS intellectual property related to PTH. In the event of a default by NPS under the Amendment and Restatement, DRI would be entitled to enforce its security interest against NPS and such intellectual property.

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. Accrued interest under the DRI agreement was \$6.2 million and \$0 as of December 31, 2014 and 2013, respectively. The repayment of the remaining \$42.8 million is secured solely by future royalty payments arising from sales of PTH by the Company. The PTH-secured debt is non-recourse to the Company.

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

As of December 31, 2014 and 2013, the outstanding principal balances on REGPARA-secured debt were \$31.0 million and \$35.2 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. As of December 31, 2014 and 2013, the Company classified \$2.8 million and \$1.9 million, respectively, of the REGPARA-secured debt as current based on royalty payments accrued as of December 31, 2014 and 2013, respectively. Accrued interest under the DRI agreement was \$576,000 and \$1.1 million as of December 31, 2014 and 2013, respectively. Through December 31, 2014, \$36.2 million has been paid to DRI. The repayment of the remaining \$31.0 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 15.6%. 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, 2014 are as follows (in thousands):

Year ending December 31:	
2015	\$ 31,964
2016	5,290
2017	4,733
2018	5,177
2019	26,894
Thereafter	25,948
Total long-term debt	<u>\$ 100,006</u>



**(10) Takeda Termination and Transition Agreement**

On March 18, 2013, the Company entered into a Termination and Transition Agreement (the Agreement), with Takeda GmbH (Takeda GmbH), and Takeda Pharma A/S (Takeda Pharma and, together with Takeda GmbH, Takeda).

The Agreement provides for the termination of the license agreement, dated July 2, 2007, as amended, which granted Takeda Pharma the exclusive license to sell, market and commercialize recombinant human parathyroid hormone 1-84 [rDNA origin] (rhPTH 1-84) worldwide, except for the U.S., Israel, and Japan, and a non-exclusive license to manufacture and develop rhPTH 1-84 (the rhPTH 1-84 License Agreement). Pursuant to the rhPTH 1-84 License Agreement the rights were returned to the Company without consideration. Preotact is the brand name that Takeda Pharma has used to market rhPTH 1-84 for the treatment of osteoporosis in certain of its licensed territories. The Company developed rhPTH 1-84 in the U.S. under the trade name Natpara for the treatment of hypoparathyroidism. In January 2015, the FDA approved the Company's second product, Natpara® (parathyroid hormone) for Injection as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism,

The Agreement also provides for the termination of the license agreement, dated September 24, 2007, as amended, which granted Takeda GmbH the exclusive license to develop and commercialize teduglutide worldwide, except for North America and Israel (the Revestive License Agreement). Takeda GmbH developed and obtained approval in the EU in August 2012 for teduglutide under the trade name Revestive for the treatment of Short Bowel Syndrome (SBS) in adults. The Company obtained U.S. Food and Drug Administration approval in the U.S. in December 2012 for teduglutide under the trade name Gattex for adult patients with SBS who are dependent on parenteral support. As a result of the termination of the License Agreements, the Company now has the exclusive rights worldwide to develop and commercialize teduglutide and PTH, except as noted in Note 9.

Takeda assigned to NPS its assets related to the two products, including all of its active pharmaceutical ingredient inventory and information related to the products' continued development, manufacture, and commercialization, including life cycle management assets. Takeda received 6.1 million shares of NPS common stock that were valued at \$54.9 million as of the date of the transaction. Takeda will also earn a \$30.0 million milestone payment in the first calendar year that combined worldwide net sales of both products exceed \$750 million. This milestone includes an early payment trigger upon a qualified change of control. NPS has the option of making this milestone payment in cash or NPS common stock. Pending the closing of the tender offer related to the Merger Agreement, that transaction would be considered a qualifying change in control.

