

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, 2008

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, 3rd Floor, Bedminster, NJ**

(Address of Principal Executive Offices)

**(908) 450-5300**

(Registrant's Telephone Number, Including Area Code)

**07921**

(Zip Code)

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

Title Of Each Class	Name Of Each Exchange On Which Registered
<b>Common Stock, \$.001 Par Value Per Share</b>	<b>The NASDAQ Stock Market LLC</b>
<b>Preferred Share Purchase Rights</b>	<b>(NASDAQ Global Market)</b>

**Securities registered pursuant to Section 12(g) of the Act: None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES  NO

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act. YES  NO

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

Indicate by check mark 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

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 \$212,272,974 as of June 30, 2008, based upon the closing price for the shares of common stock reported on The NASDAQ Global Market on such date.

As of March 5, 2009, there were 47,507,171 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 2009 Annual Meeting of Stockholders, which it intends to file with the Commission not later than 120 days after December 31, 2008, are incorporated by reference in Part III of this Form 10-K.

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## PART I

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

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

### ITEM 1. Business

#### Overview

We are a biopharmaceutical company focused on the development of new treatment options for patients with rare gastrointestinal and endocrine disorders and serious unmet medical needs. Our lead clinical programs involve two proprietary therapeutic proteins to restore or replace biological function: GATTEX™ (teduglutide) and NPSP558 (parathyroid hormone 1-84 [rDNA origin] injection). GATTEX is our analog of GLP-2, a protein involved in the regeneration and repair of the intestinal lining, and is in Phase 3 clinical development for parenteral dependent (PN) short bowel syndrome (SBS). SBS is a highly disabling condition that results from surgical resection, congenital defect or disease-associated loss of absorption and the subsequent inability to maintain fluid, electrolyte, and nutrient balances on a conventional diet. NPSP558 is our recombinant full-length human parathyroid hormone (PTH 1-84) that is in Phase 3 clinical development for hypoparathyroidism, a rare condition in which the body does not maintain normal calcium levels in the blood due to insufficient levels of parathyroid hormone. As described further herein, we previously developed this compound as PREOS® for osteoporosis.

We are currently advancing registration studies for GATTEX and NPSP558. Our study of GATTEX is known as STEPS (Study of TEduglutide in PN-dependent Short bowel syndrome) and our study of NPSP558 is known as REPLACE (REcombinant Parathyroid hormone to normaLize cAlcium and trEat hypoparathyroidism). We believe positive results from STEPS and REPLACE will enable us to seek U.S. marketing approval of GATTEX for SBS and NPSP558 for hypoparathyroidism. While SBS and hypoparathyroidism are relatively rare disorders, we believe they represent a substantial commercial opportunity to us due to the significant unmet need and lack of effective therapies, as well as the serious complications and chronic nature of these diseases.

We have collaborations or royalty agreements with a number of pharmaceutical companies. In 2008, we reported strong growth in our royalty revenue which was driven (i) primarily by Amgen’s sales of Sensipar® (cinacalcet HCl), (ii) by Nycomed’s sales of Preotact®, which is our PTH 1-84 that is approved for the treatment of osteoporosis in the European Union, and (iii) by Kyowa Kirin’s sales of REGPARA® (cinacalcet HCl) in Japan. As described further herein, we have non-recourse debt that is secured by our royalty rights related to Sensipar under our agreement with Amgen and we have sold our right to receive royalty payments under our agreement with Nycomed arising from sales of Preotact. We also have clinical-stage partnerships that may provide future milestone payments and royalties. For instance, in 2007, we granted Nycomed the rights to develop and market teduglutide outside of North America and are collaborating with Nycomed and sharing costs for the STEPS study.

#### Strategy

The three key elements of our business strategy are described below.

*Build a pipeline of specialty therapeutics for unmet medical needs.* Our internal clinical development programs focus on indications with few, if any, therapeutic options and limited competition. Patients with these rare disorders are typically treated by physician specialists. We are also mitigating our exposure to any one product or program and maintaining the flexibility to allocate resources to or accelerate the development of our most promising programs. We believe this strategy will help us create a balanced product portfolio that can be successfully commercialized through a focused and specialized sales team.

*Utilize outsourcing partners to optimize resources and limit financial exposure.* We believe this component of our strategy is an efficient and cost effective approach to our business that blends traditional outsourcing with collaborations that enhance our organization’s internal capabilities. We are applying this model to all areas of our business. Rather than investing substantial resources in building and maintaining infrastructure, we are complementing our internal knowledge base by collaborating with outside contractors who have established technological, clinical, regulatory, and commercial expertise. By blending internal and external innovation, we expect to optimize each stage of our clinical development and effectively manage our resources, risk, and time-to-market for our key clinical programs.

*Collaborate or license to manage risk and accelerate the development and commercialization of product candidates.* We believe that collaborating with pharmaceutical and biotechnology companies with relevant expertise in areas that are outside of our proprietary therapeutic or geographic focus will accelerate the development and commercialization of our products. We also selectively pursue new product development opportunities in indications that are complementary to our proprietary programs. This strategy allows us to allocate our resources to programs that we believe have an appropriate probability of development and commercial success while matching our financial capabilities.

### **Proprietary Product Candidates and Royalty-Based Agreements**

The table below summarizes our proprietary product pipeline, as well as certain royalty-based agreements.

<b>Product/Product Candidate</b>	<b>Indication</b>	<b>Status</b>	<b>Market</b>	<b>Rights</b>
<b><u>Proprietary Product Candidates:</u></b>				
GATTEX™ (teduglutide)	SBS	Phase 3	N. America	Proprietary
NPSP558 (parathyroid hormone 1-84 )	Hypoparathyroidism	Phase 3	N. America	Proprietary
PREOS® (parathyroid hormone 1-84)	Osteoporosis <sup>1</sup>	Phase 3	N. America	Proprietary
Teduglutide	Crohn’s disease <sup>1</sup>	Phase 2	N. America	Proprietary
Glycine reuptake inhibitors	CNS <sup>1</sup>	Phase 1	N. America	Proprietary
Teduglutide	Pediatric indications	Preclinical	N. America	Proprietary
Teduglutide	GI mucositis	Preclinical	N. America	Proprietary
NPSP156	CNS <sup>1</sup>	Preclinical	N. America	Proprietary
<b><u>Royalty-Based Agreements:</u></b>				
Sensipar®/Mimpara® (cinacalcet HCl) <sup>2</sup>	Secondary hyperparathyroidism	Market	Worldwide Ex-Asia	Amgen
Sensipar® (cinacalcet HCl) <sup>2</sup>	Hypercalcemia in parathyroid cancer	Market	Worldwide Ex-Asia	Amgen
Regpara® (cinacalcet HCl)	Secondary hyperparathyroidism	Market	Asia	Kyowa Kirin
Preotact® (parathyroid hormone 1-84 [rDNA origin] injection) <sup>2</sup>	Osteoporosis	Market	Worldwide Ex-U.S., Ex-Israel, Ex-Japan <sup>3</sup>	Nycomed
Teduglutide	SBS	Phase 3	Worldwide Ex-N. America	Nycomed
Cinacalcet HCl	Primary hyperparathyroidism	Phase 2	US/EU	Amgen
Ronacaleret (calcilytic compound) <sup>4</sup>	Osteoporosis and related bone disorders	Phase 2	Worldwide	GlaxoSmithKline

<sup>1</sup> This indication is outside of our core focus and we have designated it as an out-licensing or partnering opportunity

<sup>2</sup> We currently do not receive cash payments related to our Sensipar and Preotact royalties as these payments service non-recourse debt

<sup>3</sup> If we receive U.S. approval for NPSP558, Nycomed’s license in Canada and Mexico reverts to us or a licensee

- 4 In September 2008, GSK terminated its Phase 2 dose-range finding study in osteoporosis due to an observed lack of efficacy. GSK is analyzing the full results of the study and has not yet determined the ongoing development program of ronacaleret and other calcilytics under this agreement

## **Proprietary Product Candidates**

We are currently advancing two Phase 3 registration studies, a study of GATTEX in short bowel syndrome (SBS) and a study of NPSP558 in hypoparathyroidism. These double-blind, placebo-controlled safety and efficacy studies are known as STEPS (Study of TEduglutide in Parenteral nutrition dependent Short-bowel syndrome) for GATTEX and REPLACE (REcombinant Parathyroid hormone (NPSP558) to normaLize cAlCium and trEat hypoparathyroidism) for NPSP558. We believe positive results from STEPS and REPLACE will enable us to seek U.S. marketing approval for these indications. We are also advancing preclinical studies for teduglutide in other intestinal failure-related conditions, namely complications associated with preterm births, such as PN-dependent pediatric SBS or feeding intolerance, and gastrointestinal mucositis. In addition, we are pursuing out-licensing arrangements for compounds or indications within our portfolio that are outside of our proprietary therapeutic or geographic focus, including product candidates with therapeutic potential for central nervous system disorders and rights in certain Asian territories.

### *GATTEX (teduglutide)*

GATTEX is the brand name for teduglutide, our proprietary analog of naturally occurring human glucagon-like peptide 2 (GLP-2), a peptide secreted primarily in the distal intestine and involved in the regeneration and repair of the intestinal epithelium. Preclinical and clinical studies have demonstrated that GATTEX stimulates the repair and regeneration of cells lining the small intestine, expanding the surface area for absorption of nutrients. Given GATTEX's mechanism of action to promote gastrointestinal repair, we believe it has the potential to treat gastrointestinal conditions associated with intestinal failure. Intestinal failure is characterized by the inability to maintain protein-energy, fluid, electrolyte or micronutrient balances when on a conventionally accepted normal diet and typically results from obstruction, dysmotility, surgical resection, congenital defect or disease-associated loss of absorption.

We are developing GATTEX for commercialization in North America and we have licensed to Nycomed the right to develop and commercialize GATTEX in all other regions. We discuss the license agreement in further detail below under the captions "Royalty-Based Products and Product Candidates."

Our most advanced program for GATTEX is in Phase 3 clinical testing in patients with short bowel syndrome who are PN-dependent. We previously reported positive findings from completed studies in which GATTEX demonstrated a favorable safety profile and significant reductions in mean PN volume from pretreatment baseline were observed.

SBS is a highly disabling condition that can impair quality of life and lead to serious life-threatening complications. SBS typically arises after extensive resection of the bowel due to Crohn's disease or other conditions. SBS patients often suffer from malnutrition, severe diarrhea, dehydration, fatigue, osteopenia, and weight loss due to a loss in the ability to absorb adequate amounts of nutrients and water. The goals of current treatment are to maintain fluid electrolyte, and nutrient balances through dietary management, including the use of PN.

### *SBS Market Opportunity*

Scientific journal articles and our own market studies indicate there are 10,000 to 15,000 SBS patients in North America who are PN-dependent, the cost of which can exceed \$100,000 annually per patient. Currently, only somatropin (rDNA origin) for injection (human growth hormone) and glutamine when used in conjunction with a recombinant human growth hormone are FDA-approved treatments for SBS in patients receiving specialized nutritional support and are limited to only four weeks of therapy. We believe the SBS market is attractive because of the lack of effective drug therapies in this rare indication, the high cost of PN, the serious complications and morbidities associated with PN, and the clinical benefits and improvements in quality of life that we believe patients will experience with GATTEX therapy.

We have received orphan drug designation for GATTEX from the FDA for SBS, which provides a seven-year period of exclusive marketing after approval, subject to several restrictions. The European Medicines Agency (EMA) has also designated GATTEX as an orphan medicinal product for the treatment of SBS offering similar exclusive marketing rights.

#### *GATTEX for SBS*

Preclinical and clinical studies have demonstrated that GATTEX stimulates the repair and regeneration of cells lining the small intestine, expanding the available surface area for absorption of nutrients. In animal models of small bowel resections, the administration of GATTEX resulted in increased mucosal and total weight, crypt-villus height, and D-xylose absorption while restoring the adaptive capacity post-resection. Additionally, in PN-induced atrophy animal studies, the administration of GATTEX prevented PN-induced atrophy when administered prior to or with PN and restored the intestinal integrity.

In December 2008, patient enrollment began in a Phase 3 registration study to confirm previously reported data that demonstrated GATTEX was well tolerated and reduced PN dependence in SBS patients. The international, double-blind, placebo-controlled safety and efficacy study of GATTEX is known as STEPS (Study of TEDuglutide in PN-dependent Short-bowel syndrome). STEPS was designed with input from the U.S. Food and Drug Administration (FDA) and we believe positive results will enable us to seek U.S. marketing approval for GATTEX for patients with PN-dependent SBS. We are advancing STEPS with the support of our partner Nycomed with whom we are sharing external costs for the study.

STEPS will enroll approximately 86 PN-dependent SBS patients in North America and Europe. The trial includes an initial four to 16 week PN optimization and stabilization period, after which patients will be randomized 1:1 to compare daily subcutaneous dosing of 0.05 mg/kg of GATTEX to placebo over a 24-week treatment period. The primary efficacy endpoint is the percentage of patients who achieve a 20 percent or greater reduction in weekly PN volume at week 20 and maintain that response at week 24, when compared to baseline. The study's secondary objectives will evaluate efficacy variables based on reductions in PN volume or the direct effects of improved intestinal absorption of fluid. These variables include: duration of response (total number of weeks at greater than or equal to 20 percent reduction from baseline); the proportion of patients with a 20 percent or greater reduction or a two liter or greater reduction from baseline in weekly PN at week 20 and maintained through week 24; the number of patients who discontinue PN, including the time of discontinuation; and the absolute and percentage change in PN.

In October 2007, we reported results from a Phase 3 study of GATTEX in which 83 patients with SBS received a low dose of GATTEX (0.05 mg/kg/day), a higher dose (0.10 mg/kg/day) or placebo. The clinical efficacy endpoint of the study was a reduction in PN of at least 20 percent comparing baseline to weeks 20 to 24, measured as a graded response to capture reductions up to 100 percent. In an intent-to-treat analysis, forty-six percent (46%) of patients receiving the lower dose of GATTEX (n=35) responded and achieved a significant reduction in PN compared to placebo (p=0.007). Twenty-five percent (25%) of patients receiving the higher dose of GATTEX (n=32) responded and showed a trend in the difference between the treatment group and placebo, but this did not reach statistical significance (p=0.161). Two low-dose patients gained independence from and discontinued PN by week 16 and a high-dose patient discontinued PN at the end of treatment. The study's criteria for conducting the statistical analysis of the primary endpoint required that the results for the high-dose group show statistical significance before the results of the low-dose group could be considered. These results were presented at the 2008 annual Digestive Disease Week (DDW) Congress. Given GATTEX's orphan designation in SBS and the statistically strong (p=0.007) and clinically meaningful findings in the low-dose group, we met with the FDA to discuss the regulatory requirements for the development of GATTEX for SBS. During our meeting, the FDA recommended that we conduct a confirmatory Phase 3 study prior to submitting a new drug application (NDA). We plan to initiate this study and are currently finalizing a protocol that will incorporate the FDA's input, as well as the results from our Phase 3 extension study which is discussed below.

Sixty-five of the 71 patients (91 percent) of the patients who completed the pivotal Phase 3 study elected to enroll in a Phase 3-extension study. In the extension phase, patients already on GATTEX continued to receive the dose they were already receiving for an additional 28 weeks, for a total of 52 weeks of treatment, and patients who were on placebo were randomized to one of the two GATTEX doses (0.05 mg/kg/day or 0.10 mg/kg/day). The objective of the extension study was to evaluate the long-term safety and efficacy of daily dosing of GATTEX as well as its impact on reductions in PN. The results demonstrated that GATTEX was well tolerated out to one year and provided the ability to safely reduce PN dependence. The three patients who gained independence from PN during the first 24 weeks of therapy remained off PN at week 52 and one additional patient was weaned from PN during the 28-week extension

phase. These patients remained PN-independent for periods ranging from 0.5 to 3.5 years. To assess the crypt-villus architecture, investigators reviewed endoscopic biopsies obtained at weeks zero and 24 of small intestine (placebo (n=9), low-dose (n=17), and high-dose (n=20) or large intestine (placebo (n=9), low-dose (n=20), and high-dose (n=22)). The data indicate that GATTEX induced the expansion of the mucosal epithelium of adult patients with SBS and may therefore enhance capacity to digest and absorb orally consumed nutrients. Importantly, the DNA, RNA, and protein composition of the GATTEX remodeled mucosa did not differ from placebo. The foregoing data and results were presented at the 2008 American College of Gastroenterology Annual Scientific Meeting.

In a Phase 2 proof-of-concept study, 16 patients with SBS received subcutaneous injection of GATTEX for 21 days. Three patients received 0.03 mg/kg/day, ten patients received 0.10 mg/kg/day, and three patients received 0.15 mg/kg/day. Results of the Phase 2 study indicated that GATTEX was safe and well tolerated, resulted in intestinal epithelial regeneration and significantly increased intestinal absorption and body weight in PN-dependent SBS patients. These results were published in the international peer-reviewed journal *Gut* (Peppesen et al *Gut* 2005; 54:1223-1231).

We have also completed a single-center, double-blind, randomized, placebo-controlled ascending-dose study. Separate cohorts of healthy subjects were administered multiple doses of GATTEX or placebo in order to investigate the tolerability and pharmacokinetics of GATTEX. Following completion of eight days of treatment in a cohort and prior to the initiation of the next scheduled cohort(s), safety and tolerability were reviewed and assessed by an independent safety review panel. The study involved 95 subjects and results indicated that subcutaneous injections of 10 mg to 80 mg of GATTEX were safe and well tolerated.

Analysis and a final report of a two-year rat carcinogenicity study for GATTEX have been completed and will be included as part of our new drug application or NDA. All of the findings were considered to be either sporadic (not of statistical or biological significance), benign, or expected due to the pharmacological properties of the test material. Non-neoplastic changes were observed at all doses tested. No GATTEX-related malignant tumors were observed following treatment with GATTEX.

A study was conducted to assess the pharmacokinetics of a single fixed subcutaneous 20 mg dose of GATTEX in patients with moderate hepatic impairment compared to healthy subjects. This open-label single center study enrolled 24 patients. Administration of GATTEX 20 mg appeared to be safe and well tolerated by the male and female subjects with normal liver function and moderate liver impairment in this study.

#### *Teduglutide for Other Indications*

Given teduglutide's activity in promoting gastrointestinal repair, we believe it may have potential in treating other intestinal failure-related conditions, like PN-dependent pediatric SBS, pediatric feeding intolerance, and gastrointestinal mucositis. We are currently advancing preclinical studies that may support the filing of an investigational new drug application or IND for these indications.

Pediatric SBS is often caused by necrotizing enterocolitis or NEC. NEC is a gastrointestinal or GI disease that primarily affects premature infants. NEC involves infection and inflammation that causes destruction of the bowel or intestine or part of the bowel. The incidence of NEC has been estimated at 0.7 to 3.0 per 1,000 live births, and approximately one-third of these infants with NEC are expected to undergo intestinal surgery, including resection, frequently resulting in SBS. The etiology of NEC is unknown, but NEC has become a more common clinical problem as improvements in neonatal intensive care allow the survival of increasing numbers of premature and low-birth-weight infants.

Pediatric feeding intolerance is a morbidity associated with preterm infants and especially in the very low birth weight segment (less than 1500 grams). The condition is due to an immature gut and may require PN to prevent severe malnutrition. Teduglutide may accelerate intestinal maturation in infants with PN dependent feeding intolerance and thus allow a decrease in PN dependence or an earlier independence from PN in these infants.

Gastrointestinal mucositis or GIM is a side effect associated with certain cancer treatments. Some chemotherapies and radiotherapy, individually or in combination, damage rapidly dividing normal cells of the GI tract, which can result in mucositis. Mucositis can occur anywhere along the GI tract and can become a dose-limiting side effect of cancer treatment. Mucositis is one of the four major side effects that severely limit chemotherapy treatment along with nausea and vomiting, neutropenia, and anemia.

### *NPSP558 (parathyroid hormone 1-84 [rDNA origin] injection)*

NPSP558 is our proprietary recombinant, full-length (1-84), human parathyroid hormone (PTH 1-84) that we are developing in the U.S. as a potential treatment for hypoparathyroidism. Our previous clinical studies of this compound for the treatment of osteoporosis have demonstrated that daily subcutaneous dosing causes parathyroid hormone levels to rise rapidly and then return to normal levels over a period of hours. In September 2008, positive interim data from an investigator-initiated Phase 2 proof-of-concept study demonstrated that treatment with NPSP558 had a beneficial effect on abnormal bone skeletal properties in patients with hypoparathyroidism. Based on these data, we believe NPSP558 has the potential to be the first hormone replacement therapy for chronic hypoparathyroidism.

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

Hypocalcemia is the characteristic clinical feature of hypoparathyroidism. The duration, severity, and rate of development of hypocalcemia determine the nature of the symptoms associated with the condition. Hypocalcemia can present dramatically as tetany, seizures, altered mental status, refractory congestive heart failure or stridor. Generally, neuromuscular symptoms are the most prominent and include muscle cramping; twitching; numbness and paresthesias of the mouth and/or extremities; laryngeal chord or bronchial spasms; and even seizures. Other complications include damage to soft tissues, including the kidneys, the brain, and the lenses of the eye due to calcification from the abnormal calcium-phosphate levels associated with hypoparathyroidism and exacerbated by existing therapies.

### *Hypoparathyroidism Market Opportunity*

An estimated 65,000 patients suffer from hypoparathyroidism in the U.S. The most common cause of hypoparathyroidism is injury to or removal of the parathyroid glands during neck surgery. The definition of permanent post-surgical hypoparathyroidism is generally accepted to be insufficient parathyroid hormone to maintain normal calcium levels six months after surgery. Hypoparathyroidism can also be associated with autoimmune or other disorders or it can be idiopathic in nature.

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

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

Because NPSP558 is identical in structure to the 84-amino acid single-chain polypeptide human parathyroid hormone and mimics the action of natural parathyroid hormone, we believe it has the ideal mechanism of action to fulfill the unmet need of this chronic condition and offer a more physiological treatment outcome than is possible with existing treatments.

In 2007, the FDA granted orphan drug status for NPSP558 for the treatment of hypoparathyroidism.

### *NPSP558 for Hypoparathyroidism*

In December 2008, we initiated a Phase 3 registration study, known as REPLACE, evaluating NPSP558 for the treatment of hypoparathyroidism. We believe positive results from REPLACE will enable us to seek U.S. marketing approval of NPSP558 as a new standard of care for the treatment of hypoparathyroidism.



REPLACE is a double-blind, placebo-controlled trial that will randomize approximately 110 patients at over a dozen sites in the U.S., Canada, and Europe. The primary objective is to demonstrate, over a 24-week treatment period, that once-daily subcutaneous dosing with NPSP558 at doses of 50 mcg, 75mcg or 100mcg is a safe and effective hormone therapy for the treatment of patients with hypoparathyroidism.

The primary efficacy endpoint is the achievement or maintenance of normal calcium serum levels, with a 50 percent or greater reduction from baseline in calcium and vitamin D metabolite/analog supplementation by week 24. The study will consist of a 10-week screening and stabilization period followed by a 24-week treatment period marked by randomization (2:1) to NPSP558 50mcg (with the potential for titration up to 75mcg and 100mcg) or placebo. Following randomization, patients will undergo staged reductions in calcium and vitamin D supplementation. The secondary objectives of the study are designed to demonstrate that treatment with NPSP558 is associated with improvements in urinary calcium excretion or hypercalciuria.

An investigator-initiated Phase 2 proof-of-concept study of NPSP558 for the treatment of hypoparathyroidism has been conducted at Columbia University's College of Physicians and Surgeons. The open-label study evaluated the effects of every-other-day subcutaneous injections of 100 mcg of the drug on bone structure and turnover. At the 2008 Annual Meeting of the American Society for Bone and Mineral Research, investigators presented positive interim data demonstrating treatment with PTH 1-84 had beneficial effects on abnormal bone skeletal properties in patients with hypoparathyroidism.

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

To manage risk and accelerate the development and commercialization of our product candidates we complement our proprietary clinical programs with collaborative research, development or commercial agreements. These include agreements with Amgen, GlaxoSmithKline, Kyowa Kirin and Nycomed. Generally, these agreements provide for payments to us for the achievement of specified milestones, and royalties on sales of products developed under the terms of the particular agreement. In return for these financial benefits, we grant the particular company a license to the technology that is the subject of the collaboration or to intellectual property that we own or control. We believe that collaborating with pharmaceutical and biotechnology companies with relevant expertise in areas that are outside of our proprietary therapeutic or geographic focus will accelerate the development and commercialization of our products.

#### *Amgen and Kyowa 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. Cinacalcet 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 Kirin Pharma, a wholly-owned subsidiary of Kyowa Kirin Holdings, 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. to develop and commercialize cinacalcet HCl for the treatment of hyperparathyroidism.

In March 2004, Amgen received FDA approval for cinacalcet HCl for the treatment of secondary hyperparathyroidism in chronic kidney disease patients on dialysis, often referred to as "Stage V" chronic kidney disease patients, and for the treatment of hypercalcemia, or excess serum calcium levels, in patients with parathyroid carcinoma. In October 2004, Amgen received approval from the EMEA for cinacalcet HCl for the treatment of secondary hyperparathyroidism in Stage V chronic kidney disease patients and for treatment of hypercalcemia in patients with parathyroid carcinoma. Amgen markets cinacalcet HCl as Sensipar® in the U.S. and as Mimpara® in the EU.

In October 2007, Kyowa 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. In the first quarter of 2008, Kyowa Kirin began commercializing cinacalcet HCl in Japan under the trade name REGPARA® and we began receiving royalties on Kyowa Kirin's sales of REGPARA during the second half of 2008.

### *Cinacalcet HCl for Secondary Hyperparathyroidism*

Parathyroid hormone is produced by 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 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, 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.

Amgen has announced that it has elected not to file for the expanded indication for the treatment of secondary hyperparathyroidism in the setting of chronic renal insufficiency based on a completed Phase 3 study with Sensipar. Amgen indicated that all efficacy endpoints were positive, supporting the ability of Sensipar to reduce parathyroid hormone levels in these patients; however, the occurrence of asymptomatic hypocalcemia in Sensipar-treated patients as observed in this trial was felt to be incompatible with routine use of Sensipar in this setting. Amgen stated that additional analyses are underway that may permit the identification of a dosing regimen that would allow the use of Sensipar in this patient group.

The EVOLVE™ (EValuation Of cinacalcet HCl therapy to Lower cardioVascular Events) trial, initiated in 2006, is a large (3,800) patient, multi-center, international, randomized, double-blind study to assess the effects of Sensipar on mortality and cardiovascular morbidity in patients with chronic kidney disease undergoing maintenance dialysis. The EVOLVE study completed enrollment in January 2008. Additionally, Amgen is evaluating Sensipar for use in primary hyperparathyroidism.

### *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. There are currently no approved pharmaceutical therapies for the treatment of primary hyperparathyroidism. Surgical removal of the affected parathyroid gland(s) from the neck region is presently the only effective treatment.

Cinacalcet HCl may be a therapeutic alternative to surgery for patients with primary hyperparathyroidism. Cinacalcet HCl could be particularly useful for the estimated 10 percent of primary hyperparathyroidism patients with multi-parathyroid gland involvement, whose only treatment option would otherwise be surgery. A common side effect of the surgery is permanent hypoparathyroidism, or insufficient amounts of parathyroid hormone in the blood. Cinacalcet HCl has not been approved by the FDA for the treatment of primary hyperparathyroidism.

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

Amgen has paid us \$38.5 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 \$7.0 million if it achieves other development and regulatory milestones. In addition to these milestones, we recognize royalties on Amgen's sales of cinacalcet in its licensed territories.

We have partially monetized our royalty revenue from Amgen through the issuance of non-recourse debt that is both serviced and secured by our Sensipar royalty revenue. 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 are non-recourse to us and are secured by our royalty and milestone payment rights under our agreement with Amgen. Until the Class A Notes and Class B Notes are repaid, all payments from Amgen will be used for the payment of interest and principal on the notes. We pay the interest due on the Class B Notes through the issuance of additional Class B Notes in lieu of cash, and as a result, the aggregate principal amount of our outstanding Class B Notes will continue to increase until they are paid in full. As of December 31, 2008, we had approximately \$253.7 million in aggregate principal amount of Class A and Class B Notes outstanding, including \$23.7 million in Class B Notes that had been issued to cover interest payments on the Class B Notes.

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

Kyowa 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 Kirin is also required to pay us royalties on any sales of cinacalcet HCl in its territories.

#### *Nycomed (Preotact® (parathyroid hormone 1-84 [rDNA origin] injection))*

In April 2004, we signed a distribution and license agreement with Nycomed (the "2004 Agreement"), in which we granted Nycomed the exclusive right to develop and market Preotact in Europe. Preotact is the brand name that Nycomed uses to market parathyroid hormone 1-84 [rDNA origin] injection. Nycomed also made an equity investment in our business of \$40.0 million through the purchase of 1.3 million shares of our common stock in a private placement, which closed in July 2004. The 2004 Agreement required Nycomed to purchase drug product and devices from us and to pay us royalties on product sales. Additionally, the 2004 Agreement required Nycomed to pay us up to €20.8 million in milestone payments upon the receipt of specified regulatory approvals and the achievement of certain sales targets, to purchase drug product and devices from us, and to pay us royalties on product sales. Through December 31, 2008, we have received €5.6 million in milestone payments from Nycomed under the 2004 Agreement. In July 2007, we entered into a new license agreement with Nycomed ("2007 Agreement"), as described below, which superseded the 2004 Agreement.

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

The 2007 Agreement requires Nycomed to make milestone payments upon the receipt of certain approvals in Europe and the achievement of certain sales targets for Preotact. Nycomed is also required to pay us a royalty on a quarterly basis based upon sales of Preotact only in the European Union, European countries outside the European Union, the Commonwealth of Independent States and Turkey. Nycomed is also responsible to maintain our patents in its territories under the 2007 license agreement. If Nycomed reasonably determines that it has no prospects for making a reasonable profit under the 2007 Agreement, and it is unable to agree to terms on a renegotiated agreement with us within eight weeks, Nycomed may terminate the agreement by providing us with six months prior written notice; provided, however, that, upon any such termination the ownership of all rights to Preotact technology, products, regulatory filings and know-how will revert to us.

In July 2007, we entered into an agreement with DRI Capital, or DRI (formerly Drug Royalty L.P.3) under which we sold to DRI our right to receive future royalty payments arising from sales of Preotact under the 2007 Agreement. Under the agreement, DRI paid us an up-front purchase price of \$50.0 million for the royalty rights. An additional \$25.0 million will be due in 2010 if certain Preotact sales thresholds are exceeded. The agreement provides that if DRI receives royalties representing two and a half times the purchase price paid to us, the agreement will terminate and the remainder of the royalties paid by Nycomed under the 2007 Agreement, if any, will revert to us. In connection with our agreement with DRI, we granted DRI a security interest in the 2007 Agreement and certain of our patents and other intellectual property underlying that agreement.

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

In September 2007, we signed a license agreement with Nycomed in which we granted Nycomed the right to develop and commercialize teduglutide outside of North America. We received \$35.0 million in up-front fees shortly after executing the agreement. Under the terms of the agreement, we have the potential to earn more than \$190.0 million in development and sales milestone payments. Additionally, the agreement provides for royalties on sales in the licensed territories and provides an option for development cost sharing equally for indications that we elect to pursue jointly. Pursuant to a previously existing licensing agreement with a third party, we paid \$6.6 million to the licensor in 2007 and will be required to make future payments based on future GATTEX royalties and milestones earned.

