

XENOPORT INC (XNPT)

10-K

Annual report pursuant to section 13 and 15(d)

Filed on 02/29/2012

Filed Period 12/31/2011

THOMSON REUTERS ACCELUS™



THOMSON REUTERS

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, 2011

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 000-51329

XenoPort, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)
3410 Central Expressway,
Santa Clara, California
(Address of principal executive offices)

94-3330837
(IRS employer identification no.)
95051
(Zip code)

(408) 616-7200

(Registrant's telephone number, including area code)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common stock, par value \$0.001 per share	The NASDAQ Stock Market LLC

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 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 the past 90 days. Yes No

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

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

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

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

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

As of June 30, 2011 (the last business day of the registrant's most recently completed second quarter), the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$244.0 million based on the closing sale price as reported on The NASDAQ Global Select Market for such date, which excludes an aggregate of 1,169,888 shares of the registrant's common stock held by officers, directors and stockholders that the registrant has concluded are affiliates of the registrant. Exclusion of such shares should not be construed to indicate that the holder of any such shares possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by, or under common control with, the registrant.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class	Outstanding at February 1, 2012
Common stock, par value \$0.001 per share	35,627,913 shares

DOCUMENTS INCORPORATED BY REFERENCE

Document	Parts Into Which Incorporated
Portions of the Definitive Proxy Statement for the Annual Meeting of Stockholders to be held on or about May 16, 2012 to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference.	Part III, Items 10-14

[Table of Contents](#)

XENOPORT, INC.
TABLE OF CONTENTS

	<u>Page</u>
PART I.	
Item 1. Business Overview	3
Transported Prodrugs	3
Marketed Product	5
Our Product Candidates	6
Our Strategic Alliances	7
Patents and Proprietary Rights	15
Manufacturing	17
Research and Development	18
Potential Marketing and Sales of Our Product Candidates	20
Competition	20
Government Regulation	22
Pharmaceutical Pricing and Reimbursement	25
Facilities	26
Employees	26
Executive Officers of the Registrant	26
About XenoPort	28
Available Information	28
Item 1A. Risk Factors	28
Item 1B. Unresolved Staff Comments	58
Item 2. Properties	58
Item 3. Legal Proceedings	58
Item 4. Mine Safety Disclosures	59
PART II.	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	60
Item 6. Selected Financial Data	62
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	63
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	75
Item 8. Financial Statements and Supplementary Data	75
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	75
Item 9A. Controls and Procedures	75
Item 9B. Other Information	78
PART III.	
Item 10. Directors, Executive Officers and Corporate Governance	78
Item 11. Executive Compensation	78
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	79
Item 13. Certain Relationships and Related Transactions, and Director Independence	81
Item 14. Principal Accountant Fees and Services	81
PART IV.	
Item 15. Exhibits, Financial Statement Schedules	81
Signatures	86
Exhibit Index	88

XENOPORT, the XenoPort logo and Transported Prodrug are trademarks of XenoPort, Inc.
Regnite is a registered trademark of Astellas Pharma Inc.
Horizant is a registered trademark of GlaxoSmithKline.

[Table of Contents](#)

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading "Risk Factors." Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PART I.

Item 1. Business.

Overview

We are a biopharmaceutical company focused on developing and commercializing a portfolio of internally discovered product candidates for the potential treatment of neurological disorders. Our innovative product candidates are prodrugs that are typically created by modifying the chemical structure of currently marketed drugs, referred to as parent drugs, and are designed to correct limitations in the oral absorption, distribution and/or metabolism of the parent drug. We intend to focus our development and commercialization efforts on potential treatments of diseases with significant unmet medical needs, with an emphasis on central nervous system disorders. Our marketed product and each of our product candidates is an orally available, patented or patentable new chemical entity that addresses potential markets with clear unmet medical needs.

In April 2011, the U.S. Food and Drug Administration, or FDA, approved our first product, known in the United States as *Horizant* (gabapentin enacarbil) Extended-Release Tablets, for the treatment of moderate-to-severe primary restless legs syndrome, or RLS, in adults. Restless legs syndrome is a neurological disorder characterized by an urge to move the legs, usually caused or accompanied by uncomfortable and unpleasant sensations in the legs.

Glaxo Group Limited, or GSK, holds commercialization rights and certain development rights for *Horizant* in the United States. In July 2011, GSK began promoting *Horizant* for the treatment of RLS in the United States. GSK is responsible for the U.S. development of *Horizant* for RLS and postherpetic neuralgia, or PHN, a chronic type of neuropathic pain that can follow the resolution of shingles. In August 2011, GSK filed a supplemental new drug application, or sNDA, with the FDA under Section 505(b)(2) for *Horizant* for the potential management of PHN. In October 2011, the FDA accepted the sNDA for review and set a Prescription Drug User Fee Act, or PDUFA, date of June 9, 2012 as a goal for the completion of their review of the sNDA. Because June 9, 2012 is a Saturday, the effective action date is expected to be Friday, June 8, 2012.

In January 2012, we provided a notice of dispute and notice of breach and termination, or the Notice, to GSK that provided notice of our belief that, among other matters, GSK has materially breached its contractual obligation to use commercially reasonable efforts to (i) maximize the sales of *Horizant* in an expeditious manner and (ii) achieve the sales milestones set forth in our collaboration agreement. The Notice provides that the termination of the collaboration agreement would become effective at the end of the 90-day notice period.

[Table of Contents](#)

provided under the agreement, which will expire on April 24, 2012, unless GSK has cured any such breach or default prior to such date.

On February 23, 2012, GSK filed a complaint, or the GSK Complaint, in the United States District Court for the District of Delaware naming us and other unspecified individuals as defendants. Pursuant to the GSK Complaint, GSK is seeking declaratory judgment that it is not in breach of the collaboration agreement and that we do not have the right to terminate the collaboration agreement as a result of GSK's performance under the agreement to date. Following the expiration of the contractually specified period of time for resolution of the dispute by the requisite officers of the parties, on February 24, 2012, we filed a complaint, or the XenoPort Complaint, in the Superior Court of the State of California in the County of Santa Clara against GSK and its affiliates, GlaxoSmithKline LLC and GlaxoSmithKline Holdings (Americas) Inc., for breach of contract, fraud, breach of fiduciary duty, breach of the covenant of good faith and fair dealing and unfair competition. Pursuant to the XenoPort Complaint, in addition to injunctive and equitable relief, we are seeking damages for lost profits, damage to the value of *Horizant* and unattained royalties and milestone payments in an amount to be proven at trial, as well as punitive damages and restitution. We believe that we have meritorious defenses and intend to defend the GSK Complaint, and prosecute the XenoPort Complaint, vigorously. We cannot predict the outcome of the litigation related to the GSK Complaint and the XenoPort Complaint or when or if the collaboration agreement will be terminated or the ultimate terms of any termination of the agreement. In addition, we may incur substantial legal fees and costs in connection with this litigation, and may not prevail in either of these legal proceedings.

Gabapentin enacarbil is licensed to Astellas Pharma Inc. in Japan and five other Asian countries. In January 2012, the Japanese Ministry of Health, Labor and Welfare approved Astellas' NDA for the use of gabapentin enacarbil, which will be known as *Regnite* in Japan, as a treatment for patients with RLS.

We are evaluating our second product candidate, arbaclofen placarbil, or AP, as a potential treatment for patients with spasticity. We are conducting a pivotal Phase 3 clinical trial under a Special Protocol Assessment, or SPA, with the FDA, for AP as a potential treatment for spasticity in patients with multiple sclerosis, or MS. Provided a positive outcome from this trial is achieved, along with supportive data from certain additional planned studies, we intend to file an NDA under Section 505(b)(2). Section 505(b)(2) allows reference to published literature and the FDA's previous finding of safety and effectiveness for baclofen, a drug that has been approved by the FDA for the alleviation of signs and symptoms of spasticity in individuals with MS and may also be of some value in patients with spinal cord injuries and other spinal cord diseases. We anticipate reporting top-line results from this trial near the end of 2012.

We also evaluated AP for the potential adjunctive treatment of gastroesophageal reflux disease, or GERD. Following the results in March 2011 of a Phase 2 clinical trial of AP as adjunctive therapy in patients with GERD who do not experience complete relief of GERD symptoms while being treated with proton pump inhibitors, we determined that the efficacy results of this trial, which did not meet the primary endpoint, did not warrant our investment in further development for AP in GERD at the present time.

We have evaluated our third product candidate, XP21279, for the potential treatment of patients with Parkinson's disease who experience motor fluctuations. In December 2011, we reported preliminary top-line results of a Phase 2 clinical trial of patient-optimized doses of our new bi-layer tablet of XP21279/carbidopa compared to patient-optimized doses of Sinemet (levodopa/carbidopa). Results of the study indicated that XP21279/carbidopa dosed three times per day reduced mean daily "off time" by 46% compared to baseline when the patients were taking their pre-trial Sinemet dosing regimen. However, in the primary analysis of the trial, the improvement with XP21279/carbidopa was not statistically better than the improvement seen with optimized Sinemet dosed four or five times per day during the double-blind phase of the trial. At this time, we plan to defer further investment in this program pending the outcome of additional data analysis and discussions with Parkinson's disease experts and possibly with regulatory authorities.

In August 2011, we announced plans to accelerate the development of our preclinical product candidate, XP23829, as a potential treatment for relapsing-remitting MS, or RRMS, with a goal of filing an investigational new drug application, or IND, in the second quarter of 2012. XP23829 is a new chemical entity that is a prodrug of monomethyl fumarate, or MMF, a molecule that appears to have anti-inflammatory properties and the potential to modulate cellular responses to oxidative stress.

[Table of Contents](#)

In addition to our development and commercialization agreements with GSK for *Horizant* and with Astellas for *Regnite*, we plan to enter into other agreements with pharmaceutical companies for our product candidates: (1) when access to a primary care physician sales force is necessary to maximize the commercial potential of our product candidates in the United States; (2) for the development and commercialization of our product candidates outside the United States; or (3) to develop and commercialize product candidates that fall outside our core focus.

Transported Prodrugs

With our Transported Prodrug technology, we have designed innovative new chemical entities that form the foundation of our marketed product and product pipeline. The conventional approach to designing new oral drugs is to rely on the drug's ability to passively diffuse through the intestinal wall to enter the bloodstream and reach the targeted tissue. However, this can be a difficult task, because the chemical and physical properties that allow a drug to bind to its cellular target and cause the intended therapeutic effect frequently impair the drug's ability to passively diffuse through the wall of the intestines. Critical to the success of any drug is its ability to access the targeted tissues, achieve and maintain effective concentrations at the site of therapeutic action for an appropriate period of time and have minimal side effects. In addition, convenient administration is frequently necessary to ensure patient compliance. Many marketed drugs do not possess all of these attributes, leading to limitations in their therapeutic benefit and commercial potential.

If the medical need is high, drugs with poor absorption from the gastrointestinal, or GI, tract are still developed and marketed, but often with suboptimal therapeutic benefit. In some cases, drugs that are poorly absorbed from the GI tract are marketed as injectable medicines, which are inconvenient for patients. Another problem frequently encountered by drug designers occurs when a drug is well-absorbed from the intestines but does not last in the bloodstream for a sufficient period of time to maintain a therapeutic benefit. In this situation, frequent oral dosing is required, which is inconvenient for patients and can lead to poor compliance. In addition, drugs requiring frequent dosing often exhibit unwanted side effects when the drug is present in high concentration and then ineffectiveness when the concentration of the drug is insufficient. Sustained-release formulations that deliver medicine slowly as a pill travels through the entire GI tract can sometimes improve the utility of drugs that exhibit suboptimal therapeutic properties. However, drugs absorbed only in the upper GI tract do not benefit from sustained-release formulations.

Because most nutrients contain chemical features that prevent effective passive diffusion through cellular barriers, the human body contains specific membrane proteins, known as transporters, which are responsible for carrying nutrients into cells and across cell barriers. There are hundreds of different transporters in the human body that vary in the types of molecules they recognize and their localization to certain cells and tissue barriers. Active transport refers to cellular transporter mechanisms that capture nutrients and carry them across membranes.

Our proprietary technology utilizes the body's natural mechanisms for actively transporting nutrients through cellular barriers to permit certain parent drugs with suboptimal oral absorption to be effectively and efficiently delivered into the body after the oral administration of our marketed product or product candidate.

We have identified specific, high-capacity nutrient transporter proteins in the intestines and chemically modified the structure of the parent drug to create a Transported Prodrug that utilizes these transporters to gain efficient absorption into the bloodstream through active transport. Our Transported Prodrugs are engineered to split apart, releasing the parent drug and natural substances that generally have well-studied, favorable safety characteristics. Our marketed product and, in some cases, our product candidates target transporter proteins that are present throughout the entire GI tract, including the colon, so they can be formulated using sustained-release technology and thereby maintain effective blood concentrations for an extended period after dosing. As a result of their improved oral absorption, they may have improved therapeutic benefits compared to the parent drugs, such as superior clinical efficacy, reduced side effects and less frequent dosing, which result in improved patient convenience and compliance.

[Table of Contents](#)

Marketed Product

Gabapentin Enacarbil (Known as Horizant in the United States and Regnite in Japan) — A Transported Prodrug of Gabapentin

Gabapentin enacarbil is our first approved product. It was approved in the United States in April 2011 for the treatment of RLS and is being marketed by GSK under the trade name *Horizant*. It was also approved in Japan in January 2012 for the treatment of RLS. Astellas plans to market gabapentin enacarbil in Japan under the trade name *Regnite*.

Initial Indication

Restless Legs Syndrome

Background on Restless Legs Syndrome. Restless legs syndrome is a neurological condition that causes an irresistible urge to move the legs. This urge is usually caused or accompanied by unpleasant sensations of burning, creeping, tugging or tingling inside the patients' legs, ranging in severity from uncomfortable to painful. These restless legs syndrome-related symptoms typically begin or worsen during periods of rest or inactivity, particularly when lying down or sitting, and may be temporarily relieved by movement such as walking or massaging the legs. Symptoms often worsen at night, and disturbed sleep is a common result of restless legs syndrome. Left untreated, restless legs syndrome may cause exhaustion, daytime fatigue, inability to concentrate and impaired memory.

Potential Markets. Although the exact prevalence rate of RLS is uncertain, a study published in *Movement Disorders* in 2010 indicated that approximately 2% to 3% of people in the United States are afflicted with RLS. We estimate that there are approximately 5.8 million prescriptions written annually for drugs to treat RLS in the United States.

Although the exact prevalence is uncertain, Astellas estimates that there are approximately 2.1 million patients in Japan with RLS.

Current Treatments. In the United States, the currently approved and most widely prescribed treatments for RLS belong to a class of drugs called dopamine agonists and include ropinirole (marketed as Requip by GSK), pramipexole (marketed as Mirapex by Boehringer Ingelheim GmbH) and generic comparables of these drugs. Physicians also prescribe opioids, benzodiazepines and anticonvulsants, such as gabapentin, to treat patients with restless legs syndrome. In Japan, pramipexole was approved in 2010 for the treatment of RLS.

Commercialization

Under our collaboration agreement with GSK, as currently in effect, GSK holds exclusive rights to commercialize *Horizant* in the United States. We exercised our right to a co-promotion arrangement in April 2009, under which all allowable expenses and sales of *Horizant* are accounted for using a joint profit and loss, or P&L, statement, in which we and GSK share in the resulting operating pre-tax profits and losses. Our participation in the co-promotion and joint P&L arrangements enables us to elect to deploy a sales force within three years following the approval of *Horizant* in the United States, and our share of losses from the joint P&L will be forgiven up to a maximum of \$10.0 million. Our payment of additional losses, if any, would be deferred and payable without interest over a four-year period of time following the first quarter in which the joint P&L is profitable. GSK is responsible for: establishing pricing and reimbursement; creating promotional and advertising materials; managed care contracting; receiving, accepting and filling orders; distributing; controlling invoicing, order processing and collecting accounts receivable; and recording sales of *Horizant* in the United States. Expenses that can be charged to the joint P&L statement are the cost of goods and certain costs directly related to *Horizant* marketing and sales.

We share any profits on sales of *Horizant* in the United States at tiered rates that escalate as a function of annual net sales levels, from a low of 20% to a maximum of 50%. For example (and for illustrative purposes only), if the annual net sales of *Horizant* reach \$250.0 million, \$500.0 million and \$1.0 billion, we would be entitled to blended profit share rates of 25%, 34% and 42%, respectively. We may terminate our co-promotion

[Table of Contents](#)

right and participation in the profit share arrangement at any time upon notice to GSK with no penalty to us, resulting in a royalty-based compensation structure, whereby we would receive royalties on annual net sales in the United States at tiered rates that escalate as a function of net sales levels from a low of 15% to a maximum of 30%.

Pursuant to the Notice that we have provided to GSK, our collaboration agreement would terminate at the end of the 90-day notice period provided for under the agreement, which will expire on April 24, 2012, unless GSK has cured the breach set forth in the Notice prior to such date. However, pursuant to the GSK Complaint, GSK is seeking declaratory judgment that it is not in breach of the collaboration agreement and that we do not have the right to terminate the collaboration agreement as a result of GSK's performance under the agreement to date. We cannot predict the timing or outcome of the legal proceedings related to the collaboration agreement, and accordingly, we cannot predict when or if the collaboration agreement will be terminated or the ultimate terms of any termination of the agreement.

Astellas holds exclusive rights to commercialize *Regnite* in Japan. We will receive mid-teen royalties on any net sales of *Regnite*.

Intellectual Property

The patent rights relating to *Horizant* and its synthesis, formulations and methods of use are owned by us and consist of issued U.S. patents that expire at the earliest in 2022 and a number of pending U.S. patent applications. GSK has petitioned for U.S. patent term extension, which could extend the patent term until 2025. The patent rights relating to *Regnite*, its synthesis, formulations and methods of use are owned by us and expire at the earliest in 2022. We also hold patents or pending patent applications in the United States and outside the United States that are directed to the formulations and methods of synthesis and use of gabapentin enacarbil.