The Company engaged an independent valuation firm to assist it in determining the fair value of the assets acquired. Using these fair values, the Company assigned \$16.6 million to the Revestive active pharmaceutical ingredient (API), \$17.1 million to the PTH API and \$20.7 million to the Revestive product rights. The Company capitalized the Revestive and PTH API as inventory and capitalized the product rights to intangibles, net on the Company's balance sheet due to the fact that Revestive and Preotact are approved in the EU for SBS and Osteoporosis, respectively. The Company is amortizing the Revestive product rights on a straight-line basis over the estimated useful life of approximately 12 years. Through December 31, 2014, \$3.2 million of the Revestive products rights have been amortized and expensed. The estimated amortization expense for each of the next five years is approximately \$1.8 million.

**(11) Capital Stock*****Equity Financing***

In May 2013, the Company completed a public sale of 6,900,000 shares of its common stock at a per share price of \$14.53. Net proceeds to the Company from the sale totaled approximately \$93.5 million, after deducting expenses and the commission in connection with the offering paid by the Company.

***Convertible Debt***

On April 8, 2014, the holders of the 5.75% Convertible Notes converted the remaining outstanding notes at a conversion price of \$5.44 per share. The Company issued 3.0 million shares pursuant to this conversion and retired the remaining \$16.5 million of the outstanding 5.75% Convertible Notes.

**(12) Share-Based Compensation Plans**

As of December 31, 2014, the Company has five 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), the 2014 Omnibus Equity Compensation Plan (the 2014 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, 2014, there are no shares reserved for future grant under the Directors' Plan, the 1998 Plan and the 2005 Plan. As of December 31, 2014, there are 6,504,764 shares reserved for future grant under the 2014 Plan. The Company's 2014 Plan provides for the grant of nonqualified stock options, incentive stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance units, cash-based awards, dividend equivalents and other stock-based awards. Under the Company's 2014 Plan, the exercise price of stock options, the grant price of stock appreciation rights and the initial value of performance awards, will not be less than the fair market value of the Company's common stock on the date of award. Stock options generally vest 25% after year one and 6.25% every three months thereafter. 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 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, 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, 2014, the performance criteria of 884,590 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 \$192,000, \$277,000 and \$1.1 million of compensation expense during the years ended December 31, 2014, 2013 and 2012, respectively, related to these options. The final performance criteria had not been met and therefore the remaining 246,110 options have been forfeited. The Company utilized the Black-Scholes option pricing model to determine the grant date fair value of the awards.

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, 2014, 2013 and 2012, employees purchased 40,120, 72,937 and 45,553 shares, respectively, under the ESPP. The Company has 289,465 shares available for future purchase as of December 31, 2014.

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, 2014, 2013 and 2012 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, 2014, 2013 and 2012 for the Company's stock option plans, the ESPP and other share-based awards (in thousands):

	<b>Years ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Research and development	\$ 5,657	\$ 4,107	\$ 3,343
Selling, general and administrative	9,346	5,330	4,205
Amounts charged against income, before income tax expense	<u>\$ 15,003</u>	<u>\$ 9,437</u>	<u>\$ 7,548</u>

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.

	<b>Years ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Dividend yield	—	—	—
Expected volatility	57.98% — 60.69%	59.15% — 60.69%	61.22% — 67.58%
Risk-free interest rate	1.4% — 1.8%	0.7% — 3.7%	0.6% — 1.1%
Expected term (in years)	5.2 — 5.6	5.2 — 6.0	5.1 — 5.9

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

	<b>Year ended December 31, 2014</b>			
	<b>Number of options</b>	<b>Weighted average exercise price</b>	<b>Weighted average remaining contractual term</b>	<b>Aggregate intrinsic value</b>
	<b>(in thousands)</b>		<b>(in years)</b>	<b>(in thousands)</b>
Options outstanding at beginning of year	6,656	\$ 8.03		
Options granted	1,269	32.80		
Options exercised	1,245	7.48		
Options forfeited/expired	559	11.56		
Options outstanding at end of year	<u>6,121</u>	12.96	7.21	\$ 141,011
Vested and expected to vest	<u>5,838</u>	12.53	7.14	\$ 136,909
Options exercisable at end of year	<u>3,246</u>	\$ 7.16	6.11	\$ 92,865