Under the terms of the license agreement with Nycomed, we are responsible for completing the original Phase 3 GATTEX clinical trials in SBS. Nycomed is responsible for conducting Phase 4 studies in its licensed territory at its expense. We also may work with Nycomed to jointly develop, commercialize and investigate further indications for GATTEX in the licensed territories and will share future joint development costs equally for such work. In December 2008, we agreed to advance the STEPS study on a collaborative basis and the two companies will share external clinical costs for the study. Nycomed may terminate on 180-day written notice prior to the first commercial sale under the agreement. Following the first commercial sale, Nycomed must provide 365-day written notice in order to terminate. After we have received such a termination notice, we may terminate the agreement at anytime prior to the expiration of Nycomed's requisite notice period.

*Ronacaleret (751689)*

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

We received an initial upfront license fee payment from GSK of \$4.0 million, a subsequent payment of \$2.0 million by January 1, 1995, and we later began receiving payments from GSK in support of our research efforts under the initial research term of the agreement. GSK also has a first right to negotiate for an exclusive license under our patents to make, use or sell items for indications within the field of bone metabolism disorders, and an exclusive right to negotiate for a license to compounds covered under the agreement not selected for development to treat bone metabolism disorders for indications outside that field, which rights expire upon termination of this agreement.

GSK has the authority and responsibility to conduct and fund all product development, including clinical trials and regulatory submissions, and manufacturing for any compounds selected for development. We have the right to co-promote, in the U.S., products resulting from the collaboration to certain targeted physician specialties. GSK has paid us a total of \$26.1 million for license fees, research support, milestone payments and equity purchases as part of our collaboration. We will receive additional payments of up to an aggregate of \$32.0 million, which includes additional milestones under the December 2006 amendment noted below, if certain clinical milestones are achieved. Our agreement also provides for royalties on any sales by GSK of commercialized products based on compounds identified in this collaboration. In addition to the milestone and royalty payments, we have a limited right to co-promote any products that are developed through our collaboration and we will receive co-promotion revenue if we elect to exercise these rights. Upon termination, the rights and licenses we granted GSK revert to us. In December 2006, we entered into an amendment to our agreement with GSK under which we provided GSK rights to additional compounds discovered by us. In connection with such amendment GSK paid a one-time licensing fee of \$3.0 million and agreed to pay additional milestone payments for the achievement of certain clinical milestones with such compounds as well as royalties on sales of such compounds should GSK commercialize any such compounds.

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. Upon termination, the rights and licenses we granted GSK revert to us.

In September 2008, we were notified by GSK that it has decided to terminate a Phase 2 dose-range finding study of ronacaleret in post-menopausal women with osteoporosis earlier than expected due to an observed lack of efficacy based on lumbar spine and hip bone mineral density. We are not required to return to GSK any of the payments we received to date. GSK is analyzing the full results of the study and has not yet determined the ongoing development program of ronacaleret and other calcilytics under this agreement.

#### *Janssen (Glycine Reuptake Inhibitors)*

We collaborated with Janssen on glycine reuptake inhibitors to identify prospective drug candidates for schizophrenia and dementia. After the research phase of the collaboration ended, Janssen assumed full responsibility for the development of the product candidates that were identified. In August 2008, Janssen notified us that the clinical data did not meet their criteria to pursue further development and subsequently terminated the agreement. We have received research support and milestone payments totaling \$2.9 million under this agreement and none of these payments is refundable. Upon Janssen's termination of the agreement the rights to any compounds or products from the collaboration reverted to us. We are not required to return to Janssen any of the payments we received to date.

#### **Other Royalty Agreements**

##### *Ortho-McNeil Pharmaceuticals*

In December 2006, we entered into an agreement with Ortho-McNeil Pharmaceuticals, Inc. ("Ortho"), a wholly-owned subsidiary of Johnson & Johnson, pertaining to certain of our patents. Under this agreement, Ortho 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. We also received an up-front licensing fee. Ortho-McNeil pays us its royalty on a quarterly basis. We are responsible for patent prosecution and maintenance of the related patents. In November 2008, the U.S. Food and Drug Administration approved tapentadol immediate-release tablets for the relief of moderate to severe acute pain in adults 18 years of age or older. 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 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.

## 2007 Restructuring Initiatives and Discontinued Research and Development

In 2007, we restructured our operations and implemented a new business strategy to focus our resources on developing GATTEX and NPSP558 for specialty indications with high unmet medical needs. Previously, our strategic priority was to obtain U.S. regulatory approval of PREOS<sup>®</sup> (parathyroid hormone 1-84 [rDNA origin] injection) for the treatment of osteoporosis. We have studied PREOS in a number of clinical settings to document its safety and effects on bone. In 2006, we received an approvable letter and guidance from the U.S. Food and Drug Administration (FDA) to support a U.S. marketing application for PREOS. While we continue to believe that the U.S. osteoporosis market remains a viable commercial opportunity for this compound, we elected to focus our resources on specialty opportunities within our pipeline and pursue osteoporosis only on a partnered, rather than a proprietary, basis.

Supporting our new strategic direction, we are also seeking opportunities to out-license a number of proprietary compounds for areas that are outside of our proprietary therapeutic and/or geographic focus. In addition to PREOS, these include teduglutide for Crohn's disease and glycine reuptake inhibitors and NPSP156 for central nervous system disorders.

### *PREOS for Osteoporosis*

We have studied PREOS in a number of clinical settings to document its safety and effects on bone. The pivotal Phase 3 study, known as TOP (Treatment of Osteoporosis with PTH), was a multi-center, randomized, double blind, placebo-controlled trial designed to evaluate the potential of PTH to reduce the risk of first and subsequent vertebral fractures in post-menopausal women. In the TOP study, PREOS demonstrated a statistically significant reduction in the risk of new vertebral fractures in women with and without pre-existing osteoporosis-related fractures.

In May 2005, we filed an NDA with the FDA seeking approval to market PREOS in the U.S. In March 2006, we received notification from the FDA that the PREOS NDA is approvable. In the approvable letter, the FDA indicated that our pivotal Phase 3 study with PREOS demonstrated significant fracture risk reductions in post-menopausal women with osteoporosis, but noted the higher incidence of hypercalcemia with PREOS compared to placebo. The FDA expressed concern regarding hypercalcemia associated with the proposed daily dose of PREOS and requested additional clinical information. The FDA also requested additional information regarding the reliability and use of the injection device for delivery of PREOS.

We have had further communications with the FDA since receiving the approvable letter from the FDA, including an in-person meeting with senior staff from the FDA's Division of Endocrine and Metabolism Drug Products. During the meeting, the FDA proposed that we generate additional clinical data through a new clinical trial to address the hypercalcemia issue raised in the approvable letter. Since receiving the approvable letter, we have been carefully evaluating the appropriate regulatory path forward for PREOS. We submitted a new clinical trial protocol for PREOS to the FDA to support U.S. registration, and believe the protocol design is now finalized following communications with the FDA. Under this protocol, the clinical study will be a 12-month bone-mineral density bridging trial designed to evaluate the relative efficacy and safety of three dosing regimens of PREOS (100 mcg once daily, 100 mcg every-other-day, and 75 mcg once daily) compared to placebo in women with post-menopausal osteoporosis. As noted above, we would only continue our efforts to develop and commercialize PREOS for osteoporosis in the U.S. market if we were to secure a partner who would be willing to assume part of the cost and risk of such development.

### *Teduglutide for Crohn's Disease*

We have completed a Phase 2a proof-of-concept clinical study with teduglutide in patients with Crohn's disease. While we believe the data support further evaluation of teduglutide for the treatment of Crohn's disease, given our strategy to focus on indications with few, if any, therapeutic options and limited competition, we would only pursue the development of teduglutide for Crohn's disease on a partnered basis.

The four-arm, eight-week clinical trial compared three doses of teduglutide delivered by daily subcutaneous injection to a placebo. The study was designed to evaluate teduglutide's safety and potential efficacy in the treatment of Crohn's disease. The study results showed a positive and consistent trend toward efficacy and a dose response favoring the highest dose group, with 36.8% of patients receiving the highest dose of teduglutide reaching clinical remission, at week two versus 16.7% of the placebo group, while 55.6% of patients in the highest dose group reached clinical remission by week eight compared to 33.3% of the placebo group. Clinical remission was defined as a Crohn's Disease Activity Index score, or CDAI score, of less than 150 points. Teduglutide was well tolerated with no serious adverse events related to the drug. The most common treatment-related adverse event in the trial was redness at the injection

site. While this study was not powered to demonstrate statistical significance and the primary endpoint was not met due to the relatively small number of study subjects and a high placebo response, we believe clinical remission rates seen in patients receiving the highest dose of teduglutide support further evaluation of teduglutide for the treatment of Crohn's disease.

#### *Glycine Reuptake Inhibitors*

We collaborated with Janssen on glycine reuptake inhibitors to identify prospective drug candidates for schizophrenia and dementia. After the research phase of the collaboration ended, Janssen assumed full responsibility for the development of product candidates identified. In August 2008, Janssen notified us that the clinical data did not meet their criteria to pursue further development and subsequently terminated the agreement. This termination by Janssen returns the rights to any compounds or products from the collaboration to us. We are not actively engaged in the further development of these proprietary compounds and we are seeking opportunities to out-license them.

#### *NPSP156 (D-serine)*

NPSP156 is our proprietary D-serine analog of a naturally occurring neurotransmitter and endogenous ligand at the glycine site of the NMDA receptor. We believe NPSP156 may have therapeutic potential in the treatment of epilepsy, neuropathic pain, and other central nervous system (CNS) disorders. While there are many clinical-stage and commercialized products for epilepsy and neuropathic pain, we believe that the unique mechanism of action of NPSP156 could favorably position this compound in this market segment and we are seeking opportunities to out-license them.

#### **In-licensing Agreements**

We have entered into certain research and license agreements that require us to make research support payments to academic or research institutions when the research is performed. Additional payments may be required upon the accomplishment of research milestones by the institutions or as license fees or royalties to maintain the licenses.

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

We have also entered into a license agreement with Daniel J. Drucker, MD, and his Canadian corporation 1149336 Ontario Inc. The license agreement grants to us an exclusive 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. 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.

#### **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, may significantly limit the indicated uses for which our products may be marketed. 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 a new drug application or NDA.

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 an NDA. The FDA may withhold approval for an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. 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 the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

The FDA's fast track program is intended to facilitate the development and expedite the review of drugs intended for the treatment of serious or life-threatening diseases and that demonstrate the potential to address unmet medical needs for such conditions. Under this program, the FDA can, for example, review portions of an NDA for a fast track product before the entire application is complete, thus potentially beginning the review process at an earlier time. We cannot guarantee that the FDA will grant any requests that we may make for fast track designation, that any fast track designation would affect the time of review, or that the FDA will approve the NDA submitted for any of our drug candidates, whether or not fast track designation is granted. Additionally, the FDA's approval of a fast track product can include restrictions on the product's use or distribution, such as permitting use only for specified medical procedures or limiting distribution to physicians or facilities with special training or experience. Approval of fast track products can be conditional with a requirement for additional clinical studies after approval.



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 FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. 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.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic 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 exclusivity. 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, regulatory 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.

### **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.

We have been issued approximately 188 patents in the U.S. Six issued U.S. patents cover technology related to parathyroid hormone. These patents have expiration dates (not including any patent term extensions) ranging from 2011 to 2017. Seven issued U.S. patents cover technology related to calcilytic compounds. These patents have expiration dates (not including any patent term extensions) ranging from 2016 to 2019. Fifteen issued U.S. patents cover calcimimetics (including cinacalcet HCl) and calcium receptor technology. These patents have expiration dates (not including any patent term extensions) ranging from 2013 to 2017. Fifteen issued U.S. patents cover technology related to GATTEX and GLP-2, certain of which are licensed from 1149336 Ontario Inc. These patents have expiration dates (not including any patent term extensions) ranging from 2015 to 2020. Thirteen issued U.S. patents, certain of which are licensed from Glytech, Inc., cover technology related to glycine reuptake inhibitors. These patents have expiration dates (not including any patent term extensions) ranging from 2015 to 2022. Our intellectual property portfolio also includes patents in countries outside the U.S., which also cover the technology referenced above.

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. 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, including the fields of gastrointestinal disorders, hyperparathyroidism, osteoporosis, and central nervous system disorders.

Our competition for GATTEX will depend on the applicable indication. We have focused our internal research and development on niche indications of significant unmet medical need where we believe a company of our size can successfully compete. For example, we have been granted orphan drug designation in SBS, where very few competitors exist. Current therapies for SBS include parenteral nutrition, or PN, and somatropin (rDNA origin) for injection, a human growth hormone marketed by Serono and glutamine in combination with somatropin (rDNA origin) for injection. PN is a costly option as studies show that PN costs can exceed \$100,000 annually per patient. In addition, there can be a negative impact on patient quality of life as well as morbidities associated with PN. Treatment with somatropin (rDNA origin) for injection is limited to 28 days and requires a specialized diet. If approved by the FDA for SBS, GATTEX would compete directly with somatropin (rDNA origin) for injection. PN-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, 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. Treatment for Crohn's disease includes several classes of drugs including aminosalicylates, immunosuppressants, antibiotics, corticosteroids, immunomodulators, and the biologics. While GATTEX, if approved by the FDA for the treatment of Crohn's disease, would compete with these therapies as a potential treatment for Crohn's disease, GATTEX may create utility in this indication either as a mono or combination therapy.

We have been granted orphan drug status for NPSP558 for the treatment of hypoparathyroidism. Presently, the only available treatments approved for hypoparathyroidism include life-long supplementation of calcium and Vitamin D. Severe hypocalcemia can be life threatening and is treated with intravenous calcium. We believe, with its mechanism of action, NPSP558 has the potential to meet the unmet need of this chronic condition.

Many of our competitors have substantially greater financial, technical, marketing and personnel resources. In addition, some of them have considerable experience in preclinical testing, human clinical trials and other regulatory approval procedures. Moreover, certain academic institutions, governmental agencies and other research organizations are conducting research in the same areas in which we are working. These institutions are becoming increasingly aware

of the commercial value of their findings and are more actively seeking patent protection and licensing arrangements to collect royalties for the technology that they have developed. These institutions may also market competitive commercial products on their own or through joint ventures and will compete with us in recruiting highly qualified personnel. Our ability to compete successfully will depend, in part, on our ability to:

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

Our products and potential products are biological products, or biologics. Currently, generic versions of biologics cannot be approved under U.S. law. Competitors seeking approval of biologics must file their own safety and efficacy data, and address the challenges of biologics manufacturing, which involves more complex and costly processes than those of traditional pharmaceutical operations. However, the law could change in the future to allow generic biologics. Even in the absence of new legislation, the U.S. Food and Drug Administration (FDA) is taking steps toward allowing generic versions of certain biologics.

## **Manufacturing**

We do not have internal manufacturing capabilities to produce supplies of GATTEX or NPSP558 to support clinical trials or commercial launch of these products, if they are approved. We also do not have internal manufacturing capabilities to produce supplies of the injection devices used to administer NPSP558. We depend on a number of manufacturers to supply key components and finished clinical supplies of GATTEX and NPSP558.

We have an agreement with Boehringer Ingelheim Austria GmbH (BI) to produce bulk supplies of the active pharmaceutical ingredients in GATTEX and NPSP558 for our clinical and any future commercial requirements. We have a manufacturing agreement with Cangene Corporation, or Cangene, for the production of finished clinical supplies of GATTEX. Cangene is currently our sole source for our fill and finish clinical supplies for GATTEX. Although we have not received marketing approval for GATTEX in the U.S., we are currently in discussions with a number of contract manufacturing organizations regarding a formal manufacturing and supply agreement for the production of commercial quantities of finished supplies of GATTEX. Vetter Pharma-Fertigung GmbH, or Vetter, produces our finished supplies of NPSP558 for clinical use. Because the “fill and finish” aspect of the manufacturing process for NPSP558 requires the use of Vetter’s proprietary technology, Vetter is our sole source for finished supplies of NPSP558.

If we receive regulatory approval in NPSP558 for hypoparathyroidism, in order to successfully commercialize our product, we will need to develop an injection device for this indication.

We are dependent on third parties for the manufacture of our product candidates and injection devices and in most instances we are sole sourced to these manufacturers. If we are unable to contract for a sufficient supply of our product candidates or injection devices on acceptable terms, or encounter delays or difficulties in the manufacturing or supply process, we may not have sufficient product or injection devices to conduct or complete our clinical trials or support preparations for the commercial launch of our product candidates, if approved. Based on the highly-specialized and proprietary nature of the products provided to us by certain of our manufacturing partners, we could be subject to significant added costs and delays if we are required to replace our existing agreements or arrangements with those partners for any reason. If our product candidates are approved, we may also face added costs and delays if we are unable to enter into formal manufacturing contracts for commercial quantities of our products on favorable terms. 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.”

## **Employees**

As of March 5, 2009, we had approximately 47 employees. None of our employees is covered by a collective bargaining agreement and we believe our relationship with our employees is good.

## **Trademarks**

“NPS”, “NPS Pharmaceuticals”, “GATTEX”, and “PREOS” are our trademarks. In addition, “Preotact” is our registered trademark in the U.S. All other trademarks, trade names or service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

## **Available Information**

Our Internet address is [www.npsp.com](http://www.npsp.com). We make available free of charge on or through our Internet website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

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

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

### **Risks Related to Our Business**

***We have a history of operating losses. We expect to incur net losses and we may never achieve or maintain profitability.***

With the exception of 1996, we have not been profitable since our inception in 1986. As of December 31, 2008, we had an accumulated deficit of approximately \$904.9 million. To date, our revenue from product sales has been in the form of royalty payments from Amgen on sales of Sensipar (cinacalcet HCl), royalty payments from Nycomed on sales of Preotact, milestone revenue from our collaborative agreements with Nycomed, product sales to Nycomed and beginning in 2008, royalty payments on sales of REGPARA by Kyowa Kirin. In July 2007, Nycomed assumed sole responsibility for manufacturing Preotact. As described further herein, we have non-recourse debt that is secured by our royalty rights related to sales of Sensipar under our agreement with Amgen and we sold to DRI our right to receive royalty payments under our agreement with Nycomed arising from sales of Preotact. The right to royalties on Amgen’s Sensipar sales will only be returned to us if those royalties are sufficient to repay our non-recourse Class A Notes and Class B Notes on a timely basis. The right to royalties on Nycomed’s Preotact sales will only be returned to us if the amount of royalties received by DRI exceeds two and a half times the amount DRI has paid to us.

We are entirely dependent on Amgen and Nycomed for sales of Sensipar and Preotact, respectively and we cannot assure you that they will pay royalties in amounts sufficient to cause the royalty rights in Sensipar and Preotact to be returned to us. Other than the royalty payments we receive from Kyowa Kirin, we have not generated any other revenue from product sales to date, and it is possible that we will never have sufficient product sales revenue to achieve profitability. We expect to continue to incur losses for at least the next several years as we and our collaborators and licensees pursue clinical trials and research and development efforts. To become profitable, we, alone or with our collaborators and licensees, must successfully develop, manufacture and market our current product candidates and continue to identify, develop, manufacture and market new product candidates. It is possible that we will never have significant product sales revenue or receive significant royalties on our licensed product candidates to achieve profitability.

***We may require additional funds.***

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

Our current and anticipated operations require substantial capital. We expect that our existing cash, cash equivalents, and short-term investments will sufficiently fund our current and planned operations through at least 2009. However, our future capital needs will depend on many factors, including the extent to which we enter into collaboration agreements with respect to any of our proprietary product candidates, receive royalty and milestone payments from our collaborators and make progress in our development and commercialization activities. Our capital requirements will also depend on the magnitude and scope of these activities, our ability to maintain existing and establish new collaborations, the terms of those collaborations, the success of our collaborators in developing and marketing products under their respective collaborations with us, our ability to effectively out-source our clinical development, regulatory, data management, research, quality control and assurance, and other activities, the success of our contract manufacturers in producing clinical and commercial supplies of our product candidates and drug delivery devices on a timely basis and in sufficient quantities to meet our requirements, competing technological and market developments, the time and cost of obtaining regulatory approvals, the cost of preparing, filing, prosecuting, maintaining and enforcing patent and other rights and our success in acquiring and integrating complementary products, technologies or companies. We do not have committed external sources of funding, and we cannot assure you that we will be able to obtain additional funds on acceptable terms, if at all. If adequate funds are not available, we may be required to:

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

In addition, the capital and credit markets have been experiencing extreme volatility and disruption which, particularly during the latter part of 2008 and the beginning of 2009, has led to uncertainty and liquidity issues for both borrowers and investors. 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.

***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.***

We are developing GATTEX and NPSP558 as a potential treatment for a variety of gastrointestinal and/or endocrine disorders, including GATTEX for SBS and NPSP558 for hypoparathyroidism. We are currently advancing Phase 3 registration quality studies for both product candidates. See “Item 1 – Business – Proprietary Product Candidates.”

While we presently believe that we have the financial resources to fund the continued development of these product candidates in the U.S., all clinical trials are long, expensive and uncertain processes and there can be no assurance that data collected from these studies will be sufficient to support a new drug application, or NDA, or FDA approval once the studies are completed. Our ability to generate revenues to sustain our operations will be substantially impaired and our business will be materially harmed if our Phase 3 study for either of our product candidates fails to produce the required safety and efficacy data to support an NDA for that product candidate or regulatory approval by the FDA.

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

- 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 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.***

Sensipar (Mimpara in Europe), REGPARA in Japan and Preotact are our only sources, to date, of commercial revenues. Our remaining product candidates will require significant additional development, clinical trials, regulatory approvals and additional investment before their commercialization. As part of our corporate restructuring, we now outsource substantially all of our research, and development activities. If we are unable to transition to an outsourcing company in an efficient and timely manner, the development of our product candidates will be delayed. Additionally, 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 commercialize one or more of our product candidates, we cannot assure you that such product candidates 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, and storage of our product candidates and drug delivery devices; if these third parties fail to supply us with sufficient quantities of products and devices on a timely basis, or if the products and devices they provide do not meet our specifications, our clinical trials and product introductions may be delayed or suspended***

We do not have the internal manufacturing capabilities to produce the supplies of GATTEX and NPSP558 that are needed to support clinical trials or the commercial launch of these products, if they are approved. We also do not have internal manufacturing capabilities to produce supplies of the injection devices used to administer GATTEX and NPSP558. We are dependent on third parties for the manufacture, supply, and storage of our product candidates and injection devices. If we are unable to contract for a sufficient supply of our product candidates or injection devices on acceptable terms, or if we encounter delays or difficulties in the manufacturing or supply process we may not have

sufficient product or injection devices to conduct or complete our clinical trials or to support the commercial launch of our product candidates, if approved.

We depend on a number of contract manufacturers to supply key components of GATTEX and NPSP558. For a description of our agreements with these manufacturers, see “Item 1. – Business – Manufacturing.” Although we anticipate that our contract manufacturers will be able to produce the raw materials and finished product that we require, 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 pens 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.

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 clinical trials, regulatory submission, required approvals or commercialization of our products under development, entail higher costs and result in our inability to commercialize our products effectively.

In addition, if we receive regulatory approval in NPSP558 for hypoparathyroidism, in order to successfully commercialize our product, we will need to develop an injection device for this indication. There is no guarantee that we will be able to develop an injection device and find a supplier to adequately supply our potential commercial needs.

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

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

countries also have extensive requirements regarding clinical trials, market authorization and pricing. These regulatory requirements vary widely from country to country, but, in general, are subject to all of the risks associated with U.S. approvals.

If any of our products 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. In addition, results of preclinical studies and clinical trials with respect to our products could subject us to adverse product labeling requirements that could harm the sale of such products. Even if regulatory approval is obtained, later discovery of previously unknown problems may result in restrictions of the product, including withdrawal of the product from the market. Further, governmental approval may subject us to ongoing requirements for post-marketing studies. Even if we obtain governmental approval, a marketed product, its respective manufacturer and its manufacturing facilities are subject to unannounced inspections by the FDA and must comply with the FDA's cGMP and other regulations. These regulations govern all areas of production, record keeping, personnel and quality control. If a manufacturer fails to comply with any of the manufacturing regulations, it may be subject to, among other things, product seizures, recalls, fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecution. Other countries also impose similar manufacturing requirements. Our promotional materials and sales activities are governed by FDA regulation. The FDA may require us to withdraw promotional material, to issue corrected material, or to cease promotion resulting in loss of credibility with our customers, reduced sales revenue or increased costs.

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

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

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

Further, even if the results of our preclinical studies or clinical trials are initially positive, it is possible that we will obtain different results in the later stages of drug development or that results seen in clinical trials will not continue with longer-term treatment. Drugs in late stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. For example, positive results in early Phase 1 or Phase 2 clinical trials may not be repeated in larger Phase 2 or Phase 3 clinical trials. All of our potential drug candidates are prone to the risks of failure inherent in drug development. The clinical trials of any of our drug candidates, including GATTEX and NPSP558, could be unsuccessful, which would prevent us from commercializing the drug. Our failure to develop safe, commercially viable drugs would substantially impair our ability to generate revenues and sustain our operations and would materially harm our business and adversely affect our stock price.

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

Our strategy for developing, manufacturing and commercializing our products includes entering into various relationships with other pharmaceutical and biotechnology companies to advance many of our programs. We have granted development, commercialization and marketing rights to a number of our collaborators for some of our key product development programs, including cinacalcet HCl, Preotact, GATTEX, calcilytics, and glycine reuptake inhibitors. Our collaborators typically have full control over those efforts in their territories and the resources they commit to the programs. Accordingly, the success of the development and commercialization of product candidates in those programs depends on the efforts of our collaborators and is beyond our control. For us to receive any significant milestone or royalty payments from our collaborators, they must advance drugs through clinical trials, establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of those products. As a result, if a collaborator elects to terminate its agreement with us with respect to a research program, our ability to advance the program may be significantly impaired or we may elect to discontinue funding the program



altogether. For example, in early 2002, Abbott terminated its agreement with respect to isovaleramide, and Forest Laboratories terminated its agreement with us with respect to ALX-0646. As a result, these programs were discontinued. As an additional example, in September 2008, we were notified by GSK that it has decided to terminate a Phase 2 dose-range finding study of ronacaleret in post-menopausal women with osteoporosis earlier than expected due to an observed lack of efficacy based on lumbar spine and hip bone mineral density. The counterparties to certain of our collaborative research, development or commercial agreements have the right to terminate those agreements prior to their expiration after providing us with the requisite notice. See the description of these agreements under “Item 1 – Business – Royalty-Based Products and Product Candidates.”

As part of our product development and commercialization strategy, we evaluate whether to seek collaborators for our product candidates. If we elect to collaborate, we may not be able to negotiate collaborative arrangements for our product candidates on acceptable terms, if at all. If we are unable to establish collaborative arrangements, we will either need to increase our expenditures and undertake the development and commercialization activities at our own expense or delay further development of the affected product candidate.

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

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

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

***We have never marketed, sold or distributed a product and may need to rely on third parties to successfully market and sell our products and generate revenues.***

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

***Because of the uncertainty of pharmaceutical pricing, reimbursement and healthcare reform measures, we 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 legislative and regulatory proposals to change the healthcare system and further proposals are likely. Medicare’s policies may decrease the market for our products that are designed to treat patients with age-related

disorders, such as hyperparathyroidism. Significant uncertainty exists with respect to the reimbursement status of newly approved healthcare products.

In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. We might not be able to sell our products profitably or recoup the value of our investment in product development if reimbursement is unavailable or limited in scope, particularly for product candidates addressing small patient populations, such as GATTEX for the treatment of SBS and NPSP558 for hypoparathyroidism.

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 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.

In addition, our products and potential products are biological products, or biologics. Currently, generic versions of biologics cannot be approved under U.S. law. Competitors seeking approval of biologics must file their own safety and efficacy data, and address the challenges of biologics manufacturing, which involves more complex and costly processes than those of traditional pharmaceutical operations. However, the law could change in the future to allow generic biologics. Even in the absence of new legislation, the U.S. Food and Drug Administration (FDA) is taking steps toward allowing generic versions of certain biologics. Any such changes could have a material adverse effect on our business, financial condition and profitability.

***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. We have competitors in both the U.S. and internationally including major multi-national pharmaceutical companies, chemical companies, biotech companies, universities and other research organizations. Many of our competitors have drug products that have already been approved or are in development, and operate large, well-funded research and development programs in these fields. Many of our competitors have 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 of our competitors 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, our 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 product candidates obsolete and non-competitive.

Existing and future products, therapies and technological approaches will compete directly with the products we seek to develop. Current and prospective competing products may provide greater therapeutic benefits for a specific problem, may offer easier delivery or may offer comparable performance at a lower cost. Any product candidate that we develop and that obtains regulatory approval must then compete for market acceptance and market share. Our product candidates 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 interference 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. 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. Until recently, patent applications in the U.S. were maintained in secrecy until the patents issued, and publication of discoveries in scientific or patent literature often lags behind

actual 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, our management's focus will be diverted and 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 interference proceedings declared by the U.S. Patent and Trademark Office or other analogous 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 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 ANDA's 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. There can be no assurance that we would prevail in such an action and our business may be adversely affected should we fail to prevail in any such litigation.

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" and "GATTEX" trademarks with the U.S. Patent and Trademark Office. A third party may assert a claim that one of those marks is confusingly similar to its mark, and such claims or the failure to timely register a mark or objections by the FDA could force us to select a new name for our product candidates, which could cause us to incur additional expense or delay the introduction of a product candidate to market.

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

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

Our success also depends on avoiding infringement of the proprietary technologies of others. In particular, there may be certain issued patents and patent applications claiming subject matter that our collaborators or we may be required to license in order to research, develop or commercialize at least some of our product candidates, including GATTEX, NPSP558 and PREOS. 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.

***Because of our restructuring initiatives and the related reductions in our workforce, we have reallocated certain employment responsibilities and have increased our dependence on third parties to perform certain corporate functions.***

We have restructured our operations, which included reductions in our workforce as well as a transition to an outsourcing business strategy. The reductions have resulted in the loss of numerous long-term employees, the loss of institutional knowledge and expertise and the reallocation of certain employment responsibilities, all of which could adversely affect operational efficiencies, employee performance and retention. In addition, because of these reductions, we are outsourcing certain corporate functions, which makes us more dependent on third parties for the performance of these functions in connection with our business and product candidates. To the extent that we are unable to effectively reallocate employee responsibilities, retain key employees, establish and maintain agreements with competent third-party contractors on terms that are acceptable to us, or effectively manage the work performed by any retained third-party contractors, our ability to advance our business or product candidates may be significantly impaired and our stock price may be adversely affected.