Our Product Candidates

Clinical Development Programs

Product Candidate and Indication	U.S. Development Status(1)					Commercial Rights	Region
	Preclinical	Phase 1	Phase 2	Phase 3	NDA Filed		
Gabapentin Enacarbil (Previously known as XP13512)							
PHN						GSK	U.S.
Arbaclofen Placarbil, or AP (Previously known as XP19986)							
Spasticity						Unpartnered	Worldwide
XP21279							
Parkinson's Disease						Unpartnered	Worldwide
XP23829							
RRMS						Unpartnered	Worldwide

(1) Development Status indicates the most advanced stage of development that has been completed or is in process.

Gabapentin Enacarbil — A Transported Prodrug of Gabapentin

Our most advanced product candidate is gabapentin enacarbil, which is in development for the potential management of PHN. In August 2011, GSK filed an sNDA under Section 505(b)(2) for gabapentin enacarbil for the management of PHN. In October 2011, the FDA accepted the sNDA for review and set a PDUFA date of June 9, 2012 as a goal for the completion of its review of the sNDA. Because June 9, 2012 is a Saturday, the effective action date is expected to be Friday, June 8, 2012. Under the terms of our collaboration agreement with GSK, as currently in effect, GSK has development and commercialization rights to gabapentin enacarbil for the potential management of PHN, subject to our right to pursue development of gabapentin enacarbil for the management of PHN to the extent that a product label would reflect a superiority claim over a currently approved drug.

[Table of Contents](#)

Parent Drug Background

Gabapentin enacarbil is metabolized by the body to release gabapentin, a drug that has been sold by Pfizer Inc. as Neurontin since 1993 and is currently sold as a generic drug by a number of companies. Gabapentin is approved for marketing in the United States as adjunctive therapy in the treatment of partial seizures in patients with epilepsy and for the management of PHN. Gabapentin has a side effect profile that is considered favorable, with dizziness and somnolence as the most commonly reported side effects.

Despite its substantial commercial success, we believe that gabapentin therapy for the management of PHN can be improved. Gabapentin absorption is highly variable among patients, and there is a limit on the gabapentin exposure that can be achieved by direct oral administration of the parent drug. Published results from clinical trials of gabapentin in epilepsy patients indicated that, for the same dose level, some patients absorbed as little as 10% of the dose of gabapentin administered while others absorbed more than 70%. We have also conducted a clinical trial of gabapentin in neuropathic pain patients in which the high variability of gabapentin absorption was confirmed. In addition, the short duration of gabapentin in blood after oral dosing requires that it be administered three times a day, which may lead to poor compliance with the dosing regimen and, therefore, reduced efficacy in some patients.

We believe that these suboptimal characteristics of gabapentin result from the mechanism responsible for the absorption of gabapentin. Gabapentin is actively transported across the GI tract after administration. However, the specific transporter mechanism responsible for gabapentin absorption appears to have limited capacity, which seems to vary among individuals, and is predominantly expressed in the upper GI tract. Due to gabapentin's poor absorption in the lower GI tract, success in the development of effective sustained-release formulations for gabapentin has been limited.

Our Transported Prodrug

Gabapentin enacarbil is designed to address the limitations of gabapentin by targeting high-capacity nutrient transporter mechanisms expressed throughout the length of the intestinal tract. We believe that this approach can address the variable and suboptimal exposure to gabapentin experienced by patients. By targeting transporters expressed throughout the length of the intestinal tract, we have been able to develop a sustained-release formulation of gabapentin enacarbil that we believe provides more consistent absorption of gabapentin and has overcome the need for frequent dosing of gabapentin.

Gabapentin enacarbil is designed to rapidly convert to gabapentin once absorbed from the GI tract, resulting in limited systemic exposure to the intact Transported Prodrug. In addition to producing gabapentin, gabapentin enacarbil is metabolized to release other components with well-studied, favorable safety characteristics. We believe that gabapentin enacarbil has demonstrated a favorable safety profile in clinical trials conducted in humans to date, which profile is comparable to that of gabapentin.

Target Indication

Postherpetic Neuralgia

Background on Postherpetic Neuralgia. Neuropathic pain is pain that results from damage to nerves. The damage may result from a variety of causes, including injury or illnesses such as diabetes, HIV and shingles. In addition, the toxic effects of therapy used to treat patients with cancer or HIV may also cause nerve damage leading to neuropathic pain.

One form of chronic neuropathic pain is PHN. PHN is a complication of shingles, a painful outbreak of rash or blisters on the skin caused by a reactivation of the same virus that causes chicken pox. PHN is often characterized as constant stabbing, burning or electric shock-like sensations in the area affected by shingles after the rash has cleared. Approximately 10% to 15% of all patients with shingles develop PHN, which can persist for many years.

Potential Market. We estimate that the prevalence of PHN is less than 200,000 patients in the United States. In May 2006, Merck & Co. received FDA approval for Zostavax, a live attenuated vaccine, to help

[Table of Contents](#)

prevent shingles. In October 2006, the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices voted unanimously to recommend that adults 60 years of age and older be vaccinated with Zostavax for the prevention of shingles. In 2011, Zostavax was approved by the FDA for use in adults between the ages of 50 to 59 years of age. While Zostavax is not a treatment for shingles or PHN, the availability of this vaccine could impact the future market for therapies for PHN.

Current Treatments. Current classes of drugs used to treat patients with PHN include anticonvulsants, antidepressants and tricyclic drugs, with anticonvulsants representing the largest share of the PHN market. Of the anticonvulsants, gabapentin is the market leader, and pregabalin (marketed as Lyrica by Pfizer) is also widely prescribed for the treatment of PHN. Also, the FDA recently approved a once-daily formulation of gabapentin (known as Gralise from Depomed Inc.) for PHN. Other treatments used in selected patients include a capsaicin patch (marketed as Qutenza by NeurogesX, Inc.) and local application of lidocaine.

Phase 2 Clinical Trial Results. We have completed a randomized, double-blind, parallel-arm, placebo-controlled Phase 2 clinical trial of gabapentin enacarbil for the management of PHN. The trial included 101 patients at 18 clinical sites in the United States. The objective of this trial was to assess the safety, tolerability, pharmacokinetics and efficacy of 1200 mg of gabapentin enacarbil administered twice a day for 14 days and to compare the response to gabapentin enacarbil against the response to placebo. The trial included a Neurontin treatment phase to enable the evaluation of blood levels of Neurontin.

The trial met the primary endpoint of the study, demonstrating that treatment with gabapentin enacarbil was associated with a statistically significant reduction in pain as measured by an 11-point numerical pain scale compared to placebo ($p=0.032$). Additional analyses were conducted on data from those patients who received both Neurontin and gabapentin enacarbil. When administered gabapentin enacarbil, patients experienced on average a 17% increase in the steady-state average blood concentration of gabapentin compared to a dose of Neurontin that contained roughly 50% more gabapentin ($p=0.005$), indicating higher bioavailability of gabapentin when administered as gabapentin enacarbil. Thirty-six percent of evaluated patients had a greater than 30% increase in steady-state average blood gabapentin concentration for gabapentin enacarbil when compared to Neurontin. For all patients who received gabapentin enacarbil, the difference in average pain score between the last seven days of the gabapentin enacarbil treatment and the final seven days of Neurontin treatment was determined. A statistically significant reduction in pain score at the end of gabapentin enacarbil treatment was observed ($p=0.045$). Gabapentin enacarbil was well-tolerated. The most common adverse event in the gabapentin enacarbil treatment group was dizziness, which was mild to moderate in severity.

GSK has evaluated gabapentin enacarbil in two Phase 2 clinical trials for the potential treatment of PHN. In September 2009, GSK announced top-line results from a 14-week, double-blind, placebo-controlled Phase 2 clinical trial that enrolled 376 subjects with PHN who had been experiencing pain for at least three months following healing of the herpes zoster skin rash. Subjects were randomized to receive placebo, 1200, 2400 or 3600 mg/day of gabapentin enacarbil divided into twice-daily doses. The primary endpoint of the trial was the change from baseline to the end of maintenance treatment in the 24-hour average pain intensity score (using the last observation carried forward for missing data values). All doses of gabapentin enacarbil demonstrated statistically significant improvements over placebo on the primary endpoint, with the adjusted mean change from baseline in the 24-hour average pain intensity score of -1.66 for placebo, -2.47 for 1200 mg/day gabapentin enacarbil, -2.36 for 2400 mg/day gabapentin enacarbil and -2.72 for 3600 mg/day gabapentin enacarbil. The pre-specified statistical analysis included adjustment for comparisons of multiple gabapentin enacarbil doses to placebo. The adjusted p-values for comparison of 1200, 2400 and 3600 mg/day to placebo were 0.013, 0.029 and 0.002, respectively. Gabapentin enacarbil was generally well tolerated at all doses in this trial. The most common adverse events were dizziness (17% 1200 mg gabapentin enacarbil, 26% 2400 mg gabapentin enacarbil, 30% 3600 mg gabapentin enacarbil and 15% placebo) and somnolence (10% 1200 mg gabapentin enacarbil, 11% 2400 mg gabapentin enacarbil, 14% 3600 mg gabapentin enacarbil and 8% placebo), and most of these adverse events were mild or moderate in intensity. Withdrawals due to adverse events were 6% in the 1200 mg gabapentin enacarbil group, 15% in the 2400 mg gabapentin enacarbil group, 18% in the 3600 mg gabapentin enacarbil group and 13% in the placebo group. There was one serious adverse event (gastritis) in the 3600 mg/day dose group that was judged by the investigator to be related to treatment. In October 2009, GSK announced top-line results from a double-blind, two-period, cross-over Phase 2 clinical trial that enrolled 138 subjects

[Table of Contents](#)

diagnosed with PHN who had been experiencing pain for at least three months following healing of the herpes zoster skin rash. Subjects with a history of inadequate response to gabapentin entered a baseline period during which they received a dose of 1800 mg/day of gabapentin for two weeks. Subjects (N=96) who had a 24-hour average pain intensity score of at least four on the 11-point pain intensity rating scale were then randomized to receive either 1200 mg/day of gabapentin enacarbil for the first 28-day treatment period followed by 3600 mg/day for the second 28-day treatment period, or 3600 mg/day followed by 1200 mg/day. Subjects received 2400 mg/day of gabapentin enacarbil for four days in between the two treatment periods. The primary endpoint in this trial was the change from baseline to the end of the treatment period in the 24-hour average pain intensity score. A greater reduction in the 24-hour average pain score was observed for the 3600 mg/day dose than for the 1200 mg/day dose, which reduction was statistically significant. Gabapentin enacarbil was well tolerated at both doses in this study. The only treatment-emergent adverse event occurring in greater than or equal to 5% of subjects taking gabapentin enacarbil was nasopharyngitis.

Future Clinical Development of Gabapentin Enacarbil in Neuropathic Pain. Although we do not have active development programs underway, we continue to evaluate our resources and potential for pursuing development of gabapentin enacarbil in the United States for additional potential indications, including the potential management of PHN, to the extent that a product label would reflect a superiority claim over a currently approved drug, and diabetic peripheral neuropathy, or DPN.

Arbaclofen Placarbil, or AP — A Transported Prodrug of R-baclofen

We are developing our product candidate, AP, a Transported Prodrug of R-baclofen, for the potential treatment of spasticity. We previously evaluated AP as a potential treatment for GERD, but discontinued development of AP in that indication following inconclusive results from a Phase 2 clinical trial in that indication. We hold a composition-of-matter patent and methods-of-synthesis patents in the United States on AP, and hold patents or pending patent applications directed to AP formulations and methods of use in the United States and other jurisdictions.

Parent Drug Background

Baclofen is thought to act selectively on the target known as the GABA(B) receptor. Baclofen is racemic, which means it is a mixture of R and S isomers. Only the R isomer is active at GABA(B) receptors. Baclofen, which is now sold as a generic drug in the United States, has been used since 1977 for the alleviation of the signs and symptoms of spasticity in patients with MS and may also be of some value in patients with spinal cord injuries and other spinal cord diseases. Although baclofen has acceptable oral absorption, its short duration in blood of three to four hours necessitates oral dosing at least three times per day. This dosing regimen produces substantial peaks and troughs in drug exposure, which may be the cause of side effects such as significant drowsiness, weakness and dizziness during peak drug levels and diminished efficacy during trough drug levels. However, due to its poor absorption in the colon, development of a less frequently dosed sustained-release formulation of baclofen that produces a more constant level of baclofen in the blood has proven challenging to date. To address these limitations of oral baclofen, an implantable pump that delivers baclofen directly into the spinal cord fluid via a catheter has been developed. However, physicians typically reserve this invasive surgical procedure for those patients for whom oral baclofen is not effective.

Our Transported Prodrug

AP was designed to address the limitations of baclofen by targeting high-capacity nutrient transporter mechanisms expressed throughout the length of the entire GI tract, including the colon. By targeting these transporters, we believe that AP can be formulated in a sustained-release pill and thereby require less frequent dosing than baclofen. AP is a chiral molecule, which means that it exists as a single isomeric form, and produces only the R isomer of baclofen, known as R-baclofen.

AP was designed to rapidly convert to R-baclofen upon absorption, with limited systemic exposure to the intact Transported Prodrug. Once absorbed, AP converts to R-baclofen and natural substances that have well-

[Table of Contents](#)

studied, favorable safety characteristics. We believe that the inherently safe nature of the metabolic breakdown products of AP could provide AP with a safety profile that is comparable to, and potentially better than, that seen with racemic baclofen.

Phase 1 Clinical Trials

We have completed multiple Phase 1 clinical trials of AP that included a total of over 250 healthy volunteers. The results of these Phase 1 clinical trials indicated that AP was well absorbed and rapidly converted to the R isomer of baclofen. Exposure to the intact Transported Prodrug was low compared to the level of R-baclofen produced at all dose levels. Comparison of these data with historical pharmacokinetic data for racemic baclofen suggests that AP taken twice a day should be associated with a decreased peak-to-trough ratio of R-baclofen blood levels over 24 hours compared to racemic baclofen dosed three or four times a day.

Target Indication

Spasticity

Background on Spasticity. Spasticity is a debilitating condition that is associated with some common neurological disorders, such as MS, stroke and cerebral palsy, as well as spinal cord injury. The underlying cause of spasticity is unknown, but it is believed to result from an imbalance of inhibitory and excitatory functioning within the central nervous system. Patients with spasticity may experience abnormal increases in muscle tone that are associated with loss of range of motion, increased muscle stretch reflexes, weakness and problems with coordination. Common complications of spasticity include joint and muscle contracture, pain and difficulty performing activities of daily living.

Potential Market. According to "We Move", a non-profit organization providing patient information and continuing medical education to professionals, two out of every 1,000 people in North America suffer from MS and roughly 200,000 people in the United States live with a disability related to a spinal cord injury. It is estimated that spasticity affects 60% of MS patients and 40% of spinal cord injury patients.

Current Treatments. We estimate that there are approximately 4.0 million prescriptions written in the United States annually for drugs for the treatment of spasticity. Besides baclofen and tizanidine, the two most widely prescribed drugs for spasticity, diazepam and dantrolene sodium are also prescribed for patients with spasticity. Although these medications may provide symptom relief in some people, they are often only partially effective and generally require dosing three or more times a day. In addition, these medications are often associated with unwanted side effects such as sedation and weakness, as well as issues with bladder, bowel and sexual function. We believe that a Transported Prodrug of R-baclofen that can be taken twice each day to provide a steady exposure of R-baclofen may more adequately address the needs of spasticity patients than current therapies, including racemic baclofen.

Phase 2 Clinical Trial Results. In June 2009, we announced preliminary results from a multi-dose, randomized, placebo-controlled, crossover Phase 2 clinical trial of AP in spinal cord injury patients with spasticity. This trial enrolled 37 subjects at ten sites in the United States and Canada. Patients received either AP (10, 20 or 30 mg given twice daily, or BID) or placebo in the first treatment segment, and were then crossed over to the alternative treatment or placebo in the second segment of the trial. The primary endpoint in the study was the difference in Ashworth Scale score during the placebo and AP treatment segments for the muscle group with the highest Ashworth Scale score at baseline. Ashworth Scale scores were determined by the investigator prior to dosing, and again two, four and six hours after the morning dose. The primary analysis used a repeated-measures analysis of variance model and included data from the 35 subjects who completed both treatment segments.

Mean maximum baseline Ashworth Scale scores were 3.2 (n=10), 3.1 (n=12) and 3.1 (n=13) for the 10, 20 and 30 mg BID AP dose cohorts, respectively. For the primary endpoint, the overall adjusted mean differences between placebo and AP over the six-hour assessment period were -0.17 (not significant), -0.60 (p=0.0059) and -0.88 (p=0.0007) for the 10, 20 and 30 mg BID AP dose cohorts, respectively. AP treatment was associated with statistically significant differences from placebo at all time points in the 20 and 30 mg BID AP dose cohorts,

[Table of Contents](#)

indicating a treatment effect over the 12-hour dosing interval. In a secondary analysis, 20 and 30 mg BID of AP also showed a statistically significant difference from placebo in the average Ashworth Scale score for all six muscle groups.

AP was well tolerated at all dose levels. There were no withdrawals due to adverse events during the trial. The most commonly reported adverse events while on any AP dose were urinary tract infection (11% AP; 9% placebo), pain in extremity (8% AP; 0% placebo), insomnia (8% AP; 0% placebo) and nasopharyngitis (8% AP; 3% placebo). Side effects were generally mild to moderate in intensity. There were no drug-related serious adverse events.

Current Clinical Development of AP in Spasticity. We are conducting a pivotal Phase 3 clinical trial of AP as a potential treatment of spasticity in patients with MS. The trial is being conducted under an SPA whereby we reached agreement with the FDA on the clinical trial design and statistical analysis plan for determining the efficacy and safety of AP as a potential treatment for spasticity in patients with MS. The trial is a multi-center, randomized, double-blind, placebo-controlled study designed to assess the efficacy and safety of AP as a treatment for spasticity in MS patients. In addition, in accordance with the guidance that we received from the FDA at our End of Phase 2 meeting, we are conducting additional studies that are intended to be part of a potential NDA filing. For example, subjects who complete the 13-week pivotal Phase 3 efficacy trial have the option to enter a six-month, open-label safety clinical trial of AP. Together, these trials are intended to provide nine months of AP exposure for approximately 100 MS patients, as requested by the FDA. In addition, we are conducting a trial examining the effect of food with various fat contents on pharmacokinetics of AP, a renal impairment study and a pharmacokinetic comparison study in healthy subjects demonstrating that R-baclofen exposures for the highest recommended dose of AP are within exposures for the highest approved racemic baclofen dose (20 mg given four times per day). These trials, along with results from our previously completed preclinical studies, Phase 1 clinical trials and the Phase 2 clinical trial in spinal cord injury patients with spasticity, could form the basis of an NDA to be filed under Section 505(b)(2), which allows reference to published literature and the FDA's previous finding of safety and effectiveness for baclofen.