The weighted-average grant-date fair value of options granted during the years ended December 31, 2014, 2013 and 2012 was \$17.54, \$5.66 and \$4.46, 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, 2014, 2013 and 2012 was \$31.5 million, \$33.4 million and \$2.0 million, 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, 2014, 2013 and 2012, the Company granted 7,136, 35,097 and 20,334 deferred stock units, respectively, to directors for services, which did not contain any vesting restrictions. During the years ended December 31, 2014, 2013 and 2012, the Company granted 27,432, 75,940 and 106,575 restricted stock units, respectively, to directors for services, which vest over one year. At December 31, 2014, there are 649,642 deferred stock units outstanding. During the years ended December 31, 2014, 2013 and 2012 the Company granted to employees 328,916, 317,212 and 307,720 shares of restricted stock, respectively, which will vest over a period of one to three years. During the years ended December 31, 2014, 2013 and 2012 the Company granted to employees 30,412, 141,507 and 0 shares of restricted stock, respectively, which have certain performance criteria that is set by the Compensation Committee. If the performance criteria is met, the awards 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, 2014, is indicated in the following table (shares in thousands, except per share amounts):

	<b>Number of shares</b>	<b>Weighted-average grant date fair value</b>
Nonvested at beginning of year	752	\$ 8.89
Granted	394	31.07
Vested	(229)	9.19
Forfeited	(59)	12.40
Nonvested at December 31, 2014	<u>858</u>	<u>\$ 18.75</u>

As of December 31, 2014, there was \$23.2 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 2.82 years.

### (13) Income Taxes

The components of loss before income taxes for the years ended December 31, 2014, 2013 and 2012 includes the following (in thousands):

	<b>Years ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
United States	\$ 36,829	\$ (9,748)	\$ (18,735)
Foreign	(44,768)	(3,574)	-
Loss before income taxes	<u>\$ (7,939)</u>	<u>\$ (13,322)</u>	<u>\$ (18,735)</u>

The Company has recorded income tax expense for the years ended December 31, 2014, 2013 and 2012 of \$766,000, \$182,000, and \$0, respectively. The income tax expense for the year ended December 31, 2014 was primarily related to state income taxes and other non-U.S. income taxes and the income tax expense for the year ended December 31, 2013 was primarily related to a non-cash charge for state income taxes.

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):

	<b>Years ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Computed "expected" tax benefit	\$ (2,699)	\$ (4,529)	\$ (6,370)
IRC §382 adjustment	-	6,575	59,822
Change in the valuation allowance for deferred tax assets attributable to operations and other adjustments	(7,158)	2,840	(42,124)
Research credit	(9,217)	(12,237)	(10,231)
State income taxes, net of federal tax effect	527	182	-
Equity based compensation expense	1,310	678	513
Intercompany license of intellectual property	-	5,440	-
Foreign tax rate differences	15,358	940	-
Non-recourse debt	2,056	(78)	(1,663)
Other	589	371	53
	<u>\$ 766</u>	<u>\$ 182</u>	<u>\$ -</u>

The tax effects of temporary differences that give rise to the deferred tax assets at December 31, 2014 and 2013 are presented below (in thousands):

	<b>2014</b>	<b>2013</b>
Deferred tax assets:		
Net operating loss carryforward	\$ 109,751	\$ 132,101
Research credit carryforward	82,633	68,277
Capital loss carryforward	4,101	4,186
Non-recourse debt	26,060	27,769
Acquired intellectual property	26,344	29,452
Capitalization of inventory	11,021	9,429
Stock compensation expense	4,479	2,935
Accrued compensation	3,269	3,117
Other	697	555
Total deferred tax assets	<u>268,355</u>	<u>277,821</u>
Less valuation allowance	<u>(268,355)</u>	<u>(277,821)</u>
Deferred tax assets	-	-
Deferred tax liabilities	-	-
Net deferred tax asset (liability)	<u>\$ -</u>	<u>\$ -</u>

### *Carryforwards*

At December 31, 2014, the Company had U.S. federal net operating loss carryforwards of approximately \$348.9 million which begin to expire in 2018, U.S. federal research credit carryforwards of \$82.6 million, which begin to expire in 2030, and U.S. federal capital loss carryforwards of \$10.7 million which begin to expire in 2015. 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 \$337.5 million and \$15.3 million, respectively, which begin to expire in 2015, and other domestic state net operating loss carryforwards and tax credit carryforwards in varying amounts depending on the different state laws.