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

We depend heavily on our executive, managerial and clinical personnel. To the extent that we lose any of these key personnel, our ability to develop products and become profitable may suffer. The risk of being unable to retain key personnel may be increased by the fact that, other than with respect to our CEO, we have not entered into long-term employment contracts with our executives or employees. Our future success will also depend in large part on our ability to attract and retain qualified executives and employees in the future. We face competition for personnel from other companies, academic institutions, government entities and other organizations. In particular, we are highly dependent on members of our executive team to manage our business. In connection with our restructuring initiatives and our plan to transition the company to an outsourcing business strategy, certain members of our executive team are no longer with the company and new executive team members have been hired. Our transition in expertise, as with any company, will take time, resources and may result in unexpected expense and delay to our business programs. Each new 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 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 involved in securities class action litigation and shareholder derivative litigation that could become expensive and divert management's attention from operating our business.***

NPS and certain of our officers have been named as defendants in a consolidated securities class action lawsuit. In addition, certain of our officers, directors and former officers and directors have been named as defendants in several shareholder derivative lawsuits. The parties with respect to these actions have reached an agreement to settle and entered into a Memorandum of Understanding ("MOU") with respect to the same. The MOU memorializes the terms pursuant to which the plaintiffs and the defendants intend to settle the case, subject to court approval. We maintain insurance for claims of this nature, which we believe is adequate however if the ultimate cost of settling these claims is materially higher than we have anticipated, our financial position could be materially impacted.

***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 limited product liability insurance coverage for our clinical trial in humans; 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 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. Although we believe our contractors' safety procedures for these materials comply with governmental standards, we cannot eliminate the risk of accidental contamination or injury from these materials. We currently have insurance, in amounts and on terms typical for companies in businesses that are similarly situated, that could cover all or a portion of a damage claim arising from our use of hazardous and other materials. However, if an accident or environmental discharge occurs, and we are held liable for any resulting damages, the associated liability could exceed our insurance coverage and our financial resources.

### **Risks Related to Our Common Stock and Notes Payable**

***Our stock price has been and 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. We receive only limited attention by securities analysts and frequently experience an imbalance between supply and demand for our common stock. 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;
- 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;
- our ability to meet market expectations with respect to FDA approval or the timing for FDA approval for our product candidates; and
- general market conditions.

***Anti-takeover provisions in our Certificate of Incorporation, Bylaws, stockholder rights plan 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. In addition, our Board of Directors has adopted a stockholder rights plan, commonly known as a "poison pill," that may delay or prevent a change of control.

***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. Sales by existing stockholders of a large number of shares of our common stock in the public market and the sale of shares issued in connection with strategic alliances, or the perception that such additional sales could occur, could cause the market price of our common stock to drop.

***Royalty revenues received from Amgen on sales of cinacalcet HCl may not be sufficient to cover the interest and principal payments on our Class A Notes and Class B 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 Class A Notes and Class B Notes are non-recourse to us and are secured by our royalty and milestone payment rights under our agreement with Amgen. Until the Class A Notes and Class B Notes are repaid, all payments from Amgen will go to the payment of interest and principal on the notes. If the revenues received 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. The principal amount of the Class B Notes will increase through the issuance of additional notes in lieu of payment of cash interest until the initial Class A Notes are paid in full.

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

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

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

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

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

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

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

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

*The recent deterioration of the U.S. credit and capital markets has adversely affected the value of our auction-rate securities; if these conditions continue, our auction-rate securities may never be saleable and our financial condition and cash flow may be adversely impacted.*

Our investment portfolio includes investments in certain auction rate securities or ARS. ARS are variable interest rate securities tied to short-term interest rates with nominal long-term maturities. ARS have interest rate resets through a modified Dutch auction, at predetermined short-term intervals, usually every 7, 28, 35, or 49 days. With the liquidity issues experienced in global credit and capital markets, our ARS portfolio has experienced multiple unsuccessful auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders. Given the unsuccessful auctions, our ARS are illiquid until there is a successful auction for them and therefore, we have classified ARS marketable securities to non-current assets as of December 31, 2008 and December 31, 2007.

The estimated value of our ARS holdings at December 31, 2008, was \$8.8 million, which reflects \$20.9 million less than our principal value of \$29.7 million. Due to the severity of the decline in fair value, as well as the duration of time for which these securities have been in a loss position, we concluded that our ARS held December 31, 2008 and December 31, 2007, have experienced an other-than-temporary decline in fair value. Accordingly, we have recorded impairment charges of \$20.9 million \$4.1 million during the years ended December 31, 2008 and 2007, respectively. If uncertainties in the credit and capital markets continue, these markets deteriorate further or if we experience ratings downgrades on any investments in our portfolio, including on ARS, the fair value of our investment portfolio may decline further which could materially impact our liquidity, cash flow, financial flexibility and ability to fund our operations following 2009.

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

None.

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

During 2007, we consolidated our business operations into one facility in Bedminster, New Jersey. In Bedminster, we lease approximately 33,500 square feet of administrative space. The Bedminster lease will expire in February 2010.

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

##### **Securities Class Action.**

A consolidated shareholders' securities class action lawsuit is currently pending against us and certain of our present and former officers and directors in the U.S. District Court for the District of Utah, Central Division, as Case No. 2:06cv00570 DAK. By order dated September 14, 2006, the court consolidated four separately filed lawsuits into this action. By order dated November 17, 2006, the court appointed lead plaintiff and counsel for the proposed class. On January 16, 2007, the lead plaintiff and its counsel filed a consolidated amended complaint asserting two federal securities claims on behalf of lead plaintiff and all other shareholders of NPS who purchased publicly traded shares of NPS between August 7, 2001, and May 2, 2006, which period is referred to in this paragraph as the "class period." The consolidated complaint asserts two claims: a claim founded upon Section 10(b) of the Securities Exchange Act of 1934, or the 1934 Act, and SEC Rule 10b-5 promulgated thereunder, which is asserted against all defendants, and a claim founded upon Section 20(a) of the 1934 Act, which is asserted against the individual defendants. Both claims are based on the allegations that, during the class period, NPS and the individual defendants made false and misleading statements to the investing public concerning PREOS. The consolidated complaint alleges that false and misleading statements were made during the class period concerning the efficacy of PREOS as a treatment for postmenopausal osteoporosis, the potential market for PREOS, the risk of hypercalcemic toxicity as a side effect of injectable PREOS, and the prospects of FDA approval of our NDA for injectable PREOS. The complaint also alleges claims of option backdating and insider trading of NPS stock during the class period. The consolidated complaint seeks compensatory damages in an unspecified amount, unspecified equitable or injunctive relief, and an award of an unspecified amount for plaintiff's costs and attorneys fees.

On March 20, 2008, the court entered a stipulation by the parties staying the action pending mediation commencing on June 3, 2008.

Following mediation, the parties reached an agreement to settle this matter and entered into a Memorandum of Understanding ("MOU") with respect to the same. The MOU memorializes the terms pursuant to which the plaintiffs and the defendants intend to settle the case, subject to court approval. Under the terms of the MOU, the defendants' directors' and officers' liability insurers will pay \$15.0 million in resolution of the matter and all claims asserted against us, and the other named defendants will be dismissed with prejudice with no admission or finding of wrongdoing on the part of any defendant. We have recorded \$15.0 million as Litigation receivable and Litigation payable on our balance sheet as of December 31, 2008. Subsequently, on February 24, 2009, the parties executed a Stipulation of Settlement finalizing the terms of the settlement, subject to final court approvals following notices to shareholders and members of the settlement class. On March 12, 2009, the court issued a Preliminary Order approving the Stipulation of Settlement.

### **Derivative Actions.**

On August 22, 2006, an NPS shareholder filed a shareholder derivative action against certain of our present and former officers and directors. This action, which names NPS as a nominal defendant, but is asserted on NPS's behalf, is pending in the Third Judicial District Court of Salt Lake County, State of Utah, as *Deane v. Tombros, et al.*, Case No. 060913838. The complaint asserts allegations similar to those asserted in the securities class action described above and also alleges that the defendant directors and officers violated their fiduciary duties by making the allegedly false and misleading statements to the investing public concerning PREOS. The derivative complaint seeks compensatory damages in an unspecified amount, unspecified equitable or injunctive relief and an award of an unspecified amount for plaintiff's costs and attorneys fees.

Defendants filed a motion to dismiss the lawsuit, which the court granted by order dated July 8, 2007, without prejudice with leave to file an Amended Complaint. In the order, the court also granted plaintiff leave to propound a books and records inspection demand under Utah law and to amend the shareholder derivative complaint. Plaintiff served a books and records inspection demand, in response to which NPS produced the requested documents. On December 14, 2007, defendants filed a motion to stay the lawsuit pending resolution of the securities class action and similar shareholder derivative lawsuits filed in U.S. District Court for the District of Utah, which are described below. Plaintiff has opposed defendants' motion to stay, which is currently pending before the court. If the court does not grant defendants' motion to stay, plaintiff will be permitted to file an amended shareholder derivative complaint.

Three shareholder derivative actions titled *Wagner v. Tombros, et al.*, *Alvarez v. Jackson, et al.*, and *Sutton v. Tombros, et al.*, were filed in the U.S. District Court for the District of Utah on July 24, 2007, August 17, 2007, and November 14, 2007, respectively and are pending there. These lawsuits, as amended by the consolidated action described below, allege the defendants made false and misleading statements concerning PREOS, and that because of these statements, the defendants breached their fiduciary duties. The lawsuits seek compensatory damages in an unspecified amount, unspecified equitable or injunctive relief and an award of an unspecified amount for plaintiff's costs and attorneys fees.

On March 13, 2008, the parties in the *Wagner, Alvarez, and Sutton* suits filed a Stipulation and Proposed Order to Consolidate Related Actions, Appoint Lead Counsel and Liaison Counsel and Set a Schedule. The Order was entered by the court on May 9, 2008. On June 30, 2008, the plaintiffs filed a consolidated shareholder derivative complaint in this action, titled *In re NPS Pharmaceuticals, Inc. Derivative Litigation*, No. 2:07-cv-0611-DAK. On August 14, 2008, Defendants filed two motions to dismiss: one motion to dismiss on behalf of all defendants for failure to plead demand futility, and a second motion to dismiss on behalf of the individual defendants for failure to state a claim. On the same date, defendants also filed a motion in the alternative to stay the derivative suit in favor of *In re NPS Pharmaceuticals, Inc. Securities Litigation*, which is pending before the same court. On March 20, 2008, the court entered a stipulation by the parties staying the action pending mediation of all of the derivative cases commencing on June 3, 2008. On October 1, 2008, pursuant to a stipulation by the parties, the court ordered that plaintiffs' obligation to respond to the pending motions was extended until November 1, 2008.

Following mediation, the parties reached an agreement in principle to settle both the state and federal derivative actions. The parties subsequently executed a Memorandum of Understanding, pursuant to which the defendants' directors' and officers' liability insurers will pay \$1.0 million toward plaintiffs' legal fees in resolution of the matter and all claims asserted against the defendants, will be dismissed with prejudice with no admission or finding of wrongdoing on the part of any defendant. As a term of the settlement, we will also implement certain corporate governance measures. We have recorded \$1.0 million as Litigation receivable and Litigation payable on our balance sheet as of December 31, 2008. On March 16, 2009, the parties entered into a Stipulation of Settlement finalizing the terms of the settlement, subject to shareholder notice and court approval.



## **Sensipar® (Cinacalcet HCl) Patent Infringement Litigation.**

On June 16, 2008, we reported the receipt of Paragraph IV Certification Notice Letters ("Notice Letters") related to Abbreviated New Drug Applications (ANDA) submitted to the U.S. Food and Drug Administration (FDA) by Barr Laboratories Inc. ("Barr") and Teva Pharmaceutical USA, Inc. ("Teva") requesting approval to market and sell generic versions of Sensipar (Cinacalcet HCl). The Notice Letters alleged that the U.S. Patent Numbers 6,011,068 ("the '068 patent"), 6,031,003 ("the '003 patent"), 6,313,146 ("the '146 patent"), and 6,211,244 ("the '244 patent") covering Sensipar are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product described in the ANDAs.

Under our licensing agreement with Amgen, Amgen is responsible for all development and commercial activities involving Sensipar, as well as enforcing applicable patent rights, in the licensed territories. The '068 patent, the '003 patent and the '146 patent are co-owned by us and The Brigham and Women's Hospital, which licensed its rights to us. We have licensed rights to these patents and the '244 patent to Amgen. On July 25, 2008, we, The Brigham and Women's Hospital and Amgen filed a patent infringement action in United States District Court, District of Delaware, No. 1:08cv00464 HB, against Barr and Teva relating to each of the patents referenced above. On August 18, 2008, Barr and Teva filed answers, defenses, and counterclaims alleging that the '068, '003, '146, and '244 are invalid and/or not infringed. On September 8, 2008, we, The Brigham and Women's Hospital and Amgen filed answers to Barr's and Teva's counterclaims. The parties are currently engaged in active discovery and the case will be placed in the trial pool in May 2010. By statute, since plaintiffs initiated a patent infringement lawsuit against Barr and Teva within 45 days of receipt of the Notice Letters, the FDA is automatically precluded from approving the ANDAs until the earlier of September 8, 2011 or a district court decision finding the patents invalid, unenforceable or not infringed. We are confident of the validity and enforceability of these patents and in conjunction with The Brigham and Women's Hospital and Amgen will vigorously prosecute these actions to protect these patents from infringement.

In 2004 and 2007, we partially monetized our rights to receive payments from Amgen through the issuance of Class A Notes and Class B Notes, which are non-recourse to us. After repayment of this debt, Sensipar royalties, if any, will return to us.

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

Listed below is information on our executive officers as of March 5, 2009. 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: 52

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

**Luke M. Beshar, CPA**

Sr. Vice President and Chief Financial Officer

Age: 50

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. Most recently, 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. Luke Beshar obtained his B.S. degree in Accounting and Finance from Michigan State University and is a graduate of The Executive Program at the Darden Graduate School of Business at the University of Virginia.

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

Sr. Vice President and Chief Medical Officer

Age: 55

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 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 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.

**Andrew Rackear, JD**

Sr. Vice President, Legal Affairs and General Counsel

Age: 55

Andrew Rackear has served as Senior Vice President, Legal Affairs, General Counsel and Secretary since November 2007. He joined NPS in July 2007 as Associate General Counsel and served in that capacity until November 2007. Prior to joining NPS, he served as Vice President and General Counsel at Chugai Pharma since April 2005. Prior to that, he served as Vice President and General Counsel at Amersham Biosciences Corp. from 2001 until April 2005. Mr. Rackear received a J.D. from New York University and a B.A. from the University of Rochester. Mr. Rackear is a member of the New York and New Jersey state bar associations.

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

No matter was submitted to the stockholders during the fourth quarter of 2008.

## PART II

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

Since May 26, 1994, our common stock has been quoted on the Nasdaq National Market under the symbol "NPSP." In connection with NASDAQ's transition to a national securities exchange in October 2006, our common stock is now quoted on the Nasdaq Global Market under the same symbol. 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>2007</b>		
First Quarter	\$ 4.55	\$ 3.27
Second Quarter	4.54	3.48
Third Quarter	6.00	3.67
Fourth Quarter	5.68	3.75
<b>2008</b>		
First Quarter	\$ 4.20	\$ 3.56
Second Quarter	4.52	3.54
Third Quarter	8.81	4.44
Fourth Quarter	7.38	5.22

As of March 5, 2009, there were approximately 172 holders of record of our common stock.

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.

**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, 2008. This data is derived from, and qualified by reference to, our audited consolidated financial statements and notes thereto appearing elsewhere in this Form 10-K.

**Consolidated Statements of Operations Data:**

	Years Ended December 31,				
	2008	2007	2006 (1)	2005	2004
<b>(in thousands, except per share amounts)</b>					
Revenues:					
Royalties	\$ 70,217	\$ 49,626	\$ 32,078	\$ 12,533	\$ 2,159
Product sales	4,544	20,310	2,662	-	-
Milestones and license fees	27,518	16,312	13,762	292	12,078
Total revenues	<u>102,279</u>	<u>86,248</u>	<u>48,502</u>	<u>12,825</u>	<u>14,237</u>
Operating expenses:					
Cost of royalties	5,831	4,659	2,980	1,144	237
Cost of goods sold	1,350	6,180	1,413	-	-
Cost of license fees	5,665	1,547	-	-	-
Research and development (2)	18,965	36,195	62,470	112,769	140,673
Selling, general and administrative (2)	22,563	29,526	58,118	53,311	36,777
Restructuring (credits) charges	(272)	13,386	8,179	-	-
Total operating expenses	<u>54,102</u>	<u>91,493</u>	<u>133,160</u>	<u>167,224</u>	<u>177,687</u>
Other operating (gains) losses:					
Gain on sale of assets held for sale	-	(1,826)	-	-	-
Gain on sale of fixed assets	(186)	(6,384)	-	-	-
Gain on sale of assets (3)	-	(30,000)	-	-	-
Write-down of long-lived assets	-	-	8,297	-	-
Amortization of purchased intangibles	-	-	-	-	1,598
Total Other operating (gains) losses	<u>(186)</u>	<u>(38,210)</u>	<u>8,297</u>	<u>-</u>	<u>1,598</u>
Operating income (loss)	48,363	32,965	(92,955)	(154,399)	(165,048)
Other income (expense), net	<u>(80,268)</u>	<u>(36,467)</u>	<u>(19,713)</u>	<u>(15,379)</u>	<u>(1,570)</u>
Income (loss) before income tax expense (benefit)	(31,905)	(3,502)	(112,668)	(169,778)	(166,618)
Income tax expense (benefit)	(179)	780	-	(55)	1,633
Net loss	<u>\$ (31,726)</u>	<u>\$ (4,282)</u>	<u>\$ (112,668)</u>	<u>\$ (169,723)</u>	<u>\$ (168,251)</u>
Basic and diluted net loss per share (4)	<u>\$ (0.67)</u>	<u>\$ (0.09)</u>	<u>\$ (2.43)</u>	<u>\$ (4.14)</u>	<u>\$ (4.43)</u>
Basic and diluted weighted average shares outstanding (4)	47,699	46,804	46,374	41,036	37,948

- (1) We adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123R, *Share Based Payment*, or SFAS No. 123R, using the modified prospective method. The adoption of SFAS No. 123R increased our operating loss, loss before income tax expense (benefit) and net loss for 2006 by \$13.4 million and basic and diluted net loss per share by \$0.29.
- (2) We reclassified \$2.5 million, \$5.9 million, \$4.7 million and \$2.4 million for the years ended December 31, 2007, 2006, 2005 and 2004, respectively, from research and development expenses to selling, general and administrative expenses for legal costs related to patents that were previously presented in research and development expenses in prior years.
- (3) Amount relates to the sale of our mGluRs program to AstraZeneca. See note 2 to the consolidated financial statements for information concerning the AstraZeneca agreement.
- (4) See note 1 to the consolidated financial statements for information concerning the computation of net loss per share.

## Consolidated Balance Sheets Data:

	Years Ended December 31,				
	2008	2007	2006	2005	2004
(in thousands)					
Cash, cash equivalents, and current marketable investment securities	\$ 97,380	\$ 133,331	\$ 146,152	\$ 258,967	\$ 329,685
Working capital	96,607	102,921	145,222	233,907	306,349
Total assets	203,606	231,853	224,740	331,052	397,485
Long-term portion of lease financing, notes payable and other long-term liabilities	336,803	341,345	373,517	390,117	367,000
Accumulated deficit	(904,880)	(873,154)	(868,872)	(756,204)	(586,481)
Stockholders' deficit	(215,086)	(191,656)	(193,244)	(97,524)	(12,789)

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

### SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

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

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

### Overview

We are a biopharmaceutical company focused on the development of new treatment options for patients with rare gastrointestinal and endocrine disorders and serious unmet medical needs. Our lead clinical programs involve two proprietary therapeutic proteins to restore or replace biological function: GATTEX™ (teduglutide) and NPSP558 (parathyroid hormone 1-84 [rDNA origin] injection). GATTEX is our analog of GLP-2, a protein involved in the regeneration and repair of the intestinal lining, and is in Phase 3 clinical development for parenteral dependent (PN) short bowel syndrome (SBS). SBS is a highly disabling condition that results from surgical resection, congenital defect or disease-associated loss of absorption and the subsequent inability to maintain fluid, electrolyte, and nutrient balances on a conventional diet. NPSP558 is our recombinant full-length human parathyroid hormone (PTH 1-84) that is in Phase 3 clinical development for hypoparathyroidism, a rare condition in which the body does not maintain normal calcium levels in the blood due to insufficient levels of parathyroid hormone.

We are currently advancing registration studies for GATTEX and NPSP558. Our study of GATTEX is known as STEPS (Study of TEduglutide in PN-dependent Short bowel syndrome) and our study of NPSP558 is known as REPLACE (REcombinant Parathyroid hormone to normaLize cAlcium and trEat hypoparathyroidism). We believe positive results from STEPS and REPLACE will enable us to seek U.S. marketing approval of GATTEX for SBS and

NPSP558 for hypoparathyroidism. While SBS and hypoparathyroidism are relatively rare disorders, we believe they represent a substantial commercial opportunity to us due to the significant unmet need and lack of effective therapies, as well as the serious complications and chronic nature of these diseases.

We have incurred cumulative losses from inception through December 31, 2008 of approximately \$904.9 million. We expect to continue to incur significant operating losses over at least the next several years as we continue our current and anticipated development projects. Activities that will increase our future operating losses include activities to obtain FDA approval to market GATTEX and NPSP558 in the U.S.; current and future clinical trials with GATTEX and NPSP558; and clinical and manufacturing costs for GATTEX and NPSP558 in the U.S.

Our most advanced proprietary research and development projects involve GATTEX and NPSP558. See “Item 1 – Business – Proprietary Product Candidates.” During the years ended December 31, 2008, 2007 and 2006, we incurred expenses of \$7.0 million, \$19.6 million and \$15.5 million, respectively, in the research and development of GATTEX, including costs associated with the manufacture of clinical supplies of GATTEX. We have incurred costs of approximately \$137.5 million since we assumed development obligations of this product candidate upon our acquisition of Allelix Biopharmaceuticals Inc., or Allelix, in December 1999. During the years ended December 31, 2008, 2007 and 2006 we incurred \$4.9 million, \$5.4 million and \$14.3 million, respectively, in the research and development of NPSP558, including costs associated with the manufacture of clinical and commercial supplies of NPSP558. We have incurred costs of approximately \$352.0 million since we assumed development obligations for NPSP558 upon our acquisition of Allelix in December 1999. Our development administration overhead costs are included in total research and development expense for each period, but are not allocated among our various projects. 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.”

Although we are pursuing NPSP558 only for hypoparathyroidism at this time, our historical development efforts have focused on developing this compound for osteoporosis using the brand name PREOS®. The expenditures described as part of our results of operations and financial condition through 2007 relate primarily to expense incurred for the osteoporosis indication. After refocusing our proprietary clinical development on rare gastrointestinal and endocrine disorders of high unmet medical need, we have determined that we will pursue NPSP558 for osteoporosis only on a partnered basis.

## Results of Operations

The following table summarizes selected operating statement data for the years ended December 31, 2008, 2007 and 2006 (dollars in thousands):

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Revenues:			
Royalties	\$ 70,217	\$ 49,626	\$ 32,078
Product sales	4,544	20,310	2,662
Milestones and license fees	27,518	16,312	13,762
Total Revenues	\$ 102,279	\$ 86,248	\$ 48,502
Operating expenses:			
Cost of royalties	\$ 5,831	\$ 4,659	\$ 2,980
% of royalties	8 %	9 %	9 %
Cost of goods sold	\$ 1,350	\$ 6,180	\$ 1,413
% of product sales	30 %	30 %	53 %
Cost of license fees	\$ 5,665	\$ 1,547	\$ -
% of milestones and license fees	21 %	9 %	- %
Research and development	\$ 18,965	\$ 36,195	\$ 62,470
% of revenues	19 %	42 %	129 %
Selling, general and administrative	\$ 22,563	\$ 29,526	\$ 58,118
% of revenues	22 %	34 %	120 %
Restructuring (credits) charges	\$ (272)	\$ 13,386	\$ 8,179
Gain on sale of assets held for sale	\$ -	\$ (1,826)	\$ -
Gain on sale of fixed assets	\$ (186)	\$ (6,384)	\$ -
Gain on sale of assets held for sale	\$ -	\$ (30,000)	\$ -
Write-down of long-lived assets	\$ -	\$ -	\$ 8,297

### Years ended December 31, 2008 and 2007

**Revenues.** Substantially all our revenues relate to license fees, milestone payments, product sales and royalty payments from our licensees and collaborators. These revenues fluctuate from year to year. Our revenues were \$102.3 million in 2008 compared to \$86.2 million in 2007. We recognized revenue under our research and license agreements as follows:

- Under our agreement with Amgen for Sensipar<sup>®</sup> in the U.S. and Mimpara<sup>®</sup> in Europe (cinacalcet HCl), we recognized revenue of \$59.6 million in 2008 and \$46.4 million in 2007;
- Under our agreements with Nycomed for GATTEX<sup>™</sup> (teduglutide, recombinant GLP-2), we recognized revenue of \$27.7 million in 2008 and \$7.3 million in 2007;
- Under our agreement with Nycomed for Preotact<sup>®</sup> (parathyroid hormone [rDNA origin] for injection), we recognized revenue of \$11.0 million in 2008 and \$30.1 million in 2007;
- Under our agreement with Kirin, we recognized revenue of \$1.9 million in 2008 and \$2.0 million in 2007; and
- Under our agreement with Roche, we recognized revenue of \$2.0 million in 2008 and zero in 2007.

The increase in royalty revenue earned from Amgen is due to sales growth of Sensipar. Amgen pays Sensipar royalties directly to a wholly owned subsidiary of NPS and the royalties secure non-recourse debt that we issued in August 2007 and December 2004.

For the years ended December 31, 2008 and 2007, our revenues related to our agreement with Nycomed for GATTEX were \$25.2 million and \$7.3 million, respectively. In September 2007, we entered into an agreement with Nycomed for the rights to develop and commercialize GATTEX in territories outside of North America for gastrointestinal disorders. In connection with this agreement, we received a \$35.0 million up-front license fee under the Nycomed agreement and recognized \$25.2 million and \$7.3 million in revenue during the years ended December 31,

2008 and 2007, respectively. Due to our continuing involvement under the agreement we are recognizing revenue over the estimated performance period and at December 31, 2008 we had \$2.5 million of deferred revenue, which we expect to recognize as revenue in 2009. We also entered into a one-time agreement to sell bulk teduglutide to Nycomed for \$2.5 million during the year ended December 31, 2008.

For the year ended December 31, 2008, our revenues related to our agreement with Nycomed for Preotact were comprised of (i) \$8.7 million in royalty revenue; (ii) \$2.1 million in sales of finished inventory and reference standards; and (iii) \$302,000 in milestone revenue. For the year ended December 31, 2007, our revenues related to our agreement with Nycomed for Preotact were comprised of (i) \$20.3 million in sales of bulk product and finished inventory; (ii) \$6.5 million in milestone revenue; and (iii) \$3.3 million in royalty revenue. In April 2006, the European Medicines Agency or EMEA approved Preotact for the treatment of postmenopausal women with osteoporosis at high risk for fractures. In July 2007, we sold our right to receive certain future royalty payments from Nycomed's sale of Preotact in Europe to DRI Capital (previously Drug Royalty L.P.3).

For the year ended December 31, 2008, we recognized \$1.9 million in royalty revenue under our agreement with Kyowa Kirin (formerly Kirin Pharma) for sales of Regpara. During the year ended December 31, 2007 we recognized milestone revenue of \$2.0 million from Kyowa Kirin. The Japanese Pharmaceuticals and Medical Devices Agency's approval of Regpara in 2007 triggered the milestone payment. We are entitled to royalties on Kyowa Kirin's future sales of Regpara.

We recognized an up-front license fee from Roche of \$2.0 million during the year ended December 31, 2008, for a non-exclusive patent license.

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

**Cost of Royalties.** Our cost of royalties consists of royalties owed under our agreement with the Brigham and Women's Hospital on sales of cinacalcet HCl. We recorded cost of royalties of \$5.8 million and \$4.7 million, respectively, during the years ended December 31, 2008 and 2007. The increase in cost of royalties is due to increased sales of cinacalcet HCl by Amgen and the launch of REGPARA in Japan by Kyowa Kirin. Under our agreement with the Brigham and Women's Hospital, our royalty obligation is completed when cumulative royalty expense reaches \$15.0 million, which we reached during the year ended December 31, 2008, therefore, we will no longer recognize cost of royalty expense related to sales of cinacalcet HCl after December 31, 2008.

**Cost of Goods Sold.** Our cost of goods sold consists of the cost of inventory, subsequent to the April 2006 approval of Preotact<sup>®</sup> in the EU, for product sales to Nycomed. Prior to the approval of Preotact in the EU, we expensed the costs associated with inventory as research and development expense, which created an initial First In First Out (FIFO) inventory layer with a carrying value of zero. We recorded cost of goods sold of \$1.4 million and \$6.2 million, respectively, during the years ended December 31, 2008 and 2007. The decrease in cost of goods sold is due to decreased sales to Nycomed during the year ended December 31, 2008 compared to the year ended December 31, 2007. As of December 31, 2007, we have consumed all of our zero-costed inventory.

**Cost of License Fees.** Our cost of license fees relate to fees and royalties owed to a third party upon the licensing of GATTEX to Nycomed in September 2007. We recorded cost of license fees of \$5.7 million and \$1.5 million during the years ended December 31, 2008 and 2007, respectively. Under a third party licensing agreement we made cash payments of \$6.6 million, and we incurred additional costs of \$591,000 related to the Nycomed GATTEX agreement. These costs are being amortized over the same period and in the same manner as the related deferred revenue. The balance of the license fee payment cost has been deferred at December 31, 2008 and is expected to be recognized as expense in 2009.

**Research and Development.** Our research and development expenses are primarily comprised of personnel-related costs for our employees who are dedicated to development activities, and from the fees paid and costs reimbursed to outside professionals to conduct research, preclinical and clinical trials, and to manufacture drug compounds and related supplies prior to FDA approval. Historically, our research and development expenses included costs for our employees who performed research activities; however, our 2007 restructuring initiatives eliminated substantially all of our internal research functions. During 2007, we restructured our business to focus our clinical development on rare gastrointestinal and endocrine disorders of high unmet medical need. For the year ended December 31, 2008 our research and development expenses decreased to \$19.0 million from \$36.2 million for the year ended December 31, 2007. The decrease was primarily related to (i) a \$10.1 million decrease in third-party costs, consisting primarily of outside services and consulting fees, investigator grants, site management and monitoring services related to the completion of a



Phase 3 study for GATTEX in short bowel syndrome during 2007 and the corresponding decline in costs associated with that study, as well as the discontinuation of certain research and development activities due to the restructuring; (ii) a \$5.6 million decrease in personnel-related costs primarily due to the 2007 and 2006 restructurings, and (iii) a \$1.4 million decline in depreciation expense that related to research and development.

***Selling, General and Administrative.*** Our selling, general and administrative expenses consist primarily of the costs of our management and administrative staff, business insurance, property taxes, professional fees, legal fees and product planning activities. Our selling, general and administrative expenses decreased to \$22.6 million for the year ended December 31, 2008 from \$29.5 million in 2007. The reduction in selling, general and administrative expenses was primarily due to (i) a \$1.6 million decrease in personnel-related costs primarily due to our 2007 and 2006 restructurings; (ii) a \$4.0 million net decrease in legal fees, which includes a \$2.7 million insurance reimbursements from our insurance carrier related to the consolidated shareholders' securities class action lawsuit; and (iii) \$1.8 million decrease in administrative costs, including information technology, insurance, taxes and utilities.