AP Development, Commercialization and Partnering Strategy

We are evaluating the market for AP in the United States and other regions of the world. If we determine that we could maximize the value of AP through the direct commercialization by us in the U.S. market, we would seek to retain those rights. We may seek a partner for the development and commercialization of AP outside of the United States. If we determine that our commercialization of AP within the United States is not feasible, we may seek a partner for the development and commercialization of AP worldwide. Factors that we would consider in determining a strategy to partner AP include: the results of our clinical trials; whether a potential partner seeks development and commercialization rights in or outside of the United States; and whether we believe that access to a large primary care physician sales force is necessary to address our target markets.

XP21279 — A Transported Prodrug of Levodopa

We are currently evaluating the further development of our product candidate, XP21279, a Transported Prodrug of levodopa, for the potential treatment of patients with Parkinson's disease who experience motor fluctuations. We hold a composition-of-matter patent and a formulation patent in the United States on XP21279 and hold patents or pending patent applications directed to the XP21279 methods of synthesis and use in the United States. We have also filed applications directed to the XP21279 composition of matter and methods of synthesis and use in other jurisdictions. At this time, we plan to defer further investment in this program pending the outcome of additional data analysis and discussions with Parkinson's disease experts and possibly with regulatory authorities.

Parent Drug Background

Patients with Parkinson's disease have a deficiency of the neurotransmitter dopamine resulting from neuronal degeneration within certain nerve cells in an area of the brain collectively known as the substantia nigra.

[Table of Contents](#)

Levodopa is an immediate precursor of dopamine that, unlike dopamine, readily crosses the blood brain barrier. When administered in conjunction with carbidopa (and, in some cases, with benzerazide or carbidopa and entacapone), levodopa is protected from rapid metabolism by enzymes that are found throughout the body outside of the brain. Once levodopa crosses the blood-brain barrier it is able to be converted to dopamine at its desired site of action in the brain. Levodopa is widely viewed as one of the most effective treatments of Parkinson's disease, and virtually all patients with Parkinson's disease ultimately require it. However, levodopa has many undesirable pharmacokinetic characteristics, including its rapid breakdown by gastric and other peripheral enzymes, a narrow absorption window within the GI tract and a short duration of exposure in blood after oral dosing that leads to the fluctuation of drug plasma concentrations upon frequent dosing. The poor colonic absorption of levodopa has precluded the development of a satisfactory sustained-release formulation of levodopa that would prolong absorption beyond the small intestine.

Our Transported Prodrug

We believe that XP21279 has the potential to improve upon the limitations of levodopa. XP21279 is designed to engage natural nutrient transport mechanisms located throughout the length of the GI tract and then be rapidly converted to levodopa by the body's naturally occurring enzymes. In addition to levodopa, the metabolic breakdown products of XP21279 are substances with favorable safety characteristics. Because XP21279 is designed to be well absorbed from the lower GI tract, we believe that it can be formulated for sustained release, thus reducing fluctuations of levodopa levels in the bloodstream. From December 2002 to December 2004, we were engaged in a collaboration with ALZA, now a subsidiary of Johnson & Johnson, to jointly develop Transported Prodrugs of levodopa. In March 2005, ALZA relinquished all rights to such Transported Prodrugs, subject to a low single-digit royalty upon net sales of certain product candidates if they are ultimately commercialized.

Phase 1 Clinical Trials in Healthy Volunteers

We have conducted three Phase 1 clinical trials of XP21279 that included a total of 82 healthy volunteers. The trials evaluated the pharmacokinetic profile of different formulations of XP21279 administered with carbidopa compared to a combination of levodopa/carbidopa. The results of these Phase 1 clinical trials indicated that XP21279/carbidopa was well absorbed and rapidly converted to levodopa. Exposure to the intact Transported Prodrug was negligible. Data from the trials indicated that compared to the pharmacokinetic data of levodopa/carbidopa, XP21279/carbidopa was associated with a decreased peak-to-trough ratio of levodopa blood levels over 24 hours compared to levodopa/carbidopa. XP21279 was generally well tolerated, with no serious adverse events reported in these trials.

Target Indication

Parkinson's Disease

Background on Parkinson's Disease. Parkinson's disease is a motor system disorder that results from the loss of dopamine-producing nerve cells in the brain. Dopamine is a chemical that is naturally produced by the body. It is responsible for smooth, coordinated function of the body's muscles and movement. When approximately 80% of dopamine-producing cells are damaged, the symptoms of Parkinson's disease appear. The primary symptoms of Parkinson's disease are tremor or shaking, slowness of movement, rigidity or stiffness and difficulty with balance.

Potential Market. It is estimated that as many as 1.5 million people in North America are living with Parkinson's disease. According to the National Institute of Neurological Disorders and Stroke, the average age of onset is 60, though some people are diagnosed at age 40 or younger. We estimate that there are approximately 4.0 million prescriptions written annually for levodopa drugs indicated for the treatment of Parkinson's disease in the United States.

Current Treatments. At present, there is no cure for Parkinson's disease, but a variety of medications provide relief from the symptoms. Levodopa acts to replenish dopamine in the brain. It is usually administered

[Table of Contents](#)

with carbidopa, or a combination of carbidopa and entacapone, which delays the premature conversion of levodopa to dopamine in peripheral tissues. According to the National Institute of Neurological Disorders and Stroke, treatment with levodopa helps patients in at least three-quarters of Parkinson's disease cases.

Another class of drugs, called dopamine agonists, is also commonly used to treat Parkinson's disease. Dopamine agonists, which include bromocriptine, pergolide, pramipexole and ropinirole, mimic the role of dopamine in the brain, which causes neurons to react as they would to dopamine. In spite of their wide use, both levodopa and dopamine agonists remain suboptimal in treating the symptoms of Parkinson's disease. Levodopa therapy has been associated with "wearing-off," a condition where treatment effects diminish over time as the disease progresses, and "on-off" dyskinesias, or impairment of movement, due to changes in levodopa plasma concentrations. Dopamine agonists are generally considered the next most powerful drug class in treating the symptoms of Parkinson's disease, but are more likely to cause hallucinations, confusion and psychosis, especially in the elderly.

Phase 1 Clinical Trial in Parkinson's Disease Patients. In January 2010, we reported preliminary results from an open-label, crossover, Phase 1 clinical trial of XP21279 administered with carbidopa in ten Parkinson's disease patients who were sequentially administered levodopa/carbidopa three or four times per day for 14 days followed by administration of XP21279/carbidopa three times per day for 14 days. Dosing for both levodopa/carbidopa and XP21279/carbidopa was optimized to minimize "off-time" (the period in which patients believe their medication is not working well or causing worsening of Parkinson's symptoms), with no appreciable increase in duration of dyskinesias (involuntary movements). The primary objective of the study was the comparison of pharmacokinetic profiles of XP21279/carbidopa compared to levodopa/carbidopa. XP21279 taken three times a day showed less variation in average levodopa concentrations over 16 hours compared to levodopa/carbidopa dosed three or four times a day, with a lower peak to trough ratio for XP21279. Efficacy assessments at the end of each treatment period showed improvements with XP21279 over levodopa. However, because the trial was not blinded, i.e., subjects knew what treatment was administered, the results of the efficacy analyses must be viewed with caution. XP21279 was well tolerated.

Phase 2 Clinical Trial Result. In December 2011, we reported preliminary results of a Phase 2, randomized, crossover clinical trial of XP21279 that compared optimized treatment with either Sinemet (immediate-release levodopa/carbidopa) or XP21279 co-formulated with carbidopa (XP21279/CD) in advanced Parkinson's disease patients with motor fluctuations. The trial enrolled patients with Parkinson's disease at 12 U.S. sites who were on a stable regimen of Sinemet dosed four or five times per day. Subjects were required to have "off time" in at least half of the inter-dose intervals between the first and last daily doses of Sinemet and an average daily "off time" greater than or equal to two hours during the three day baseline assessment period.

The trial consisted of an open-label, crossover optimization phase followed by a double-blind, crossover treatment phase. Thirty-five subjects entered the open-label phase of the trial, during which doses of Sinemet and XP21279/CD were each optimized for two weeks in a random order using the same protocol-specified guidelines. For Sinemet, doses were optimized while maintaining the same four or five times per day dosing frequency that the subject was taking during the baseline period. For XP21279/CD, doses were optimized using a fixed, three times per day regimen. Qualified subjects then entered the double-blind phase, during which they received the optimized doses of Sinemet and XP21279/CD for two weeks each in random order.

XP21279/CD dosed three times per day reduced mean daily "off time" by 46% compared to baseline when the patients were taking their pre-trial Sinemet dosing regimen. However, in the primary analysis of the trial, the improvement with XP21279/CD was not statistically better than the improvement seen with optimized Sinemet dosed four or five times per day during the double-blind phase of the trial. The primary analysis was performed on the difference between Sinemet and XP21279/CD in the change from baseline in mean daily "off time" at the end of each period during the double-blind phase of the trial. The efficacy analysis included 28 subjects who completed the double-blind phase of the trial. The baseline mean daily "off time" for the analysis population was 6.4 hours. At the end of the open-label phase, mean daily "off time" was reduced from baseline by 2.0 hours for Sinemet compared to 3.4 hours for XP21279/CD. At the end of the double-blind phase, mean daily "off time" was reduced from baseline by 2.6 hours for Sinemet compared to 2.9 hours for XP21279/CD. The mean difference between Sinemet and XP21279/CD at the end of the double-blind phase of the trial was not statistically significant.

[Table of Contents](#)

All treatment-emergent adverse events were mild to moderate in severity. During the double-blind phase of the trial, dyskinesias were the most common adverse event. The incidence of new or worsening dyskinesias during the double-blind phase of the trial was 11% for Sinemet and 13% for XP21279/CD. There were no serious adverse events.

Further Clinical Development of XP21279 in Parkinson's Disease. We intend to further analyze the Phase 2 clinical trial data and discuss these results with Parkinson's disease experts and possibly with regulatory authorities to determine next steps, if any. We plan to defer further investment in this program pending the outcome of our data analysis and these discussions.

XP21279 Development, Commercialization and Partnering Strategy

We plan to retain rights to XP21279 in the United States, while seeking a partner for the development and commercialization of XP21279 as a treatment for Parkinson's disease outside the United States.

Preclinical Development Candidate — XP23829

We are conducting preclinical development of XP23829, a novel prodrug of MMF that we believe may provide more consistent and predictable efficacy due to less variable blood levels of MMF and exhibit less gastric irritation than dimethyl fumarate, or DMF, another prodrug of MMF (BG00012) under development by Biogen Idec Inc. Prodrugs of MMF, a molecule that appears to have anti-inflammatory properties, may be useful in the potential treatments of patients with RRMS or psoriasis. In preclinical studies that compared molar equivalent doses of XP23829 to DMF, XP23829 provided higher blood levels of the biologically active molecule MMF, superior efficacy in an animal model of MS and fewer and less severe stomach lesions in an animal model of gastric irritation. We plan to file an IND for XP23829 in the second quarter of 2012 and begin a human clinical trial of XP23829 later in 2012.

Our Strategic Alliances

Astellas Pharma Inc.

In December 2005, we entered into an agreement in which we licensed to Astellas exclusive rights to develop and commercialize gabapentin enacarbil, to be marketed in Japan under the trade name *Regnite*, in Japan, Korea, the Philippines, Indonesia, Thailand and Taiwan. Under the terms of this agreement, we received an initial license payment of \$25.0 million and have subsequently received \$30.0 million in milestone payments as of December 31, 2011. We received \$10.0 million associated with the approval of *Regnite* in Japan in January 2012, and, as of February 2012, we remain eligible to receive potential clinical and regulatory milestone and contingent payments totaling up to an additional \$20.0 million. We will receive percentage-based mid-teen royalties on any net sales of *Regnite*/gabapentin enacarbil in the Astellas territory. Astellas is solely responsible for the manufacturing of *Regnite*/gabapentin enacarbil to support its development and commercialization within the Astellas territory. Astellas may terminate the collaboration at its discretion; in such event, all *Regnite*/gabapentin enacarbil product rights would revert to us and we would be entitled to specified transition assistance from Astellas.

Glaxo Group Limited

In February 2007, we entered into an exclusive collaboration agreement with GSK to develop and commercialize gabapentin enacarbil, known in the United States by the trade name *Horizant* (gabapentin enacarbil) Extended-Release Tablets, in all countries of the world excluding the Astellas territory. In November 2010, we amended and restated our collaboration agreement with GSK, pursuant to which we reacquired all rights to gabapentin enacarbil outside of the United States previously granted to GSK (which excludes the Astellas territory) and obtained the right, but not the obligation, to pursue development of *Horizant* for: (i) the potential treatment of DPN; (ii) the potential treatment of PHN to the extent that a product label would reflect a superiority claim over a currently approved drug; and (iii) any additional indications in the United States. GSK remains responsible for further development and regulatory matters with respect to *Horizant* for the potential management of PHN and manufacturing and commercialization of *Horizant* in the United States for all indications.

[Table of Contents](#)

Under the terms of the amended and restated collaboration agreement, as currently in effect, we are eligible to receive a total of \$312.5 million in aggregate clinical and regulatory event-based potential payments, of which \$120.0 million has been received as of December 31, 2011. We remain eligible to receive up to an additional \$290.0 million upon the achievement of specified sales levels.

We exercised our right to the co-promotion arrangement in April 2009, under which all allowable expenses and sales of *Horizant* are accounted for using a joint P&L statement, in which we and GSK share in the resulting operating pre-tax profits and losses. Under the amended and restated collaboration agreement, as currently in effect, our participation in the co-promotion and joint P&L arrangements remains unchanged, except that we can delay the deployment of our sales force for up to three years following the approval of *Horizant* in the United States and our share of losses from the joint P&L will be forgiven up to a maximum of \$10.0 million. Our payment of additional losses, if any, would be deferred and payable without interest over a four-year period following the first quarter in which the joint P&L is profitable. GSK is responsible for: establishing pricing and reimbursement; creating promotional and advertising materials; managed care contracting; receiving, accepting and filling orders; distributing; controlling invoicing, order processing and collecting accounts receivable; and recording sales of *Horizant* in the United States. Expenses that can be charged to the joint P&L statement are the cost of goods and certain costs directly related to *Horizant* marketing and sales.

We will share any profits or losses on sales of *Horizant* in the United States at tiered rates that escalate as a function of annual net sales levels, from a low of 20% to a maximum of 50%. For example (and for illustrative purposes only), if the annual net sales of *Horizant* reach \$250.0 million, \$500.0 million and \$1.0 billion, we would be entitled to blended profit share rates of 25%, 34% and 42%, respectively. We may terminate our co-promotion right and participation in the profit share arrangement at any time upon notice to GSK with no penalty to us, resulting in a royalty-based compensation structure, whereby we would receive royalties on annual net sales in the United States at tiered rates that escalate as a function of net sales levels from a low of 15% to a maximum of 30%. For example (and for illustrative purposes only), if the annual net sales of *Horizant* reach \$250.0 million, \$500.0 million and \$1.0 billion, we would be entitled to blended royalty rates of 17%, 21% and 25%, respectively. GSK may terminate our co-promotion right for our not meeting a minimum sales requirement, for our uncured material breach in conducting co-promotional activities or upon our change of control in certain circumstances. GSK may terminate our collaboration agreement in its entirety for any reason and at any time. In such event, certain *Horizant* product rights would revert to us, and we would be entitled to specified transition assistance from GSK.

In January 2012, pursuant to the Notice, we provided notice to GSK of our belief that, among other matters, GSK has materially breached its contractual obligation to use commercially reasonable efforts to (i) maximize the sales of *Horizant* in an expeditious manner and (ii) achieve the sales milestones set forth in our collaboration agreement. The collaboration agreement provides that disputes arising with respect to certain matters related to the agreement shall, prior to initiating legal proceedings, first be presented to our Chief Executive Officer and the Chief Operating Officer of GSK, or their respective designees, for resolution during a contractually specified period of time. The collaboration agreement also provides that we may terminate the agreement in the event that GSK shall have materially breached or defaulted in the performance of any of its material obligations under the agreement, and such default shall have continued for 90 days after the date of GSK's receipt of written notice of the breach. The Notice provides that any such termination would become effective at the end of such 90-day period, which will expire on April 24, 2012, unless GSK has cured any such breach or default prior to such date. If the agreement is terminated as a result of breach by GSK, certain *Horizant* product rights would revert to us, and we would be entitled to specified transition assistance from GSK.

However, on February 23, 2012, GSK filed the GSK Complaint in the United States District Court for the District of Delaware naming us and other unspecified individuals as defendants. Pursuant to the GSK Complaint, GSK is seeking declaratory judgment that it is not in breach of the collaboration agreement and that we do not have the right to terminate the collaboration agreement as a result of GSK's performance under the agreement to date. Following the expiration of the contractually specified period of time for resolution of the dispute by the requisite officers of the parties, on February 24, 2012, we filed the XenoPort Complaint in the Superior Court of the State of California in the County of Santa Clara against GSK and its affiliates, GlaxoSmithKline LLC and GlaxoSmithKline Holdings (Americas) Inc., for breach of contract, fraud, breach of fiduciary duty, breach of the

[Table of Contents](#)

covenant of good faith and fair dealing and unfair competition. Pursuant to the XenoPort Complaint, in addition to injunctive and equitable relief, we are seeking damages for lost profits, damage to the value of *Horizant* and unattained royalties and milestone payments in an amount to be proven at trial, as well as punitive damages and restitution. We believe that we have meritorious defenses and intend to defend the GSK Complaint, and prosecute the XenoPort Complaint, vigorously. We cannot predict the outcome of the litigation related to the GSK Complaint and the XenoPort Complaint or when or if the collaboration agreement will be terminated or the ultimate terms of any termination of the agreement. In addition, we may incur substantial legal fees and costs in connection with this litigation, and may not prevail in either of these legal proceedings.