The Company uses the "with-and-without" approach in determining the order in which tax attributes are utilized. Using the "with-and-without" approach, the Company will only recognize a tax benefit from stock-based awards in additional paid-in capital if an incremental tax benefit is realized after all other net operating loss carryforwards currently available to the Company have been utilized, but prior to the utilization of other tax attributes.

The U.S. federal net operating loss carryforwards of approximately \$348.9 million include approximately \$10.1 million of excess tax benefits related to share-based payments that are presented on a tax effected basis within the deferred tax assets. Since this amount was recorded through additional paid-in capital, the related valuation allowance on these net operating loss carryforwards will be reversed through additional paid-in capital when these excess tax benefits are realized. Also, included in the U.S. federal net operating loss carryforwards are excess tax benefits related to share-based payments of approximately \$51.8 million that are not recognized as a deferred tax asset as the amounts would not have resulted in a reduction in current taxes payable if all other net operating loss carryforwards currently available to the Company were utilized. The benefit of these deductions will be recognized through additional paid-in capital at the time the tax deduction results in a reduction of current taxes payable.

Section 382 of the Internal Revenue Code can potentially limit a company's ability to use net operating loss, tax credits, capital loss, and other tax attributes in periods subsequent to a change in ownership. The Company periodically updates 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. As a result, the Company determined that certain net operating loss, tax credit and capital loss carryforwards will expire prior to their utilization due to the expected annual Section 382 limitation, and accordingly the net operating loss, tax credit, and capital loss carryforwards on the above deferred tax asset table have been reduced.

#### *Valuation Allowance*

The Company determines the need for a valuation allowance by assessing the probability of realizing deferred tax assets, taking into consideration all available positive and negative evidence, including historical operating results, expectations of future taxable income, carryforward periods available to the Company for tax reporting purposes, various income tax strategies and other relevant factors. Significant judgment is required in making this assessment and to the extent future expectations change, the Company would have to assess the recoverability of its deferred tax assets at that time.

At December 31, 2014 and 2013, the Company maintained a full valuation allowance on its deferred tax assets. The Company has a history of cumulative losses. The Company's cumulative loss position was significant negative evidence in assessing the need for a valuation allowance. The valuation allowance for deferred tax assets decreased by \$9.5 million in 2014 and increased by \$215,000 in 2013.

#### *Unrecognized Tax Benefits*

A reconciliation of the beginning and ending amounts of gross unrecognized tax benefits (excluding interest and penalties) is as follows (in thousands):

	<b>Unrecognized Tax Benefits</b>
Balance as of January 1, 2013	\$ 4,614
Additions for current year tax positions	-
Reductions for prior year tax positions	(677)
Balance as of December 31, 2013	3,937
Additions for current year tax positions	-
Reductions for prior year tax positions	-
Balance as of December 31, 2014	\$ 3,937

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 reasonably possible that the balance of gross unrecognized tax benefits will not 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.

Due to the Company's net operating loss carryforwards, any adjustment related to an unrecognized tax benefit would not be expected to result in a cash tax liability. Accordingly, the Company has not accrued for interest or penalties for the U.S. (both Federal and State) as of December 31, 2014 and 2013. Assuming the continued existence of a full valuation allowance on the Company's 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 the United States and various foreign jurisdictions. Of the major jurisdictions, the Company is subject to examination in: the United States for U.S. federal purposes for 2011 and forward and for New Jersey for 2011 and forward. 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. In May 2013, the State of New Jersey completed its examination of the Company's New Jersey income tax returns through the year ended December 31, 2010. There were no adjustments as a result of these examinations.