***Restructuring Charges.*** Our restructuring charges relate to our initiatives to restructure operations as announced in March 2007 and June 2006. In connection with our restructuring initiatives, we reduced our worldwide workforce, including employees and contractors; eliminated all commercial sales and related field-based activities; terminated certain collaboration agreements; and closed and sold facilities located outside of New Jersey. The reductions in workforce involved all functional disciplines within the company. Restructuring credits or charges for the years ended December 31, 2008 and 2007 were a credit of \$272,000 and a charge of \$13.4 million, respectively. The credit during the year ended December 31, 2008 relates primarily to the reversal of previously accrued severance for certain employees who had previously been expected to be terminated and had earned their severance and had no further service obligations, but who we later retained. These costs were partially offset by employee termination benefits. Restructuring charges during the year ended December 31, 2007 were primarily comprised of employee termination benefits.

***Gain on Sale of Assets Held for Sale.*** Our gain on sale of assets held for sale during the year ended December 31, 2008 and 2007 was zero and \$1.8 million, respectively. The gain recorded during the year ended December 31, 2007 relates to the sale of our laboratory and administrative office building, including equipment, located in Mississauga, Ontario, Canada in June 2007.

***Gain on Sale of Fixed Assets.*** We reported a gain on sale of fixed assets for the year ended December 31, 2008 and 2007 of \$186,000 and \$6.4 million, respectively. The gain in 2007 was primarily due to the sale of our laboratory and administrative office building, including equipment, located in Salt Lake City, Utah in July 2007, and the sale of our leasehold improvements and equipment at a laboratory facility in Toronto, Canada in August 2007.

***Gain on Sale of Assets.*** Our gain on sale of assets during the year ended 2007 was \$30.0 million. This gain was related the sale of our interests in our metabotropic glutamate receptors or mGluRs, program to AstraZeneca, or AZ, which we sold in connection with our 2007 restructuring initiatives.

***Total Other Expense, Net.*** Our total other expense, net, increased to \$80.3 million for the year ended December 31, 2008 from \$36.5 million for the year ended December 31, 2007. The increase in total other expense, net, was primarily due to an \$18.2 million increase in interest expense, under the effective interest method, on debt agreements entered into in 2007, which included (i) the Class B Notes (\$11.5 million increase), (ii) the 5.75% Convertible Notes (\$1.8 million increase) and (iii) DRI Capital's purchase of our Preotact royalty which we account for as debt, (\$4.9 million). The increase was also attributable to a \$14.0 million increase in interest expense, under the effective interest method, on the Class A Notes due to an increased forecast of sales of Sensipar which increased our redemption premium; a \$16.8 million increase in other than temporary impairment charges related to certain ARS and also attributable to a \$4.7 million decrease in interest income due to a lower average cash balance during 2008 compared to 2007.

The increases in interest expense were partially offset by a gain of \$1.3 million on the extinguishment of our 3% convertible notes which occurred during 2007 and did not recur in 2008. The increase was also offset by (i) a reduction in interest expense from our repayment of substantially all of our 3% convertible notes during the fourth quarter of 2007 (\$5.5 million decrease); (ii) a reduction in interest expense on the Class A notes due to a \$24.5 million principal payment in March 2008 (\$1.9 million decrease); and (iii) a reduction in interest expense on the lease financing obligation, which related to the Salt Lake City building that we sold in 2007 (\$808,000 decrease). The increase was also offset by a \$1.3 million increase in gains on foreign currency transactions and a \$970,000 loss on the extinguishment of lease financing obligations related to the Salt Lake City building in 2007.

**Income Taxes.** Our income tax (benefit) expense was a \$179,000 benefit in 2008 and a \$780,000 expense in 2007 related to the United States Federal alternative minimum tax.

As of December 31, 2008, we had a United States federal and New Jersey state income tax net operating loss carryforward of approximately \$294.9 million and \$211.1 million, respectively, and a United States federal income tax research credit carryforward of approximately \$6.7 million. We also had a Canadian federal and provincial income tax net operating loss carryforward of approximately \$448.6 million and \$448.6 million, respectively, a Canadian research pool carryforward of approximately \$153.8 million, a Canadian investment tax credit carryforward of approximately \$18.5 million and an Ontario Harmonization tax credit of approximately \$2.7 million. Our ability to utilize the United States operating loss and credit carryforwards against future taxable income will be subject to annual limitations in future periods pursuant to the “change in ownership rules” under Section 382 of the Internal Revenue Code of 1986.

#### **Years ended December 31, 2007 and 2006**

**Revenues.** Our revenues were \$86.2 million in 2007 compared to \$48.5 million in 2006. We recognized revenue under our research and license agreements as follows:

- Under our agreement with Amgen, we recognized revenue of \$46.4 million in 2007 and \$31.9 million in 2006;
- Under our agreement with Nycomed for Preotact, we recognized revenue of \$30.1 million in 2007 and \$3.1 million in 2006;
- Under our agreement with Nycomed for GATTEX, we recognized revenue of \$7.3 million in 2007 and zero in 2006;
- Under our agreement with Ortho, we recognized revenue of zero in 2007 and \$8.0 million in 2006;
- Under our agreement with Kirin, we recognized revenue of \$2.0 million in 2007 and \$2.0 million in 2006; and
- Under our agreement with GSK, we recognized revenue of zero in 2007 and \$3.0 million in 2006.

The increase in royalty revenue earned from Amgen is due to the growth of cinacalcet HCl. For the year ended December 31, 2007, our revenues related to our agreement with Nycomed for Preotact were comprised of (i) \$20.3 million in sales of bulk product and finished inventory; (ii) \$6.5 million in milestone revenue; and (iii) \$3.3 million in royalty revenue. For the year ended December 31, 2006, our revenues related to our agreement with Nycomed for Preotact were comprised of (i) \$2.7 million in sales of bulk product inventory; (ii) \$0.3 million in milestone revenue; and (iii) \$0.1 million in royalty revenue.

For the year ended December 31, 2007, we recognized \$7.3 million in license fee revenue under our agreement with Nycomed for GATTEX. In September 2007, we entered into an agreement with Nycomed for the rights to develop and commercialize GATTEX in territories outside of North America for gastrointestinal disorders. In connection with this agreement, we received a \$35.0 million up-front license fee under the Nycomed agreement but only recognized \$7.3 million in revenue due to our continuing involvement under the agreement we are recognizing revenue over the estimated performance period and for the year ended December 31, 2007, we recognized \$7.3 million in license fee revenue.

During each of the years ended December 31, 2007 and 2006 we recognized milestone revenue of \$2.0 million and \$2.0 million, respectively, from Kyowa Kirin. The Japanese Pharmaceuticals and Medical Devices Agency’s approval of Regpara in 2007 and Kyowa Kirin’s filing of a new drug application in 2006 triggered the milestone payments. We are entitled to royalties on Kyowa Kirin’s future sales of Regpara.

We recognized an upfront license fee from Ortho of \$8.0 million for a commitment not to sue for patent infringement and we recognized an up-front license fee from GSK of \$3.0 million for the addition of certain compounds to the collaboration during the year ended December 31, 2006.

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

**Cost of Goods Sold.** We recorded cost of goods sold of \$6.2 million and \$1.4 million, respectively, during 2007 and 2006. The increase in cost of goods sold is due to increased sales to Nycomed and the previous utilization of zero-costed inventory layers.

**Cost of Royalties.** We recorded cost of royalties of \$4.7 million and \$3.0 million, respectively, during 2007 and 2006. The increase in cost of royalties is due to increased sales of cinacalcet HCl by Amgen.

**Cost of License Fees.** We recorded cost of license fees of \$1.5 million and zero during the years ended December 31, 2007 and 2006 respectively. Under a third party licensing agreement we made cash payments of \$6.6 million, and we incurred additional costs of \$591,000 related to the Nycomed GATTEX agreement. These costs are being amortized over the same period and in the same manner as the related deferred revenue.

**Research and Development.** Our research and development expenses are primarily comprised of personnel-related costs for our employees who are dedicated to development activities, and from the fees paid and costs reimbursed to outside professionals to conduct research, preclinical and clinical trials, and to manufacture drug compounds and related supplies prior to FDA approval. Historically, our research and development expenses also included costs for our employees who performed research activities; however, as a result of our restructuring, we eliminated substantially all of our internal research functions. As a result, our research and development expenses decreased to \$36.2 million for the year ended December 31, 2007 from \$62.5 million for the year ended December 31, 2006. The reduction in research and development expenses primarily related to: (i) a \$22.0 million decrease in personnel-related costs primarily due to the 2007 and 2006 restructurings; (ii) a \$3.9 million decrease in facilities costs due to the consolidation of our operations into one New Jersey facility; and (iii) a \$3.7 million decline in expenses due to the discontinuation of research and other development activities that were no longer strategically aligned; and (iv) other overall decreases in overhead. The declines in 2007 research and development expenses were partially offset by a \$4.1 million increase in costs associated with advancing our clinical program for GATTEX for short bowel syndrome.

**Selling, General and Administrative.** Our selling, general and administrative expenses consist primarily of the costs of our management and administrative staff, business insurance, property taxes, professional fees, legal fees, product planning activities, and the cost of our sales force through June 2006. Our selling, general and administrative expenses decreased to \$29.5 million for the year ended December 31, 2007 from \$58.1 million in 2006. The decrease in selling, general and administrative expenses was primarily due to (i) a \$14.0 million decrease in personnel-related costs; (ii) a \$9.9 million decline in costs due to the discontinuation of commercial activities associated with PREOS and 2006 co-promotional activities that were terminated; (iii) a \$1.0 million decrease in other overall selling, general and administrative overhead, including facility costs, information technology and depreciation; and (iv) a \$1.2 million reduction in recruiting fees. All of these declines were attributable to the restructuring of our business during 2007.

**Restructuring Charges.** Our restructuring charges relate to our initiatives to restructure operations as announced in March 2007 and June 2006. In connection with our restructuring initiatives, we reduced our worldwide workforce, including employees and contractors; eliminated all commercial sales and related field-based activities; terminated certain collaboration agreements; and closed and sold facilities located outside of New Jersey. The reductions in workforce involved all functional disciplines. Restructuring charges for the years ended December 31, 2007 and 2006 were \$13.4 million and \$8.2 million, respectively. Restructuring charges were primarily comprised of employee termination benefits.

**Gain on Sale of Assets Held for Sale.** Our gain on sale of assets held for sale of \$1.8 million in 2007 related to the sale of our laboratory and administrative office building, including equipment, located in Mississauga, Canada.

**Gain on Sale of Fixed Assets.** Our gain on sale of fixed assets of \$6.4 million in 2007 related primarily to the sale of our laboratory and administrative office building, including equipment, located in Salt Lake City, Utah in July 2007, and the sale of our leasehold improvements and equipment at a laboratory facility in Toronto, Canada in August 2007.

**Gain on Sale of Assets.** During the year ended December 31, 2007, in connection with the restructuring of our business, we recorded a gain of \$30.0 million related to the sale of our interests in our metabotropic glutamate receptors or mGluRs, program to AstraZeneca, or AZ.

**Write-down of Long-Lived Assets.** In connection with our decision to close our facilities in Salt Lake City, Utah and Toronto, Canada, we determined that the fair value of the property and equipment located in Toronto was less than its carrying value at December 31, 2006. Accordingly, during the year ended December 31, 2006, we recorded an \$8.3 million write-down of the assets. We had no write-down during the year ended December 31, 2007.

**Total Other Expense, Net.** Our total other expense, net, increased to \$36.5 million for the year ended December 31, 2007 from \$19.7 million for the prior year. The increase in total other expense, net, is due primarily to an \$11.8 million increase in interest expense, under the effective interest method, on debt agreements entered into in 2007, which included: (i) the class B notes (\$6.5 million increase), (ii) the 5.75% convertible notes (\$1.2 million increase) and, (iii) DRI Capital's purchase of our Preotact royalty rights, which we account for as debt, (\$4.1 million). The increase was also attributable to a \$4.2 million increase in interest expense, under the effective interest method, on the redemption

premium associated with the Class A notes due to an increased forecast of sales of Sensipar, a \$4.1 million other than temporary impairment charge related to certain ARS, a \$970,000 loss on the extinguishment of lease financing obligations related to termination of the Salt Lake City building and \$815,000 loss on foreign currency transactions. The increase was partially offset by a reduction in interest expense from our repayment of substantially all of our 3% convertible notes during the fourth quarter of 2007 (\$1.5 million decrease), a reduction in interest expense on the Class A notes due to a \$19.3 million principal payment in April 2007 (\$666,000 decrease), increased interest income of \$398,000 and a gain of \$1.3 million on the extinguishment of our 3% convertible notes.

**Income Taxes.** Our income tax expense was \$780,000 in 2007 related to United States Federal alternative minimum tax compared to zero in 2006.

## Liquidity and Capital Resources

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

	<u>December 31, 2008</u>		<u>December 31, 2007</u>
Cash, cash equivalents, and current marketable securities	\$ 97,380	\$	133,331
Total assets	203,606		231,853
Current debt	35,498		24,992
Non-current debt	318,291		336,449
Stockholders' deficit	\$ (215,086)	\$	(191,656)

We require cash to fund our operating expenses, to make capital expenditures, acquisitions and investments and to service our debt. We have financed operations since inception primarily through payments received under collaborative research and license agreements, the private and public issuance and sale of equity securities, and the issuance and sale of secured debt, convertible debt and lease financing. Through December 31, 2008, we have recognized \$349.7 million of cumulative revenues from payments for research support, license fees, product sales, milestone and royalty payments, \$563.8 million from the sale of equity securities for cash and \$555.2 million from the sale of secured debt and convertible debt for cash.

Our principal sources of liquidity are cash, cash equivalents, and current marketable investment securities, which totaled \$97.4 million at December 31, 2008. 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.

Our investment portfolio includes investments in certain auction rate securities or ARS. ARS are variable interest rate securities tied to short-term interest rates with nominal long-term maturities. ARS have interest rate resets through a modified Dutch auction, at predetermined short-term intervals, usually every 7, 28, 35, or 49 days. With the liquidity issues experienced in global credit and capital markets, our ARS portfolio has experienced multiple unsuccessful auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders. Given the unsuccessful auctions, our ARS are illiquid until there is a successful auction for them and therefore, we have classified ARS marketable securities to non-current assets as of December 31, 2008 and December 31, 2007.

The estimated value of our ARS holdings at December 31, 2008, was \$8.8 million, which is \$20.9 million less than the principal value of \$29.7 million. In estimating the fair value of our ARS, we have used the fair values which were determined based on valuations performed by Pluris Valuation Advisors LLC. The fair values were determined using proprietary valuation models using the quality of the underlying securities or assets securing the ARS investments, the fair values of comparable securities, the quality of credit enhancement (if any) applicable to the specific security, estimated time to maturity or unwinding of the arrangement, an analysis of the terms of the indentures and other factors depending on the individual ARS.

In October 2008, we entered into a settlement agreement to sell certain of our ARS back to our investment advisor no later than June 2010 at par of \$1.8 million, and we transferred these ARS from the available for sale category to the trading category. The fair values of these ARS are \$1.3 million, which has been recorded as a long-term ARS, and we have recognized \$351,000 as a put option in other long-term assets at December 31, 2008 and a corresponding gain in other income for the year ended December 31, 2008. Under SFAS No. 159, *The Fair Value Option for Financial Assets*

*and Financial Liabilities – including an amendment of FASB Statement No. 115, (“SFAS No. 159”)* entities are permitted to choose to measure many financial instruments and certain other items at fair value. We elected the fair value measurement option under SFAS No. 159 for our ARS put option. The fair value election was made to minimize the net volatility of earnings in future periods as the change in fair value of the put option will approximate the opposite change in fair value of the related ARS. In estimating the fair value of this put option, we have used the fair values which were determined based on valuations performed by Pluris Valuation Advisors LLC. The fair values were determined using proprietary valuation models.

Due to the severity of the decline in fair value as well as the duration of time for which these securities have been in a loss position, we have concluded that our ARS held as of December 31, 2008 and December 31, 2007 have experienced other-than-temporary declines in fair value and have recorded a corresponding impairment charge of \$20.9 million and \$4.1 million during the years ended December 31, 2008 and 2007, respectively. If uncertainties in the credit and capital markets continue, these markets deteriorate further or if we experience ratings downgrades on any investments in our portfolio, including on ARS, the fair value of our investment portfolio may decline further. This would result in a realized loss and would negatively affect our financial position, results of operations and liquidity.

We believe that based on our current cash, cash equivalents and current marketable securities balances at December 31, 2008, the current lack of liquidity in the credit and capital markets will not have a material impact on our liquidity, cash flow, financial flexibility or ability to fund our operations in 2009.

In August 2007, we repurchased and retired \$20.2 million of our 3% Convertible Notes for \$19.5 million plus accrued interest. Additionally, in October 2007, we closed a tender offer in which \$171.2 million in 3% Convertible Notes were tendered to us for \$169.1 million plus accrued interest. After acquiring these 3% Convertible Notes, we retired them in October 2007. As of December 31, 2007, \$598,000 in 3% Convertible Notes remain outstanding. We purchased and retired the remaining notes when they matured in June 2008.

In October 2007, we entered into an Asset Purchase Agreement with AZ in which we agreed to sell our rights, including intellectual property, in drugs targeting mGluRs to AZ for \$30.0 million. Additionally, NPS and AZ agreed to terminate the collaborative research and development agreement related to drugs targeting mGluRs that was entered into in 2001. As a result of this termination, we are no longer required to provide research FTE support or pay for an equal share of external discovery costs, including patent related costs.

In September 2007, we signed a license agreement with Nycomed in which we granted Nycomed the right to develop and commercialize GATTEX outside the United States, Canada and Mexico for the treatment of gastrointestinal disorders. We received \$35.0 million in up-front fees under the agreement, of which \$25.2 million and \$7.3 million was recognized as licensing revenue during the years ended December 31, 2008 and 2007, respectively. Under the terms of the agreement, we have the potential to earn up to \$190.0 million in development and sales milestone payments and additional royalties on product sales. Under the terms of the agreement, we are responsible to complete the on-going Phase 3 GATTEX clinical trials in SBS and Nycomed may elect to share equally the future development costs with NPS to advance and broaden the indications for GATTEX. Additionally, under a previously existing licensing agreement with a third party, we made a \$6.6 million payment to the licensor as a result of the \$35.0 million license fee we received from Nycomed in 2007, and will be required to make future payments based on GATTEX royalties and milestones earned.

In August 2007, we completed a private placement of \$50.0 million of our 5.75% Convertible Notes due August 7, 2014, or 5.75% Notes. Interest on the 5.75% Notes is payable quarterly in arrears on the first day of the succeeding calendar quarter commencing January 1, 2008. The holders may convert all or a portion of the 5.75% Notes into common stock at any time, subject to certain milestones, on or before August 7, 2014. The 5.75% Notes are convertible into our common stock at a conversion rate equal to approximately \$5.44 per share, subject to adjustment in certain events. On or after August 7, 2012, we may redeem any or all of the 5.75% Notes at a redemption price of 100% of their principal amount, plus accrued and unpaid interest to the day preceding the redemption date. The 5.75% Notes are unsecured senior debt obligations and rank equally in right of payment with all existing and future unsecured indebtedness. Neither we nor any of our subsidiaries are restricted under the indenture from paying dividends, incurring debt, or issuing or repurchasing our securities. Accrued interest on the 5.75% Notes was \$725,000 and \$1.2 million as of December 31, 2008 and 2007, respectively.

In August 2007, our wholly owned subsidiary, Cinacalcet Royalty Sub LLC, closed a private placement of \$100.0 million of its Pharmaceutical Royalty Monetization Asset<sup>SM</sup> (PhaRMA<sup>SM</sup>) Secured 15.5% Class B Notes due 2017, or Class B Notes. We received net proceeds from the issuance of the Class B Notes of approximately \$97.0 million, after deducting costs associated with the offering. The Class B Notes are secured by certain royalty and related rights under

our agreement with Amgen and are non-recourse to NPS Pharmaceuticals, Inc. The only source for interest payments and principal repayment of the Class B Notes is limited to royalty and milestone payments received from Amgen and only after the Class A Notes, as described in Note 11 to the consolidated financial statements in this report, are paid in full. Accrued interest on the Class B Notes was \$23.7 million and \$6.2 million as of December 31, 2008 and 2007, respectively. We incurred related debt issuance costs of \$3.6 million, which were deferred and are being amortized using the “effective interest-rate” method. The effective interest rate on the Class B Notes, including debt issuance costs, is approximately 16.0%.

In July 2007, we entered into a Lease Termination Agreement with the MaRS Discovery District, or MaRS, under which our operating lease for the office and laboratory space in Toronto, Canada was terminated. Pursuant to the Lease Termination Agreement, we sold our leasehold tenant improvements to a third party for \$2.4 million. The termination of our operating lease and sale of our leasehold tenant improvements was part of our restructuring initiatives, which included a plan to close our Mississauga and Toronto facilities and discontinue all operations in Canada.

In July 2007, we entered into an Agreement for the Sale and Assignment of Rights with DRI Capital (previously Drug Royalty Corporation), pursuant to which we sold to DRI our right to receive future royalty payments arising from sales of Preotact under our license agreement with Nycomed. Under the agreement, DRI paid us an up-front purchase price of \$50.0 million. An additional \$25.0 million will be due to us in 2010 if certain Preotact sales thresholds are achieved. If and when DRI receives two and a half times the amount of principal advanced, the agreement will terminate and the remainder of the royalties, if any, will revert back to us.

In July 2007, we entered into a new License Agreement with Nycomed to allow Nycomed to commercialize Preotact in all non-U.S. territories, excluding Japan and Israel, and amend certain rights and obligations of NPS and Nycomed under the 2004 license agreement. The agreement provides for the assumption by Nycomed of our manufacturing and supply obligations to Nycomed and patent prosecution and maintenance obligations under the 2004 License Agreement. As part of the manufacturing and supply transfer, Nycomed paid us \$11.0 million for a significant portion of our existing bulk drug inventory.

In July 2007, we sold our 93,000 square foot laboratory and office building, including certain laboratory and office equipment and furnishings, located in Salt Lake City, Utah for \$21.0 million. The sale of this facility was part of our restructuring initiative which included a plan to close our Salt Lake City facility and to discontinue all Salt Lake City operations. We recorded a gain on the sale of these fixed assets of \$3.3 million during the year ended December 31, 2007.

In June 2007, we closed on our Agreement of Purchase and Sale to sell our land and 85,795 square foot laboratory and office building located in Mississauga, Ontario, Canada for \$4.4 million. The sale of this facility was also part of our restructuring initiatives, which included a plan to discontinue all operations in Canada. We recorded a gain on the sale of these fixed assets of \$1.8 million during the year ended December 31, 2007.

In March 2007, we announced that we were restructuring the company and decreased our employees from 196 to 35 as of December 31, 2007. In conjunction with the reduction in force we also closed our operations in Toronto, Canada and Salt Lake City, Utah. We believe the restructuring will enhance our ability to focus on our late stage product opportunities, including additional indications with our lead product candidates, preserve cash, allocate resources rapidly to different programs, and reallocate internal resources more effectively.

In May 2007, we repurchased from BioMed Realty, L.P. our 93,000 square foot laboratory and office building located in Salt Lake City, Utah, for \$20.0 million which extinguished the balance of our related 15-year lease obligation. The repurchase of the laboratory and office building is considered an early extinguishment of debt and the amount paid to repurchase the building was in excess of the carrying value of the lease financing obligation. Accordingly, we recorded a loss of \$1.0 million during the year ended December 31, 2007 on such extinguishment. As discussed above, in July 2007 we closed our transaction with the University of Utah and sold this building along with certain equipment and furnishings for \$21.0 million.

In June 2006, as a result of the uncertainty with respect to the regulatory approval of PREOS by the FDA, we announced an initiative to restructure operations, referred to as our 2006 Restructuring Plan. The primary objective of the 2006 Restructuring Plan was to maximize shareholder value by significantly reducing cash burn, reprioritizing our development portfolio and leveraging our proprietary research and development assets. Under the 2006 Restructuring Plan, we reduced our worldwide workforce, including employees and contractors, by approximately 250 positions, eliminated all commercial sales and related field based activities, terminated our agreement with Allergan, Inc. to co-

promote its proprietary drug, Restasis® Ophthalmic Emulsion to rheumatologists, and closed our technical operations facility in Mississauga, Ontario, Canada.

The following table summarizes our cash flow activity for the years ended December 31, 2008, 2007 and 2006 (amounts in thousands):

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Net cash provided by (used in) operating activities	\$ (1,655)	\$ 27,602	\$ (103,912)
Net cash provided by (used in) investing activities	(3,437)	62,632	49,250
Net cash used in financing activities	\$ (36,768)	\$ (35,484)	\$ (8,085)

Net cash used in operating activities was \$1.7 million in 2008 and \$103.9 million in 2006 compared to cash provided by operating activities of \$27.6 million in 2007. The swing to net cash used in operating activities in 2008 compared to the cash provided by operating activities in 2007 resulted primarily from a \$35 million decrease related to the agreement in 2007 with Nycomed for GATTEX and \$30.0 million received on the sale of assets to AZ in 2007, offset by a reduction in spending as a result of the restructuring activities undertaken during 2007. The swing to net cash provided by operating activities in 2007 compared to the cash used in operating activities in 2006 resulted primarily from the difference of recording net loss of \$4.3 million in 2007 as compared to a \$112.7 million net loss in 2006 (a \$108.4 million difference), a \$3.9 million decrease in operating assets due to lower accounts receivable in 2007 and a \$13.7 million decrease in accounts payable and other current accrued expenses in 2007. The majority of our royalty revenue is pledged to service the principal and interest on our secured notes and is not available to fund operations.

Net cash used in investing activities was \$3.4 million in 2008 compared to cash provided by investing activities of \$62.6 million in 2007 and \$49.3 million in 2006. Net cash used in investing activities was primarily the result of investing excess cash not currently required to fund operations. Net cash provided by investing activities during 2007 was primarily the result of selling marketable investment securities to fund current operations. Additionally, during 2007, we received proceeds from the sales of our assets held for sale and our fixed assets of \$4.4 million and \$24.7 million, respectively. Additionally, capital expenditures for 2008, 2007 and 2006 were \$128,000, \$160,000 and \$1.3 million, respectively.

Net cash used in financing activities was \$36.8 million in 2008 compared to \$35.5 million in 2007 and \$8.1 million in 2006. Cash used in financing activities in 2008 primarily relates to principal payments of \$24.5 and \$598,000 on our Class A Notes and 3% convertible notes, respectively and a \$12.5 million increase in our restricted cash balances related to our Class A Notes. Cash used in financing activities in 2007 primarily related to the repurchase and retirement of substantially all of our 3% convertible notes for \$189.3 million, principal payments of \$19.3 million on our Class A Notes; the purchase of our Salt Lake City administrative and office building and related retirement of our lease financing obligations for \$20.0 million in May 2007; and the payment of \$4.7 million in debt issuance costs; and the \$2.6 million increase in our restricted cash balances related to our Class A Notes. Cash used in financing activities was partially offset by the issuance of \$100.0 million Class B notes, the \$50.0 million issuance in 5.75% convertible notes, and the \$50.0 million sale of Preotact royalties to DRI. Cash used in financing activities in 2006 primarily relates to principal payments of \$1.3 million on our Class A Notes and increases in our restricted cash balances of \$12.3 million related to our Class A Notes. Additionally, we received cash from the exercise of employee stock options and proceeds from the sale of stock by us pursuant to 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 \$790,000, \$448,000, and \$1.1 million, respectively, of cash during 2008, 2007 and 2006. Proceeds from the exercise of employee stock options vary from period to period based upon, among other factors, fluctuations in the market value 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 \$231.9 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 certain research and license agreements that require us to make research support payments to academic or research institutions when the research is performed. Additional payments may be required upon the accomplishment of research milestones by the institutions or as license fees or royalties to maintain the licenses. As of December 31, 2008, we have a total commitment of up to \$279,000 for future research support and milestone payments. Further, depending on the commercial success of certain of our products, we may be required to pay license fees or royalties. For example, we are required to make royalty payments to certain licensors on GATTEX net sales and cinacalcet HCl royalty revenues. We expect to enter into additional sponsored research and license agreements in the future.

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

The following represents our contractual obligations as of December 31, 2008 (in millions):

<u>Contractual Obligations</u>	<u>Total</u>	<u>Less than 1 year</u>	<u>2-3 years</u>	<u>4-5 years</u>	<u>More than 5 years</u>
Operating leases	\$ 0.6	\$ 0.5	\$ 0.1	\$ -	\$ -
Purchase commitments (1)	24.7	21.2	3.5	-	-
Convertible notes payable	50.0	-	-	-	50.0
Interest on convertible notes payable	16.9	3.6	5.8	5.8	1.7
Secured notes payable (2)	303.7	35.4	106.4	124.7	37.2
Interest on secured notes payable (2)	199.4	23.9	133.8	28.8	12.9
Capital lease obligation	0.1	0.1	-	-	-
Royalty payment obligation	10.6	1.0	2.0	2.0	5.6

- (1) Purchase obligations primarily represent commitments for services (\$19.0 million), manufacturing agreements (\$4.9 million) and other research and purchase commitments (\$800,000).
- (2) Amounts shown as contractual commitments under our Secured Notes payable represent our estimate of expected principal repayment based on anticipated cinacalcet HCl royalty income. Amounts shown in interest on Secured Notes include our expected premium redemption payment based on cinacalcet HCl royalty income levels.

We expect that our existing capital resources excluding marketable investment securities classified as long-term, including interest earned thereon, will be sufficient to allow us to maintain our current and planned operations through at least 2009. However, our actual needs will depend on numerous factors, including the progress and scope of our internally funded development and commercialization activities; our ability to comply with the terms of our research funding agreements; our ability to maintain existing collaborations; our decision to seek additional collaborators; the success of our collaborators in developing and marketing products under their respective collaborations with us; our success in producing clinical and commercial supplies of our product candidates on a timely basis sufficient to meet the needs of our clinical trials and commercial launch; the costs we incur in obtaining and enforcing patent and other proprietary rights or gaining the freedom to operate under the patents of others; and our success in acquiring and integrating complementary products, technologies or businesses. Our clinical trials may be modified or terminated for several reasons including the risk that our product candidates will demonstrate safety concerns; the risk that regulatory authorities may not approve our product candidates for further development or may require additional or expanded clinical trials to be performed; and the risk that our manufacturers may not be able to supply sufficient quantities of our drug candidates to support our clinical trials or commercial launch, which could lead to a disruption or cessation of the clinical trials or commercial activities. We may also be required to conduct unanticipated clinical trials to obtain regulatory approval of our product candidates, GATTEX and NPSP558. If any of the events that pose these risks comes to fruition, our actual capital needs may substantially exceed our anticipated capital needs and we may have to substantially modify or terminate current and planned clinical trials or postpone conducting future clinical trials. As a result, our business may be materially harmed, our stock price may be adversely affected, and our ability to raise additional capital may be impaired.