Patents and Proprietary Rights

We will be able to protect our technology from unauthorized use by third parties only to the extent that our technology is covered by valid and enforceable patents or effectively maintained as trade secrets and able to be utilized without infringing the proprietary rights of others. Our success in the future will depend in part on obtaining patent protection for our technologies and product candidates. Accordingly, patents and other proprietary rights are essential elements of our business. Our policy is to actively seek in the United States and selected foreign countries patent protection for novel technologies and compositions of matter that are commercially important to the development of our business.

Issued U.S. and foreign patents generally expire 20 years after filing. We hold a number of issued patents in the United States, including composition-of-matter patents on *Horizant*/gabapentin enacarbil, AP and XP21279. We have a number of pending patent applications in the United States. Of the U.S. patents that we hold, many patents are related to compounds, pharmaceutical compositions containing the compounds and therapeutic methods of using the compounds and compositions. We also have U.S. patents that are related to methods of synthesis, proteomics methodology and screening methodology. We also hold a number of issued foreign patents. We have pending Patent Cooperation Treaty regional applications that permit us to pursue patents outside of the United States, pending European regional patent applications that permit us to pursue patents in various European countries and foreign national patent applications. The claims in these various patents and patent applications are directed to compositions of matter, including claims covering product candidates, lead compounds and key intermediates, pharmaceutical compositions, methods of use and processes for making our compounds, along with methods of design, synthesis, selection and use of Transported Prodrugs in general and to our research and development programs in particular.

The patent rights relating to *Horizant*, its synthesis, formulations and methods of use are owned by us and consist of issued U.S. patents that expire at the earliest in 2022 and a number of pending U.S. patent applications. GSK has petitioned for U.S. patent term extension, which could extend the patent term until 2025. In addition, a second patent directed at the crystalline form of *Horizant* could extend the effective patent coverage of *Horizant* until 2026. We believe that in all countries in which we hold or have licensed rights to patents or patent applications related to *Horizant*, *Regnite* and gabapentin enacarbil, the composition-of-matter patents relating to gabapentin have expired. For AP, U.S. composition-of-matter patents have issued that will expire no earlier than 2025. For XP21279, a U.S. composition-of-matter patent has issued that will expire no earlier than 2025. Although third parties may challenge our rights to, or the scope or validity of, our patents, to date, other than the European opposition described below, we have not received any communications from third parties challenging our patents or patent applications covering *Horizant*, *Regnite* or our product candidates.

In September 2008, a law firm, on behalf of an undisclosed client, filed an opposition against the patent grant of one of our European patent applications covering gabapentin enacarbil. The European patent office, at an opposition hearing in April 2010, undertook a full review of the grant of the European patent, and ruled that our European patent covering the composition of matter of gabapentin enacarbil is valid. While the law firm that filed the opposition initially appealed the ruling on behalf of the undisclosed client, that appeal was withdrawn in November 2010.

The composition-of-matter patent on gabapentin, the parent drug of *Horizant/Regnite*/gabapentin enacarbil, expired in 2000, but Pfizer sold gabapentin exclusively based on a formulation patent until September 2004. This formulation patent, which expires in 2017, has been the subject of ongoing litigation between Pfizer and several

[Table of Contents](#)

generic manufacturers, including Alpharma, Inc. and Teva Pharmaceutical Industries, Ltd. Pfizer currently markets generic gabapentin through its Greenstone Ltd. subsidiary. Alpharma and Teva, along with many others, currently market gabapentin as a generic drug. In May 2011, this suit was settled and Pfizer granted the generic gabapentin makers a license to make and sell gabapentin under the patent. We have not been a party to this litigation, and we believe that the manufacturing process for gabapentin enacarbil does not infringe the patent that was the subject of this litigation. Since the settlement apparently did not enjoin or limit the sale of generic gabapentin, GSK and/or Astellas are not limited in their choices of potential suppliers.

Certain product candidates that we develop may be submitted to the FDA for approval under Section 505(b)(2) of the Food, Drug and Cosmetic Act, or FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as Paragraph IV certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the Section 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the Section 505(b)(2) application. Under the Hatch-Waxman Act, the holder of patents that the Section 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) application. Accordingly, we may invest a significant amount of time and expense in the development of one or more products only to be subject to significant delay and patent litigation before such products may be commercialized, if at all.

We also rely on trade secret protection and confidentiality agreements to protect our proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery process that involve proprietary know-how and technology that is not covered by patent applications, especially where patent protection is not believed to be appropriate or obtainable. We require all of our employees, consultants and advisors to enter into confidentiality agreements. Where it is necessary to share our proprietary information or data with outside parties, our policy is to make available only that information and data required to accomplish the desired purpose and only pursuant to a duty of confidentiality on the part of those parties.

Manufacturing

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of *Horizant*, *Regnite* or any of our product candidates. To date, we have relied on, and we expect to continue to rely on, a limited number of third-party compound manufacturers and active pharmaceutical ingredient, or API, formulators for the production of preclinical, clinical and commercial quantities of our product candidates. We do not have commercial supply agreements with any of these third parties, and our agreements with these parties are generally terminable at will by either party at any time.

Under the terms of our collaboration agreement with GSK, as currently in effect, GSK is solely responsible for the commercial manufacture and supply of *Horizant* to support its development and commercialization within the United States. GSK is currently relying on a single source supplier for commercial and clinical supplies of *Horizant*. If GSK fails to qualify alternative manufacturers of *Horizant*, the current contract manufacturer terminates its agreement with GSK and GSK is otherwise unable to manufacture or contract to manufacture sufficient quantities of *Horizant*, the development and commercialization of *Horizant* could be impaired or delayed. If our collaboration agreement with GSK is terminated, we are entitled to specified manufacturing transition assistance from GSK, but would then be responsible for the manufacturing of *Horizant* following the transition period. Under the terms of our collaboration with Astellas, Astellas is solely responsible for the manufacture of *Regnite*/gabapentin enacarbil to support its development and commercialization within the Astellas territory. To our knowledge, Astellas is currently relying on single source suppliers for clinical supplies

[Table of Contents](#)

of *Regnite*/gabapentin enacarbil in API form. As a result, if Astellas fails to manufacture or contract to manufacture sufficient quantities of *Regnite*/gabapentin enacarbil or API, development and commercialization of *Regnite*/gabapentin enacarbil could be impaired or delayed in the Astellas territory. If we pursue development with respect to the rights we maintain on *Horizant*/gabapentin enacarbil or if our collaboration agreement with GSK is terminated, we will need to obtain clinical supplies from GSK or another supplier. As a result, if we are unable to obtain sufficient quantities of *Horizant*/gabapentin enacarbil from GSK at prices that are commercially attractive, and if we are unable to qualify an alternative supplier, it could delay the development of, and impair our ability to commercialize, *Horizant*/gabapentin enacarbil.

We rely on two suppliers of R-baclofen, the active agent used to make AP, under purchase orders issued from time to time. In the event that both suppliers determine to not sell R-baclofen to us at a price that is commercially attractive, and if we were unable to qualify an alternative supplier of R-baclofen, this could delay the development of, and impair our ability to commercialize, this product candidate.

We rely on a single source supplier of our current worldwide requirements of AP in API form under a manufacturing services and product supply agreement. Our current agreement with this supplier does not provide for a supply of API that would be necessary for full-scale commercialization. In the event that the parties cannot agree to the terms and conditions for this supplier to provide some or all of our API clinical and commercial supply needs, we would not be able to manufacture API until an alternative supplier is identified and qualified, which could also delay the development of, and impair our ability to commercialize, this product candidate. The API is manufactured using a four-step synthetic process that uses commercially available starting materials for each step. There are no complicated chemistries or unusual equipment required in the manufacturing process.

We rely on a single source supplier of AP formulated in sustained-release tablets at specified transfer prices under quotations agreed upon by the parties as a part of a master services agreement. We do not have an agreement with this supplier for the commercial supply of AP sustained-release tablets. In the event that such supplier terminates our agreement under specified circumstances, or we are not able to come to an agreement for the commercial supply of AP on reasonable terms, we would not be able to commercialize AP sustained-release tablets until an alternative supplier is qualified. This could delay the development of, and impair our ability to commercialize, AP.

We rely on a single source supplier of levodopa, which is used to make XP21279, under purchase orders issued from time to time. We are aware of several alternative suppliers of levodopa, and we believe at least one alternative manufacturer could potentially supply levodopa in the event that our supplier determines to not sell levodopa to us at a price that is commercially attractive. If we determine to continue the development of XP21279 and were unable to qualify an alternative supplier of levodopa, this could further delay the development of, and impair our ability to commercialize, XP21279.

We rely on a single source supplier of XP21279 in API form under a manufacturing services and product supply agreement. In the event that such supplier terminates the agreement under specified circumstances, we would not be able to manufacture API until a qualified alternative supplier is identified and qualified, which could also further delay the development of, and impair our ability to commercialize, this product candidate. The API is manufactured by a four-step synthetic process that uses commercially available starting materials. There are no complicated chemistries or unusual equipment required in the manufacturing process.

We have purchased XP21279 formulated in sustained-release tablets from a single source supplier at specified transfer prices under quotations agreed upon by the parties as part of a master services agreement. We have recently qualified another supplier for the manufacture of XP21279 with carbidopa bi-layer tablets to be supplied under quotations agreed upon by the parties as part of a master services agreement. In the event that either supplier terminates its agreement under specified circumstances for the manufacture of XP21279 sustained-release tablets or carbidopa bi-layer tablets, we would not be able to manufacture XP21279 until an alternative supplier is qualified. If we determine to continue the development of XP21279, this could further delay the development of, and impair our ability to commercialize, XP21279.

Our contract manufacturers may own process technology related to the manufacture of our compounds. This would increase our reliance on this manufacturer. However, we have been successful in negotiating agreements

[Table of Contents](#)

with our contract manufacturers that include licenses, with the right to grant sublicenses, to any technology incorporated into the manufacture of our compounds or that is invented by employees of the contract manufacturers during the course of work conducted on our product candidates.

Research and Development

Since inception, we have devoted a significant amount of resources to develop our product candidates. For the years ended December 31, 2011, 2010 and 2009, we recorded \$43.8 million, \$52.5 million and \$70.7 million, respectively, in research and development expenses. As part of a restructuring that we implemented in March 2010 due to a significant delay in the regulatory review of *Horizant*, we eliminated our discovery research department, which prevents us from being able to discover additional product candidates at this time.

Potential Marketing and Sales of Our Product Candidates

Under the terms of our agreement with GSK, as currently in effect, if *Horizant* were approved for marketing by the FDA for the management of PHN, GSK would be responsible for: establishing pricing and reimbursement; creating promotional and advertising materials; managed care contracting; receiving, accepting and filling orders; distributing; controlling invoicing, order processing and collecting accounts receivable; and recording sales of *Horizant* in the United States for PHN. We would continue to share in the profits from the sale of *Horizant* in the United States for PHN. In connection with our *Horizant* co-promote arrangement, if we elect to deploy a sales force within three years following the approval of *Horizant* for RLS in the United States, we would also be responsible for co-promotion of *Horizant*, if approved for PHN. We may also be able to utilize that same sales force to promote other products in our pipeline, resulting in a more efficient commercial structure.

We also plan to establish additional development and commercialization partnerships with pharmaceutical and biotechnology companies to accelerate the completion of regulatory approval and product introduction and to maximize the breadth of the commercial opportunity of our other product candidates.

Competition

The pharmaceutical and biotechnology industries are intensely competitive. Any product candidate developed by us would compete with existing drugs and therapies. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engaged in research and development of products targeting the same markets as our product candidates. Many of these organizations have substantially greater financial, technical, manufacturing and marketing resources than we have. Several of them have developed or are developing therapies that could be used for treatment of the same diseases that we are targeting. In addition, many of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug development to:

- develop products that are superior to other products in the market;
- attract and retain qualified scientific, product development and commercial personnel;
- obtain patent and/or other proprietary protection for our products and technologies;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the development and commercialization of new products.

We expect to compete on, among other things, product efficacy and safety, time to market, price, extent of adverse side effects experienced and convenience of treatment procedures. In order to compete successfully, we will need to develop and exploit these pharmaceutical products commercially before others are able to develop competitive products.

[Table of Contents](#)

In addition, our ability to compete may be affected if insurers and other third-party payors seek to encourage the use of generic products, making branded products less attractive to buyers from a cost perspective.

We believe that our product development programs will be subject to significant competition from companies utilizing alternative technologies. In addition, as the principles of active transport become more widely known and appreciated based on patent and scientific publications and regulatory filings, we expect the field to become highly competitive. Pharmaceutical companies, biotechnology companies and academic and research institutions may succeed in developing products based upon the principles underlying our proprietary technologies earlier than us, obtaining approvals for such products from the FDA more rapidly than us or developing products that are safer, more effective and/or more cost effective than those under development or proposed to be developed by us.

Our objective is to discover, develop and commercialize new medicines with superior efficacy, convenience, tolerability and/or safety. To the extent that we are able to develop medicines, they are likely to compete with existing drugs that have long histories of effective and safe use and with new therapeutic agents. We expect that any medicines that we commercialize with our collaborative partners or on our own will compete with existing, market-leading medicines.

Horizant/Regnite. Products that we believe compete with *Horizant* in the United States include the following drugs approved for the treatment of RLS: Mirapex (pramipexole) from Boehringer Ingelheim and generic pramipexole; and Requip (ropinirole) from GSK and generic ropinirole. In addition, *Horizant* could experience competition from Neupro (the rotigotine transdermal system), a dopamine agonist patch from UCB, which filed its NDA for the treatment of RLS with the FDA in 2007 to which the FDA provided a Complete Response letter in April 2010 that recommended reformulation of Neupro before making it available in the U.S. market for the treatment of RLS. In Japan, we believe that *Regnite* could compete with pramipexole, which was approved in 2010 for the treatment of RLS. In addition, Otsuka Pharmaceutical Co., Ltd. filed an NDA in Japan in December 2011 for the Rotigotine Patch, a transdermal patch that has been developed as a treatment for RLS, which, if approved, could compete with *Regnite*.

If *Horizant* is approved for the management of PHN, products that we believe could compete with *Horizant* in the United States include drugs that act on the same target as *Horizant*, such as Lyrica (pregabalin), Neurontin (gabapentin) from Pfizer, generic gabapentin and Gralise (once-daily formulation of gabapentin) from Depomed, Inc. *Horizant* could also experience competition from a capsaicin patch (marketed as Qutenza by NeurogesX, Inc.) and transdermal patches containing the anesthetic known as lidocaine, which are sometimes used for the management of PHN.

AP. We anticipate that, if approved, AP would experience competition from several generic drugs approved for the treatment of spasticity, including racemic baclofen, diazepam, dantrolene sodium and tizanidine. In addition, the FDA has approved Botox (onabotulinumtoxin A) from Allergan Inc. to treat spasticity in the flexor muscles of the elbow, wrist and fingers in adults. Therapies in development for the treatment of spasticity based on sustained-release versions of baclofen include IPX056 from Impax Laboratories, Inc. and Baclofen GRS from Sun Pharma Advanced Research Company Limited.

XP21279. We anticipate that, if approved, XP21279 would compete with therapies including: generic levodopa/carbidopa drugs and other drugs approved for the treatment of Parkinson's disease, including Stalevo, a combination therapy of levodopa/carbidopa/entacapone that is marketed in the United States by Novartis; dopamine agonists such as Mirapex (pramipexole) as well as Requip (ropinirole) and Requip XL (ropinirole extended-release tablets), which are marketed by Boehringer Ingelheim and GSK, respectively; as well as generic dopamine agonists, including pramipexole and ropinirole. In addition, XP21279 could also experience competition from the rotigotine transdermal system (a dopamine agonist patch known as Neupro by UCB) that was previously approved for the treatment of Parkinson's disease; however, in April 2010, the FDA provided UCB a Complete Response letter that recommended reformulation of Neupro before making it available in the U.S. market for the treatment of Parkinson's disease. In December 2011, Impax Labs submitted an NDA for IPX066, an extended-release formulation of levodopa/carbidopa. Other therapies under development in the United States include levodopa/carbidopa formulations such as Duodopa (a levodopa/carbidopa gel delivered by a portable pump directly into the duodenum being developed by Solvay) as well as DM-1992 and OS-320

[Table of Contents](#)

(extended-release formulations of levodopa/carbidopa being developed by Depomed and Osmotica Pharmaceutical Corp., respectively).

There may be other compounds of which we are not aware that are at an earlier stage of development and may compete with our product or product candidates. If any of those compounds are successfully developed and approved, they could compete directly with our product and product candidates.

Government Regulation

Product Approval Process

The clinical testing, manufacturing, labeling, storage, record keeping, advertising, promotion, export and marketing, among other things, of our product and product candidates are subject to extensive regulation by governmental authorities in the United States and other countries. The FDA, under the FDCA, regulates pharmaceutical products in the United States. The steps required before a drug may be approved for marketing in the United States generally include:

- preclinical laboratory tests and animal tests;
- the submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;
- the submission to the FDA of an NDA;
- FDA acceptance, review and approval of the NDA; and
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with current Good Manufacturing Practices, or cGMPs.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain. The FDA 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.

Preclinical studies include laboratory evaluations of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

Clinical trials involve the administration of the product candidates to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Clinical trials typically are conducted in three sequential phases prior to approval, but the phases may overlap. These phases generally include the following:

Phase 1. Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects, frequently healthy volunteers. In Phase 1, the product candidate is usually tested for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamics.

Phase 2. Phase 2 clinical trials usually involve studies in a limited patient population to (1) evaluate the efficacy of the product candidate for specific indications, (2) determine dosage tolerance and optimal dosage and (3) identify possible adverse effects and safety risks.

[Table of Contents](#)

Phase 3. If a product candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 studies, the clinical trial program will be expanded to Phase 3 clinical trials to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical study sites.