#### **(14) 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, 2014, 2013 and 2012, 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, 2014, 2013, and 2012 of \$1.6 million, \$1.1 million and \$620,000, respectively.

#### **(15) 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 May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers," which requires entities to recognize revenue in the way it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most of the existing revenue recognition requirements in U.S. GAAP when it becomes effective. This pronouncement is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period and is to be applied retrospectively, with early application not permitted. The Company is currently evaluating the effect that this pronouncement will have on its financial statements and related disclosures.

#### **(16) 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 \$17.4 million with external marketing, commercial readiness and market research organizations relating to pre-launch activities for Revestive and Natpara. These agreements are cancellable on notice of up to six months. The Company also has approximately \$43.2 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 \$ / 5. / million for drug substance, drug product and other manufacturing processes as of December 31, 2014 for the manufacture of clinical and commercial supplies of Gattex/Revestive 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, 2014, 2013 and 2012 were \$14.8 million, \$15.0 million and \$25.9 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 Canadian \$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 (\$5.1 million at December 31, 2014).

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

The following is a summary of the quarterly results of operations for the years ended December 31, 2014 and 2013 (in thousands, except for per share amounts):

	<b>Quarters Ended</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
<b>(in thousands, except per share amounts)</b>				
<b>2014</b>				
Revenues	\$ 44,040	\$ 56,127	\$ 57,200	\$ 66,695
Operating (loss) income	(2,948)	5,790	1,351	857
Net (loss) income	(6,576)	1,992	(2,146)	(1,975)
Basic (loss) income per common share	\$ (0.06)	\$ 0.02	\$ (0.02)	\$ (0.02)
Diluted (loss) income per common and potential common share	\$ (0.06)	\$ 0.02	\$ (0.02)	\$ (0.02)
<b>2013</b>				
Revenues	\$ 25,434	\$ 36,505	\$ 39,202	\$ 54,451
Operating (loss) income	(4,531)	(9,321)	1,769	10,588
Net (loss) income	(7,796)	(12,389)	(1,087)	7,768
Basic (loss) income per common share	\$ (0.09)	\$ (0.13)	\$ (0.01)	\$ 0.08
Diluted (loss) income per common and potential common share	\$ (0.09)	\$ (0.13)	\$ (0.01)	\$ 0.07

### 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, 2014.

***(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, 2014. 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 (2013)*. Based on our assessment we believe that, as of December 31, 2014, 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, 2014. This report appears on page 65 of this report.

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

On January 1, 2014, the Company adopted the Committee of Sponsoring Organizations new internal control framework ("COSO 2013"), which did not have a material impact on the Company's disclosure controls and procedures and internal controls over financial reporting. Other than the adoption of COSO 2013, 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 2015 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 2015 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 2015 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 2015 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 2015 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>
2.1	Termination and Transition Agreement, dated as of March 18, 2012, by and among Takeda GmbH, Takeda Pharma A/S and the Registrant, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed March 19, 2013.
2.2	Agreement and Plan of Merger, dated as of January 11, 2015, among NPS Pharmaceuticals, Inc., Shire Pharmaceutical Holdings Ireland Limited, Knight Newco 2, Inc. and Shire plc, incorporated herein by reference to the Registrant's Current Report on Form 8-K, filed January 12, 2015.