We will need to raise substantial additional funds to support our long-term research, product development, and commercialization programs. We regularly consider various fund raising alternatives, including, for example, partnering of existing programs, monetizing of potential revenue streams, debt or equity financing 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, or eliminate one or more of our research and development programs, 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.

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

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

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

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

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

We apply the provisions of Staff Accounting Bulletin No. 104, *Revenue Recognition*, or SAB No. 104, to all of our revenue transactions and Emerging Issues Task Force, or EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, to all revenue transactions entered into in fiscal periods beginning after June 15, 2003. We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured and we have no further performance obligations. All revenues from product sales are recorded net of the applicable provision for returns in the same period the related sales are recorded. We recognize revenue from milestone payments as agreed upon events representing the achievement of substantive steps in the development process are achieved and where the amount of the milestone payment approximates the value of achieving the milestone. We recognize revenue from up-front nonrefundable license fees on a straight-line basis over the period we have continuing involvement in the research and development project. Royalties from licensees are based on third-party sales of licensed products and are recorded in accordance with the contract terms when third-party results are reliably measurable and collectability is reasonably assured. Cash received in advance of the performance of the related research and development support and for nonrefundable license fees when we have continuing involvement is recorded as deferred revenue. Where questions arise about contract interpretation, contract performance, or possible breach, we continue to recognize revenue unless we determine that such circumstances are material and/or that payment is not probable.

We analyze our arrangements entered into after June 15, 2003 to determine whether the elements can be separated and accounted for individually or as a single unit of accounting in accordance with EITF No. 00-21. Allocation of revenue to individual elements which qualify for separate accounting is based on the estimated fair value of the respective elements.

**Accrual of Research and Development Expenses.** Research and development costs are expensed as incurred and include salaries and benefits; costs paid to third-party contractors to perform research, conduct clinical trials, develop and manufacture drug materials and delivery devices; and associated overhead expenses and facilities costs. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. Invoicing from third-party contractors for services performed can lag several months. We accrue the costs of services rendered in connection with third-party contractor activities based on our estimate of management fees, site management and monitoring costs and data management costs. Differences between actual clinical trial costs from estimated clinical trial costs have not been material and are adjusted for in the period in which they become known.

**Share-Based Payments.** We grant options to purchase our common stock to our employees and directors under our stock option plans. The benefits provided under these plans are share-based payments subject to the provisions of revised SFAS No. 123R. Effective January 1, 2006, we use the fair value method to apply the provisions of SFAS No. 123R with a modified prospective application which provides for certain changes to the method for valuing share-based compensation. The valuation provisions of SFAS No. 123R apply to new awards and to awards that are outstanding on the effective date and subsequently modified or cancelled. Under the modified prospective application, prior periods are not revised for comparative purposes. Share-based compensation expense recognized under SFAS No. 123R during 2008 was \$4.3 million. At December 31, 2008, total unrecognized estimated compensation expense related to non-vested stock options, restricted stock and restricted stock units was \$6.2 million, which is expected to be recognized over a weighted-average period of 1.14 years.

Upon adoption of SFAS No. 123R, we began estimating the value of stock option awards on the date of grant using a Black-Scholes pricing model (Black-Scholes model). Similarly, prior to the adoption of SFAS No. 123R, the value of all share-based awards was estimated on the date of grant using the Black-Scholes model for the pro forma information required to be disclosed under SFAS No. 123. 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 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 the application of SFAS No. 123R in future periods, the compensation expense that we record under SFAS No. 123R 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.

The guidance in SFAS No. 123R and SAB 107 is relatively new, and best practices are not well established. The application of these principles may be subject to further interpretation and refinement over time. There are significant differences among valuation models, and there is a possibility that we will adopt different valuation models in the future. This may result in a lack of consistency in future periods and materially affect the fair value estimate of share-based payments. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

For purposes of estimating the fair value of stock options granted during 2008 using the Black-Scholes model, we have made an estimate regarding our stock price volatility. We used a combination of historical volatility and the implied volatility of market-traded options in our stock for the expected volatility assumption input to the Black-Scholes model, consistent with the guidance in SFAS No. 123R and SAB No. 107. In calculating the estimated volatility for 2008, we weighted implied volatility at zero percent and historical volatility at 100 percent. The risk-free interest rate is based on the yield curve of U.S. Treasury strip securities for a period consistent with the expected life of the option in effect at the time of grant (weighted-average of 3.0% for 2008). We do not target a specific dividend yield for our dividend payments, but we are required to assume a dividend yield as an input to the Black-Scholes model. The dividend yield assumption is based on our history and expectation of dividend payouts (weighted-average of zero for 2008). The expected term is estimated using historical option exercise information (weighted-average of 5.8 years for 2008).

**Valuation of Marketable Investment Securities.** We account for our marketable investment securities in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and classify our marketable investment securities as available for sale or trading securities. Available for sale securities are recorded at fair value. Unrealized holding gains and losses, net of the related tax effect, are excluded from earnings and are reported as a separate component of stockholders' deficit until realized. A decline in the market value below cost that is deemed other than temporary is charged to results of operations if it is probable that contractual amounts will not be received, resulting in the establishment of a new cost basis for the security. Trading securities are also recorded at fair value, however, holding gains and losses, net of the related tax effect, are charged to results of operations when incurred. Our marketable securities consist primarily U.S. dollar denominated corporate or government debt securities. Debt securities generally are long long-term securities with coupons that may or may not reset periodically against a benchmark interest rate.

Our investment portfolio includes investments in certain auction rate securities or ARS. ARS are variable interest rate securities tied to short-term interest rates with nominal long-term maturities. ARS have interest rate resets through a modified Dutch auction, at predetermined short-term intervals, usually every 7, 28, 35, or 49 days. With the liquidity issues experienced in global credit and capital markets, our ARS portfolio has experienced multiple unsuccessful auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders. Given the unsuccessful auctions, our ARS are illiquid until there is a successful auction for them and therefore, we have classified ARS marketable securities to non-current assets as of December 31, 2008 and December 31, 2007.

The estimated value of our ARS holdings at December 31, 2008, was \$8.8 million, which is \$20.9 million less than the principal value of \$29.7 million. In estimating the fair value of our ARS, we have used the fair values which were determined based on valuations performed by Pluris Valuation Advisors LLC. The fair values were determined using proprietary valuation models using the quality of the underlying securities or assets securing the ARS investments, the fair values of comparable securities, the quality of credit enhancement (if any) applicable to the specific security, estimated time to maturity or unwinding of the arrangement, an analysis of the terms of the indentures and other factors depending on the individual ARS.

In October 2008, we entered into a settlement agreement to sell certain of our ARS back to our investment advisor no later than June 2010 at par of \$1.8 million, and we transferred these ARS from the available for sale category to the trading category. The fair values of these ARS are \$1.3 million, which has been recorded as a long-term ARS, and we have recognized \$351,000 as a put option in other long-term assets at December 31, 2008 and a corresponding gain in other income for the year ended December 31, 2008. Under SFAS No. 159, entities are permitted to choose to measure many financial instruments and certain other items at fair value. We elected the fair value measurement option under SFAS No. 159 for our ARS put option. The fair value election was made to minimize the net volatility of earnings in future periods as the change in fair value of the put option will approximate the opposite change in fair value of the related ARS. In estimating the fair value of this put option, we have used the fair values which were determined based on valuations performed by Pluris Valuation Advisors LLC. The fair values were determined using proprietary valuation models.

Due to the severity of the decline in fair value as well as the duration of time for which these securities have been in a loss position, we have concluded that our ARS held as of December 31, 2008 and December 31, 2007, have experienced an other-than-temporarily decline in fair value and have recorded a corresponding impairment charge of \$20.9 million and \$4.1 million during the years ended December 31, 2008 and 2007, respectively. If uncertainties in the credit and capital markets continue, these markets deteriorate further or if we experience ratings downgrades on any investments in our portfolio, including on ARS, the fair value of our investment portfolio may decline further. This would result in a realized loss and would negatively affect our financial position, results of operations and liquidity.

**Accrued Redemption Premium and Effective Interest Computation.** We accrue for estimated redemption premiums on our Class A Notes as provided for in our December 2004 loan agreement. The Class A Notes accrue interest at an annual rate of 8.0%. Additionally, in the event we receive royalty and milestone payments under our agreement with Amgen above certain specified amounts, a redemption premium on principal payments is owed. The redemption premium ranges from 0% to 41.5% of principal payments, depending on the annual net sales of Sensipar by Amgen. We estimate future net sales of Sensipar by Amgen, compare our estimate to specified amounts in the Class A Note agreement to determine estimated redemption premiums over the life of the Class A Notes, and then calculate the effective interest-rate on the Class A Notes by including the forecasted redemption premiums. As a result, the effective interest-rate is comprised of the stated interest rate of 8.0% on Class A Notes plus the estimated redemption premiums on the Class A Notes. Changes to the future Sensipar net sales forecast may have a material impact on interest expense. Management evaluates its future Sensipar net sales estimates on a quarterly basis and adjusts the effective interest-rate

and corresponding accrued redemption premium when information indicates that the estimate is materially above or below the prior estimate.

In July 2007, we entered into an agreement with DRI Capital, or DRI, in which we sold to DRI our right to receive future royalty payments arising from sales of Preotact under our licensing agreement with Nycomed. We received an up-front purchase price of \$50.0 million and may receive an additional milestone of \$25.0 million if future sales thresholds are achieved. If and when DRI receives two and a half times the principal advanced, 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 initial up-front purchase price as debt and amortize this using the effective interest-rate method over the estimated period to recover two and a half times the initial principal advanced. We estimate future net sales of Preotact by Nycomed and then calculate the effective interest-rate on the DRI Secured Notes. Changes to the future Preotact net sales forecast may have a material impact on interest expense. Management evaluates its future Preotact net sales estimates on a quarterly basis and adjusts the effective interest-rate when information indicates that the estimate is materially above or below the prior estimate.

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

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

Our balance sheet reflects net long-lived assets of \$9.7 million, including goodwill of \$9.4 million as of December 31, 2008.

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 by our management to be commensurate with the risk inherent in our current business model. Provision has been made for any impairment losses related to our long-lived assets.

Goodwill represents the excess of costs over fair value of assets of businesses acquired. Goodwill and intangible assets acquired in a purchase business combination and determined to have an indefinite useful life are not amortized, but instead tested for impairment at least annually.

### **Recent Accounting Pronouncements**

In May 2008, the Financial Accounting Standards Board (“FASB”) issued FASB Staff Position, or FSP, No. APB 14-1 *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. This FSP clarifies that convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) are not addressed by paragraph 12 of APB Opinion No. 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants*. Additionally, this FSP specifies that issuers of such instruments should separately account for the liability and equity components in a manner that will reflect the entity’s nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. This FSP will be effective for our financial statements issued in the first quarter of 2009. We do not expect this adoption to have an impact on our consolidated financial statements.

On October 10, 2008, the FASB issued Staff Position No. 157-3 (FSP 157-3), which provided guidance on how to determine the fair value of financial assets when the markets for those assets are not active. FSP 157-3 states that the objective of a fair-value measurement is to estimate the price that would be received to sell an asset currently in an orderly transaction that is not a forced liquidation or a distress sale. Further, entities must include appropriate risk adjustments that market participants would make, including adjustments for nonperformance and liquidity risks. The adoption of FSP 157-3 did not have a material impact on our consolidated financial statements.

At its December 2007 meeting, the FASB ratified the consensus reached by the EITF in EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF Issue 07-01. The EITF concluded that a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other accounting literature. Payments to or from collaborators would be evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity's business and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are to be disclosed along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however, required disclosure under EITF Issue 07-1 applies to the entire collaborative agreement. EITF Issue 07-01 is effective for fiscal years beginning after December 15, 2008, and is to be applied using a modified retrospective method to all periods presented for all collaborative arrangements existing as of the effective date. We do not expect this adoption to have a material impact on our consolidated financial statements.

In June 2007, the FASB ratified the EITF consensus on EITF Issue No. 07-3, *Advance Payments for Research and Development Activities*. EITF Issue No. 07-3 requires companies to record non-refundable advance research and development payments to acquire goods and services as an asset if the contracted party has not yet performed the related activities. The amount capitalized is then recognized as expense when the research and development activities are performed. We adopted EITF Issue No. 07-3 on January 1, 2008, which is to be applied prospectively for new contractual agreements entered into after that date. The adoption of EITF Issue No. 07-3 did not have a material effect on our consolidated financial statements.

In February 2007, the FASB issued Statement on Financial Accounting Standard No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115* ("SFAS No. 159"). This statement provides a fair value option election that allows companies to irrevocably elect fair value as the initial and subsequent measurement attribute for certain financial assets and liabilities, with changes in fair value recognized in earnings as they occur. SFAS No. 159 permits the fair value option election on an instrument by instrument basis at initial recognition of an asset or liability or upon an event that gives rise to a new basis of accounting for that instrument. Further, it provides entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. We adopted SFAS No. 159 on January 1, 2008. We have elected the fair value option for its ARS put option for the year-ended December 31, 2008, however this election did not have a material impact on our consolidated financial statements.

#### **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 secured 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. For certain securities, such as ARS, there are limits on the interest rate these securities can pay contractually. Increases in interest rates in excess of these contractual limits could cause the value of our investments to decline. 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 market 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' equity (deficit). Our 5.75% Convertible Notes due 2014, our 8.0% Class A Notes due 2017, and our 15.5% Class B Notes due 2017, each have a fixed interest rate. As of December 31, 2008, our Convertible Notes, Class A Notes, and Class B Notes had \$50.0 million, \$130.0 million and \$123.7 million, respectively, in aggregate principal amount outstanding. The fair value of the Convertible Notes is affected by changes in the interest rates and by changes in the price of our common stock. The fair value of the Class A Notes and Class B Notes are affected by changes in the interest rates and by historical rates of royalty revenues from cinacalcet HCl sales.

**Marketable Securities Risk.** At December 31, 2008, included within our investment portfolio are investments in auction rate securities (ARS) with a fair value of \$8.8 million. With the liquidity issues experienced in the global credit and capital markets, our ARS have experienced multiple failed auctions. While we continue to earn interest on these investments at the maximum contractual rate, the estimated market values of these ARS no longer approximates the principal value. As of December 2008, we have recognized an impairment charge of \$20.9 million for auction rate securities with declines in value deemed to be other than temporary. See Note 5 to the consolidated financial statements.

**Foreign Currency Risk.** We have significant clinical and commercial manufacturing agreements which are denominated in Euros and Canadian Dollars. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar and the Canadian dollar or Euro, or by weak economic conditions in Canada or Europe. When the U.S. dollar strengthens against the Canadian dollar or Euros, the cost of expenses in Canada or Europe decreases. When the U.S. dollar weakens against the Canadian dollar or Euro, the cost of expenses in Canada or Europe increases. The monetary assets and liabilities in our foreign subsidiary which are impacted by the foreign currency fluctuations are cash, accounts payable, and certain accrued liabilities. A hypothetical ten percent increase or decrease in the exchange rate between the U.S. dollar and the Canadian dollar or Euro from the December 31, 2008 rate would cause the fair value of such monetary assets and liabilities in our foreign subsidiary to change by an insignificant amount. We are not currently engaged in any foreign currency hedging activities.

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

**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**

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## Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of NPS Pharmaceuticals, Inc. and subsidiaries as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' deficit and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2008. 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, 2008 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

As discussed in Notes 5 and 17 to the consolidated financial statements, the Company has changed its method of accounting for fair value and advanced payments for research and development activities in 2008 due to the adoption of Statement of Financial Accounting Standards No. 157, "Fair Value Measurements", Statement of Financial Accounting Standards No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities-Including an amendment of FASB Statements No. 115" and EITF Issue No. 07-3, "Advance Payments for Research and Development Activities".

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, 2008, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 16, 2009, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Princeton, New Jersey  
March 16, 2009



## 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, 2008, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). NPS Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting appearing under Item 9A(b). Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, NPS Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of NPS Pharmaceuticals, Inc. as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' deficit and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2008, and our report dated March 16, 2009 expressed an unqualified opinion on these consolidated financial statements.

/s/ KPMG LLP

Princeton, New Jersey  
March 16, 2009

**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**Consolidated Balance Sheets**  
**December 31, 2008 and 2007**  
(In thousands, except share data)

	<u>2008</u>	<u>2007</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 50,834	\$ 91,682
Marketable investment securities	46,546	41,649
Restricted cash and cash equivalents	37,016	24,560
Accounts receivable	25,406	19,518
Prepaid expenses	1,144	1,239
Litigation settlement receivable	16,000	-
Other current assets	1,550	6,437
Total current assets	<u>178,496</u>	<u>185,085</u>
Equipment, net	285	309
Goodwill	9,429	11,088
Marketable investment securities	8,752	28,357
Debt issuance costs, net of accumulated amortization of \$5,744 and \$3,891, respectively	5,158	7,014
Other assets	1,486	-
	<u>\$ 203,606</u>	<u>\$ 231,853</u>
<b>Liabilities and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 830	\$ 3,369
Accrued expenses and other current liabilities	4,024	4,931
Accrued research and development expenses	3,754	5,128
Accrued restructuring charges	217	2,337
Accrued interest expense	19,072	12,387
Litigation settlement payable	16,000	-
Deferred revenue	2,494	29,020
Current installments of notes payable and capital lease obligation	35,498	24,992
Total current liabilities	<u>81,889</u>	<u>82,164</u>
Notes payable, less current portion	318,277	336,357
Capital lease, less current portion	14	92
Accrued interest expense, less current portion	7,627	-
Other liabilities	10,885	4,896
Total liabilities	<u>418,692</u>	<u>423,509</u>
Commitments and contingencies (notes 9, 10, 11, 13, 18 and 19)		
Stockholders' deficit:		
Preferred stock, \$0.001 par value. Authorized 5,000,000 shares; issued and outstanding no shares	-	-
Common stock, \$0.001 par value. Authorized 105,000,000 shares; issued and outstanding 47,467,164 shares and 46,834,216 shares, respectively	47	47
Additional paid-in capital	689,947	683,955
Accumulated other comprehensive loss	(200)	(2,504)
Accumulated deficit	(904,880)	(873,154)
Total stockholders' deficit	<u>(215,086)</u>	<u>(191,656)</u>
	<u>\$ 203,606</u>	<u>\$ 231,853</u>

See accompanying notes to consolidated financial statements.

**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**Consolidated Statements of Operations**  
**Years ended December 31, 2008, 2007 and 2006**  
**(In thousands, except per share data)**

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Revenues:			
Royalties	\$ 70,217	\$ 49,626	\$ 32,078
Product sales	4,544	20,310	2,662
Milestones and license fees	27,518	16,312	13,762
Total revenues	<u>102,279</u>	<u>86,248</u>	<u>48,502</u>
Operating expenses:			
Cost of royalties	5,831	4,659	2,980
Cost of goods sold	1,350	6,180	1,413
Cost of license fees	5,665	1,547	-
Research and development	18,965	36,195	62,470
Selling, general and administrative	22,563	29,526	58,118
Restructuring (credits) charges	(272)	13,386	8,179
Total operating expenses	<u>54,102</u>	<u>91,493</u>	<u>133,160</u>
Other operating (gains) losses:			
Gain on sale of assets held for sale	-	(1,826)	-
Gain on sale of fixed assets	(186)	(6,384)	-
Gain on sale of assets	-	(30,000)	-
Write down of long-lived assets	-	-	8,297
Total other operating (gains) losses	<u>(186)</u>	<u>(38,210)</u>	<u>8,297</u>
Operating income (loss)	48,363	32,965	(92,955)
Other income (expense):			
Interest income	4,778	9,518	9,120
Interest expense	(65,373)	(41,397)	(28,970)
Loss on marketable investment securities	(20,950)	(4,113)	(156)
Gain on extinguishment of debt	-	1,315	-
Loss on extinguishment of lease financing obligation	-	(970)	-
Foreign currency transaction gain (loss)	504	(815)	170
Other	773	(5)	123
Total other expense, net	<u>(80,268)</u>	<u>(36,467)</u>	<u>(19,713)</u>
Income (loss) before income tax expense (benefit)	(31,905)	(3,502)	(112,668)
Income tax expense (benefit)	(179)	780	-
Net loss	<u>\$ (31,726)</u>	<u>\$ (4,282)</u>	<u>\$ (112,668)</u>
Basic and diluted net loss per common and potential common share	<u>\$ (0.67)</u>	<u>\$ (0.09)</u>	<u>\$ (2.43)</u>
Weighted average common and potential common shares outstanding—basic and diluted	<u>47,699</u>	<u>46,804</u>	<u>46,374</u>

See accompanying notes to consolidated financial statements.

**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Stockholders' Deficit and Comprehensive Loss**  
**Years ended December 31, 2008, 2007 and 2006**  
(In thousands, except share data)

	Preferred stock	Common stock	Additional paid-in capital	Deferred compensation	Comprehensive loss	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' deficit
Balances, December 31, 2005	\$ -	\$ 46	\$ 664,042	\$ (3,120)		\$ (2,288)	\$ (756,204)	\$ (97,524)
Issuance of 8,662 shares of common stock for cash under option plans	-	-	73	-		-	-	73
Issuance of 37,703 shares of common stock for deferred stock units	-	-	-	-		-	-	-
Issuance of 169,712 shares of common stock for cash under employee purchase plan	-	-	1,036	-		-	-	1,036
Reversal of deferred compensation upon adoption of SFAS 123R (note 11)	-	-	(3,120)	3,120		-	-	-
Compensation expense on restricted stock, deferred stock units and restricted stock units	-	-	2,011	-		-	-	2,011
Compensation expense on stock options and stock appreciation rights	-	-	13,432	-		-	-	13,432
Gross unrealized gains on marketable securities					\$ 406			
Reclassification for realized losses on marketable securities					<u>156</u>			
Net unrealized gains on marketable investment securities	-	-	-	-	562	562	-	562
Foreign currency translation gain	-	-	-	-	(166)	(166)	-	(166)
Net loss	-	-	-	-	<u>(112,668)</u>	-	(112,668)	(112,668)
Comprehensive loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>\$ (112,272)</u>	<u>-</u>	<u>-</u>	<u>-</u>
Balances, December 31, 2006	<u>-</u>	<u>46</u>	<u>677,474</u>	<u>-</u>		<u>(1,892)</u>	<u>(868,872)</u>	<u>(193,244)</u>
Issuance of 10,386 shares of common stock for cash under option plans	-	-	52	-		-	-	52
Issuance of 247,347 shares of common stock for deferred and restricted stock units	-	1	-	-		-	-	1
Issuance of 229,733 shares of common stock for services rendered		-	942					942
Issuance of 123,101 shares of common stock for cash under employee purchase plan	-	-	395	-		-	-	395
Compensation expense on restricted stock, deferred stock units and restricted stock units	-	-	1,509	-		-	-	1,509
Compensation expense on stock options, stock appreciation rights and employee stock purchase plan	-	-	3,583	-		-	-	3,583
Gross unrealized loss on marketable securities					\$ (2,118)			
Reclassification for realized losses on marketable investment securities					<u>49</u>			
Net unrealized losses on marketable investment securities	-	-	-	-	(2,069)	(2,069)	-	(2,069)
Foreign currency translation gain	-	-	-	-	1,457	1,457	-	1,457
Net loss	-	-	-	-	<u>(4,282)</u>	-	(4,282)	(4,282)
Comprehensive loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>\$ (4,894)</u>	<u>-</u>	<u>-</u>	<u>-</u>
Balances, December 31, 2007	<u>\$ -</u>	<u>\$ 47</u>	<u>\$ 683,955</u>	<u>\$ -</u>		<u>\$ (2,504)</u>	<u>\$ (873,154)</u>	<u>\$ (191,656)</u>

**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Stockholders' Deficit and Comprehensive Loss—(Continued)**  
**Years ended December 31, 2008, 2007 and 2006**  
**(In thousands, except share data)**

	Preferred stock	Common stock	Additional paid-in capital	Deferred compensation	Comprehensive loss	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' deficit
Balances, December 31, 2007	\$ -	\$ 47	\$ 683,955	\$ -		\$ (2,504)	\$ (873,154)	\$ (191,656)
Issuance of 173,629 shares of common stock for cash under option plans	-	-	790	-		-	-	790
Issuance of 459,319 shares of common stock for services rendered	-	-	894	-		-	-	894
Compensation expense on restricted stock	-	-	119	-		-	-	119
Compensation expense on stock options and stock appreciation rights	-	-	4,189	-		-	-	4,189
Gross unrealized gain on marketable investment securities					\$ 2,813			
Reclassification for realized losses on marketable investment securities					<u>52</u>			
Net unrealized gains on marketable investment securities	-	-	-	-	2,865	2,865	-	2,865
Foreign currency translation loss	-	-	-	-	(561)	(561)	-	(561)
Net loss	-	-	-	-	<u>(31,726)</u>	-	(31,726)	(31,726)
Comprehensive loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>\$ (29,422)</u>	<u>-</u>	<u>-</u>	<u>-</u>
Balances, December 31, 2008	<u>\$ -</u>	<u>\$ 47</u>	<u>\$ 689,947</u>	<u>\$ -</u>		<u>\$ (200)</u>	<u>\$ (904,880)</u>	<u>\$ (215,086)</u>

See accompanying notes to consolidated financial statements.

**NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**Consolidated Statements of Cash Flows**  
**Years ended December 31, 2008, 2007 and 2006**  
(In thousands)

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Cash flows from operating activities:			
Net loss	\$ (31,726)	\$ (4,282)	\$ (112,668)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	77	3,984	6,487
Realized gain on disposition of assets held for sale	-	(1,826)	-
Loss (gain) on sale or disposal of fixed assets	10	(6,384)	16
Non-cash interest expense	27,964	9,179	-
Realized gain on extinguishment of debt and lease financing obligation	-	(345)	-
Write down of long-lived assets	-	-	8,297
Recognized loss on marketable investment securities	20,950	4,113	156
Bad debt expense	-	-	50
Compensation expense on share based awards	4,308	6,035	15,443
Decrease (increase) in operating assets:			
Accounts receivable	(7,096)	(4,645)	(11,313)
Prepaid expenses, other current assets and other assets	(12,507)	(3,786)	(223)
Inventory	-	396	(374)
Increase (decrease) in operating liabilities:			
Accounts payable and accrued expenses	16,903	587	(13,136)
Deferred revenue	(26,526)	22,581	3,902
Other liabilities	5,988	1,995	(549)
Net cash (used in) provided by operating activities	<u>(1,655)</u>	<u>27,602</u>	<u>(103,912)</u>
Cash flows from investing activities:			
Sales of marketable investment securities	33,405	373,738	126,450
Maturities of marketable investment securities	17,345	49,996	32,856
Purchases of marketable investment securities	(54,059)	(389,975)	(108,765)
Acquisitions of equipment and leasehold improvements	(128)	(160)	(1,302)
Proceeds from sale of assets held for sale	-	4,371	-
Proceeds from sale of fixed assets	-	24,662	11
Net cash (used in) provided by investing activities	<u>(3,437)</u>	<u>62,632</u>	<u>49,250</u>
Cash flows from financing activities:			
Proceeds from issuance of notes payable	-	200,000	-
Principal payments on notes payable, capital lease and lease financing obligation	(25,102)	(228,546)	(1,266)
Principal payments under lease financing obligations	-	-	(105)
Payment of debt issuance costs	-	(4,747)	(434)
Proceeds from issuance of common stock	790	448	1,109
Increase in restricted cash and cash equivalents	(12,456)	(2,639)	(7,389)
Net cash used in financing activities	<u>(36,768)</u>	<u>(35,484)</u>	<u>(8,085)</u>
Effect of exchange rate changes on cash	1,012	688	279
Net increase (decrease) in cash and cash equivalents	<u>(40,848)</u>	<u>55,438</u>	<u>(62,468)</u>
Cash and cash equivalents at beginning of year	91,682	36,244	98,712
Cash and cash equivalents at end of year	<u>\$ 50,834</u>	<u>\$ 91,682</u>	<u>\$ 36,244</u>

See accompanying notes to consolidated financial statements.

## NPS PHARMACEUTICALS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements December 31, 2008, 2007 and 2006

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

The consolidated financial statements are comprised of the financial statements of NPS Pharmaceuticals, Inc. and its subsidiaries (NPS), collectively referred to as the Company or NPS. NPS is a biopharmaceutical company focused on the development of new treatment options for patients with rare gastrointestinal and endocrine disorders and serious unmet medical needs. The Company's lead clinical programs involve two proprietary therapeutic proteins to restore or replace biological function: GATTEX™ (teduglutide) and NPSP558 (parathyroid hormone 1-84 [rDNA origin] injection). GATTEX is an analog of GLP-2, a protein involved in the regeneration and repair of the intestinal lining, and is in Phase 3 clinical development for parenteral dependent (PN) short bowel syndrome (SBS). SBS is a highly disabling condition that results from surgical resection, congenital defect or disease-associated loss of absorption and the subsequent inability to maintain fluid, electrolyte, and nutrient balances on a conventional diet. NPSP558 is a recombinant full-length human parathyroid hormone (PTH 1-84) that is in Phase 3 clinical development for hypoparathyroidism, a rare condition in which the body does not maintain normal calcium levels in the blood due to insufficient levels of parathyroid hormone.

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

In 2006 and 2007, the Company announced plans to restructure operations and in 2007 implemented a new business strategy to focus resources on developing GATTEX and NPSP558 for specialty indications with high unmet medical need. Previously, the Company's strategic priority was to obtain U.S. regulatory approval of PREOS® (parathyroid hormone 1-84 [rDNA origin] injection) for the treatment of osteoporosis. In connection with the implementation of its new plan, during 2007 the Company suspended or monetized programs within its product portfolio that were no longer deemed strategic and discontinued investment in discovery and early stage research. Since inception, the Company's principal activities have been performing research and development, raising capital and establishing research and license agreements. All monetary amounts are reported in U.S. dollars unless specified otherwise.

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, 2008 and 2007 consist of commercial paper, money market funds, debt securities and other highly liquid instruments of approximately \$49.0 million and \$85.7 million, respectively. At December 31, 2008 and 2007, the book value of cash equivalents approximates fair value.

Total restricted cash and cash equivalent balances at December 31, 2008 and 2007 were \$37.0 million and \$24.6 million, respectively. The restricted amount at December 31, 2008 and 2007 consists of amounts for estimated redemption premiums, interest and principal on the Class A Notes (see Note 11), and is classified as current.

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

The Company classifies its marketable investment securities as available for sale or as trading securities. Available for sale and trading securities are recorded at fair value. Unrealized holding gains and losses on available for sale securities, net of the related tax effect, are excluded from earnings and are reported as a separate component of stockholders' deficit until realized. A decline in the market value below cost of available for sale securities that is deemed other than temporary is charged to results of operations if it is probable that contractual amounts will not be received, resulting in the establishment of a new cost basis for the security. Premiums and discounts are amortized or accreted into the cost basis over the life of the related security as adjustments to the yield using the effective-interest method. Unrealized holding gains and losses on trading securities are included in earnings in each period. Interest income is recognized when earned. Realized gains and losses from the sale of marketable investment securities are based on the specific identification method and are included in results of operations and are determined on the specific-identification basis.

***(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, 2008 and 2007 and recorded bad debt expense of \$50,000 for the year ended December 31, 2006. At December 31, 2008 and 2007 the allowance for bad debts was zero.