Phase 4 clinical trials are conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA in the form of post-market requirements or commitments. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirements. These clinical trials are often referred to as Phase 3/4 post-approval clinical trials. Failure to promptly conduct Phase 4 clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

The results of preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that our or our collaborative partners' data is insufficient for approval and require additional preclinical, clinical or other studies. For example, in November 2008, GSK and we agreed to withdraw the initial NDA submission for *Horizant* following discussions with the FDA in which the FDA requested that we reformat existing data for a submitted Phase 3 clinical trial. The NDA for this product candidate was then resubmitted in January 2009 with the appropriate data reformatted, and subsequently, in February 2010, GSK received a Complete Response letter from the FDA regarding the NDA for *Horizant*. The letter indicated that a preclinical finding of pancreatic acinar cell tumors in rats was of sufficient concern to preclude approval of the *Horizant* NDA for RLS in its form at that time. In November 2010, the FDA accepted for review GSK's NDA resubmission for *Horizant* for the treatment of RLS, designated the *Horizant* NDA resubmission as a Class 2 response and set a new PDUFA date of April 6, 2011, at which time the FDA approved *Horizant* for the treatment of patients with RLS in the United States.

Generally, regulatory approval of a new drug by the FDA may follow one of three routes. The most traditional of these routes is the submission of a full NDA under Section 505(b)(1) of the FDCA. A second route, which is possible where an applicant chooses to rely in part on data generated or approvals obtained previously by other parties and/or on data described in published literature, is to submit a more limited NDA described in Section 505(b)(2) of the FDCA. The final route is the submission of an Abbreviated New Drug Application for products that are shown to be pharmaceutically and therapeutically equivalent to previously approved drug products as permitted under Section 505(j) of the FDCA.

Both Section 505(b)(1) and Section 505(b)(2) applications are required by the FDA to contain full reports of investigations of safety and effectiveness. However, in contrast to a traditional NDA submitted pursuant to Section 505(b)(1) in which the applicant submits all of the data demonstrating safety and effectiveness, we believe an application submitted pursuant to Section 505(b)(2) can rely upon previous findings by the FDA that the parent drug is safe and effective in that indication, and/or upon data described in published literature. As a consequence, the preclinical and clinical development programs leading to the submission of an NDA under Section 505(b)(2) may be less expensive to carry out and could be concluded in a shorter period of time than programs required for a Section 505(b)(1) application. In its review of any NDA submission, however, the FDA has broad discretion to require an applicant to generate additional data related to safety and efficacy, and it is impossible to predict the number or nature of the studies that may be required before the FDA will grant approval.

Pursuant to the terms of our collaboration agreement with GSK, as currently in effect, GSK is the sponsor of the NDA for *Horizant* for the treatment of RLS, the sponsor of the sNDA for *Horizant* for the management of PHN and is responsible for leading the registration of *Horizant* for any additional indications in the United States. For our other product candidates that are undergoing clinical trials, we intend to follow the development pathway permitted under the FDCA that will maximize the commercial opportunities for these Transported Prodrugs. We are evaluating both Section 505(b)(1) and Section 505(b)(2) NDA routes for our Transported Prodrugs. In the event that we decide to utilize Section 505(b)(2) of the FDCA to pursue an approval of our

[Table of Contents](#)

Transported Prodrugs in indications for which the relevant parent drug has previously been approved, we will engage in discussions with the FDA to determine which, if any, portions of our development program can be modified.

In addition, for NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as Paragraph IV certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the Section 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the Section 505(b)(2) application. Under the Hatch-Waxman Act, the holder of patents that the Section 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) application. A Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the approved product. The FDA may also reject our future Section 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which could cause delay and be considerably more expensive and time consuming.

Once the NDA submission has been accepted for filing, the FDA sets a PDUFA date that informs the applicant of the specific date in which the FDA intends to complete their review. This is typically 10 months from the date of filing the NDA application. The review process is often extended by FDA requests for additional information or clarification. Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMPs. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied, the FDA requires additional testing or information and/or the FDA requires post-marketing testing and surveillance to monitor safety or efficacy of a product. FDA approval of any NDA submitted by us or GSK will be at a time the FDA chooses.

Post-Marketing Regulations

If the FDA grants regulatory approval of a product, such approval may entail limitations on the indicated uses for which such product may be marketed. The FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards and requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require additional clinical trials, including Phase 4 post-marketing studies, to provide additional data on safety, to monitor the effect of approved products or for other reasons. The failure of such trials can result in a range of regulatory actions, including limiting further marketing of the product or withdrawal of the product from the market. The FDA approval for *Horizant* for the treatment of RLS included requirements for GSK to conduct a program of post-marketing commitments, or PMCs, and post-marketing requirements, or PMRs, in adults, including a 12-week, double-blind, placebo-controlled efficacy study, two simulated driving studies, a drug-drug interaction study with morphine and a cardiovascular safety study. As part of this program, the FDA also requested an evaluation of 300 mg and 450 mg tablets of *Horizant*, dosed once per day. GSK will also conduct a pediatric program for subjects 13 years and older. The pediatric clinical program, which is scheduled to commence after requested adult data is obtained and reviewed by the FDA, includes a pharmacokinetics study, a parallel, fixed-dose response efficacy study, a long-term safety study and a simulated driving study. The specific protocol submission and trial completion dates for these PMCs/PMRs range from April 2011 through July 2024. If our collaboration agreement with GSK is terminated, we could be responsible for completing these PMCs and PMRs.

If we or our collaborative partners obtain regulatory approval for a product, this clearance will be limited to those diseases and conditions for which the FDA agrees that the product is safe and effective, as demonstrated through clinical trials and as described in the FDA-approved product label. Thus, further studies will be required

[Table of Contents](#)

to gain approval for the use of a product as a treatment for clinical indications other than the indication for which the product was initially approved. For example, even though *Horizant* has been approved by the FDA for the treatment of RLS, we or GSK will need to obtain FDA approval in order to market *Horizant* for other indications, including PHN. Even if regulatory approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, it is necessary to submit an application to the FDA seeking approval of such changes. Also, the FDA can place restrictions on approval and marketing utilizing its authority under applicable regulations. Discovery of previously unknown problems with a medicine, manufacturer or facility may result in restrictions on the marketing or manufacturing of an approved product, including costly recalls or withdrawal of the product from the market. The FDA has broad post-market regulatory and enforcement powers, including the ability to suspend or delay issuance of approvals, seize or recall products, withdraw approvals, enjoin violations and institute criminal prosecution. Additionally, the FDA regulates the labeling, storage, record-keeping, advertising and promotion of prescription pharmaceuticals. In the course of practicing medicine, physicians may legally prescribe FDA-approved drugs for an indication that has not been approved by the FDA and which, therefore, is not described in the product's approved labeling. This prescribing practice is known as "off-label use." The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA and other governmental agencies do, however, restrict communications on the subject of off-label use by a manufacturer or those acting on behalf of a manufacturer, and companies may not promote FDA-approved drugs for off-label uses. Marketed products are subject to continued regulatory oversight by the FDA's Office of Prescription Drug Promotion. Certain products approved by the FDA may only be marketed if the promotional materials advertising such products carry certain warnings. Failure to comply with applicable regulations could result in marketing restrictions, financial or criminal penalties and/or other sanctions.

The Controlled Substances Act imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products. A principal factor in determining the particular requirements, if any, applicable to a product is its actual or potential abuse profile. The U.S. Drug Enforcement Agency, or DEA, regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Pregabalin is classified as a controlled substance (Schedule V), which could increase the possibility that *Horizant* would be classified as a controlled substance in the future because they are believed to act on the same therapeutic target. If any of our product candidates contains a scheduled substance, it would be subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, and the DEA would regulate the amount of the scheduled substance that would be available for clinical trials and commercial distribution.

We and our collaborative partners also are subject to a variety of foreign regulations governing clinical trials and the marketing of our products. Outside the United States, our ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we and our collaborative partners will only be permitted to commercialize our products if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality and efficacy. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The time needed to secure approval may be longer or shorter than that required for FDA approval. The regulatory approval and oversight process in other countries includes all of the risks associated with the FDA process described above.

Pharmaceutical Pricing and Reimbursement

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental change. Initiatives to reduce the federal deficit and to reform healthcare delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review

[Table of Contents](#)

and assess alternative benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls on pharmaceuticals and other fundamental changes to the healthcare delivery system. Any proposed or actual changes could limit or eliminate our spending on development projects and affect our ultimate profitability. In March 2010, the Patient Protection Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 were signed into law. Such laws are anticipated to have a wide range of effects on the management of healthcare in the United States, including potentially on the pricing and availability of government reimbursement for pharmaceutical products. The full effect of the healthcare reform acts are still unknown, and we are evaluating the impact such laws could have on our business. Legislative debate is expected to continue in the future, and market forces are expected to drive reductions of healthcare costs.

In both domestic and foreign markets, sales of any products for which we or our collaborative partners receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare product candidates. We or our collaborative partners may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective.

Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, Medicare beneficiaries are eligible to obtain subsidized prescription drug coverage from a choice of private sector plans. Approximately 90% of Medicare beneficiaries now have coverage for prescription medicines. The use of pharmaceuticals has increased slightly among some patients as the result of the expanded access to medicines afforded by coverage under Medicare. However, such expanded utilization has been largely offset by increased pricing pressure and competition due to the enhanced purchasing power of the private sector plans that negotiate on behalf of Medicare beneficiaries and by an increase in the use of generic medicines in this population.

Facilities

We lease approximately 162,000 square feet of office and laboratory space in two adjacent buildings in Santa Clara, California, where we conduct our operations in one of the buildings and the other is vacant. The leases expire concurrently in August 2013, although we have the option to extend both leases for two additional terms of five years each. The 2011 aggregate annual rental amount payable under the leases was approximately \$5.5 million.

Employees

As of December 31, 2011, we had 112 full-time employees, 68 of whom were engaged in product development activities. Sixty-six employees hold post-graduate degrees, including five with M.D. degrees and 26 with Ph.D. degrees. Our employees are not represented by a collective bargaining agreement. We believe our relations with our employees are good.

Executive Officers of the Registrant

The following sets forth certain information regarding our executive officers as of February 1, 2012:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Ronald W. Barrett, Ph.D.	56	Chief Executive Officer and Director
Vincent J. Angotti	44	Senior Vice President, Chief Commercialization Officer
Gianna M. Bosko.	42	Senior Vice President, Chief Administrative Officer, General Counsel and Secretary
Kenneth C. Cundy, Ph.D.	52	Senior Vice President of Preclinical and Clinical Sciences
William G. Harris	53	Senior Vice President of Finance and Chief Financial Officer
David R. Savello, Ph.D.	66	Senior Vice President of Development Operations

[Table of Contents](#)

Ronald W. Barrett is one of our founders and has served as our chief executive officer since September 2001. He served as our chief scientific officer from 1999 to 2001. Dr. Barrett has been a director since August 1999. From 1989 to 1999, he held various positions at Affymax Research Institute, a company employing combinatorial chemistry and high-throughput target screening for drug discovery, the most recent of which was senior vice president of research. Glaxo Wellcome plc, a pharmaceutical company, acquired Affymax Research Institute in 1995. Glaxo Wellcome subsequently merged with SmithKline Beecham plc, a pharmaceutical company, in 2000 to form GlaxoSmithKline plc, a pharmaceutical company. Prior to Affymax Research Institute, Dr. Barrett was a molecular pharmacologist in the Neuroscience Group at Abbott Laboratories, a healthcare company, from 1986 to 1989. Dr. Barrett received a B.S. from Bucknell University and a Ph.D. in pharmacology from Rutgers University.

Vincent J. Angotti has been our senior vice president and chief commercialization officer since May 2008. From 2001 to 2008, he held several positions with Reliant Pharmaceuticals, Inc., a pharmaceutical company, the most recent of which was senior vice president of sales and marketing. GlaxoSmithKline acquired Reliant Pharmaceuticals in 2008. Prior to Reliant Pharmaceuticals, from 1991 to 2001, Mr. Angotti held several positions at Novartis Pharmaceuticals Corporation, a pharmaceutical company, most recently as executive director, field operations. Mr. Angotti received a B.S. from Cornell University and an M.B.A. from Columbia University.

Gianna M. Bosko has been our senior vice president, chief administrative officer, general counsel and secretary since August 2010. She was previously our vice president, general counsel and secretary from 2007 to 2010, and senior corporate counsel from 2005 to 2007. From 2004 to 2005, Ms. Bosko was a legal consultant, providing general corporate and in-house legal consulting services for private and public companies, including Xenoport. From 1996 to 2004, she was an associate at Cooley LLP, a law firm, practicing general corporate and securities law, with an emphasis on securities transactions and mergers and acquisitions. Ms. Bosko received an A.B. from Stanford University and a J.D. from the University of Chicago Law School.

Kenneth C. Cundy has been our senior vice president of preclinical and clinical sciences since November 2010. He was previously our senior vice president of preclinical development from 2004 to November 2010. He was our vice president of biopharmaceutics from 2000 to 2004. From 1992 to 2000, he was senior director of biopharmaceutics at Gilead Sciences, Inc. Prior to Gilead Sciences, from 1988 to 1992, Dr. Cundy was principal research investigator at Sterling Drug, a pharmaceutical division of Eastman Kodak Company. He received a B.S. from the University of Manchester and a Ph.D. in pharmaceutical sciences from the University of Kentucky.

William G. Harris has been our senior vice president of finance and chief financial officer since November 2001. From 1996 to 2001, he held several positions with Coulter Pharmaceutical, Inc., a biotechnology company engaged in the development of novel therapies for the treatment of cancer and autoimmune diseases, the most recent of which was senior vice president and chief financial officer. Corixa Corp., a developer of immunotherapeutic products, acquired Coulter Pharmaceutical in 2000. Prior to Coulter Pharmaceutical, from 1990 to 1996, Mr. Harris held several positions at Gilead Sciences, the most recent of which was director of finance. Mr. Harris received a B.A. from the University of California, San Diego and an M.B.A. from Santa Clara University, Leavey School of Business and Administration.

David R. Savello has been our senior vice president of development operations since November 2010. He was previously our senior vice president of development from 2007 to November 2010. He was responsible for our regulatory affairs, quality and project management from 2005 to 2007. From 1999 to 2005, Dr. Savello was executive vice president and chief scientific officer for the Pharmaceutical Technology and Services Sector of Cardinal Health, Inc. Prior to joining Cardinal Health, from 1997 to 1999, he was senior vice president for drug development at Guilford Pharmaceuticals Inc. From 1985 to 1997, Dr. Savello held several positions at Glaxo and Glaxo Wellcome including both vice president of drug development and vice president of regulatory affairs and compliance. Prior to that, he held R&D management and executive management positions at Boehringer Ingelheim GmbH, and 3M Company. Dr. Savello received his B.S. degree from the Massachusetts College of Pharmacy and both an M.S. and a Ph.D. in pharmaceuticals from the University of Maryland School of Pharmacy.

[Table of Contents](#)

About XenoPort

We were incorporated in Delaware in May 1999. Our principal offices are located at 3410 Central Expressway, Santa Clara, California 95051, and our telephone number is (408) 616-7200. Our Web site address is www.XenoPort.com. Information found on, or accessible through, our Web site is not a part of, and is not incorporated into, this Annual Report on Form 10-K. XENOPORT, the XenoPort logo and Transported Prodrug are our trademarks. Service marks, trademarks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners. Unless the context requires otherwise, references in this Annual Report on Form 10-K to "the company," "we," "us" and "our" refer to XenoPort, Inc.

Available Information

We file electronically with the U.S. Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our Web site at www.XenoPort.com, free of charge, copies of these reports as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Further, copies of these reports are located at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a Web site that contains reports, proxy and information statements, and other information regarding our filings, at www.sec.gov.

Item 1A. Risk Factors.

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

Risks Related to Our Business and Industry

We have incurred cumulative operating losses since inception, we expect to continue to incur losses for the foreseeable future and we may never sustain profitability.

We have a limited operating history and have incurred cumulative losses of \$420.8 million since our inception in May 1999, including net losses of \$33.4 million, \$82.5 million and \$66.3 million for the years ended December 31, 2011, 2010 and 2009, respectively. If we decide to establish a sales force or achieve regulatory approval of additional product candidates, we may incur significant expenses. Annual losses have had, and will continue to have, an adverse effect on our stockholders' equity.

Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve or sustain profitability. On April 6, 2011, the U.S. Food and Drug Administration, or FDA, approved our first product, known in the United States as *Horizant* (gabapentin enacarbil) Extended-Release Tablets, for the treatment of moderate-to-severe primary restless legs syndrome, or RLS, in adults. Glaxo Group Limited, or GSK, began promoting *Horizant* in the United States in July 2011 pursuant to a collaboration agreement with us. On January 17, 2012, the Japanese Ministry of Health, Labor and Welfare, or MHLW, approved Astellas Pharma Inc.'s new drug application, or NDA, for the use of gabapentin enacarbil, which will be known as *Regnite* in Japan, as a treatment for patients with RLS.

To date, we have not generated substantial revenue from *Horizant* or *Regnite*. We have financed our operations primarily through the sale of equity securities, non-equity payments from collaborative partners and interest earned on investments. We have devoted substantially all of our efforts to research and development,

[Table of Contents](#)

including clinical trials. If we or our collaborative partners are unable to develop and commercialize our product candidates, if development is delayed or if sales-related revenue from *Horizant*, *Regnite* or any other product candidate that receives marketing approval is insufficient, we may never become profitable. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our success depends substantially on the success of Horizant and Regnite, and we currently depend on GSK and Astellas to commercialize Horizant and Regnite, respectively. If GSK or Astellas do not successfully market and sell Horizant and Regnite, we may be unable to generate significant product revenue from Horizant and Regnite.