- 3.1A Amended and Restated Certificate of Incorporation of the Registrant, incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-74318), filed January 21, 1994.
- 3.1B Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated December 16, 1999, incorporated herein by reference to the Registrant's Registration Statement on Form S-3 (SEC File No. 333-45274), filed September 6, 2000.
- 3.1C Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated September 30, 2003, 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), filed February 10, 2004.
- 3.1D Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated May 19, 2011, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed May 24, 2011.
- 3.2 Amended and Restated Bylaws of the Registrant, incorporated herein by reference to the Registrant's Current Report on Form 8-K, filed January 12, 2015.
- 3.3A Certificate of Designation of Series A Junior Participating Preferred Stock of the Registrant, dated December 18, 1996, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed December 19, 1996.
- 3.3B Amendment to Certificate of Designation of Series A Junior Participating Preferred Stock of the Registrant, dated September 5, 2000, incorporated herein by reference to the Registrant's Registration Statement on Form S-3 (SEC File No. 333-45274), filed September 6, 2000.
- 4.1 Specimen Common Stock Certificate, incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-74318), filed January 21, 1994.
- 4.2 Indenture, dated as of August 8, 2013, between the Registrant and The Bank of New York Mellon, as trustee, incorporated herein by reference to the Registrant's Registration Statement on Form S-3 (SEC File No. 333-190494), filed August 8, 2013.
- 10.1A\*\* 1998 Stock Option Plan (reflects all amendments by the Board of Directors through May 2008), incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed May 28, 2008.
- 10.1B\*\* Form of Performance-Based Stock Option Agreement under the NPS Pharmaceutical, Inc. 1998 Stock Option Plan, 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), filed March 16, 2009.
- 10.2\*\* Form of Indemnity Agreement entered into between the Registrant and each of its officers and directors, incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-74318), filed January 21, 1994.
- 10.3\*\* Change in Control Severance Pay Plan, as amended, incorporated herein by reference to the Registrant's Current Report on Form 8-K, filed January 12, 2015.
- 10.4A Collaborative Research and License Agreement between the Registrant and SmithKline Beecham Corporation (now GlaxoSmithKline), dated November 1, 1993, incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-74318), filed January 21, 1994.



10.4B

Amendment Agreement to Collaborative Research and License Agreement between GlaxoSmithKline, effective June 29, 1995, 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), filed March 29, 1996.

10.4C

Amendment Agreement between the Registrant and GlaxoSmithKline, dated October 28, 1996, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed December 19, 1996.

10.4D

Amendment Agreement between the Registrant and GlaxoSmithKline, dated October 27, 1997, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed January 27, 1998.

10.4E

Amendment to Collaborative Research and License Agreement between the Registrant and GlaxoSmithKline, dated November 26, 1997, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed January 27, 1998.

10.4F

Letter, dated January 24, 2000, from SmithKline Beecham to the Registrant Re: Amendment Agreement to Amend the November 26, 1997 Amendment Agreement, 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), filed March 21, 2003.

10.4G

Letter, dated May 15, 2000, from SmithKline Beecham to the Registrant Re: Amendment Agreement, 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), filed March 21, 2003.

10.4H

Letter, dated August 1, 2001, from GlaxoSmithKline to the Registrant Re: Amendment Agreement to Amend the January 24, 2000 Amendment Agreement, 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), filed March 21, 2003.

10.4I

Amendment Agreement between the Registrant and SmithKline Beecham Corporation (d/b/a GlaxoSmithKline), dated December 14, 2006, 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), filed March 14, 2007.

10.4J\*

Exclusive Patent License Agreement between the Registrant and GlaxoSmithKline LLC dated July 29, 2011, 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), filed November 3, 2011.

10.5A

Patent Agreement between the Registrant and The Brigham and Women's Hospital, Inc., dated February 19, 1993, incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-74318), filed January 21, 1994.

10.5B

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., 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), filed March 21, 2003.

10.5C

Amendment to Patent Agreement between the Registrant and The Brigham and Women's Hospital, Inc., effective February 7, 1996, 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), filed March 29, 1996.

10.5D

1999 Patent Agreement Amendment between the Registrant and The Brigham and Women's Hospital, Inc., effective February 18, 1999, 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), filed March 21, 2003.