***(d) Inventory***

Inventory is recorded at the lower of cost or market and only capitalized once compounds have been approved by the appropriate regulatory agencies. Cost, which includes amounts related to materials, labor and overhead, is determined using the first-in, first-out (FIFO) method.

***(e) Plant and Equipment***

Plant and equipment are stated at cost. Depreciation of plant was calculated on the straight-line method over its estimated useful life of 25 years in Mississauga, Ontario, Canada and 39 years in Salt Lake City, Utah. Depreciation and amortization of equipment are 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. Assets held for sale, if any, are reported at the lower of the carrying amount, or fair value, less cost to sell. Depreciation is no longer recorded once management has identified an asset as held for sale.

***(f) Goodwill***

Goodwill represents the excess of costs over fair value of assets of businesses acquired. Goodwill and intangible assets acquired in a purchase business combination and determined to have an indefinite useful life are not amortized, but instead tested for impairment at least annually.

***(g) Income Taxes***

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

***(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, research and development support payments and product sales. The Company recognizes revenue from up-front nonrefundable license fees on a straight-line basis over the period wherein the Company has continuing involvement in the research and development project. The Company recognizes revenue from up-front nonrefundable license fees upon receipt when there is no continuing involvement in the research and development project. The Company recognizes revenue from its milestone payments as agreed-upon events representing the achievement of substantive steps in the development process are achieved and where the amount of the milestone payment approximates the value of achieving the milestone. Royalties from licensees are based on third-party sales of licensed products and are recorded in accordance with contract terms when sales results are reliably measurable and collectability is reasonably assured. The Company recognizes revenue



from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured and the Company has no further performance obligations. All revenues from product sales are recorded net of the applicable provision for returns in the same period the related sales are recorded. Cash received for nonrefundable licensee fees in which the Company has continuing involvement is recorded as deferred revenue.

***(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: salaries and benefits, overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs.

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

***(j) Selling, general and administrative expenses***

Selling, general and administrative expenses are primarily comprised of salaries and benefits associated with sales and marketing, finance, legal, and other administrative personnel; outside marketing expenses; overhead and occupancy costs; and other general and administrative costs.

***(k) 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.

***(l) Share-Based Compensation***

Prior to January 1, 2006, the Company employed the footnote disclosure provisions of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, and SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*, an amendment of SFAS No. 123. SFAS No. 123 encouraged entities to adopt a fair-value-based method of accounting for stock options or similar equity instruments. However, it also allowed an entity to continue measuring compensation cost for stock-based compensation using the intrinsic-value method of accounting prescribed by the Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*. The Company had elected to continue to apply the provisions APB Opinion No. 25, under which no compensation cost was recognized when the exercise price of the option equaled the market price of the stock on the date of grant for options granted to employees.

Effective January 1, 2006, the Company adopted the fair value recognition provision of SFAS No. 123R, *Share Based Payment*, using the modified prospective method. Under this method, compensation cost during the years ended December 31, 2008, 2007 and 2006 includes the portion vesting during the year for (1) all share-based payments granted prior to, but not vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provision of SFAS No. 123 and (2) all share-based payments granted subsequent to December 31, 2005, based on the grant date fair value estimated using the Black-Scholes option-pricing model. The Company uses the straight-line method of amortization for share-based compensation.

***(m) 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. Actual results could differ from those estimates.

***(n) 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. The Company reports all monetary amounts in U.S. dollars unless specified otherwise.

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

As described in (f), goodwill is tested for impairment at least annually. The Company reviews all other long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets held and used is measured by a comparison of the carrying amount of an asset to future net cash flows (undiscounted) expected to be generated by the asset. In addition, future events impacting cash flows for existing assets could render write-down necessary where, previously, no such write-down was required. If such assets are considered to be impaired, the impairment to be recognized is measured by 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.

***(p) 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 were reported as a separate component of accumulated other comprehensive loss in stockholders' deficit. Certain transactions of the foreign subsidiaries 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. The Company's foreign subsidiaries had net liabilities of approximately \$1.1 million and \$37.4 million as of December 31, 2008 and December 31, 2007, respectively.

***(q) Operating Segments***

The Company is engaged in the development and commercialization of pharmaceutical products, and in its current state of development, considers its operations to be a single reportable segment. Financial results of this reportable segment are presented in the accompanying consolidated financial statements. During 2008, the Company and its subsidiary, NPS Allelix Corp. (Allelix), entered into purchase and sale agreements that sold the intellectual property and substantially all other assets and liabilities that were owned by Allelix to NPS. The Company's subsidiaries operating outside of the United States had long-lived assets, including goodwill, of approximately zero and \$11.1 million as of December 31, 2008 and 2007, respectively. The Company recognized non-United States revenue of \$42.6 million, \$39.4 million and \$5.5 million, respectively, during the years ended December 31, 2008, 2007 and 2006. Substantially all of the Company's revenues for the year ended December 31, 2008 were from six licensees of the Company. The majority of the Company's revenue for the years ended December 31, 2007 and 2006 were from five licensees of the Company. As of December 31, 2008 and 2007, the majority of the Company's accounts receivable balances were from four licensees and two licensees, respectively.

***(r) Comprehensive Income (Loss)***

Comprehensive income (loss) consists of net income (loss) and other gains and losses affecting stockholders' equity (deficit) that, under U.S. generally accepted accounting principles, 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 loss as of December 31, 2008 and 2007 consists of accumulated net unrealized gains on marketable investment securities of \$470,000 million and losses of \$2.4 million, respectively, and foreign currency translation losses of \$670,000 and \$109,000, respectively.

***(s) Concentration of Suppliers***

The Company has entered into agreements with contract manufacturers to manufacture clinical 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.

***(t) Leases***

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

***(u) Reclassifications and Error Corrections***

Certain prior year amounts have been reclassified to conform with the current year presentation.

***Prior Year Errors Corrected in 2008***

The Company recorded several adjustments during the fourth quarter of 2008 which relate to earlier periods. These were recorded in the fourth quarter of 2008 as the Company believes that the effect of these adjustments was not material to its financial position, results of operations or cash flows for any period presented. The Company's net loss for the quarter ended December 31, 2008, was increased by \$738,000, or \$0.02 per diluted share. The significant components of this charge were a decrease in milestone and license fee revenue of \$988,000 and an increase in gain on sale of fixed assets of \$186,000.

***Revisions to Previously Issued 2007 and 2006 Financial Statements***

The Company reclassified \$2.5 million and \$5.9 million for the years ended December 31, 2007 and 2006, respectively, from research and development expenses to selling, general and administrative expenses for legal costs related to patents that were incorrectly included in research and development expenses in prior years.

***(v) Deferred Financing Costs***

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

Costs incurred under the agreement with DRI Capital, or DRI, formerly Drug Royalty L.P.3, in which the Company sold to DRI its right to receive future royalty payments arising from sales of Preotact under its license agreement with Nycomed 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.

***(w) 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.

***(x) Legal Defense Costs***

Legal defense costs are expensed as incurred.

**(2) Collaborative and License Agreements**

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

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

The Company has a development and license agreement with Amgen to develop and commercialize compounds for the treatment of hyperparathyroidism and indications other than osteoporosis. Amgen also acquired an equity investment in the Company in 1995. 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. To date, Amgen has paid the Company \$19.0 million in milestone payments. Amgen is incurring all costs of developing and commercializing these products. Amgen received exclusive worldwide rights excluding Japan, China, Korea, and Taiwan. The Company recognized royalties from product sales of \$59.6 million, \$46.4 million and \$31.9 million in 2008, 2007 and 2006, respectively, under the contract.

**(b) AstraZeneca AB**

In 2001, the Company entered into a collaborative effort with AstraZeneca AB (AstraZeneca) to discover, develop, and market new small molecule therapies for the treatment of various disorders of the central nervous system. Under the terms of the agreement, the Company licensed to AstraZeneca its proprietary technology related to protein structures known as metabotropic glutamate receptors (mGluRs). Additionally, the Company granted AstraZeneca exclusive rights to commercialize mGluRs subtype-selective compounds. The Company was required to co-direct the research and pay for an equal share of the preclinical research costs, including capital and a minimum number of personnel, through March 2009 unless terminated earlier by AstraZeneca or the Company upon six months advance written notice. During 2008, 2007 and 2006, the Company incurred zero, \$2.3 million and \$4.8 million, respectively in research and development expenses under the agreement while all other collaboration costs were borne by AstraZeneca.

On October 9, 2007, the Company entered into an Asset Purchase Agreement with Astra Zeneca in which the Company agreed to sell its rights, including intellectual property, in drugs targeting mGluRs to AstraZeneca for \$30.0 million. As the net assets sold had no book basis, the Company recorded a gain of \$30.0 million. Additionally, the Company and AstraZeneca agreed to terminate the collaborative research and development agreement related to drugs targeting mGluRs that was entered into in 2001. As a result of this termination, the Company is no longer required to provide research FTE support or pay for an equal share of external discovery costs, including patent related costs.

**(c) GlaxoSmithKline**

In 1993, the Company entered into an agreement with GlaxoSmithKline (GSK) to collaborate on the research, development and commercialization of calcium receptor active compounds to treat osteoporosis and other bone metabolism disorders, excluding hyperparathyroidism. GSK also acquired an equity investment in the Company in 1993. Under the terms of the agreement, the Company may receive milestone payments of up to \$23.0 million and royalties from any product sales under the license. To date, GSK has paid the Company \$12.0 million in milestone payments. A total of \$5.0 million in milestone payments may still be earned under the agreement. 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 and GSK agreed to pay up to an additional \$27.0 million upon achievement of certain milestones for these compounds.

Under the GSK agreement, the Company recognized research and licensing revenue of \$3.0 million in 2006. The Company recognized no research and licensing revenue in 2008 and 2007. The Company is entitled to receive additional payments upon the achievement of specific development and regulatory milestones. The Company is entitled to receive royalties on sales of such compounds by GSK and a share of the profits from co-promoted products.

In September 2008, the Company was notified by GSK that they have decided to terminate a Phase 2 dose-range finding study with Ronacaleret (SB-751689) in post-menopausal women with osteoporosis (study "CR9108963") earlier than expected due to an observed lack of efficacy based on lumbar spine and hip bone mineral density. Ronacaleret (751689) is a calcilytic compound developed under the November 1993 collaborative research and worldwide exclusive license agreement.

**(d) Janssen Pharmaceutica N.V.**

In 1998, Allelix entered into a collaborative agreement with Janssen Pharmaceutica N.V. (Janssen), a wholly owned subsidiary of Johnson & Johnson, for the research, development, and marketing of new drugs for neuropsychiatric disorders. Johnson & Johnson Development Corporation also acquired an equity investment in Allelix in 1998. Under the terms of the agreement, the Company may receive royalties from any product sales under this license. Janssen has the right to market products worldwide, subject to a company option for co-promotion in Canada. Janssen is incurring all costs of developing and commercializing products. Janssen had informed the Company that they

plan to seek a third party to share in the future development costs and risks of the program. Under the Janssen agreement, the Company recognized no research and licensing revenue in 2008, 2007 and 2006.

On August 4, 2008, Janssen notified the Company that they were terminating the collaborative agreement. As a result of this termination by Janssen, the rights to any compounds or products will be transferred to the Company, however no payments are required to be made to the other by either party as a result of the termination.

*(e) Kyowa Kirin*

In 1995, the Company entered into an agreement with the pharmaceutical division of Kyowa Kirin, formerly Kirin Pharma, a Japanese company, to develop and commercialize compounds for the treatment of hyperparathyroidism in Japan, China, Korea, and Taiwan. Kyowa Kirin paid the Company a \$5.0 million license fee 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 Kirin is incurring all costs of developing and commercializing products. Any payments subsequent to June 2000 represent milestone and royalty payments. To date, Kyowa Kirin has paid the Company \$13.0 million in milestone payments. In October 2007, Kyowa 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, where the Company achieved the 2007 milestone. The parties participate in a collaborative research program utilizing the Company's parathyroid calcium receptor technology. The Company recognized license fee revenue of zero, \$2.0 million and \$2.0 million in 2008, 2007 and 2006, respectively. The Company recognized royalty revenue of \$1.9 million in 2008, zero in 2007 and zero in 2006 under the agreement.

*(f) Nycomed Danmark ApS*

**GATTEX**

In September 2007 the Company entered into a license agreement with Nycomed Danmark ApS (Nycomed) in which the Company granted Nycomed the right to develop and commercialize GATTEX, or teduglutide, outside the United States, Canada and Mexico for the treatment of gastrointestinal disorders. The Company received \$35.0 million in up-front fees under the agreement. Nycomed paid the Company \$10.0 million upon signing the license agreement and paid the Company an additional \$25.0 million in up-front license fees in the fourth quarter of 2007. Under the terms of the agreement, the Company has the potential to earn up to \$190.0 million in development and sales milestone payments plus royalties on product sales. Under the terms of the agreement, the Company is responsible to complete the on-going Phase 3 GATTEX clinical trials in SBS and Nycomed may elect to share equally the future development costs with NPS to advance and broaden the indications for GATTEX. Additionally, under a previously existing licensing agreement with a third party, the Company was required to pay \$6.6 million to the licensor and will be required to make future payments based on GATTEX royalties and milestone payments earned. Due to the Company's continuing involvement, the Company is recognizing revenue over the estimated performance period and for the years ended December 31, 2008 and 2007, the Company has recognized \$25.2 and \$7.3 million in license fee revenue, respectively. The balance of the up-front license fee has been deferred at December 31, 2008 and is expected to be recognized as revenue in 2009. The Company did not recognize any revenue in 2006.

In December 2008, Nycomed and the Company agreed to share equally in both companies' external costs for the clinical trial for GATTEX in SBS. Reimbursements from Nycomed for their portion of the research and development activities are characterized as a reduction of the Company's research and development costs because performing contract research and development services is not part of the Company's ongoing operations. During the year ended December 31, 2008 the Company recorded \$1.3 million as a reduction of research and development expenses.

**Preotact®**

In 2004, the Company signed a distribution and license agreement with Nycomed in which the Company granted Nycomed the right to develop and market Preotact® in Europe. Nycomed also acquired an equity investment in the Company of \$40.0 million through the purchase of 1.33 million shares of the Company's common stock. The agreement requires Nycomed to pay the Company up to 20.8 million Euros in milestone payments upon regulatory approvals and achievement of certain sales targets and pay the Company royalties on product sales. In July 2007, the Company entered into a new license agreement with Nycomed, pursuant to which the Company granted to Nycomed the right to commercialize PREOS in all non-U.S. territories, excluding Japan and Israel. Nycomed's licensed rights in Canada and Mexico, however, revert back to the Company if PREOS receives regulatory approval in the U.S. The 2007 license agreement contains milestone and royalty payment obligations which are similar to those under the 2004 distribution and license agreement. Nycomed is required to pay the Company royalties on sales of Preotact only in the European

Union, the Commonwealth of Independent States and Turkey. The 2007 license agreement provides for the assumption by Nycomed of NPS' manufacturing and supply obligations and patent prosecution and maintenance obligations under the 2004 license agreement, which occurred in 2008. As part of the manufacturing and supply transfer, Nycomed paid the Company \$11.0 million during 2007, for a significant portion of the Company's existing bulk drug inventory. To date, the Company has received 5.6 million Euros in milestone payments from Nycomed. The Company recognized revenue in 2008, 2007 and 2006 of \$11.0 million, \$30.1 million and \$3.1 million, respectively.

***(g) Ortho-McNeil Pharmaceuticals, Inc.***

In December 2006, the Company entered into an agreement with Ortho-McNeil Pharmaceuticals, Inc. (Ortho), a wholly owned subsidiary of Johnson & Johnson, pertaining to certain NPS patents. Ortho paid the Company an \$8.0 million fee and agreed to pay royalties on product sales. 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 Ortho 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. Ortho 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 tapentadol hydrochloride immediate release (IR) tablets for the relief of moderate to severe acute pain. This compound is covered under our agreement and Ortho is required to pay us a royalty on the product's sales. Tapentadol is a novel investigational, centrally acting oral analgesic. The Company recognized revenue of \$8.0 million in 2006. The Company did not recognize any revenue in 2008 and 2007.

***(h) 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 agreed to pay us the Company an upfront licensing fee of \$2.0 million, and to make additional payments for the achievement of certain regulatory milestones. Further, Roche agreed to pay royalties on sales of licensed products, if any. Either party may terminate the agreement on 30 days written notice due to a material breach by the other, or in the case of the other party's insolvency. Amounts due prior to termination will remain due thereafter. NPS will not incur any development or commercialization costs for these products. The Company recognized revenue of \$2.0 million in 2008 as the Company had no continuing involvement in the arrangement. The Company did not recognize any revenue in 2007 and 2006.

***(i) In-License and Purchase Agreements***

The Company has entered into certain sponsored research, license, and purchase agreements that require the Company to make research support and milestone payments to academic or commercial research institutions. During 2008, 2007 and 2006, the Company paid to these institutions \$551,000, \$239,000, and \$1.2 million, respectively, in sponsored research payments and license fees. As of December 31, 2008, the Company had a total commitment of up to \$279,000 for future research support. 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, \$4.4 million has been paid. Annual payments due are limited to a maximum of \$1.0 million. Accruals of \$9.6 million and \$1.0 million at December 31, 2008 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 13.4 million, 13.1 million and 11.8 million during the years ended December 31, 2008, 2007 and 2006, respectively, that could potentially dilute basic earnings per 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, 2008, 2007 and 2006 include approximately 9.2 million, 7.8 million and 5.2 million, common shares related to convertible debentures, respectively, and 4.2 million, 5.3 million, and 6.5 million shares, respectively, related to stock options, stock appreciation rights, and restricted stock units.

#### **(4) Cash, Cash Equivalents and Marketable Investment Securities**

The Company's investment portfolio includes investments in certain auction-rate securities (ARS). ARS are variable interest rate securities tied to short-term interest rates with nominal long-term maturities. ARS have interest rate resets through a modified Dutch auction, at predetermined short-term intervals, usually every 7, 28, 35, or 49 days. With the liquidity issues experienced in global credit and capital markets, the Company's ARS portfolio continues to experience unsuccessful auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders. Given the unsuccessful auctions, the Company's ARS are illiquid and will be until there is a successful auction for them and therefore, the Company has classified ARS as non-current assets as of December 31, 2008 and 2007.

The estimated value of the Company's ARS holdings at December 31, 2007, was \$53.3 million, which reflects \$2.4 million less than the its principal value of \$55.7 million. In establishing the estimated market value of its ARS, the Company used the market value determined by its investment advisors. The market values were determined using a proprietary valuation model using the quality of the underlying securities or assets securing the ARS investments, the market values of comparable securities, the quality of credit enhancement (if any) applicable to the specific security, estimated time to maturity or unwinding of the arrangement, an analysis of the terms of the indentures and other factors depending on the individual ARS.

In March 2008, the Company agreed to sell certain of its ARS, or the Sold ARS, to one of the Company's investment advisors for \$26.0 million. The fair value and the principal value of the Sold ARS as of December 31, 2007 were \$24.9 million and \$30.1 million, respectively. During the fourth quarter 2007, the Company recognized an other-than-temporary loss of \$4.1 million on the Sold ARS in the Statement of Operations and \$1.1 million was recorded as an unrealized loss on the Sold ARS in Accumulated Other Comprehensive Loss at December 31, 2007. Excluding the Sold ARS, the Company believed that the decrease in market value on its ARS was temporary in nature due to the underlying assets securing the ARS, the AAA ratings by Standard & Poors as of December 31, 2007 and February 29, 2008, the Company's belief that historical liquidity would return to the global credit and capital markets, and the Company's intent and ability to hold to recovery. None of the ARS are backed by sub-prime mortgages. Accordingly, a \$1.3 million unrealized loss was recorded at December 31, 2007 in Accumulated Other Comprehensive Loss section of the Balance Sheet related to the ARS, excluding the Sold ARS. The fair value of these ARS, excluding the Sold ARS, was estimated to be \$28.4 million at December 31, 2007 and \$26.4 million at February 29, 2008.

The estimated value of the Company's ARS holdings at December 31, 2008, was \$8.8 million, which is \$20.9 million less than the principal value of \$29.7 million. In estimating the fair value of the Company's ARS, the Company has used the fair values which were determined based on valuations performed by Pluris Valuation Advisors LLC. The fair values were determined using proprietary valuation models using the quality of the underlying securities or assets securing the ARS investments, the fair values of comparable securities, the quality of credit enhancement (if any) applicable to the specific security, estimated time to maturity or unwinding of the arrangement, an analysis of the terms of the indentures and other factors depending on the individual ARS.

In October 2008, the Company entered into a settlement agreement to sell certain of its ARS back to its investment advisor no later than June 2010 at par of \$1.8 million, and the Company transferred these ARS from the available for sale category to the trading category. The fair values of these ARS are \$1.3 million, which has been recorded as a long-term ARS, and the Company has recognized \$351,000 as a put option in other long-term assets at December 31, 2008 and a corresponding gain in other income for the year ended December 31, 2008. Under SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – including an amendment of FASB Statement No. 115*, ("SFAS No. 159") entities are permitted to choose to measure many financial instruments and certain other items at fair value. The Company elected the fair value measurement option under SFAS No. 159 for its ARS put option. The fair value election was made to minimize the net volatility of earnings in future periods as the change in fair value of the put option will approximate the opposite change in fair value of the related ARS. In estimating the fair value of this put option, the Company has used the fair values which were determined based on valuations performed by Pluris Valuation Advisors LLC. The fair values were determined using proprietary valuation models.

Due to the severity of the decline in fair value, as well as the duration of time for which these securities have been in a loss position, the Company concluded that its ARS held as of December 31, 2008, except those subject to the settlement, have experienced an other-than-temporary decline in fair value. Accordingly, the Company has recorded impairment charges of \$20.9 million during the year ended December 31, 2008. If uncertainties in the credit and capital markets continue, these markets deteriorate further or if the Company experiences ratings downgrades on any investments in its portfolio, including on ARS, the fair value of the Company's investment portfolio may decline further.

Cash, cash equivalents and marketable investment securities available for sale and trading as of December 31, 2008 are summarized as follows (in thousands):

	<u>Amortized cost</u>	<u>Gross unrealized holding gains</u>	<u>Gross unrealized holding losses</u>	<u>Fair value</u>
<b>Cash and Cash Equivalents:</b>	\$ 50,825	\$ 9	\$ -	\$ 50,834
<b>Available for Sale:</b>				
Debt securities:				
Corporate	\$ 2,992	\$ 51	\$ -	\$ 3,043
Government agency	43,093	412	(2)	43,503
Total investments in marketable securities-current	<u>\$ 46,085</u>	<u>\$ 463</u>	<u>\$ (2)</u>	<u>\$ 46,546</u>
Debt securities:				
Auction rate securities	7,404	-	-	7,404
Total investments in marketable securities-noncurrent	<u>\$ 7,404</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 7,404</u>
<b>Trading:</b>				
Debt securities:				
Auction rate securities	1,348	-	-	1,348
Total investments in marketable securities-noncurrent	<u>\$ 1,348</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 1,348</u>

Marketable investment securities available for sale as of December 31, 2007 are summarized as follows (in thousands):

	<u>Amortized cost</u>	<u>Gross unrealized holding gains</u>	<u>Gross unrealized holding losses</u>	<u>Fair value</u>
Debt securities:				
Corporate	\$ 11,845	\$ 49	\$ (31)	\$ 11,863
Government agency	4,870	3	(16)	4,857
Auction rate securities	26,036	-	(1,107)	24,929
Total investments in marketable securities-current	<u>\$ 42,751</u>	<u>\$ 52</u>	<u>\$ (1,154)</u>	<u>\$ 41,649</u>
Debt securities:				
Auction rate securities	29,650	-	(1,293)	28,357
Total investments in marketable securities-noncurrent	<u>\$ 29,650</u>	<u>\$ -</u>	<u>\$ (1,293)</u>	<u>\$ 28,357</u>



Marketable investment securities available for sale in an unrealized loss position as of December 31, 2008 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>Available for Sale:</b>						
Debt securities:						
Government agency	\$ 2,998	\$ 2	\$ -	\$ -	\$ 2,998	\$ 2
	<u>\$ 2,998</u>	<u>\$ 2</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 2,998</u>	<u>\$ 2</u>

All securities in an unrealized loss position as of December 31, 2008 are debt securities and the decline in fair value is due primarily to liquidity issues experienced in global credit and capital markets and the resulting failures in auction of our auction rate securities.

Maturities of investment securities available for sale and trading securities are as follows at December 31, 2008 (in thousands):

	<u>Amortized cost</u>	<u>Fair value</u>
Due within one year	\$ 39,482	\$ 39,820
Due after one year through five years	7,951	8,074
Due after five years through ten years	-	-
Due after ten years	7,404	7,404
Total debt securities	<u>\$ 54,837</u>	<u>\$ 55,298</u>

## (5) Fair Value Measurement

The Company adopted Financial Accounting Standards Board (“FASB”) Statement of Financial Accounting Standards No. 157 *Accounting for Fair Value Measurements* (“SFAS No. 157”) on January 1, 2008. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (an exit price). SFAS No. 157 outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. Under U.S. generally accepted accounting principles, certain assets and liabilities must be measured at fair value, and SFAS No. 157 details the disclosures that are required for items measured at fair value. In February 2008, the FASB issued Staff Position No. 157-2 (FSP 157-2), which delays the effective date of SFAS No. 157 for one year for all nonfinancial assets and liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. Based on this guidance, the Company expects to adopt the provisions of SFAS No. 157 as related to nonfinancial assets and nonfinancial liabilities, effective January 1, 2009 and this adoption is not expected to have a material impact on the Company’s consolidated financial statements.

Under SFAS No. 159, entities are permitted to choose to measure many financial instruments and certain other items at fair value. The Company elected the fair value measurement option under SFAS No. 159 for its ARS put option.

The Company has marketable investment securities that must be measured under SFAS No. 157. 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, 2008 (in thousands):

	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	<b>Total as of December 31, 2008</b>
Marketable investment securities	\$ 46,546	\$ -	\$ -	\$ 46,546
Marketable investment securities, non-current	-	-	8,752	8,752
Total assets at fair value	<u>\$ 46,546</u>	<u>\$ -</u>	<u>\$ 8,752</u>	<u>\$ 55,298</u>

The following table summarizes the changes in fair value of the Company's Level 3 assets (in thousands):

	<b>Fair Value Measurement of Assets Using Level 3 Inputs</b>
Beginning balance at January 1, 2008	\$ 53,286
Total gains (losses) (realized or unrealized)	
Included in earnings	(20,898)
Included in other comprehensive income	650
Transfers in (out) of Level 3	1,750
Sales	<u>(26,036)</u>
Ending balance at December 31, 2008	<u>\$ 8,752</u>
Losses for 2008 included in	
earnings attributable to change in unrealized gains	
or losses (including other-than-temporary impairments)	
relating to assets still held at the reporting date	\$ 20,898

## (6) Inventory

Inventory consists of material purchased and manufactured subsequent to the April 2006 approval of Preotact in the European Union (EU). Costs associated with inventory production that were incurred prior to EU approval of Preotact have been previously expensed as research and development expense, creating an initial FIFO inventory layer with a carrying value of zero. The Company does not have any inventory as of December 31, 2008 and 2007 because the Company sold its entire inventory on hand to Nycomed pursuant to the July 2007 license agreement with Nycomed (see Note 2(f)) which provided for the assumption by Nycomed of the Company's manufacturing and supply obligations to Nycomed.

## (7) Equipment

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

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Equipment	\$ 646	\$ 582
Less accumulated depreciation	(361)	(273)
Total equipment	\$ 285	\$ 309

In July 2007, the Company entered into a Lease Termination Agreement with the MaRS Discovery District, or MaRS, under which the Company's operating lease for the office and laboratory space in Toronto, Canada was terminated. Pursuant to the Lease Termination Agreement, the Company sold its leasehold tenant improvements to a third party for \$2.4 million. In August 2007, the Company auctioned off the remaining Toronto facility equipment for \$1.1 million. The Company recognized a gain on sale of fixed assets during the year ended December 31, 2007 of \$3.2 million on these transactions. The termination of the Company's operating lease and sale of its leasehold tenant improvements was part of the Company's restructuring initiatives, which included a plan to close its Mississauga and Toronto facilities and discontinue all operations in Canada.

In May 2007, the Company closed an Agreement of Purchase and Sale to repurchase its 93,000 square foot laboratory and office building located in Salt Lake City, UT, for \$20.0 million. Under the terms of the agreement, the Company's 15-year lease obligation was extinguished. The repurchase of the laboratory and office building is considered an early extinguishment of debt. The amount paid to repurchase the laboratory and office building was in excess of the carrying value of the lease financing obligation. Accordingly, the Company recorded a loss of \$1.0 million during the year ended December 31, 2007 on such extinguishment.

In July 2007, the Company sold its 93,000 square foot laboratory and office building, including certain laboratory and office equipment and furnishings, located in Salt Lake City, Utah for \$21.0 million. As part of the sale, the University of Utah agreed to release the Company from all obligations under a 40 year ground lease for land upon which the building is located. The Company recognized a gain on sale of fixed assets during the year ended December 31, 2007 of \$3.3 million on this transaction. The sale of this facility was part of the Company's restructuring initiative which included a plan to close its Salt Lake City facility and to discontinue all Salt Lake City operations.

During the fourth quarter of 2006, the Company performed impairment testing of its fixed assets located in Salt Lake City, Utah and Toronto, Canada. The Company evaluated alternative courses of action that were finalized with the decision in 2007 that operations at these sites would be closed. As a result, the Company determined that no impairment charge was required for the property, plant and equipment located at Salt Lake City, Utah. The Company, however, determined that the fair value of the property and equipment and leasehold improvements located at Toronto, Canada was less than the carrying value, resulting in an \$8.3 million write-down of the assets. The Company estimated fair value based on a combination of present value techniques and market value of assets.

In June 2007, the Company sold its land and 85,795 square foot laboratory and office building, including certain equipment and furnishings, located in Mississauga, Ontario, Canada for \$4.4 million. The Company recognized a gain on sale of assets held for sale during the year ended December 31, 2007 of \$1.8 million on this transaction.

## (8) Goodwill

The cost of acquired companies in excess of the fair value of the net assets and purchased intangible assets at acquisition date was recorded as goodwill. As of December 31, 2008 and 2007 the Company had goodwill of \$9.4 million and \$11.1 million from the acquisition of Allelix in December 1999. As a result of the annual impairment test performed by management at year-end, it was noted that fair value exceeded the carrying value of the reporting unit.

## (9) Leases

The Company has a non-cancelable operating lease for its office space in Bedminster, New Jersey that expires in 2010 and non-cancelable operating leases for certain equipment that expire between 2009 and 2010. Rent-free periods and other incentives granted under the lease 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 \$443,000, \$2.4 million, and \$1.2 million for 2008, 2007 and 2006, respectively. The future lease payments under non-cancelable operating leases as of December 31, 2008 are as follows (in thousands):

	<u>Operating leases</u>
Year ending December 31:	
2009	\$ 483
2010	80
2011	4
2012	-
2013	-
Thereafter	-
Total minimum lease payments	<u>\$ 567</u>

## (10) Restructuring Charges

In June 2006, as a result of the uncertainty with respect to the regulatory approval of PREOS for osteoporosis, the Company began an initiative to restructure operations (the 2006 Restructuring Plan). Under the 2006 Restructuring Plan, NPS reduced its worldwide workforce, including employees and contractors, by approximately 250 positions, eliminated all commercial sales and related field based activities, terminated its agreement with Allergan Inc. to promote Restasis® Ophthalmic Emulsion to rheumatologists and closed and planned to sell the Company's technical operations facility in Mississauga, Ontario, Canada. The reduction in workforce involved all functional disciplines including selling, general and administrative employees as well as research and development personnel.