GSK commercially launched *Horizant* in the United States in July 2011. Until such time, if any, as we exercise the right to revert to a net sales royalty under the GSK collaboration agreement, assuming the agreement is not terminated, we are sharing profits and losses from net sales of *Horizant*. Although we have elected the co-promotion arrangement, we have the right to delay the deployment of our sales force for up to three years following the approval of *Horizant* in the United States, and our share of losses from the joint profit and loss will be forgiven up to a maximum of \$10.0 million. Under the terms of the collaboration agreement, as currently in effect, prior to the time that we establish our sales force, GSK remains responsible for the commercialization of *Horizant* for RLS and any other indications that may obtain regulatory approval. We have limited control over the amount and timing of resources that GSK dedicates to the marketing of *Horizant*. Our ability to generate revenue from our co-promotion and contingent payments from GSK depends on GSK's ability to achieve market acceptance of, and to otherwise effectively market, *Horizant* for the treatment of RLS. For the year ended December 31, 2011, net sales in the United States of *Horizant* as recorded by GSK were only \$2.0 million. We believe that GSK has failed to devote sufficient resources to the commercialization, marketing and distribution of *Horizant*, including by failing to develop or expand the sales forces necessary for the most effective promotion of *Horizant*. For example, as part of a restructuring within its organization in 2011, GSK realigned its promotion efforts on *Horizant*, including reducing the number of territories represented by its neurology-focused sales team primarily promoting *Horizant* from approximately 500 to 300 territories. In addition, in 2011, GSK announced new corporate policies, including that it would no longer use individual sales targets as a component of compensation for its sales force. In January 2012, we delivered a notice of dispute and notice of breach and termination to GSK, and in February 2012, we and GSK each initiated legal proceedings in connection with the collaboration agreement. If our collaboration agreement with GSK is not terminated and GSK does not increase the amount of resources promoting *Horizant*, the commercial potential of *Horizant* will be harmed or limited and our business will suffer. In the event that our agreement with GSK terminates and commercialization rights to *Horizant* revert to us, we may be unable to successfully market and sell *Horizant* or enter into arrangements with third parties to do so.

In addition, GSK (or we, in the event that our agreement with GSK terminates and commercialization rights to *Horizant* revert to us) could fail to comply with applicable regulatory guidelines with respect to the marketing and manufacturing of *Horizant* or with post-marketing commitments or requirements mandated by the FDA, which could result in administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of production and refusal to approve any NDAs. Any of these results could limit or prevent our or GSK's ability to successfully market and sell *Horizant*, and we may be unable to generate significant product revenue from *Horizant*.

Regnite was approved in Japan in January 2012. We will receive mid-teen royalties on any net sales of *Regnite*. We have limited control over the amount and timing of resources that Astellas will dedicate to the marketing of *Regnite*, and Astellas could fail to commercialize, market and distribute *Regnite*.

Horizant or *Regnite* may not achieve significant sales, even if we, GSK or Astellas devote substantial resources to its commercialization. The success of *Horizant* and *Regnite* is dependent on a number of factors, which include competition from alternative treatments for RLS, including generic treatments in the United States, pricing pressures and whether *Horizant* and *Regnite* can obtain sufficient third-party coverage or reimbursement, among other factors that are described below.

[Table of Contents](#)

We and GSK have each initiated litigation proceedings related to the collaboration agreement, and we have delivered a notice of termination of the agreement to GSK. The timing and outcome of such legal proceedings are uncertain, and such proceedings could be costly and divert management's time and attention, thereby harming our business.

In January 2012, we provided notice, or the Notice, to GSK of our belief that, among other matters, GSK has materially breached its contractual obligation to use commercially reasonable efforts to (i) maximize the sales of *Horizant* in an expeditious manner and (ii) achieve the sales milestones set forth in our collaboration agreement. The collaboration agreement provides that we may terminate the agreement in the event that GSK shall have materially breached or defaulted in the performance of any of its material obligations under the agreement, and such default shall have continued for 90 days after the date of GSK's receipt of written notice of the breach. The Notice provides that any such termination would become effective at the end of such 90-day period, which will expire on April 24, 2012, unless GSK has cured any such breach or default prior to such date. If the agreement is terminated as a result of breach by GSK, certain *Horizant* product rights would revert to us, and we would be entitled to specified transition assistance from GSK.

However, on February 23, 2012, GSK filed a complaint, or the GSK Complaint, in the United States District Court for the District of Delaware naming us and other unspecified individuals as defendants. Pursuant to the GSK Complaint, GSK is seeking declaratory judgment that it is not in breach of the collaboration agreement and that we do not have the right to terminate the collaboration agreement as a result of GSK's performance under the agreement to date. Following the expiration of the contractually specified period of time for resolution of the dispute by the requisite officers of the parties, on February 24, 2012, we filed a complaint, or the XenoPort Complaint, in the Superior Court of the State of California in the County of Santa Clara against GSK and its affiliates, GlaxoSmithKline LLC and GlaxoSmithKline Holdings (Americas) Inc., for breach of contract, fraud, breach of fiduciary duty, breach of the covenant of good faith and fair dealing and unfair competition. Pursuant to the XenoPort Complaint, in addition to injunctive and equitable relief, we are seeking damages for lost profits, damage to the value of *Horizant* and unattained royalties and milestone payments in an amount to be proven at trial, as well as punitive damages and restitution.

We cannot predict the outcome of the litigation related to the GSK Complaint and the XenoPort Complaint or when or if the collaboration agreement will be terminated or the ultimate terms of any termination of the agreement. These lawsuits are subject to inherent uncertainties, including with respect to the timing and ultimate outcome of any resolution thereof, and the actual cost of pursuing or defending these lawsuits will depend upon many unknown factors. Pursuing or defending these legal proceedings will also be time-consuming for our management and will detract from our ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with this litigation, and may not prevail in either of these legal proceedings. In addition, the uncertainty of the litigation could lead to more volatility in our stock price and more uncertainty as to the prospects for *Horizant*.

If the commercialization rights to Horizant revert to us and we are unable to establish sales, marketing and distribution capabilities to market Horizant, or enter into arrangements with third parties to do so, sales of Horizant and our business will be harmed.

In the event that our agreement with GSK terminates and product rights to *Horizant* revert to us, we may need to obtain the assistance of a pharmaceutical company or other entity with a large distribution system and a large direct sales force, or we may need to build a substantial marketing and sales force with appropriate technical expertise and supporting distribution capabilities. We may not be able to enter into such arrangements with third parties in a timely manner or on acceptable terms, or to establish sales, marketing and distribution capabilities of our own. Such additional contracting or development of a sales organization could be time-consuming and delay our potential commercialization of *Horizant*.

If we establish our own sales force, factors that may inhibit our efforts to commercialize *Horizant* or any other approved product candidates include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

[Table of Contents](#)

- the inability of sales personnel to obtain access to adequate numbers of physicians to provide information on the advantages and risks of prescribing *Horizant* or other products that may result from our product candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage compared to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

In the event we do establish a sales force, the competition for qualified personnel in the pharmaceutical and biotechnology field is intense, and we may experience difficulties in recruiting, hiring and retaining qualified individuals. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. If the commercialization rights to *Horizant* revert to us, our future financial performance and, if we do establish a sales force, our ability to commercialize *Horizant* and compete effectively will depend, in part, on our ability to manage any future growth effectively. Because of the numerous risks and uncertainties involved with establishing our own sales and marketing capabilities, we are unable to predict when, or if, we will establish our own sales and marketing capabilities. If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing *Horizant* or our product candidates, which would adversely affect our business and financial condition.

Our success also depends substantially on our advanced product candidates that are still under development. If we or our collaborative partners are unable to bring any of these product candidates to market, or experience significant delays in doing so, our ability to generate product revenue and our likelihood of success will be reduced.

Our ability to generate product revenue in the future will depend heavily on the successful development and commercialization of our product candidates. GSK filed a 505(b)(2) supplemental NDA, or sNDA, with the FDA in August 2011 for *Horizant* for the potential management of postherpetic neuralgia, or PHN. We have initiated a Phase 3 clinical program to evaluate our second product candidate, arbaclofen placarbil, or AP (previously known as XP19986), for the potential treatment of spasticity in multiple sclerosis, or MS, patients. Our other product candidates are either in Phase 2 clinical development or in various stages of preclinical development. Any of our product candidates could be unsuccessful if it:

- does not demonstrate acceptable safety and efficacy in preclinical studies or clinical trials or otherwise does not meet applicable regulatory standards for approval;
- does not offer therapeutic or other improvements over existing or future drugs used to treat the same conditions;
- is not capable of being produced in commercial quantities at acceptable costs;
- is not accepted in the medical community; or
- is not reimbursed by third-party payors or is reimbursed only at limited levels.

For example, in March 2011, we announced that we would not be investing further in the development of AP at this time as adjunctive treatment of gastroesophageal reflux disease, or GERD, following completion of a Phase 2 clinical trial of AP that did not demonstrate statistically significant improvements of AP over placebo in the analysis of the primary endpoint. In addition, in December 2011, following our preliminary results of a Phase 2 clinical trial of XP21279 for the potential treatment of patients with Parkinson's disease who were experiencing motor fluctuations, we announced that we plan to defer further investment in the program pending the outcome of our data analysis and discussions with Parkinson's disease experts and possibly regulatory authorities. If we or our collaborative partners are unable to make additional product candidates commercially available, we may not be able to generate substantial product revenues, which would adversely affect our business and financial condition. The results of our clinical trials to date do not provide assurance that acceptable efficacy or safety will be shown upon completion of future clinical trials.

[Table of Contents](#)

If we or our partners are not able to obtain or maintain required regulatory approvals, we or our partners will not be able to commercialize Horizant, Regnite or our product candidates, our ability to generate revenue will be materially impaired and our business will not be successful.

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA and other agencies in the United States and by comparable authorities in other countries. The inability to obtain or maintain FDA approval or approval from comparable authorities in other countries would prevent us and our collaborative partners from commercializing *Horizant*, *Regnite* or our product candidates in the United States or other countries. Although *Horizant* and *Regnite* have been approved for commercial sale in the United States and Japan, respectively, we or our collaborative partners may never receive regulatory approval for the commercial sale of our product candidates, including *Horizant* for the management of PHN and AP for the treatment of spasticity. In addition, even if a product candidate ultimately receives regulatory approval, the regulatory process may include significant delays that could harm our business. For example, in February 2010, GSK received a Complete Response letter from the FDA in which a preclinical finding of pancreatic acinar cell tumors in rats precluded approval of the *Horizant* NDA for the treatment of RLS at that time. GSK responded to questions raised by the FDA in the Complete Response letter with an NDA resubmission, which included new data from nonclinical studies of *Horizant* and two epidemiology studies conducted by GSK exploring gabapentin use and cancer based on the UK General Practice Research Database, as well as a final safety update that provided updated or new safety information on patients in clinical studies who had been treated with *Horizant*. GSK also amended the NDA from a Section 505(b)(1) to a 505(b)(2) application in order for the FDA to be able to consider published gabapentin nonclinical data in their assessment of *Horizant*. *Horizant* subsequently received approval from the FDA in April 2011. However, our business was harmed due to the delay in obtaining approval for *Horizant* as a treatment for RLS. Moreover, if the FDA requires that any of our products or product candidates be scheduled by the U.S. Drug Enforcement Agency, or DEA, we or our collaborative partners will be unable to continue or begin commercial sale of that product until the DEA completes scheduling proceedings. If any of our products or product candidates is classified as a controlled substance by the DEA, we or our collaborative partners would have to register annually with the DEA and those products or product candidates would be subject to additional regulation.

We have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of applying for regulatory approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the product candidates involved. The application process begins with the submission of an NDA that the FDA initially reviews and either accepts or rejects for filing. NDA submissions are complex electronic filings, which include vast compilations of data sets, integrated documents and data calculations. The FDA has substantial discretion in the submission process and may refuse to accept an NDA submission for insufficient information or if there are errors or omissions relating to the electronic transmittal process, data entry, data compilation or formatting. For example, in November 2008, GSK withdrew a previously submitted NDA for *Horizant* for the treatment of RLS in connection with the FDA's request that the data from a single study be reformatted.

Changes in the regulatory approval policy during the development period, changes in, or the enactment of, additional regulations or statutes or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an NDA. If the FDA were to miss a Prescription Drug User Fee Act, or PDUFA, timing goal for one of our product candidates, the development and commercialization of the product candidate could be delayed or impaired. For example, in November 2009, the FDA notified GSK that it was extending the PDUFA timing goal for *Horizant* for the treatment of RLS to February 2010, and it is possible that the FDA could extend the PDUFA timing goal for *Horizant* for the management of PHN. In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, mandates FDA advisory committee reviews of all new molecular entities as part of the NDA approval process, although the FDA maintains discretion under FDAAA to approve NDAs for new molecular entities without advisory committee reviews in certain instances. The FDA may convene an advisory committee at any time during the review process. The advisory committee review process can be a lengthy and uncertain process that could delay the FDA's NDA approval and delay or impair the development and commercialization of our product candidates.

[Table of Contents](#)

The FDA has substantial discretion in the approval process and may refuse to approve any application or decide that our or our collaborative partners' data is insufficient for approval and require additional preclinical, clinical or other studies. Varying interpretations of the data obtained from preclinical and clinical testing or other studies could delay, limit or prevent regulatory approval of any of our product candidates. For example, in the epidemiology studies that GSK conducted in connection with the *Horizant* NDA resubmission, some significant associations between gabapentin use and cancer were seen in the analyses, but only when no time lag was used and/or cumulative dose was low, duration of exposure was low or number of prescriptions was low. When analyses were conducted that took into account two common potential sources of bias in epidemiology studies — protopathic bias and carcinogenic latency — the studies did not demonstrate significant associations between gabapentin use and cancer. In total, we believe that these observations were inconsistent with gabapentin being a carcinogen. Protopathic bias can occur when a pharmaceutical agent is prescribed for an early manifestation of a disease that has not yet been diagnostically detected or formally recorded in the medical record. In this case, gabapentin use could appear to be associated with cancer because it could be prescribed for pain (a common symptom of certain cancers) prior to the diagnosis of the underlying cancer. Carcinogenic latency refers to the time gap between the moment that a drug initiates a carcinogenic process and the time that a tumor is diagnosed and entered into the database. Epidemiologists often use a time lag between drug use and cancer diagnosis when selecting cases to be included in analyses in order to eliminate false positives that are biologically implausible. The FDA does not define standards for controlling protopathic bias or appropriate time lags for considering carcinogenic latency.

As part of their review process, the FDA could require additional studies or trials to satisfy particular safety concerns. For example, although we have had discussions with the FDA regarding the studies that could be required for filing an NDA for AP as a potential treatment of spasticity, the FDA could change their guidance in the future. Thus, although the FDA has indicated that a study to assess the effect of AP on driving would not be required as part of an NDA for AP for spasticity at this time, FDA guidance could change in the future and a driving study could be required at a later date.

Even if the FDA or other regulatory agency approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product and may impose ongoing commitments or requirements for post-approval studies, including additional research and development and clinical trials, and we or our collaborative partners may be unable to maintain regulatory approvals for our products. For example, the FDA approval for *Horizant* for the treatment of RLS included requirements for GSK to conduct a number of post-marketing studies, including a 12-week, double-blind, placebo-controlled efficacy study, two simulated driving studies, a drug-drug interaction study with morphine and a cardiovascular safety, or QTc, study. As part of this program, the FDA also requested an evaluation of 300 mg and 450 mg tablets of *Horizant*, dosed once per day, as a post-marketing commitment, or PMC. GSK will also conduct a pediatric program for subjects 13 years and older. The specific protocol submission and trial completion dates for these studies range from April 2011 through July 2024. In the event that our collaboration agreement with GSK terminates and rights to *Horizant* revert to us, we may be responsible for fulfilling these post-marketing study requirements, which could increase our costs and divert management time and resources away from our commercialization efforts or the development of our product candidates. In addition, the FDA and other agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

We and our collaborative partners will need to obtain regulatory approval from authorities in foreign countries to market our product candidates in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we or our collaborative partners fail to obtain approvals from foreign jurisdictions, the geographic market for our product candidates would be limited.

[Table of Contents](#)

Although we have reached agreement with the FDA on a Special Protocol Assessment, or SPA, relating to our pivotal Phase 3 clinical trial of AP for the treatment of spasticity in patients with MS, this agreement does not guarantee any particular outcome with respect to regulatory review of the pivotal trial or with respect to regulatory approval of AP.

The protocol for the pivotal Phase 3 clinical trial of AP for the treatment of spasticity in patients with MS was reviewed by the FDA under the SPA process, which allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of an NDA and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. Reaching agreement with the FDA on an SPA is not an indication of approvability. Even if we believe that the data from the pivotal Phase 3 clinical trial are supportive, an SPA agreement is not a guarantee of approval, and we cannot be certain that the design of, or data collected from, the pivotal Phase 3 clinical trial will be adequate to demonstrate the safety and efficacy of AP for the treatment of spasticity in patients with MS, or will otherwise be sufficient to support FDA or any foreign regulatory approvals. Further, the SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise, new drugs are approved in the same indication or if we fail to comply with the agreed upon trial protocols. In addition, the SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from the pivotal Phase 3 clinical trial. As a result, we do not know how the FDA will interpret the parties' respective commitments under the SPA agreement, how it will interpret the data and results from the pivotal trial or whether AP will receive any regulatory approvals. Therefore, despite the potential benefits of the SPA agreement, significant uncertainty remains regarding the clinical development of and regulatory approval process for AP for the treatment of spasticity in patients with MS, and it is possible that we might never receive any regulatory approvals for AP.

We depend on collaborations to complete the development and commercialization of some of our product candidates. These collaborations may place the development of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

In December 2005, we entered into a collaboration agreement with Astellas for the development and commercialization of gabapentin enacarbil, also known as *Regnite*, in Japan, Korea, the Philippines, Indonesia, Thailand and Taiwan. In February 2007, we entered into an exclusive collaboration with GSK to develop and commercialize gabapentin enacarbil (also known by the trade name *Horizant* (gabapentin enacarbil) Extended-Release Tablets in the United States) worldwide, excluding the Astellas territory. In November 2010, we amended and restated our collaboration agreement with GSK, pursuant to which we reacquired all rights to gabapentin enacarbil outside of the United States previously granted to GSK and obtained the right to pursue development of *Horizant* for: (i) the potential treatment of diabetic peripheral neuropathy, or DPN; (ii) the potential treatment of PHN, to the extent that a product label would reflect a superiority claim over a currently approved drug; and (iii) any additional indications in the United States.