- 10.0 Collaborative Research and License Agreement between the Registrant and Kirin Brewery Company, Ltd. dated June 29, 1995, 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).
- 10.7\* Development and License Agreement between the Registrant (conformed copy through Fifth Amendment, dated as of June 29, 2012), incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed February 18, 2014.
- 10.8A\*\* 2005 Omnibus Incentive Plan, as amended through May 18, 2011, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed May 24, 2011.
- 10.8B\*\* 2005 Omnibus Incentive Plan, as amended through May 7, 2013, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed May 9, 2013.
- 10.8C\*\* Form of Stock Option Grant Agreement, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed February 13, 2013.
- 10.8D\*\* Form of Restricted Stock Unit Agreement for Non-Employee Directors, Incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed February 13, 2013.
- 10.8E\*\* Form of Restricted Stock Unit Agreement for Employees, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed February 13, 2013.
- 10.8F\*\* Form of Restricted Stock Unit Agreement for Employees, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed February 13, 2013.
- 10.8G\*\* Form of Restricted Stock Unit Agreement for Employees, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed February 13, 2013.
- 10.8H\*\* Non-Employee Director Compensation Program, 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), filed May 3, 2012.
- 10.9A\*\* Non-Employee Director Deferred Compensation Program, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed July 1, 2005.
- 10.9B\*\* Form of Deferred Stock Unit Award Agreement, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed July 1, 2005.
- 10.10\* License Agreement, dated September 28, 1995, between 1149336 Ontario Inc., Daniel J. Drucker, and Allelix Biopharmaceuticals Inc., 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), filed November 9, 2007.
- 10.11 Asset Purchase Agreement, dated October 9, 2007, between AstraZeneca AB and the Registrant, 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), filed March 17, 2008.
- 10.12A\* Commercial Manufacturing Agreement, dated October 18, 2002, by and between NPS Allelix Corp. and Boehringer Ingelheim Austria GmbH, 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), filed March 17, 2008.

- 10.12B\* Amending Agreement, dated March 15, 2004, by and between NPS Allelix Corp. and Boehringer Ingelheim Austria GmbH, 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), filed March 17, 2008.
- 10.12C\* Amendment Number One to Amending Agreement, dated December 22, 2005, by and between NPS Allelix Corp. and Boehringer Ingelheim Austria GmbH, 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), filed March 17, 2008.
- 10.12D\* Amendment Number Two to Amending Agreement, dated August 28, 2007, by and between NPS Allelix Corp. and Boehringer Ingelheim Austria GmbH, 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), filed May 3, 2011.
- 10.12E\* Letter Agreement, dated January 19, 2009, by and between the Registrant and Boehringer Ingelheim Austria GmbH, 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), filed May 3, 2011.
- 10.12F\* Amendment Number Three to Amending Agreement, dated February 1, 2011, by and between the Registrant and Boehringer Ingelheim Austria GmbH, 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), filed May 3, 2011.
- 10.13A\*\* Employment Agreement with Francois Nader, 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), filed May 19, 2008.
- 10.13B\*\* First Amendment to the Employment Agreement with Francois Nader, 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), filed March 16, 2009.
- 10.13C\*\* Second Amendment to the Employment Agreement with Francois Nader, 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), filed March 16, 2009.
- 10.14\*\* First Amendment to Restrictive Covenant Agreement with Francois Nader, 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), filed May 19, 2008.
- 10.15\*\* Employment Agreement with Roger Garceau, 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), filed March 16, 2009.
- 10.16\* Agreement for Sale and Assignment of Rights, dated February 26, 2010, between the Registrant and LSRC II S.ÀR.L., 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), filed March 11, 2010.
- 10.17\*\* NPS Pharmaceuticals, Inc. 2010 Employee Stock Purchase Plan, incorporated herein by reference to the Registrant's Current Report on Form 8-K (SEC File No. 000-23272), filed May 24, 2010.
- 10.18A\* Development and Supply Agreement between the Registrant and Hospira Worldwide, Inc. dated March 25, 2009, 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), filed May 3, 2011.