The charges related to the 2006 Restructuring Plan during the years ended December 31, 2008, 2007 and 2006 were zero, \$476,000 and \$8.2 million, respectively. Associated severance payments related to the 2006 Restructuring Plan were paid primarily in the second and third quarters of 2006 for severed United States employees and were completely paid during 2008 for severed Canadian employees. The cumulative restructuring charges through December 31, 2008 related to the 2006 Restructuring Plan were \$8.7 million.

In March 2007, the Company announced an initiative to restructure operations and to reduce its work force from 196 employees to approximately 35 employees by the end of 2007 (the 2007 Restructuring Plan). Under the 2007 Restructuring Plan, the Company closed its operations in Toronto, Canada and Salt Lake City, Utah. These steps are part of the Company's strategy to transition to an organization that will rely primarily on outsourcing research, development activities and manufacturing operations, as well as other functions critical to its business.

The charge related to the 2007 Restructuring Plan during the years ended December 31, 2008 and 2007 were a credit of \$272,000 and a charge of \$12.9 million, respectively. The credit during the year ended December 31, 2008 relates primarily to a reversal of previously accrued severance for employees the Company has retained who had previously been expected to be terminated and had earned their severance and had no further service obligations. These credits were partially offset by employee termination benefits. The charge during the year ended December 31, 2007 was comprised of \$8.7 million in severance related cash expenses, \$1.0 million for accelerated vesting of options under existing employee severance agreements and retirement plan, \$2.7 million for accelerated vesting of restricted stock units under employee retention plans and \$485,000 for stock awards under employee severance enhancement agreements. Associated severance payments were substantially paid by February 28, 2008 for severed US employees and are anticipated to be paid by December 31, 2009 for severed Canadian employees. During 2008, \$771,000 of the 2007 accrued restructuring charges were satisfied through the issuance of common stock. The cumulative restructuring charges through December 31, 2008 related to the 2007 Restructuring Plan were \$12.6 million. Total anticipated restructuring charges as a result of the 2007 Restructuring Plan are estimated to be approximately \$12.7 million.

A summary of accrued restructuring costs is as follows (in thousands):

	<u>December 31,</u> <u>2006</u>	<u>Charges</u>	<u>Cash</u>	<u>Non-Cash</u>	<u>December 31,</u> <u>2007</u>
2006 Restructuring Plan:					
Severance	\$ 607	\$ 476	\$ (1,076)	\$ -	\$ 7
2007 Restructuring Plan:					
Severance	-	12,910	(7,143)	(3,437)	2,330
	<u>\$ 607</u>	<u>\$ 13,386</u>	<u>\$ (8,219)</u>	<u>\$ (3,437)</u>	<u>\$ 2,337</u>
	<u>December 31,</u> <u>2007</u>	<u>Charges</u>	<u>Cash</u>	<u>Non-Cash</u>	<u>December 31,</u> <u>2008</u>
2006 Restructuring Plan:					
Severance	\$ 7	-	(7)	-	-
2007 Restructuring Plan:					
Severance	2,330	(272)	(1,070)	(771)	217
	<u>\$ 2,337</u>	<u>\$ (272)</u>	<u>\$ (1,077)</u>	<u>\$ (771)</u>	<u>\$ 217</u>

### (11) Long-term Debt Obligations

The following table reflects the carrying value of our long-term debt obligations under our various financing arrangements as of December 31, 2008 and 2007 (in thousands):

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Convertible notes	\$ 50,000	\$ 50,598
Secured notes	303,697	310,697
Capital lease	92	146
Total borrowings	<u>353,789</u>	<u>361,441</u>
Less current portion	35,498	24,992
Total long-term debt obligations	<u>\$ 318,291</u>	<u>\$ 336,449</u>

#### (a) Convertible Notes

In August 2007, the Company completed a private placement of \$50.0 million in 5.75% Convertible Notes due August 7, 2014 (5.75% Convertible Notes). The Company received net proceeds from the 5.75% Convertible Notes of approximately \$49.4 million, after deducting costs associated with the offering. The 5.75% Convertible Notes accrue interest at an annual rate of 5.75% payable quarterly in arrears on the first day of the succeeding calendar quarter commencing January 1, 2008. Accrued interest on the 5.75% Convertible Notes was approximately \$725,000 and \$1.2 million as of December 31, 2008 and 2007, respectively. The holders may convert all or a portion of the 5.75% Convertible Notes into common stock at any time, subject to certain milestones, on or before August 7, 2014. The 5.75% Convertible Notes are convertible into common stock at a conversion price of \$5.44 per share, subject to adjustments in certain events. The 5.75% Convertible Notes are unsecured debt obligations and rank equally in right of payment with all existing and future unsecured senior indebtedness. On or after August 7, 2012, the Company may redeem any or all of the 5.75% Convertible Notes at a redemption price of 100% of their principal amount, plus accrued and unpaid interest to the day preceding the redemption date. The 5.75% Convertible Notes provide for certain events of default, including payment defaults, breaches of covenants and certain events of bankruptcy, insolvency and reorganization. The 5.75% Convertible Notes also provide that if there shall occur a fundamental change, as defined, at any time prior to the maturity of the Note, then the holder shall have the right, at the Holder's option, to require the Company to redeem the notes, or any portion thereof plus accrued interest and liquidated damages, if any. If a change of control, as defined, occurs and if the holder converts notes in connection with any such transaction, the Company will pay a make whole premium by increasing the conversion rate applicable to the notes. If any event of default occurs and is continuing, the principal amount of the 5.75% Convertible Notes, plus accrued and unpaid interest, if any, may be declared immediately due and payable. The Company has filed a registration statement with the SEC, which has been

declared effective, covering the common stock issuable upon conversion of the 5.75% Convertible Notes. The Company incurred debt issuance costs of approximately \$600,000, which have been deferred and which are being amortized over a seven-year period. The effective interest rate on the 5.75% Convertible Notes, including debt issuance costs, is 5.9%.

Pursuant to the Registration Rights Agreement, the Company has filed a shelf registration statement with the SEC, covering resales of the common stock issuable upon conversion of the 5.75% Convertible Notes. The registration statement has been declared effective. The Company agreed to use its reasonable best efforts to keep the registration statement effective until the earlier of (i) the date as of which holders may sell all of the securities covered by the registration statement without restriction pursuant to Rule 144(k) promulgated under the Securities Act of 1933 or (ii) the date on which holders shall have sold all of the securities covered by the registration statement. If the Company fails to comply with these covenants or suspends use of the registration statement for periods of time that exceed what is permitted under the Registration Rights Agreement, the Company is required to pay liquidated damages in an amount equivalent to 1% per annum of (a) the principal amount of the notes outstanding, or (b) the conversion price of each underlying share of common stock that has been issued upon conversion of a note, in each case, until the Company is in compliance with these covenants. The Company believes the likelihood of such an event occurring is remote and, as such, the Company has not recorded a liability as of December 31, 2008.

In July 2003, the Company completed a private placement of \$192.0 million in 3.0% Convertible Notes due June 15, 2008 (3% Convertible Notes). The Company received net proceeds from the 3% Convertible Notes of approximately \$185.9 million, after deducting costs associated with the offering. The Company incurred debt issuance costs of \$6.1 million, which were deferred and were being amortized over a five-year period.

In August 2007 the Company repurchased \$20.2 million par value of outstanding 3% Convertible Notes in the open market at a price of \$19.5 million plus accrued interest. Additionally, in October 2007, the Company closed a tender offer in which \$171.2 million of the 3.0% Convertible Notes were tendered to the Company for \$169.1 million plus accrued interest. These 3% Convertible Notes were subsequently retired during the year ended December 31, 2007. As of December 31, 2007, the Company had \$598,000 of the 3% Convertible Notes outstanding. The repurchase and subsequent retirement of the 3% Convertible Notes is considered an early extinguishment of debt. The amount paid to repurchase the 3% Convertible Notes was less than the carrying value of the 3% Convertible Notes. Accordingly, the Company recorded a gain of \$1.3 million, which is net of the write-off of \$823,000 of deferred financing costs, during the year ended December 31, 2007 on such extinguishment in accordance with the provisions of Accounting Principles Board Opinion No. 26, *Early Extinguishment of Debt* (APB No. 26). The Company had \$598,000 of the 3% Convertible Notes outstanding as of December 31, 2007. In accordance with the terms of the notes, the remaining outstanding balance was paid during the second quarter of 2008.

#### ***(b) Secured Notes Payable***

In December 2004, the Company completed a private placement of \$175.0 million in Class A Notes. The Company received net proceeds from the issuance of the Class A Notes of approximately \$169.3 million, after deducting costs associated with the offering. The Class A Notes accrue interest at an annual rate of 8.0% payable quarterly in arrears on March 30, June 30, September 30 and December 30 of each year (Payment Date). The Class A Notes are secured by certain royalty and related rights of the Company under its agreement with Amgen. Additionally, the only source for interest payments and principal repayment of the Class A Notes is limited to royalty and milestone payments received from Amgen plus any amounts available in the restricted cash reserve account and earnings thereon as described later. The Class A Notes are non-recourse to NPS Pharmaceuticals, Inc. Payments of principal will be made on March 30 of each year commencing March 30, 2006, to the extent there is sufficient cash available for such principal payment. As of December 31, 2008 and 2007, the outstanding principal balance on the Class A Notes was \$130.0 million and \$154.5 million, respectively. In connection with the issuance of the Class A Notes, the Company was required to place \$14.2 million of the Class A Notes proceeds into a restricted cash reserve account to pay any shortfall of interest payments through December 30, 2006. All remaining amounts of this \$14.2 million were used to repay principal in March 2007. In the event the Company receives royalty and milestone payments under its agreement with Amgen above certain specified amounts, a redemption premium on principal repayment will be owed. The redemption premium ranges from 0% to 41.5% of principal payments, depending on the annual net sales of Sensipar by Amgen. As of December 31, 2008 and 2007, the Company classified \$35.4 million and \$24.3 million, respectively, of the Class A Notes as current based on royalty payments accrued during the year ended December 31, 2008 plus available balances in the restricted cash reserve account less estimated redemption premiums. The Company may repurchase, in whole but not in part, the Class A Notes on any Payment Date at a premium ranging from 0% to 41.5% of outstanding principal, depending on the preceding four quarters' sales of Sensipar by Amgen. The Company is accruing the estimated redemption premiums over the estimated life of the debt of six years using the "effective interest-

rate” method. The estimated life is based on projections of royalties to be earned from Sensipar sales. Accrued interest on the Class A Notes was approximately \$21.9 million and \$8.8 million as of December 31, 2008 and 2007, respectively, which includes the Company’s estimate of the redemption premium. The Company incurred debt issuance costs of \$5.7 million, which are also being amortized using the “effective interest-rate” method. The current effective interest rate on the Class A Notes, including debt issuance costs and estimated redemption premiums, is approximately 26.9%.

In July 2007, the Company entered into an agreement with DRI Capital, or DRI, formerly Drug Royalty L.P.3, in which the Company sold to DRI its right to receive future royalty payments arising from sales of Preotact under its license agreement with Nycomed. Under the agreement, DRI paid the Company an up-front purchase price of \$50.0 million. An additional \$25.0 million will be due to the Company in 2010 if certain Preotact sales thresholds are achieved. If and when DRI receives two and a half times the principal advanced, the agreement will terminate and the remainder of the royalties, if any, will revert back to the Company. The Company has determined that it should classify the initial up-front purchase price as debt and amortize using the effective interest rate method over an estimated life of 11 years. The liability recorded related to the DRI transaction was \$50.0 million as of December 31, 2008 and 2007, and accrued interest under the DRI agreement was \$4.1 million and \$2.5 million as of December 31, 2008 and 2007, respectively. The repayment of the \$50.0 million is secured solely by future royalty payments arising from sales of Preotact by Nycomed. The effective interest rate under the agreement, including issuance costs, is approximately 15.7%.

In August 2007, the Company completed a private placement of \$100.0 million in Secured 15.5% Notes due March 30, 2017 (Class B Notes). The Company received net proceeds from the issuance of the Class B Notes of approximately \$97.0 million, after deducting costs associated with the offering. The Class B Notes accrue interest at an annual rate of 15.5% payable quarterly in arrears on March 30, June 30, September 30 and December 30 of each year. The Class B Notes are secured by certain royalty and related rights of the Company under its agreement with Amgen. Additionally, the only source for interest payments and principal repayment of the Class B Notes is limited to royalty and milestone payments received from Amgen and only after the Class A Notes are paid in full. Prior to repayment in full of the Class A Notes, interest on the Class B Notes will be paid in kind through the issuance of notes (the PIK Notes) which will be part of the same class and have the same terms and rights as the Class B Notes, except that interest on the PIK Notes will begin to accrue from the date that such PIK Notes are issued. The Class B Notes are non-recourse to NPS Pharmaceuticals, Inc. The Company may repurchase, in whole but not in part, the Class B Notes at a calculated Redemption Price based on the timing of repurchase and the source of proceeds for the repurchase. The Redemption Price varies between 100.0% and 107.75% depending on these variables. The outstanding principal balance on the Class B Notes, including PIK Notes of \$23.7 million and \$6.2 million, were \$123.7 million and \$106.2 million, as of December 31, 2008 and 2007, respectively. The Company incurred debt issuance costs of \$3.6 million, which are being amortized using the “effective interest-rate” method. The effective interest rate on the Class B Notes, including debt issuance costs, is approximately 16.0%.

### ***(c) Lease Financing Obligations***

In December 2005, the Company completed a sale-leaseback transaction with BioMed Realty, in which the Company sold its 93,000 square foot laboratory and office building located in Salt Lake City, Utah for \$19.0 million and leased back the property under a 15-year lease. Net proceeds from the sale were \$19.0 million. Because the lease agreement in the sale-leaseback transaction contained a purchase option by the Company, the Company accounted for the transaction as a financing arrangement where the gain on the sale of \$4.3 million was deferred.

In May 2007, the Company closed an Agreement of Purchase and Sale to repurchase from BioMed Realty its 93,000 square foot laboratory and office building for \$20.0 million. Under the terms of the agreement, the Company’s 15-year lease obligation was extinguished. The repurchase of the laboratory and office building is considered an early extinguishment of debt. The amount paid to repurchase the laboratory and office building was in excess of the carrying value of the lease financing obligation. Accordingly, the Company recorded a loss of \$1.0 million during the year ended December 31, 2007 on such extinguishment. See Note 7.

***(d) Contractual maturities of long-term debt obligations***

The aggregate contractual maturities of long-term debt obligations, including estimated maturities of the Secured Notes, due subsequent to December 31, 2008 are as follows (in thousands):

Year ending December 31:	
2009	\$ 35,498
2010	47,306
2011	59,110
2012	117,740
2013	6,954
Thereafter	87,181
Total long-term debt obligations	<u>\$ 353,789</u>

**(12) Capital Stock**

***Stockholder Rights Plan***

In December 1996, the board of directors approved the adoption of a Stockholder Rights Plan (the Rights Plan). The Rights Plan was subsequently amended on December 31, 2001 to increase the purchase price of a share of Series A Junior Participating Preferred Stock and to extend the expiration date of the Rights Plan. The Rights Plan provides for the distribution of a preferred stock purchase right (Right) as a dividend for each outstanding share of the Company's common stock. This Right entitles stockholders to acquire stock in the Company or in an acquirer of the Company at a discounted price in the event that a person or group acquires 20% or more of the Company's outstanding voting stock or announces a tender or exchange offer that would result in ownership of 20% or more of the Company's stock. Each right entitles the registered holder to purchase from the Company 1/100th of a share of Series A Junior Participating Preferred Stock, par value \$0.001 per share at a price of \$300 per 1/100th of a preferred share, subject to adjustment. The Rights may only be exercised on the occurrence of certain events related to a hostile takeover of the Company as described above. In any event, the Rights will expire on December 31, 2011. The Rights may be redeemed by the Company at \$0.01 per right at any time prior to expiration or the occurrence of an event triggering exercise. At December 31, 2008, the Rights were not exercisable.

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

As of December 31, 2008, the Company has five equity incentive plans: the 1987 Stock Option Plan (the 1987 Plan), the 1994 Equity Incentive Plan (the 1994 Plan), the 1994 Nonemployee Directors' Stock Option Plan (the Directors' Plan), the 1998 Stock Option Plan (the 1998 Plan), and the 2005 Omnibus Incentive Plan (the 2005 Plan). An aggregate of 8,203,593 shares are authorized for future issuance under the five plans.

As of December 31, 2008, there are no shares reserved for future grant under the 1987 Plan, the 1994 Plan and the Directors' Plan. As of December 31, 2008, there are 283,249 and 1,957,292 shares reserved for future grant under the 2005 Plan and 1998 Plan, respectively. The Company's 2005 Plan provides for the grant of nonqualified stock options, incentive stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, cash-based awards and other stock-based awards. The Company's 1998 Plan provides for the grant of nonqualified stock options and incentive stock options. 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. During 2008, 2007 and 2006, directors of the Company were granted 151,038, 197,357 and 178,836, respectively, in deferred stock units for services that were recorded at fair value. During 2006, certain employees and executive officers of the Company were granted 835,798 restricted stock units which vest subject to continued employment over a two or three year period. Under the Company's 1998 Plan, the exercise price of options is generally not less than the fair market value of the Company's common stock on the date of grant. The number of shares, terms, and exercise period are determined by the board of directors on a grant-by-grant basis, and the exercise period does not extend beyond ten years from the date of the grant. Stock options generally vest 28% after one year and 2% to 3% per month thereafter.



The Company also had an Employee Stock Purchase Plan (the Purchase Plan) whereby qualified employees were 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 or purchase period. The Company authorized 685,000 shares for purchase by employees. Employees purchased zero, 123,101 and 169,712 shares under the Purchase Plan in the years ended December 31, 2008, 2007 and 2006, respectively, and 13 shares remain available for future purchase. The Purchase Plan has been discontinued until additional shares are made available.

Under SFAS No. 123R, the Company estimates expected volatility using a blend of 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 calculating the estimated volatility for the years ended December 31, 2008 and 2007, the Company weighted implied volatility at zero percent and historical volatility at 100%. The Company had no cumulative effect adjustment upon adoption of SFAS No. 123R under the modified prospective method on January 1, 2006. The Company's policy is to recognize compensation cost for awards with only service conditions and a graded vesting schedule 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 and stock appreciation right exercises or grants of restricted shares or deferred stock units.

The compensation expense under SFAS No. 123R is recorded in cost of goods sold, research and development expense, selling, general and administrative expense and restructuring charges based on the specific allocation of employees receiving the awards. Additionally, the Company eliminated the January 1, 2006 deferred compensation balance against additional paid-in capital upon adoption of SFAS No. 123R.

The following table summarizes the effect of compensation cost arising from share-based payment arrangements on the Company's statements of operations for the years ended December 31, 2008, 2007 and 2006 for the Company's stock option plans, the employee stock purchase plan and other share-based awards: (in thousands)

	<b>Year Ended</b> <b>December 31, 2008</b>	<b>Year Ended</b> <b>December 31, 2007</b>	<b>Year Ended</b> <b>December 31, 2006</b>
Research and development	\$ 504	\$ 1,000	\$ 7,790
Selling, general and administrative	3,804	4,005	7,425
Restructuring charges	-	1,030	227
Total cost of share-based compensation	<u>4,308</u>	<u>6,035</u>	<u>15,442</u>
Amount capitalized in inventory during the year	-	-	18
Amount recognized in income for amount previously capitalized in inventory	-	<u>(18)</u>	-
Amounts charged against income, before income tax expense (benefit)	<u>\$ 4,308</u>	<u>\$ 6,017</u>	<u>\$ 15,460</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 life of the options.
- The Company uses historical data to estimate the expected life of the option; separate groups of employees that have similar historical exercise behavior are considered separately for valuation purposes. The expected life 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 life 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 life of the option.

	Years ended December 31,		
	2008	2007	2006
Dividend yield range	—	—	—
Expected volatility range	59.9% – 66.7%	58.5% – 62.4%	51.4% – 64.9%
Risk-free interest rate range	2.6% – 3.4%	4.3% – 5.0%	4.4% – 5.1%
Expected term (in years)	5.4 – 6.2	3.2 – 4.1	3.2 – 4.1

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

	Year ended December 31, 2008			
	Number of options (in thousands)	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Options outstanding at beginning of year	4,890	\$ 12.59		
Options granted	1,038	4.51		
Options exercised	174	4.55		
Options canceled	1,266	14.02		
Options outstanding at end of year	<u>4,488</u>	10.79	5.35	\$ 4,227
Vested and expected to vest	<u>4,185</u>	11.23	5.08	\$ 3,728
Options exercisable at end of year	<u>2,821</u>	\$ 14.47	3.20	\$ 1,270

The weighted-average grant-date fair value of options granted during the years ended December 31, 2008, 2007 and 2006 was \$2.64, \$2.05 and \$3.87, 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, 2008, 2007 and 2006 was \$408,000, \$9,000 and \$25,000, respectively.

Restricted stock, restricted stock units and deferred stock unit grants consist of the Company's common stock. The fair value of each restricted stock grant, restricted stock unit and deferred stock unit is equal to the market price of the Company's stock at the date of grant. Restricted stock and restricted stock unit grants are time vested. During 2006 certain grants of restricted stock units to employees contained performance vesting criteria. During the years ended December 31, 2008, 2007 and 2006, the Company granted 151,038, 197,357 and 178,836 deferred stock units, respectively, which did not contain any vesting restrictions. A summary of activity related to aggregate restricted stock and restricted stock units as of December 31, 2008, is indicated in the following table (shares in thousands):

	Number of shares	Weighted-average grant date fair value
Nonvested at beginning of year	207	\$ 4.99
Granted	489	4.07
Vested	(610)	4.36
Forfeited	(14)	4.76
Nonvested at December 31, 2008	<u>72</u>	\$ 4.12

As of December 31, 2008, there was \$6.2 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 1.14 years. During the year ended December 31, 2008, cash received from stock options exercised was \$790,000.

#### (14) Income Taxes

The Company has recorded income tax expense (benefit) for the years ended December 31, 2008, 2007 and 2006 of (\$179,000), \$780,000 and zero, respectively.

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

	Years ended December 31,		
	2008	2007	2006
Computed "expected" tax expense	\$ (10,848)	\$ (1,191)	\$ (38,307)
Expiration of tax attributes	-	6,025	2,726
Foreign tax rate differential	(837)	(812)	967
Change in the valuation allowance for deferred tax assets attributable to operations and other adjustments	27,040	(48,407)	17,327
Adjustment to deferred tax assets for changes in foreign taxes, laws and rates	(11,353)	38,478	13,321
U.S. and foreign credits	(334)	-	(431)
State income taxes, net of federal tax effect	2	2,083	(421)
Equity based compensation expense	726	58	1,039
Other	(4,575)	4,546	3,779
	<u>\$ (179)</u>	<u>\$ 780</u>	<u>\$ -</u>

The Company recorded income tax benefit of \$179,000 during the year ended December 31, 2008 for refundable income tax credits relating to research and development activities in the province of Quebec and changes in estimates in the calculation of U.S. alternative minimum tax for 2007. The Company recorded income tax expense of \$780,000 during the year ended December 31, 2007 for U.S. alternative minimum tax.

Domestic and foreign components of income (loss) before taxes are as follows (in thousands):

	Years ended December 31,		
	2008	2007	2006
Domestic	\$ (199,307)	\$ 34,806	\$ (15,927)
Foreign	167,402	(38,308)	(96,741)
Total loss before taxes	<u>\$ (31,905)</u>	<u>\$ (3,502)</u>	<u>\$ (112,668)</u>

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets at December 31, 2008 and 2007 are presented below (in thousands):

	2008		2007	
	Domestic	Foreign	Domestic	Foreign
Deferred tax assets:				
Stock compensation expense	\$ 4,770	\$ -	\$ 5,362	\$ -
Accrued compensation	81	-	69	-
Equipment and leasehold improvements, principally due to differences in depreciation and write down of assets	(58)	-	(40)	-
Other accrued expenses	43	-	45	-
Intangible assets	-	-	-	5,039
Research and development pool carryforward	-	44,591	-	63,389
Net operating loss carryforward	108,190	130,106	82,211	189,966
Research credit carryforward	6,686	-	7,021	-
Minimum tax credit	697	-	780	-
Investment tax credit carryforward	-	13,124	-	18,080
Unrealized gain/loss marketable investment securities	9,850	-	1,915	-
Acquired intellectual property	49,206	-	-	-
State credits	-	-	-	-
Deferred royalty income	-	-	-	16,207
Other	(3)	7,514	-	210
Total gross deferred tax assets	<u>179,462</u>	<u>195,335</u>	<u>97,363</u>	<u>292,891</u>
Less valuation allowance	<u>(179,462)</u>	<u>(195,335)</u>	<u>(97,363)</u>	<u>(292,891)</u>
Deferred tax assets	-	-	-	-
Deferred tax liabilities	-	-	-	-
Net deferred tax asset (liability)	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

Subsequently recognized tax benefits relating to the valuation allowance for deferred tax assets as of December 31, 2008 will be allocated as follows: 1) To the extent that the Allelix acquired net deferred tax assets are recognized, the tax benefit will be applied to reduce any remaining unamortized goodwill. At December 31, 2008, the remaining unamortized goodwill equaled \$9.4 million. 2) Tax benefits in excess of the acquired goodwill related to the acquisition will be reported as a reduction of income tax expense. The valuation allowance includes the benefit for stock option exercises which increased the domestic net operating loss carryforwards. Future reductions to the domestic valuation allowance will be allocated \$169.5 million to operations and \$9.9 million to paid-in capital.

The net change in the Company's total valuation allowance for the years ended December 31, 2008, 2007 and 2006 was a decrease of \$15.5 million and increases of \$4.8 million and \$23.0 million, respectively. The Company has a cumulative loss for the previous three years and projects losses into the future. Accordingly, as of December 31, 2008, the Company believes that it is not more likely than not that results of future operations will generate insufficient income to realize any of our gross deferred tax assets and has recorded a 100% valuation allowance.

At December 31, 2008, the Company had domestic and foreign net operating loss and credit carryforwards available to offset future income for tax purposes approximately as follows (in thousands):

	Domestic net operating loss carryforward for regular income tax purposes	Domestic research credit carry- forward	Canadian net operating loss carryforward for regular income tax purposes		Canadian research pool carry- forward	Canadian investment tax credit carry- forward	Ontario harmon- ization
			Federal	Provincial			
Expiring							
2009	\$ -	\$ 317	\$ 45,171	\$ 45,171		\$ -	\$ -
2010	-	166	103,787	103,787		-	-
2011	-	360	-	-		-	-
2012	-	846	-	-		-	-
2013	-	-	-	-		-	2,706
2014	-	-	123,957	123,957		-	-
2015	-	-	98,877	98,877		-	-
2016	-	-	-	-		3,175	-
2017	-	-	-	-		2,552	-
2018	7,109	1,035	-	-		235	-
2019	18,695	989	-	-		-	-
2020	16,136	722	-	-		1,565	-
2021	3,951	240	-	-		2,421	-
2022	16,083	363	-	-		2,290	-
2023	66,194	296	-	-		2,940	-
2024	34,616	412	-	-		3,005	-
2025	53,043	511	-	-		132	-
2026	7,513	429	76,851	76,851		169	-
2027	-	-	-	-		-	-
2028	71,592	-	-	-		-	-
Total	\$ <u>294,932</u>	\$ <u>6,686</u>	\$ <u>448,643</u>	\$ <u>448,643</u>	\$ <u>153,761</u>	\$ <u>18,484</u>	\$ <u>2,706</u>

The Company also has New Jersey state net operating loss carryforwards of approximately \$211.1 million and other domestic state net operating loss carryovers and tax credit carryforwards in varying amounts depending on the different state laws. The Company's domestic tax loss carryover for alternative minimum tax purposes is approximately the same as the Company's regular tax loss carryover. For the year ended December 31, 2008 certain Canadian research pool carryforward amounts were reclassified to Canadian net operating loss carryforwards as a result of audit by Canadian and Quebec tax authorities. The remaining Canadian research pool carryforward of \$153.8 million carries forward indefinitely.

As measured under the rules of the Tax Reform Act of 1986, the Company has undergone one or more greater than 50% changes of ownership since 1986. Consequently, use of the Company's domestic net operating loss carryforward and research credit carryforward against future taxable income in any one year may be limited. The maximum amount of carryforwards available in a given year is limited to the product of the Company's fair market value on the date of ownership change and the federal long-term tax-exempt rate, plus any limited carryforward not utilized in prior years.

Effective January 1, 2007, the Company adopted FIN 48, *Accounting for Uncertainty in Income Taxes – an interpretation of FAS 109*, which was issued in July 2006. FIN 48 clarifies the accounting for uncertainty in income taxes and prescribes a recognition threshold and measurement attributes for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company adopted FIN 48-1, *Definition of Settlement in FASB Interpretation No. 48*, retroactive to the adoption of FIN 48. FIN 48-1 provides guidance on how an enterprise should determine whether a tax position is effectively settled for the purpose of recognizing previously unrecognized tax benefits.

A reconciliation of the unrecognized tax benefits for the years ended December 31, 2008 and 2007 is as follows (in thousands):

	<b>Unrecognized Tax Expense</b>
Balance as of January 1, 2007	\$ 5,148
Additions for current year tax positions	-
Reductions for prior year tax positions	(280)
Balance as of December 31, 2007	<u>4,868</u>
Additions for current year tax positions	923
Reductions for prior year tax positions	(55)
Balance as of December 31, 2008	<u><u>\$ 5,736</u></u>

Unrecognized tax benefits amounted to \$5.7 million at December 31, 2008, and did not include any accrued potential penalties or interest. The Company anticipates a possible reversal of an accrued tax liability of approximately \$1.0 million within the next twelve months related to the expiration of a statute of limitations.

The Company accounts for penalties or interest related to uncertain tax positions as part of its provision for income taxes. Due to the Company's net operating loss carryforwards the adjustment related to the FIN 48 liability would not expect to result in a cash tax liability. Accordingly, the Company has not accrued for penalties or interest for both the U.S. (both Federal and State) and Canada as of December 31, 2008 and 2007. Also, due to the Company's net operating loss carryforwards, the Company does not believe any of its unrecognized tax benefits would have an impact on the effective tax rate.

The Company files income tax returns in various jurisdictions with varying statutes of limitations. As of December 31, 2008, the statute of limitations for income tax audits in Canada remains open for the tax years ended on or after December 31, 2003. The statute of limitations for income tax audits in the US remains open for the tax years ended on or after December 31, 2003.

#### **(15) Employee Benefit Plan**

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, 2008, 2007 and 2006, 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, 2008, 2007 and 2006 of \$249,000, \$602,000 and \$927,000, respectively.