We may enter into additional collaborations with third parties to further develop and commercialize gabapentin enacarbil and/or to develop and commercialize some of our product candidates. Our dependence on Astellas and GSK for the development and commercialization of *Regnite* and *Horizant*, respectively, subjects us to, and our dependence on future collaborators for development and commercialization of our product candidates will subject us to, a number of risks, including:

- we are not able to control the amount and timing of resources that Astellas and GSK devote to the development or commercialization of *Regnite* and *Horizant*, respectively, or to their marketing and distribution;
- disputes may arise between us and our collaborators, such as the current litigation proceedings with GSK, that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;

[Table of Contents](#)

- we may not be able to control the amount and timing of resources that our potential future collaborators may devote to the development or commercialization of product candidates or to their marketing and distribution;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- if we co-promote a product with a collaborator, if we do not receive timely and accurate information from our collaborator regarding sales activities, expenses and resulting operating profits and losses, our estimates at a given point of time could be incorrect and we could be required to record adjustments in future periods or restate our financial results for prior periods;
- collaborators may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;
- collaborators may receive regulatory sanctions relating to other aspects of their business that could adversely affect the approval or commercialization of our product candidates;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors;
- collaborators may experience financial difficulties; and
- the collaborations may be terminated or allowed to expire, which would delay the development or commercialization and may increase the cost of developing or commercializing our product candidates.

For example, in October 2007, we entered into a collaboration agreement with Xanodyne Pharmaceuticals, Inc. for the development and commercialization of XP21510 in the United States. Effective July 2009, Xanodyne terminated the collaboration agreement.

As a further example, we cannot control the process for securing FDA approval of *Horizant* for the potential management of PHN. GSK is responsible for all interactions with the FDA. If the FDA requires additional studies or trials evaluating the safety or efficacy of *Horizant* for PHN, or imposes conditions on any approval of *Horizant* for the management of PHN, GSK would be responsible for performing such studies or trials and would control decisions with respect to the acceptance and implementation of any conditions to approval. We cannot control the amount and timing of resources that GSK or Astellas devotes to the development or commercialization of *Horizant* or *Regnite*, respectively, or their marketing and distribution. In February 2010, GSK announced that it proposed to cease discovery research in certain neuroscience areas, including depression and pain. GSK or Astellas may abandon further development or the pursuit of regulatory approval of *Horizant* or *Regnite* and may terminate their respective collaboration agreements with us at any time, which could delay or impair the development and commercialization of *Horizant* or *Regnite* and harm our business.

If we do not establish collaborations for our product candidates, we will have to alter our development and commercialization plans.

Our strategy includes selectively collaborating with leading pharmaceutical and biotechnology companies to assist us in furthering development and potential commercialization of some of our product candidates. We intend to do so, especially for indications that involve a large, primary care market that must be served by large sales and marketing organizations. We face significant competition in seeking appropriate collaborators, and these collaborations are complex and time consuming to negotiate and document. We may not be able to

[Table of Contents](#)

negotiate additional collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional collaborations because of the numerous risks and uncertainties associated with establishing additional collaborations. If we are unable to negotiate additional collaborations, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, reduce the scope of our sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenues.

We will continue to need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will continue to need to raise additional capital to fund our operations and complete the development of our product candidates. In addition, we may need to raise additional capital to fund our commercialization efforts, including the potential establishment of a sales force and marketing and distribution capabilities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress, results and cost of our preclinical testing, clinical trials and other research and development activities;
- the timing and amount of our share of operating losses from our GSK collaboration;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from *Horizant*, *Regnite* and our other potential products;
- the timing of any milestone and contingent payments under our collaborative arrangements;
- the costs and expenses associated with the litigation proceedings related to the XenoPort Complaint, the GSK Complaint and the notice of termination of the collaboration agreement with GSK;
- if our collaboration with GSK is not terminated, the timing and costs of our establishment of a sales force to support our co-promotion of *Horizant* for the treatment of RLS, if we establish a sales force;
- if our collaboration with GSK is terminated and rights to *Horizant* revert to us, the timing and costs of establishing third party arrangements to market and sell *Horizant* if we choose or are unable to establish sufficient sales, marketing and distribution capabilities on our own;
- the cost of manufacturing clinical, and establishing commercial, supplies of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue, including rights related to *Horizant* that we obtained pursuant to our amended and restated collaboration agreement with GSK or that we may obtain if the collaboration with GSK is terminated;
- the cost, timing and outcomes of regulatory approvals, if any;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish or modify;
- the cost and expenses associated with any potential litigation, including any further litigation arising from our collaboration agreement with GSK;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the extent of product development funding under our current collaborative arrangements; and
- the extent to which we acquire or invest in businesses, products or technologies that complement our business, although we have no commitments or agreements relating to any of these types of transactions.

[Table of Contents](#)

Until we can generate a sufficient amount of product revenues, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. If we raise additional funds by issuing our common stock, or securities convertible into or exchangeable or exercisable for common stock, our stockholders will experience dilution. Any debt financing or additional equity that we raise may contain terms that are not favorable to our stockholders or us. To the extent that we raise additional capital through licensing arrangements or arrangements with collaborative partners, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize ourselves. Our ability to raise additional funds and the terms upon which we are able to raise such funds may be adversely impacted by the uncertainty regarding our financial condition, the outcome of the litigation proceedings with GSK, including whether our collaboration with GSK will terminate and on what terms, and/or current economic conditions, including the effects of disruptions to and volatility in the credit and financial markets in the United States, the European Union and other regions of the world, including those resulting from or associated with rising government debt levels.

We believe that our existing capital resources and anticipated milestone payments, together with interest thereon, will be sufficient to meet our projected operating requirements into the third quarter of 2013. This estimate assumes receipt of a potential \$10.0 million milestone payment from GSK associated with the possible approval of *Horizant* for the management of PHN, assuming such approval occurs and the collaboration agreement with GSK is effective at the time of such approval. We have based our cash sufficiency estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We have no credit facility or committed sources of capital other than potential milestones receivable under our current collaborations.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not, or we anticipate that they may not be, available on a timely basis, we may:

- terminate or delay clinical trials for one or more of our product candidates;
- curtail significant drug development programs that are designed to identify new product candidates;
- delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize *Horizant* or our product candidates; or
- exercise the right to revert to a net sales royalty-based compensation structure and forego the right to co-promote *Horizant* in the United States, if our agreement with GSK is not terminated.

For example, in January 2009, we suspended preclinical development activities for XP20925, our Transported Prodrug of propofol, to focus our resources on development of later-stage product candidates. In addition, in March 2010, as a result of the Complete Response letter that precluded approval of the *Horizant* NDA for RLS in its form at that time, we implemented a restructuring plan to reduce expenses, focus our resources on advancement of our later-stage product candidates and eliminate our discovery research efforts. In connection with this restructuring, we postponed the commencement of additional clinical trials of AP as a potential treatment for spasticity until 2011 to focus our clinical development resources on the completion of the Phase 2 clinical trial of AP as a potential treatment for GERD.

If our preclinical studies do not produce successful results or our clinical trials do not demonstrate safety and efficacy in humans, we will not be able to commercialize our product candidates.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical studies and clinical trials, that the product candidate is safe and effective in humans. Preclinical and clinical testing is expensive, can take many years and has an uncertain outcome. A failure of one or more of our clinical trials could occur at any stage of testing. For example, in July 2010, GSK announced top-line results from a 30-week, double-blind, placebo-controlled, Phase 2 clinical trial of *Horizant* as a potential prophylactic treatment for migraine headaches in which *Horizant* did not demonstrate a

[Table of Contents](#)

statistically significant improvement on the primary endpoint when compared to placebo. Long-term safety concerns may also prevent the approval of any of our product candidates by a regulatory authority. For example, in February 2010, safety concerns related to a preclinical finding of pancreatic acinar cell tumors in rats precluded FDA approval of the *Horizant* NDA for RLS in its form at that time. In addition, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process, which could delay or prevent our or our collaborative partners' ability to commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial at a prospective trial site;
- our preclinical testing or clinical trials may produce negative or inconclusive results, which may require us to conduct additional preclinical or clinical testing or to abandon projects that we expect to be promising;
- we may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks;
- risks associated with clinical trial design may result in a failure of the clinical trial to show statistically significant results even if the product candidate is effective;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects.

As an example of an unforeseen event, after having been discharged from a Phase 1 clinical trial in which a single dose of *Horizant* was administered almost two days earlier, a volunteer died of a self-inflicted gunshot wound following a domestic dispute. We do not believe that this incident was related to *Horizant*. However, any unforeseen event could cause us to experience significant delays in, or the termination of, clinical trials. Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which would adversely impact our financial results.

Any failure or delay in commencing or completing clinical trials for our product candidates could severely harm our business.

The commencement and completion of clinical trials for our product candidates may be delayed or terminated as a result of many factors, including:

- delays in patient enrollment, which we have experienced in the past, unanticipated high patient drop-out rates and variability in the number and types of patients available for clinical trials;
- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of product candidates during clinical trials;
- unforeseen safety issues or side effects; and
- governmental or regulatory delays and changes in regulatory requirements, policies and guidelines.

For example, based on the results of a planned interim analysis of the clinical data, although no safety concerns were noted, Astellas terminated its Phase 2 clinical trial of *Regnite* as a potential treatment for DPN due to difficulty in demonstrating a statistically significant advantage of *Regnite* over placebo. As a result, Astellas does not intend to continue the development of *Regnite* in Japan as a potential treatment for DPN at this time. Any delay in commencing or completing clinical trials for our product candidates would delay commercialization

[Table of Contents](#)

of our product candidates and severely harm our business and financial condition. In addition, unforeseen safety issues or side effects could result from our collaborators' current or future clinical trials, which could delay or negatively impact commercialization of our product candidates. It is also possible that none of our product candidates will complete clinical trials in any of the markets in which we or our collaborators intend to sell those product candidates. Accordingly, we or our collaborators would not receive the regulatory approvals needed to market our product candidates, which would severely harm our business and financial condition.

We rely on third parties to conduct our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.

We do not have the ability to independently conduct clinical trials for our product candidates, and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators, collaborative partners and contract laboratories, to conduct our clinical trials. We have, in the ordinary course of business, entered into agreements with these third parties. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. For example, we need to prepare, and ensure our compliance with, various procedures required under good clinical practices, even though third-party contract research organizations have prepared and are complying with their own, comparable procedures. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates.

As an illustrative example, in 2011, the FDA announced that certain bioanalytical studies conducted by a contract research organization may need to be repeated or confirmed by the pharmaceutical company sponsors of the marketing applications that included such studies. The FDA's decision was the result of two inspections and an internal audit at a facility that identified significant instances of misconduct and violations of federal regulations, including falsification of documents and manipulation of samples. Although we have not contracted with this contract research organization for any studies or clinical trials, if one of the contract research organizations that conducted trials on our behalf were found to have similar or other violations, the FDA may require such trials to be repeated or it may affect the approvability of our product candidates and harm our business.

An NDA submitted under Section 505(b)(2) of the Food, Drug and Cosmetic Act subjects us to the risk that we or a collaborative partner may be subject to a patent infringement lawsuit that would delay or prevent the review and approval of our product candidate.

Certain product candidates that we develop may be submitted to the FDA for approval under Section 505(b)(2) of the Food, Drug and Cosmetic Act, or FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. For example, in connection with the October 2010 *Horizant* NDA resubmission, GSK amended the *Horizant* NDA from a Section 505(b)(1) to a Section 505(b)(2) application in order for the FDA to be able to consider published gabapentin nonclinical data in its assessment of *Horizant*. GSK filed a Section 505(b)(2) supplemental NDA application for *Horizant* as a potential treatment for PHN in August 2011. In addition, if we receive positive results in our Phase 3 clinical trials of AP as a potential treatment for spasticity in MS patients, we intend to file an NDA with the FDA under Section 505(b)(2) seeking approval of AP in this

[Table of Contents](#)

indication. The Section 505(b)(2) application would enable us to reference published literature and the FDA's previous finding of safety and effectiveness for baclofen, a drug that has been approved by the FDA for the alleviation of signs and symptoms of spasticity in patients with MS and may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as Paragraph IV certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book, with respect to any product referenced in the Section 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the Section 505(b)(2) application. Under the Hatch-Waxman Act, the holder of patents that the Section 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) application. Accordingly, we may invest a significant amount of time and expense in the development of one or more products only to be subject to significant delay and patent litigation before such products may be commercialized, if at all. A Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the approved product. The FDA may also reject our future Section 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which could cause delay and be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

The commercial success of Horizant, Regnite or any other products that we or our partners may develop will depend upon the degree of market acceptance among physicians, patients, healthcare payors and the medical community.

Horizant, Regnite or any other products that result from our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues and we may not become profitable. The degree of market acceptance of *Horizant, Regnite* or any products resulting from our product candidates will depend on a number of factors, including:

- the ability to offer such products for sale at competitive prices;
- sufficient third-party coverage or reimbursement for such products;
- the product labeling required by the FDA, the Japanese MHLW or any other regulatory authorities;
- demonstration of efficacy and safety in clinical trials;
- the prevalence and severity of any side effects;
- potential or perceived advantages over alternative treatments;
- perceptions about the relationship or similarity between our product candidates and the parent drug upon which each Transported Prodrug candidate is based;
- the timing of market entry relative to competitive treatments;
- relative convenience and ease of administration; and
- the strength of marketing and distribution support.

[Table of Contents](#)

Our ability to generate revenue from Horizant, Regnite or any other products that we may develop will depend on reimbursement and drug pricing policies and regulations.

In both U.S. and foreign markets, our ability to commercialize our products successfully and to attract strategic partners for our products depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Many patients may be unable to pay for *Horizant*, *Regnite* or any other products that we or our collaborative partners may develop. We cannot be sure that significant reimbursement in the United States, Japan, Europe or elsewhere will be available for *Horizant*, *Regnite* or any other products that we or our partners may develop, and any reimbursement that may become available may be decreased or eliminated in the future. In Japan, under the National Health Insurance, the MHLW sets reimbursement pricing for pharmaceutical products, and will set the price that Astellas may charge for *Regnite*. If the price for *Regnite* is not set at a commercially reasonable level, Astellas may reduce their promotional efforts for, or may not commercialize, *Regnite*. Third-party payors increasingly are challenging prices charged for medical products and services, and many third-party payors may refuse to provide reimbursement for particular drugs when an equivalent generic drug is available. Although we believe *Horizant*, *Regnite* and any other products that may result from our product candidates represent an improvement over the parent drugs upon which they are based and should be considered unique and not subject to substitution by a generic parent drug, it is possible that a third-party payor may consider *Horizant*, *Regnite* or our product candidates and the generic parent drug as equivalents and only offer to reimburse patients for the generic drug. Even if we show improved efficacy or improved convenience of administration with *Horizant*, *Regnite* or our product candidates, pricing of the existing parent drug may limit the amount we will be able to charge for *Horizant*, *Regnite* or our product candidates. If reimbursement is not available or is available only at limited levels, we or our partners may not be able to successfully commercialize *Horizant*, *Regnite* or our product candidates, and may not be able to obtain a satisfactory financial return on such products.

The trend toward managed healthcare in the United States and the changes in health insurance programs, as well as the healthcare reform bill enacted in 2010, may result in lower prices for pharmaceutical products, including *Horizant* or any other products that may result from our product candidates. In addition, any future regulatory changes regarding the healthcare industry or third-party coverage and reimbursement may affect demand for *Horizant* or any other products that we may develop and could harm our sales and profitability.

Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, or the 2003 Medicare Modernization Act, Medicare beneficiaries are eligible to obtain subsidized prescription drug coverage from a choice of private sector plans. Approximately 90 percent of Medicare beneficiaries now have coverage for prescription medicines. The use of pharmaceuticals has increased slightly among some patients as a result of the expanded access to medicines afforded by coverage under Medicare. However, such expanded utilization has been largely offset by increased pricing pressure and competition due to the enhanced purchasing power of the private sector plans that negotiate on behalf of Medicare beneficiaries and by an increase in the use of generic medicines in this population. In addition, legislative changes have been proposed to mandate government rebates in Medicare and to allow the federal government to directly negotiate prices with pharmaceutical manufacturers. If legislation were enacted to mandate rebates or provide for direct government negotiation in Medicare prescription drug benefits, access and reimbursement for *Horizant* or our product candidates upon commercialization could be restricted.

If our competitors are able to develop and market products that are more effective, safer or less costly than Horizant, Regnite or any other products that we may develop, our commercial opportunity will be reduced or eliminated.

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than *Horizant*, *Regnite* or any other products that we may develop. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair our ability to effectively commercialize our product candidates.

[Table of Contents](#)

Products that we believe compete with *Horizant* in the United States include the following drugs approved for the treatment of RLS: Mirapex (pramipexole) from Boehringer Ingelheim and generic pramipexole; and Requip (ropinirole) from GSK and generic ropinirole. In addition, *Horizant* could experience competition from Neupro (the rotigotine transdermal system), a dopamine agonist patch from UCB, which filed its NDA for the treatment of RLS with the FDA in 2007 to which the FDA provided a Complete Response letter in April 2010 that recommended reformulation of Neupro before making it available in the U.S. market for the treatment of RLS. In Japan, we believe that *Regnite* could compete with pramipexole, which was approved in 2010 for the treatment of RLS. In addition, Otsuka Pharmaceutical Co., Ltd. filed an NDA in Japan in December 2011 for the rotigotine transdermal system, which, if approved, could compete with *Regnite*.

If *Horizant* is approved for the management of PHN, products that we believe could compete with *Horizant* in the United States include drugs that act on the same target as *Horizant*, such as Lyrica (pregabalin), Neurontin (gabapentin) from Pfizer Inc., generic gabapentin and Gralise (once-daily formulation of gabapentin) from Depomed, Inc. *Horizant* could also experience competition from a capsaicin patch (marketed as Qutenza by NeurogesX, Inc.) and transdermal patches containing the anesthetic known as lidocaine, which are sometimes used for the management of PHN.

We believe that AP, our product candidate that is a Transported Prodrug of R-baclofen, could experience competition from several generic drugs approved for the treatment of spasticity, including racemic baclofen, diazepam, dantrolene sodium and tizanidine. In addition, the FDA has approved Botox (onabotulinumtoxin A) from Allergan Inc. to treat spasticity in the flexor muscles of the elbow, wrist and fingers in adults. Therapies in development for the treatment of spasticity based on sustained-release versions of baclofen include IPX056 from Impax Laboratories, Inc., and Baclofen GRS from Sun Pharma Advanced Research Company Limited.