- 10.18B\*\* First Amendment to Development and Supply Agreement, effective as of May 14, 2014, by and between Hospira Worldwide, Inc. and the Registrant, incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014, filed November 10, 2014.
- 10.19\*\* Amended and Restated Employment Agreement with Eric Pauwels dated May 6, 2014, incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014, filed May 8, 2014.
- 10.20\* Manufacturing Agreement between the Registrant and SynCo Bio Partners B.V., dated August 1, 2009, 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), filed November 3, 2011.
- 10.21\* Commercial Manufacturing Agreement between the Registrant and Vetter Pharma International GmbH dated December 21, 2009, incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2012 (SEC File No. 000-23272), filed November 9, 2012.
- 10.22\* Amended and Restated Agreement for the Sale and Assignment of Rights, dated as of December 20, 2013, by and between the Registrant and Drug Royalty L.P. 3, incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed February 18, 2014.
- 10.23\*\* Offer Letter of Susan Graf, dated as of April 29, 2013, incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed February 18, 2014.
- 10.24\* Contract Manufacturing and Supply Agreement, dated as of September 7, 2012, by and between Patheon UK Limited and the Registrant, as assignee of Takeda GmbH (f/k/a Nycomed Danmark ApS), incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed February 18, 2014.
- 10.25\*\* NPS Pharmaceuticals, Inc. 2014 Omnibus Equity Compensation Plan, incorporated herein by reference to the Registrant's Current Report on Form 8-K, filed May 7, 2014.
- 10.26\*\* Form of Incentive Stock Option Award Agreement, incorporated herein by reference to the Registrant's Current Report on Form 8-K, filed May 7, 2014.
- 10.27\*\* Form of Nonqualified Stock Option Award Agreement, incorporated herein by reference to the Registrant's Current Report on Form 8-K, filed May 7, 2014.
- 10.28\*\* Form of Restricted Stock Unit Award Agreement, incorporated herein by reference to the Registrant's Current Report on Form 8-K, filed May 7, 2014.
- 10.29\*\* NPS Pharmaceuticals, Inc. Deferred Compensation Plan, incorporated herein by reference to the Registrant's Current Report on Form 8-K, filed May 7, 2014.
- 10.30\*\* Employment Agreement with Christine Mikail, dated January 30, 2014, incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014, filed May 8, 2014.
- 10.31\*\* Offer Letter with Robin Friedman dated January 30, 2014, incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014, filed May 8, 2014.
- 10.32\*\* Employment Agreement with Paul Firuta dated March 3, 2014, incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014, filed May 8, 2014.



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
101INS	XBRL Instance Document
101SCH	XBRL Taxonomy Extension Schema Document
101CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101DEF	XBRL Taxonomy Extension Definition Linkbase Document
101LAB	XBRL Taxonomy Extension Label Linkbase Document
101PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ 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.

**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 18, 2015

By: /s/ FRANCOIS NADER

\_\_\_\_\_  
**Francois Nader**  
**President and Chief Executive Officer (Principal**  
**Executive Officer) and Director**

Date: February 18, 2015

By: /s/ LUKE M. BESHAR

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**Luke M. Beshar**  
**Executive Vice President and 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>
/s/ FRANCOIS NADER _____ Francois Nader	President and Chief Executive Officer (principal executive officer) and Director	February 18, 2015
/s/ LUKE M. BESHAR _____ Luke M. Beshar	Executive Vice President and Chief Financial Officer (principal financial and accounting officer)	February 18, 2015
/s/ MICHAEL W. BONNEY _____ Michael W. Bonney	Director	February 18, 2015
/s/ COLIN BROOM _____ Colin Broom	Director	February 18, 2015
/s/ GEORGES GEMAYEL _____ Georges Gemayel	Director	February 18, 2015

/s/ PEDRO GRANADILLO _____ Pedro Granadillo	Director	February 18, 2015
/s/ JAMES G. GRONINGER _____ James G. Groninger	Director	February 18, 2015
/s/ PIERRE LEGAULT _____ Pierre Legault	Director	February 18, 2015
/s/ RACHEL R. SELISKER _____ Rachel R. Selisker	Director	February 18, 2015
/s/ PETER G. TOMBROS _____ Peter G. Tombros	Chairman of the Board of Directors	February 18, 2015

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