Additionally, the Company maintains a tax-qualified defined contribution pension plan for its Canadian employees. Employees may elect to reduce their current compensation by 2% or 4% of eligible compensation up to a maximum of Cnd. \$10,500 per year in 2008, and have the amount of such reduction contributed to the pension plan. The Company matches 100% of such contributions. The Company recorded an expense associated with these matching contributions for the years ended December 31, 2008, 2007 and 2006 of Cnd. \$46,000, Cnd. \$137,000, and Cnd. \$328,000, respectively.

#### **(16) Disclosure about the Fair Value of Financial Instruments**

The carrying value for certain short-term financial instruments that mature or reprice frequently at market rates approximates fair value. Such financial instruments include: cash and cash equivalents, accounts receivable, accounts payable, and accrued and other liabilities. The fair values of marketable investment securities are based on quoted market prices at the reporting date or other methods as more fully described in Note 4. The fair value of the Company's 5.75% convertible notes are estimated to be approximately \$50.7 million and \$51.5 million as of December 31, 2008 and 2007, respectively. The fair value of the Company's Secured Notes was estimated to be \$140.4 million and

\$156.0 million as of December 31, 2008 and 2007, respectively for the Class A Notes and \$75.0 million \$106.2 million as of December 31, 2008 and 2007, respectively, for the Class B Notes, based on broker estimates. The Company does not invest in derivatives.

### **(17) Recent Accounting Pronouncements**

In May 2008, the Financial Accounting Standards Board (“FASB”) issued FASB Staff Position, or FSP, No. APB 14-1 *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. This FSP clarifies that convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) are not addressed by paragraph 12 of APB Opinion No. 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants*. Additionally, this FSP specifies that issuers of such instruments should separately account for the liability and equity components in a manner that will reflect the entity’s nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. This FSP will be effective for the Company’s financial statements issued in the first quarter of 2009. The Company does not expect this adoption to have a material impact on its consolidated financial statements.

On October 10, 2008, the FASB issued Staff Position No. 157-3 (FSP 157-3), which provided guidance on how to determine the fair value of financial assets when the markets for those assets are not active. FSP 157-3 states that the objective of a fair-value measurement is to estimate the price that would be received to sell an asset currently in an orderly transaction that is not a forced liquidation or a distress sale. Further, entities must include appropriate risk adjustments that market participants would make, including adjustments for nonperformance and liquidity risks. The adoption of FSP 157-3 did not have a material impact on the Company’s consolidated financial statements.

At its December 2007 meeting, the FASB ratified the consensus reached by the EITF in EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF Issue 07-01. The EITF concluded that a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other accounting literature. Payments to or from collaborators would be evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity’s business and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are to be disclosed along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however, required disclosure under EITF Issue 07-1 applies to the entire collaborative agreement. EITF Issue 07-01 is effective for fiscal years beginning after December 15, 2008, and is to be applied using a modified retrospective method to all periods presented for all collaborative arrangements existing as of the effective date. The Company does not expect this adoption to have a material impact on its consolidated financial statements.

In June 2007, the FASB ratified the EITF consensus on EITF Issue No. 07-3, *Advance Payments for Research and Development Activities*. EITF Issue No. 07-3 requires companies to record non-refundable advance research and development payments to acquire goods and services as an asset if the contracted party has not yet performed the related activities. The amount capitalized is then recognized as expense when the research and development activities are performed. The Company adopted EITF Issue No. 07-3 on January 1, 2008, which is to be applied prospectively for new contractual agreements entered into after that date. The adoption of EITF Issue No. 07-3 did not have a material effect on the Company's consolidated financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115* (“SFAS No. 159”). This statement provides a fair value option election that allows companies to irrevocably elect fair value as the initial and subsequent measurement attribute for certain financial assets and liabilities, with changes in fair value recognized in earnings as they occur. SFAS No. 159 permits the fair value option election on an instrument by instrument basis at initial recognition of an asset or liability or upon an event that gives rise to a new basis of accounting for that instrument. Further, it provides entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The Company adopted SFAS No. 159 on January 1, 2008. The Company has elected the fair value option for its ARS put option for the year-ended December 31, 2008, however this election did not have a material impact on its consolidated financial statements.

## **(18) 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 entered into long-term agreements with various third-party contract manufacturers for the production and packaging of drug product and vials. Under the terms of these various contracts, we are required to purchase certain minimum quantities of drug product each year.

The Company has contractual commitments of \$4.9 million for drug product for the year ending December 31, 2009 for the manufacture of clinical supplies of PREOS and GATTEX. 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, 2008, 2007 and 2006 were \$4.0 million, \$11.4 million and \$19.4 million, respectively.

## **(19) Legal Proceedings**

### **Securities Class Action.**

A consolidated shareholders' securities class action lawsuit is currently pending against the Company and certain of its present and former officers and directors in the U.S. District Court for the District of Utah, Central Division, as Case No. 2:06cv00570 DAK. By order dated September 14, 2006, the court consolidated four separately filed lawsuits into this action. By order dated November 17, 2006, the court appointed lead plaintiff and counsel for the proposed class. On January 16, 2007, the lead plaintiff and its counsel filed a consolidated amended complaint asserting two federal securities claims on behalf of lead plaintiff and all other shareholders of NPS who purchased publicly traded shares of NPS between August 7, 2001, and May 2, 2006, which period is referred to in this paragraph as the "class period." The consolidated complaint asserts two claims: a claim founded upon Section 10(b) of the Securities Exchange Act of 1934, or the 1934 Act, and SEC Rule 10b-5 promulgated thereunder, which is asserted against all defendants, and a claim founded upon Section 20(a) of the 1934 Act, which is asserted against the individual defendants. Both claims are based on the allegations that, during the class period, NPS and the individual defendants made false and misleading statements to the investing public concerning PREOS. The consolidated complaint alleges that false and misleading statements were made during the class period concerning the efficacy of PREOS as a treatment for postmenopausal osteoporosis, the potential market for PREOS, the risk of hypercalcemic toxicity as a side effect of injectable PREOS, and the prospects of FDA approval of the Company's NDA for injectable PREOS. The complaint also alleges claims of option backdating and insider trading of NPS stock during the class period. The consolidated complaint seeks compensatory damages in an unspecified amount, unspecified equitable or injunctive relief, and an award of an unspecified amount for plaintiff's costs and attorneys fees.

On March 19, 2007, the defendants filed a motion to dismiss the consolidated complaint, which the court denied on July 3, 2007. On August 1, 2007, the court entered a scheduling order setting a trial date for the action on April 20, 2009. On November 1, 2007, lead plaintiff filed its motion to certify the class of shareholders that it seeks to represent in the action. On January 30, 2008, defendants filed an opposition to this motion. On February 29, 2008, lead plaintiff filed its reply brief in support of the motion for class certification. On March 20, 2008, the court entered a stipulation by the parties staying the action pending mediation commencing on June 3, 2008.

Following mediation, the parties reached an agreement to settle this matter and entered into a Memorandum of Understanding (MOU) with respect to the same. The MOU memorializes the terms pursuant to which the plaintiffs and the defendants intend to settle the case, subject to court approval. Under the terms of the MOU, the defendants' directors' and officers' liability insurers will pay \$15.0 million in resolution of the matter and all claims asserted against the Company, and the other named defendants will be dismissed with prejudice with no admission or finding of wrongdoing on the part of any defendant. The Company has recorded \$15.0 million as Litigation receivable and Litigation payable on its balance sheet as of December 31, 2008. Subsequently, on February 24, 2009, the parties executed a Stipulation of Settlement finalizing the terms of the settlement, subject to final court approvals following notices to shareholders and members of the settlement class. On March 12, 2009, the court issued a Preliminary Order approving the Stipulation of Settlement.



## **Derivative Actions.**

On August 22, 2006, an NPS shareholder filed a shareholder derivative action against certain of the Company's present and former officers and directors. This action, which names NPS as a nominal defendant, but is asserted on NPS's behalf, is pending in the Third Judicial District Court of Salt Lake County, State of Utah, as *Deane v. Tombros, et al.*, Case No. 060913838. The complaint asserts allegations similar to those asserted in the securities class action described above and also alleges that the defendant directors and officers violated their fiduciary duties by making the allegedly false and misleading statements to the investing public concerning PREOS. The derivative complaint seeks compensatory damages in an unspecified amount, unspecified equitable or injunctive relief and an award of an unspecified amount for plaintiff's costs and attorneys fees.

Defendants filed a motion to dismiss the lawsuit, which the court granted by order dated July 8, 2007, without prejudice with leave to file an Amended Complaint. In the order, the court also granted plaintiff leave to propound a books and records inspection demand under Utah law and to amend the shareholder derivative complaint. Plaintiff served a books and records inspection demand, in response to which NPS produced the requested documents. On December 14, 2007, defendants filed a motion to stay the lawsuit pending resolution of the securities class action and similar shareholder derivative lawsuits filed in U.S. District Court for the District of Utah, which are described below. Plaintiff has opposed defendants' motion to stay, which is currently pending before the court. If the court does not grant defendants' motion to stay, plaintiff will be permitted to file an amended shareholder derivative complaint.

Three shareholder derivative actions titled *Wagner v. Tombros, et al.*, *Alvarez v. Jackson, et al.*, and *Sutton v. Tombros*, et al., were filed in the U.S. District Court for the District of Utah on July 24, 2007, August 17, 2007, and November 14, 2007, respectively and are pending there. These lawsuits, as amended by the consolidated action described below, allege the defendants made false and misleading statements concerning PREOS, and that because of these statements, the defendants breached their fiduciary duties. The lawsuits seek compensatory damages in an unspecified amount, unspecified equitable or injunctive relief and an award of an unspecified amount for plaintiff's costs and attorneys fees.

On March 13, 2008, the parties in the *Wagner, Alvarez, and Sutton* suits filed a Stipulation and Proposed Order to Consolidate Related Actions, Appoint Lead Counsel and Liaison Counsel and Set a Schedule. The Order was entered by the court on May 9, 2008. On June 30, 2008, the plaintiffs filed a consolidated shareholder derivative complaint in this action, titled *In re NPS Pharmaceuticals, Inc. Derivative Litigation*, No. 2:07-cv-0611-DAK. On August 14, 2008, Defendants filed two motions to dismiss: one motion to dismiss on behalf of all defendants for failure to plead demand futility, and a second motion to dismiss on behalf of the individual defendants for failure to state a claim. On the same date, defendants also filed a motion in the alternative to stay the derivative suit in favor of *In re NPS Pharmaceuticals, Inc. Securities Litigation*, which is pending before the same court. On March 20, 2008, the court entered a stipulation by the parties staying the action pending mediation of all of the derivative cases commencing on June 3, 2008. On October 1, 2008, pursuant to a stipulation by the parties, the court ordered that plaintiffs' obligation to respond to the pending motions was extended until November 1, 2008.

Following mediation, the parties reached an agreement in principle to settle both the state and federal derivative actions. The parties subsequently executed a Memorandum of Understanding, pursuant to which the defendants' directors' and officers' liability insurers will pay \$1.0 million toward plaintiffs' legal fees in resolution of the matter and all claims asserted against the defendants, will be dismissed with prejudice with no admission or finding of wrongdoing on the part of any defendant. As a term of the settlement, the Company will also implement certain corporate governance measures. The Company has recorded \$1.0 million as Litigation receivable and Litigation payable on its balance sheet as of December 31, 2008. On March 16, 2009, the parties entered into a Stipulation of Settlement finalizing the terms of the settlement, subject to shareholder notice and court approval.

## **Sensipar® (Cinacalcet HCl) Patent Infringement Litigation.**

On June 16, 2008, the Company reported the receipt of Paragraph IV Certification Notice Letters ("Notice Letters") related to Abbreviated New Drug Applications (ANDA) submitted to the U.S. Food and Drug Administration (FDA) by Barr Laboratories Inc. ("Barr") and Teva Pharmaceutical USA, Inc. ("Teva") requesting approval to market and sell generic versions of Sensipar (Cinacalcet HCl). The Notice Letters alleged that the U.S. Patent Numbers 6,011,068 ("the '068 patent"), 6,031,003 ("the '003 patent"), 6,313,146 ("the '146 patent"), and 6,211,244 ("the '244 patent") covering Sensipar are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product described in the ANDAs.

Under the Company's licensing agreement with Amgen, Amgen is responsible for all development and commercial activities involving Sensipar, as well as enforcing applicable patent rights, in the licensed territories. The '068 patent, the '003 patent and the '146 patent are co-owned by the Company and The Brigham and Women's Hospital, which licensed its rights to the Company. The Company has licensed rights to these patents and the '244 patent to Amgen. On July 25, 2008, The Brigham and Women's Hospital, Amgen and the Company filed a patent infringement action in United States District Court, District of Delaware, No. 1:08cv00464 HB, against Barr and Teva relating to each of the patents referenced above. On August 18, 2008, Barr and Teva filed answers, defenses, and counterclaims alleging that the '068, '003, '146, and '244 are invalid and/or not infringed. On September 8, 2008, the Company, The Brigham and Women's Hospital and Amgen filed answers to Barr's and Teva's counterclaims. The parties are currently engaged in active discovery and the case will be placed in the trial pool in May 2010. By statute, since plaintiffs initiated a patent infringement lawsuit against Barr and Teva within 45 days of receipt of the Notice Letters, the FDA is automatically precluded from approving the ANDAs until the earlier of September 8, 2011 or a district court decision finding the patents invalid, unenforceable or not infringed. The Company is confident of the validity and enforceability of these patents and in conjunction with The Brigham and Women's Hospital and Amgen will vigorously prosecute these actions to protect these patents from infringement.

**(20) Supplemental Cash Flow Information and Non-cash Investing and Financing Activities:**

(in thousands)

	<b>Year Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
<i>Cash Paid for:</i>			
Interest	\$ 24,349	\$ 31,442	\$ 18,530
Income taxes	900	-	-
<i>Noncash Investing and Financing Activities:</i>			
Unrealized gains (losses) on marketable investment securities	\$ 2,865	\$ (2,069)	\$ 562
Accrued acquisition of equipment, leasehold improvements and construction-in-progress	67	-	-
Debt issued in lieu of interest	17,450	6,246	-
Royalties transferred in lieu of interest	7,453	1,675	-

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

The following is a summary of the quarterly results of operations for the years ended December 31, 2008 and 2007 (in thousands, except for per share amounts):

	Quarters Ended			
	March 31	June 30	September 30	December 31
<b>(in thousands, except per share amounts)</b>				
<b>2008</b>				
Revenues	\$ 25,180	\$ 26,959	\$ 26,075	\$ 24,065
Operating income	5,088	16,334	14,545	12,396
Net income (loss)	(13,093)	1,203	(11,359)	(8,477)
Basic income (loss) per common share	\$ (0.28)	\$ 0.03	\$ (0.24)	\$ (0.18)
Diluted income (loss) per common and potential common share	\$ (0.28)	\$ 0.03	\$ (0.24)	\$ (0.18)
<b>2007</b>				
Revenues	\$ 9,991	\$ 13,115	\$ 29,161	\$ 33,981
Operating income (loss)	(15,937)	(9,200)	21,412	36,690
Net income (loss)	(21,144)	(14,807)	14,089	17,580
Basic income (loss) per common share	\$ (0.45)	\$ (0.32)	\$ 0.30	\$ 0.37
Diluted income (loss) per common and potential common share	\$ (0.45)	\$ (0.32)	\$ 0.28	\$ 0.32

### 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, 2008. We previously reported that we had material weaknesses because the Company did not have a sufficient number of accounting and finance personnel with an appropriate level of knowledge and experience of U.S. generally accepted accounting principles (GAAP) commensurate with our financial reporting requirements. As part of our evaluation described below, management has determined that we have successfully remediated these material weaknesses.

#### 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, 2008. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*. Based on our assessment we believe that, as of December 31, 2008, 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, 2008. This report appears on page 57 of this report.

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

During the most recent fiscal quarter, we completed changes in our internal control over financial reporting that included an extensive review of our internal control processes, procedures and documentation and training for accounting personnel to ensure appropriate knowledge of GAAP and SEC reporting. There have been no other changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

***Remediation of Material Weaknesses in Internal Control over Financial Reporting***

During the year ended December 31, 2008, we made the following modifications to our internal control over financial reporting, which remediated our previously reported material weaknesses, and provided overall improvements to our existing controls:

- We hired an assistant controller to increase the level of GAAP and SEC reporting knowledge and experience;
- Initiated and completed an extensive review of our internal control processes, procedures and documentation; and
- Increased training for accounting personnel to ensure appropriate knowledge of GAAP and SEC 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 2009 Annual Meeting of Stockholders, under the captions "Election of Directors," and "Compliance with Section 16(a) of the Exchange Act" and "Code of Ethics" and is incorporated into this section by reference. For information regarding executive officers see Part I of this Form 10-K under the caption "Executive Officers of the Registrant."

### **ITEM 11. Executive Compensation.**

Certain of the information required by this item will be contained in our definitive Proxy Statement with respect to our 2009 Annual Meeting of Stockholders, under the captions “Executive Compensation” and except for the information appearing under the captions “Report of the Compensation Committee of the Board of Directors” is incorporated into this section by reference.

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

Certain of the information required by this item will be contained in our definitive Proxy Statement with respect to our 2009 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 section by reference.

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

Certain of the information required by this item will be contained in our definitive Proxy Statement with respect to our 2009 Annual Meeting of Stockholders under the captions “Certain Relationships and Related Transactions” and is incorporated into this section by reference.

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

Certain of the information required by this item will be contained in our definitive Proxy Statement with respect to our 2009 Annual Meeting of Stockholders, under the captions “Principal Accountant Fees and Services” and is incorporated into this section by reference.

## **PART IV**

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

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

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

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

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

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1A	Amended and Restated Certificate of Incorporation of the Registrant (1)
3.1B	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated December 16, 1999 (2)
3.1C	Certificate of Designation of Series A Junior Participating Preferred Stock of the Registrant, dated December 18, 1996 (3)
3.1D	Amendment to Certificate of Designation of Series A Junior Participating Preferred Stock of the Registrant, dated September 5, 2000 (2)
3.1E	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated September 30, 2003 (14)
3.2A	Amended and Restated Bylaws of the Registrant (32)
3.2B	Certificate of Adoption of Amendments to the Amended and Restated Bylaws of the Registrant, dated February 19, 2003 (11)
4.1	Specimen Common Stock Certificate (1)

- 4.2A Rights Agreement, dated as of December 4, 1996, between the Registrant and American Stock Transfer & Trust, Inc., with Exhibit A, Form of Certificate of Designation of Series A Junior Participating Preferred Stock of the Registrant; Exhibit B, Form of Right Certificate; and Exhibit C, Summary of Rights to Purchase Shares of Preferred Stock of the Registrant (5)
- 4.2B First Amendment to the Rights Agreement and Certificate of Compliance with Section 27 thereof, dated December 31, 2001 (4)
- 4.2C Second Amendment to the Rights Agreement and Certificate of Compliance with Section 27 thereof, dated February 19, 2003 (5)
- 4.3 Indenture, dated as of June 17, 2003, between Registrant and U.S. Bank National Association, as Trustee, including the form of 3% Convertible Subordinated Notes due 2008 attached as Exhibit A thereto. (13)
- 4.4A Composite Indenture, dated as of December 22, 2004, by and between Cinacalcet Royalty Sub LLC, a wholly-owned subsidiary of Registrant, and U.S. National Bank Association, incorporating the amendments provided for in the Supplemental Indenture dated as of February 2, 2005, between the same parties (the "Indenture") (16)
- 4.4B Second Supplemental Indenture dated October 20, 2006 to the Indenture(23)
- 4.4C Third Supplemental Indenture dated July 9, 2007 to the Indenture(23)
- 4.4D Fourth Supplemental Indenture dated August 1, 2007 to the Indenture(23)
- 4.4E Fifth Supplemental Indenture dated August 7, 2007 to the Indenture(23)
- 10.1A 1998 Stock Option Plan (28)
- 10.1B 1998 Stock Option Plan, as amended December 2002 (11)
- 10.1C 1998 Stock Option Plan, as amended June 2003 (14)
- 10.1D 1998 Stock Option Plan (reflects all amendments by the Board of Directors through December 2008)(31)
- 10.1E† Form of Performance-Based Stock Option Agreement under the NPS Pharmaceutical, Inc. 1998 Stock Option Plan.
- 10.2 Form of Indemnity Agreement entered into between the Registrant and each of its officers and directors (1)
- 10.3A† Change in Control Severance Pay Plan, as amended
- 10.3B Form of Agreement Providing Specified Benefits Following Termination of Employment Incident to a Merger, Acquisition or Other Change of Control or to Some Other Strategic Corporate Event, between the Registrant and each of its executive officers (14)
- 10.4A Collaborative Research and License Agreement between the Registrant and SmithKline Beecham Corporation (now GlaxoSmithKline), dated November 1, 1993 (1)
- 10.4B Amendment Agreement to Collaborative Research and License Agreement between GlaxoSmithKline, effective June 29, 1995 (8)
- 10.4C Amendment Agreement between the Registrant and GlaxoSmithKline, dated October 28, 1996 (3)
- 10.4D Amendment Agreement between the Registrant and GlaxoSmithKline, dated October 27, 1997 (9)
- 10.4E Amendment Agreement between the Registrant and GlaxoSmithKline, dated September 26, 1997 (9)
- 10.4F Amendment to Collaborative Research and License Agreement between the Registrant and GlaxoSmithKline, dated November 26, 1997 (9)
- 10.4G Letter, dated January 24, 2000, from SmithKline Beecham to NPS Re: Amendment Agreement to Amend the November 26, 1997 Amendment Agreement to Amend the November 26, 1997 Amendment Agreement (11)

- 10.4H Letter, dated May 15, 2000, from SmithKline Beecham to NPS Re: Amendment Agreement (11)
- 10.4I Letter, dated August 1, 2001, from GlaxoSmithKline to NPS Re: Amendment Agreement to Amend the January 24, 2000 Amendment Agreement (11)
- 10.4J Amendment Agreement dated December 14, 2006 between the Registrant and SmithKline Beecham Corporation, dba GlaxoSmithKline(24)
- 10.5A Patent Agreement between the Registrant and The Brigham and Women's Hospital, Inc., dated February 19, 1993 (1)
- 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. (11)
- 10.5C Amendment to Patent Agreement between the Registrant and The Brigham and Women's Hospital, Inc., effective February 7, 1996 (10)
- 10.5D 1999 Patent Agreement Amendment between the Registrant and The Brigham and Women's Hospital, Inc., effective February 18, 1999 (11)
- 10.6 Collaborative Research and License Agreement between the Registrant and Kirin Brewery Company, Ltd. dated June 29, 1995 (10)
- 10.7 Development and License Agreement between the Registrant and Amgen Inc. effective as of December 27, 1995 (8)
- 10.8 Manufacturing Agreement between NPS Allelix Corp. and SynCo Bio Partners B.V., effective as of May 17, 2001 (12)
- 10.9 Addendum to Manufacturing Agreement between NPS Allelix Corp. and SynCo Bio Partners B.V., effective as of October 26, 2001 (12)
- 10.10 Lease Agreement between Registrant and University of Utah, effective December 10, 2003 (14)
- 10.11 Lease Agreement between MaRS Discovery District and Registrant, dated April 12, 2004 (15)
- 10.12A\* Distribution and License Agreement between Registrant and Nycomed Danmark ApS, dated April 26, 2004 (15)
- 10.12B\* First Amendment to Distribution and License Agreement between the Registrant and Nycomed Danmark ApS, dated July 1, 2004 (15)
- 10.12C\* License Agreement, dated July 2, 2007, between NPS Allelix Corp. and Nycomed Danmark ApS(27)
- 10.13 Compensation Agreement (17)
- 10.14A 2005 Omnibus Incentive Plan (18)(29)
- 10.14B Form of Stock Option Grant Agreement under the 2005 Omnibus Incentive Plan (20)
- 10.15A Non-Employee Director Deferred Compensation Program (19)
- 10.15B Form of Deferred Stock Unit Award Agreement (19)
- 10.16 Employment Agreement with N. Anthony Coles, M.D. (21)
- 10.17A Agreement of Purchase and sale between Registrant and Biomed Realty, L.P. dated December 20, 2005 (21)
- 10.17B Lease Agreement between Registrant and BMR-383 Colorow Drive, LLC dated December 22, 2005 (21)
- 10.17C Agreement of Purchase and Sale, dated May 9, 2007, between NPS Pharmaceuticals, Inc. and BMR-383 Colorow Drive LLC (25)
- 10.18 Separation Agreement dated July 31, 2007 by and between NPS Pharmaceuticals, Inc. and Gregory M. Torre (29)

- 10.19 Agreement of Purchase and Sale, dated May 9, 2007, between NPS Allelix Corp. and Transglobe Property Management Services Ltd. in Trust(25)
- 10.20 Sublease Agreement, dated June 19, 2007, between NPS Pharmaceuticals, Inc. and Celanese Americas Corporation(26)
- 10.21 Purchase and Sale Agreement, dated June 29, 2007, by and between NPS Pharmaceuticals, Inc. and the University of Utah.(26)
- 10.22A Securities Purchase Agreement dated as of August 7, 2007 among NPS Pharmaceuticals, Inc. (the “Issuer”) and Visium Balanced Fund, LP, Visium Balanced Offshore Fund, Ltd., Visium Long Bias Fund, LP, Visium Long Bias Offshore Fund, Ltd. and Atlas Master Fund (collectively, the “Investors”)(23)
- 10.22B Form of Note issued pursuant to the Securities Purchase Agreement referred to in Exhibit 10.25A above(23)
- 10.22C Registration Rights Agreement dated as of August 7, 2007 among the Issuer and the Investors(23)
- 10.23\* Agreement for Sale and Assignment of Rights, dated July 16, 2007, among NPS Pharmaceuticals, Inc., NPS Allelix Corp. and DRI(27)
- 10.24\* Distribution and License Agreement, dated September 24, 2007, among NPS Pharmaceuticals, Inc., NPS Allelix Corp. and Nycomed GmbH(27)
- 10.25\* Amendment Agreement to the Distribution and License Agreement, dated September 24, 2007, among NPS Pharmaceuticals, Inc., NPS Allelix Corp. and Nycomed GMBH(27)
- 10.26\* License Agreement, dated September 28, 1995, between 1149336 Ontario Inc., Daniel J. Drucker, and Allelix Biopharmaceuticals Inc.(27)
- 10.27 Asset Purchase Agreement, dated October 9, 2007, between Astrazeneca AB and NPS Pharmaceuticals, Inc. (29)
- 10.28 Separation Agreement dated December 7, 2007 by and between NPS Pharmaceuticals, Inc. and Val R. Antczak (29)
- 10.29 Separation Agreement dated November 19, 2007 by and between NPS Pharmaceuticals, Inc. and Gerard J. Michel(29)
- 10.30A\* Commercial Manufacturing Agreement, dated October 18, 2002, by and between NPS Allelix Corp. and Boehringer Ingelheim Austria GmbH(29)
- 10.30B\* Amending Agreement, dated March 15, 2004, by and between NPS Allelix Corp. and Boehringer Ingelheim Austria GmbH(29)
- 10.30C\* Amendment Number One to Amending Agreement, dated December 22, 2005, by and between NPS Allelix Corp. and Boehringer Ingelheim Austria GmbH(29)
- 10.31 Employment Agreement with Francois Nader(30)
- 10.32 First Amendment to Restrictive Covenant Agreement with Francois Nader(30)
- 10.33† First Amendment to the Employment Agreement with Francois Nader
- 10.34† Second Amendment to the Employment Agreement with Francois Nader
- 10.35† Employment Agreement with Roger Garceau
- 12.1† Computation Ratio of Earnings Available to Cover Fixed Charges
- 21.1 List of Subsidiaries (29)
- 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



† 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.

- (1) Incorporated herein by reference to the Registrant's Registration Statement on Form S-1 filed on January 21, 1994 (SEC File No. 333-74318).
- (2) Incorporated herein by reference to the Registrant's Registration Statement on Form S-3 filed on September 6, 2000 (SEC File No. 333-45274, Film No. 717603).
- (3) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated December 19, 1996 (SEC File No. 000-23272, Film No. 96683282).
- (4) Incorporated herein by reference to the Registrant's Registration Statement on Form 8-A12G/A (SEC File No. 000-23272, Film No. 1826478, filing date December 31, 2001).
- (5) Incorporated herein by reference to the Registrant's Registration Statement on Form 8-A/A (SEC File No. 000-23272, Film No. 03575669, filing date February 21, 2003).
- (6) Incorporated herein by reference to the Registrant's Registration Statement on Form S-8 (SEC File No. 333-17521, Film No. 96677983, filing date December 9, 1996).
- (7) Incorporated herein by reference to the Registrant's Definitive Proxy Statement (SEC File No. 000-23272, Film No. 98590984, filing date April 9, 1998).
- (8) 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, filed on March 29, 1996.
- (9) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated January 27, 1998 (SEC File No. 000-23272, Film No. 98513828).
- (10) Incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.
- (11) 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, Film No. 03612691, filing date March 21, 2003).
- (12) Incorporated herein by reference to the Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2002 (SEC File No. 000-23272, Film No. 03739737, filing date June 11, 2003).
- (13) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2003 (SEC File No. 000-23272, Film No. 03838243, filing date August 12, 2003).
- (14) 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, Film No. 04582125, filing date February 10, 2004).
- (15) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2004 (SEC File No. 000-23272, Film No. 04962020, filing date August 9, 2004).
- (16) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated February 2, 2005 (SEC File No. 000-23272, Film No. 05578512, filing date February 7, 2005).
- (17) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated February 9, 2005 (SEC File No. 000-23272, Film No. 05587185, filing date February 9, 2005).
- (18) Incorporated herein by reference to the Registrant's Definitive Proxy Statement (SEC File No. 000-23272, Film No. 05744588, filing date April 11, 2005).
- (19) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated July 1, 2005 (SEC File No. 000-23272, Film No. 05933233, filing date July 1, 2005).
- (20) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2005 (SEC File No. 000-23272, Film No. 05974685, filing date July 26, 2005).
- (21) Incorporated herein by reference to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2005 (SEC File No. 000-23272, Film No. 06663187, filing date March 3, 2006).
- (22) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2006 (SEC File No. 000-23272, Film No. 061002758, filing date August 3, 2006).
- (23) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated August 31, 2007 (SEC File No. 000-23272, Film No. 071094546, filing date August 31, 2007).
- (24) 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, Film No. 07693379, filing date March 14, 2007).
- (25) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2007 (SEC File No. 000-23272, Film No. 07833270, filing date May 9, 2007).
- (26) Incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2007 (SEC File No. 000-23272, Film No. 071032512, filing date August 7, 2007).

- (27) 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, Film No. 071231813, filing date August 7, 2007).
- (28) Incorporated herein by reference to the Registrant's Definitive Proxy Statement (SEC File No. 000-23272, Film No. 98590984, filing date April 9, 1998).
- (29) 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, Film No. 08691123, filing date March 17, 2008).
- (30) 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, Film No. 08845693, filing date May 19, 2008).
- (31) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated May 22, 2008 (SEC File No. 000-23272, Film No. 08864183, filing date May 28, 2008).
- (32) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated August 14, 2008 (SEC File No. 000-23272, Film No. 081030212, filing date August 20, 2008).