Products that could compete with XP21279, our product candidate that is a Transported Prodrug of levodopa, include: generic levodopa/carbidopa drugs and other drugs approved for the treatment of Parkinson's disease, including Stalevo, a combination therapy of levodopa/carbidopa/entacapone that is marketed in the United States by Novartis; dopamine agonists such as Mirapex (pramipexole) as well as Requip (ropinirole) and Requip XL (ropinirole extended-release tablets), which are marketed by Boehringer Ingelheim and GSK, respectively; as well as generic dopamine agonists, including pramipexole and ropinirole. In addition, we could also experience competition from the rotigotine transdermal system (a dopamine agonist patch known as Neupro by UCB) that was previously approved for the treatment of Parkinson's disease; however, in April 2010, the FDA provided UCB a Complete Response letter that recommended reformulation of Neupro before making it available in the U.S. market for the treatment of Parkinson's disease. In December 2011, Impax Labs submitted an NDA for IPX066, an extended-release formulation of levodopa/carbidopa. Other therapies under development in the United States include levodopa/carbidopa formulations such as Duodopa (a levodopa/carbidopa gel delivered by a portable pump directly into the duodenum being developed by Solvay) as well as DM-1992 and OS-320 (extended-release formulations of levodopa/carbidopa being developed by Depomed and Osmotica Pharmaceutical Corp., respectively).

There may be other compounds of which we are not aware that are at an earlier stage of development and may compete with our products or product candidates. If any of those compounds are successfully developed and approved, they could compete directly with our products or product candidates.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Established pharmaceutical companies may invest heavily to quickly discover and develop novel compounds that could make *Horizant*, *Regnite* or our product candidates obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. In addition, these third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do. We are also aware of other companies that may currently be engaged in the discovery of medicines that will

[Table of Contents](#)

compete with *Horizant*, *Regnite* or the product candidates that we are developing. In addition, in the markets that we are targeting, we expect to compete against current market-leading medicines. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition will suffer.

Off-label sale or use of generic gabapentin products could decrease sales of Horizant/gabapentin enacarbil and could lead to pricing pressure if such products become available at competitive prices and in dosages that are appropriate for the indications for which we or our collaborative partners are commercializing Horizant or developing Horizant/gabapentin enacarbil.

U.S. physicians are permitted to prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those uses tested and approved by the FDA. The occurrence of such off-label uses could significantly reduce our or our partners' ability to market and sell *Horizant* or any other products that we or our partners may develop.

We believe that in all countries in which we hold or have licensed rights to patents or patent applications related to *Horizant*/gabapentin enacarbil, the composition-of-matter patents relating to gabapentin have expired. Off-label prescriptions written for gabapentin for indications for which we or our partners are marketing or developing *Horizant*/gabapentin enacarbil could adversely affect our ability to generate revenue from the sale of *Horizant*/gabapentin enacarbil, if approved for commercial sale in such indications. This could result in reduced sales and increased pricing pressure on *Horizant*/gabapentin enacarbil, if approved in such indications, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

If product liability lawsuits are brought against us, we will incur substantial liabilities and may be required to limit commercialization of Horizant/Regnite or any other products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and face an even greater risk once our products become commercially available. If we cannot successfully defend ourselves against claims that our product candidates or products that we successfully develop caused injuries, we will incur substantial liabilities.

Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We have product liability insurance that covers our clinical trials up to a \$10.0 million annual aggregate limit. Insurance coverage is increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

[Table of Contents](#)

If some or all of our patents expire, are invalidated or are unenforceable, or if some or all of our patent applications do not yield issued patents or yield patents with narrow claims, competitors may develop competing products using our intellectual property and our business will suffer.

Our success will depend in part on our ability to obtain and maintain patent and trade secret protection for our technologies, *Horizant*, *Regnite* and product candidates both in the United States and other countries. We have a number of U.S. and foreign patents, patent applications and rights to patents related to our compounds, product candidates, products and technology, but we cannot guarantee that issued patents will be enforceable or that pending or future patent applications will result in issued patents. Alternatively, a third party may successfully circumvent our patents. Our rights under any issued patents may not provide us with sufficient protection against competitive products or otherwise cover commercially valuable products or processes.

The degree of future protection for our proprietary technologies, *Horizant*, *Regnite* and product candidates is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications will result in issued patents;
- any patents issued to us or our collaborators may not provide a basis for commercially viable products or may be challenged by third parties; or
- the patents of others may have an adverse effect on our ability to do business.

Even if valid and enforceable patents cover *Horizant*, *Regnite* or our product candidates and technologies, the patents will provide protection only for a limited amount of time.

Our and our collaborators' ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Furthermore, the policies governing biotechnology patents outside the United States are even more uncertain. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Even if patents are issued regarding *Horizant*, *Regnite* or our product candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid and/or unenforceable. For example, in September 2008, a law firm on behalf of an undisclosed client filed an opposition against the patent grant of one of our European patent applications covering gabapentin enacarbil. The European patent office, at an opposition hearing in April 2010, undertook a full review of the grant of the European patent, and ruled that our European patent covering the composition of matter of gabapentin enacarbil is valid. While the law

[Table of Contents](#)

firm that filed the opposition initially appealed the ruling on behalf of the undisclosed client, that appeal was withdrawn in November 2010. Patents also may not protect *Horizant*, *Regnite* or our product candidates if competitors devise ways of making them or similar products without legally infringing our patents. The FDCA and FDA regulations and policies provide incentives to manufacturers to challenge patent validity and these same types of incentives encourage manufacturers to submit NDAs that rely on literature and clinical data not prepared for or by the drug sponsor.

We may obtain patents for certain product candidates many years before marketing approval is obtained for those products. Because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to apply for patent term extensions.

As part of the approval process of our product candidates in the United States, the FDA may determine that the product candidates be granted an exclusivity period during which other manufacturers' applications for approval of generic versions of our products will not be granted. Generic manufacturers often wait to challenge the patents protecting products that have been granted exclusivity until one year prior to the end of the exclusivity period. For example, the FDA granted *Horizant* five years of regulatory exclusivity based on its being a new chemical entity. It is possible that generic manufacturers are considering attempts to seek FDA approval for a similar or identical drug as *Horizant* or our product candidate through an abbreviated NDA, which is the application form typically used by manufacturers seeking approval of a generic drug. If our patents are subject to challenges, we may need to spend significant resources to defend such challenges and we may not be able to defend our patents successfully.

We also rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Our research and development collaborators may have rights to publish data and other information in which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. In most cases, these individuals or entities are, at the least, precluded from publicly disclosing our confidential information and are only allowed to disclose other data or information generated during the course of the research after we have been afforded an opportunity to consider whether patent and/or other proprietary protection should be sought. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our technology and other confidential information, then our ability to receive patent protection or protect our proprietary information may be jeopardized.

Third-party claims of intellectual property infringement would require us to spend significant time and money and could prevent us from developing or commercializing our products.

Our commercial success depends in part on not infringing the patents and proprietary rights of other parties and not breaching any licenses that we have entered into with regard to our technologies and products. Because others may have filed, and in the future are likely to file, patent applications covering products or other technologies of interest to us that are similar or identical to ours, patent applications or issued patents of others may have priority over our patent applications or issued patents. For example, we are aware of a family of third-party patent applications relating to prodrugs of gabapentin. We believe the applications have been abandoned in the United States, the European Patent Office, Canada, Australia and the United Kingdom. With respect to the claims contained in these patent applications and patents, we believe that our activities do not infringe the patents at issue and/or that the third-party patent or patent applications are invalid. In addition, we believe that in all countries in which we hold or have licensed rights to patents or patent applications related to *Horizant*, *Regnite* or gabapentin enacarbil, the composition-of-matter patents relating to gabapentin have expired.

[Table of Contents](#)

However, it is possible that a judge or jury will disagree with our conclusions regarding non-infringement, invalidity and/or expiration, and we could incur substantial costs in litigation if we are required to defend against patent suits brought by third parties or if we initiate these suits. Any legal action against our collaborators or us claiming damages and seeking to enjoin commercial activities relating to the affected products and processes could, in addition to subjecting us to potential liability for damages, require our collaborators or us to obtain a license to continue to manufacture or market the affected products and processes. Licenses required under any of these patents may not be available on commercially acceptable terms, if at all. Failure to obtain such licenses could materially and adversely affect our ability to develop, commercialize and sell *Horizant*, *Regnite* or our product candidates. We believe that there may continue to be significant litigation in the biotechnology and pharmaceutical industry regarding patent and other intellectual property rights. If we become involved in litigation, it could consume a substantial portion of our management and financial resources and we may not prevail in any such litigation.

Furthermore, our commercial success will depend, in part, on our ability to develop additional product candidates in current indications of interest or opportunities in other indications. Some of these activities may involve the use of genes, gene products, screening technologies and other research tools that are covered by third-party patents. Court decisions have indicated that the exemption from patent infringement afforded by 35 U.S.C. § 271(e)(1) does not encompass all research and development activities associated with product development. In some instances, we may be required to obtain licenses to such third-party patents to conduct our development activities, including activities that may have already occurred. It is not known whether any license required under any of these patents would be made available on commercially acceptable terms, if at all. Failure to obtain such licenses could materially and adversely affect our ability to maintain a pipeline of potential product candidates and to bring new products to market. If we are required to defend against patent suits brought by third parties relating to third-party patents that may be relevant to our development activities, or if we initiate such suits, we could incur substantial costs in litigation. Moreover, an adverse result from any legal action in which we are involved could subject us to damages and/or prevent us from conducting some of our development activities.

If third parties do not manufacture Horizant, Regnite or our product candidates in sufficient quantities or at an acceptable cost, commercialization of Horizant, Regnite and clinical development and commercialization of our product candidates would be harmed or delayed.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of *Horizant*, *Regnite* or any of our product candidates. To date, we have relied on, and we expect to continue to rely on, a limited number of third-party compound manufacturers and active pharmaceutical ingredient, or API, formulators for the production of preclinical, clinical and commercial quantities of our product candidates. We do not have commercial supply agreements with any of these third parties, and our agreements with these parties are generally terminable at will by either party at any time. If, for any reason, these third parties are unable or unwilling to perform under our agreements or enter into new agreements, we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire sufficient quantities of our product candidates in a timely manner from these third parties could delay clinical trials and prevent us or our partners from developing and commercializing our product candidates in a cost-effective manner or on a timely basis.

Under the terms of our collaboration with GSK, as currently in effect, GSK is solely responsible for the commercial manufacture and supply of *Horizant* to support its development and commercialization within the United States. GSK is currently relying on a single source supplier for commercial and clinical supplies of *Horizant*. If GSK fails to qualify alternative manufacturers of *Horizant*, the current contract manufacturer terminates its agreement with GSK and GSK is otherwise unable to manufacture or contract to manufacture sufficient quantities of *Horizant*, the development and commercialization of *Horizant* could be impaired or delayed. If our collaboration agreement with GSK is terminated, we are entitled to specified manufacturing transition assistance from GSK, but would then be responsible for the manufacturing of *Horizant* following the transition period. Under the terms of our collaboration with Astellas, Astellas is solely responsible for the manufacture of *Regnite*/gabapentin enacarbil to support its development and commercialization within the Astellas territory. To our knowledge, Astellas is currently relying on single source suppliers for clinical supplies

[Table of Contents](#)

of *Regnite*/gabapentin enacarbil in API form. As a result, if Astellas fails to manufacture or contract to manufacture sufficient quantities of *Regnite*/gabapentin enacarbil or API, development and commercialization of *Regnite*/gabapentin enacarbil could be impaired or delayed in the Astellas territory. If we pursue development with respect to the rights we maintain on *Horizant*/gabapentin enacarbil or if our collaboration agreement with GSK is terminated, we will need to obtain clinical supplies from GSK or another supplier. As a result, if we are unable to obtain sufficient quantities of *Horizant*/gabapentin enacarbil from GSK at prices that are commercially attractive, and if we are unable to qualify an alternative supplier, it could delay the development of, and impair our ability to commercialize, *Horizant*/gabapentin enacarbil.

We rely on two suppliers of R-baclofen, the active agent used to make AP, under purchase orders issued from time to time. In the event that both suppliers determine to not sell R-baclofen to us at a price that is commercially attractive, and if we were unable to qualify an alternative supplier of R-baclofen, this could delay the development of, and impair our ability to commercialize, this product candidate.

We rely on a single source supplier of our current worldwide requirements of AP in API form under a manufacturing services and product supply agreement. Our current agreement with this supplier does not provide for a supply of API that would be necessary for full-scale commercialization. In the event that the parties cannot agree to the terms and conditions for this supplier to provide some or all of our API clinical and commercial supply needs, we would not be able to manufacture API until an alternative supplier is identified and qualified, which could also delay the development of, and impair our ability to commercialize, this product candidate. The API is manufactured using a four-step synthetic process that uses commercially available starting materials for each step. There are no complicated chemistries or unusual equipment required in the manufacturing process.

We rely on a single source supplier of AP formulated in sustained-release tablets at specified transfer prices under quotations agreed upon by the parties as a part of a master services agreement. We do not have an agreement with this supplier for the commercial supply of AP sustained-release tablets. In the event that such supplier terminates our agreement under specified circumstances, or we are not able to come to an agreement for the commercial supply of AP on reasonable terms, we would not be able to commercialize AP sustained-release tablets until an alternative supplier is qualified. This could delay the development of, and impair our ability to commercialize, AP.

We rely on a single source supplier of levodopa, which is used to make XP21279, under purchase orders issued from time to time. We are aware of several alternative suppliers of levodopa, and we believe at least one alternative manufacturer could potentially supply levodopa in the event that our supplier determines to not sell levodopa to us at a price that is commercially attractive. If we determine to continue the development of XP21279 and were unable to qualify an alternative supplier of levodopa, this could further delay the development of, and impair our ability to commercialize, XP21279.

We rely on a single source supplier of XP21279 in API form under a manufacturing services and product supply agreement. In the event that such supplier terminates the agreement under specified circumstances, we would not be able to manufacture API until a qualified alternative supplier is identified and qualified, which could also further delay the development of, and impair our ability to commercialize, this product candidate. The API is manufactured by a four-step synthetic process that uses commercially available starting materials. There are no complicated chemistries or unusual equipment required in the manufacturing process.

We have purchased XP21279 formulated in sustained-release tablets from a single source supplier at specified transfer prices under quotations agreed upon by the parties as part of a master services agreement. We have recently qualified another supplier for the manufacture of XP21279 with carbidopa bi-layer tablets to be supplied under quotations agreed upon by the parties as part of a master services agreement. In the event that either supplier terminates its agreement under specified circumstances for the manufacture of XP21279 sustained-release tablets or carbidopa bi-layer tablets, we would not be able to manufacture XP21279 until an alternative supplier is qualified. If we determine to continue the development of XP21279, this could further delay the development of, and impair our ability to commercialize, XP21279.

[Table of Contents](#)

If we are required to obtain alternate third-party manufacturers, it could delay or prevent the clinical development and commercialization of our product candidates.

We may not be able to maintain or renew our existing or any other third-party manufacturing arrangements on acceptable terms, if at all. If we are unable to continue relationships with GSK for supplies of *Horizant*/gabapentin enacarbil, or our other suppliers for AP and XP21279, or to continue relationships at an acceptable cost or if these suppliers fail to meet our requirements for these product candidates for any reason, we would be required to obtain alternative suppliers. Any inability to obtain qualified alternative suppliers, including an inability to obtain, or delay in obtaining, approval of an alternative supplier from the FDA, would delay or prevent the clinical development and commercialization of these product candidates.

Use of third-party manufacturers may increase the risk that we or our partners will not have adequate supplies of our product candidates.

Our and our partners' current, and anticipated future, reliance on third-party manufacturers will expose us and our partners to risks that could result in higher costs or lost product revenues or delay or prevent:

- the initiation or completion of clinical trials by us or our partners;
- the submission of applications for regulatory approvals; and
- the approval of our product candidates by the FDA or foreign regulatory authorities or the commercialization of our products.

In particular, our or our partners' contract manufacturers:

- could encounter difficulties in achieving volume production, quality control and quality assurance or suffer shortages of qualified personnel, which could result in their inability to manufacture sufficient quantities of drugs to meet clinical schedules or to commercialize *Horizant*, *Regnite* or our product candidates;
- could terminate or choose not to renew manufacturing agreements, based on their own business priorities, at a time that is costly or inconvenient for us or our partners;
- could fail to establish and follow FDA-mandated current good manufacturing practices, or cGMPs, which are required for FDA approval of our product candidates, or fail to document their adherence to cGMPs, either of which could lead to significant delays in the availability of material for clinical study, delay or prevent marketing approval for our product candidates or require costly recalls of products already having received approval;
- could encounter financial difficulties that would interfere with their obligations to supply *Horizant*, *Regnite* or our product candidates; and
- could breach, or fail to perform as agreed under, manufacturing agreements.

If we or our partners are not able to obtain adequate supplies of *Horizant*, *Regnite* or our product candidates, it will be more difficult to commercialize *Horizant* or *Regnite*, develop our product candidates and compete effectively. *Horizant*, *Regnite*, our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities.

In addition, the manufacturing facilities of certain of our suppliers are located outside of the United States. This may give rise to difficulties in importing our product candidates or their components into the United States or other countries as a result of, among other things, regulatory agency import inspections, incomplete or inaccurate import documentation or defective packaging.

Safety issues with the parent drugs or other components of our product candidates, or with approved products of third parties that are similar to our product candidates, could give rise to delays in the regulatory approval process, restrictions on labeling or product withdrawal.

Discovery of previously unknown problems, or increased focus on a known problem, with an approved product may result in restrictions on its permissible uses, including withdrawal of the medicine from the market.

[Table of Contents](#)

Although gabapentin, baclofen (which includes the R-isomer of baclofen) and levodopa, the parent drugs of *Horizant/Regnite*/gabapentin enacarbil, AP and XP21279, respectively, have been used successfully in patients for many years, newly observed toxicities or worsening of known toxicities, in preclinical studies of, or in patients receiving, gabapentin, baclofen and levodopa, or reconsideration of known toxicities of gabapentin, baclofen or levodopa in the setting of new indications, could result in increased regulatory scrutiny of *Horizant/Regnite*/gabapentin enacarbil, AP and XP21279, respectively. For example, the label for baclofen, the R-isomer of which is the parent drug of AP, includes a warning that hallucinations and seizures have occurred on abrupt withdrawal of baclofen dosing without proper tapering in spasticity patients. The FDA has substantial discretion in the NDA approval process and may refuse to approve any application if the FDA concludes that the risk/benefit analysis of a potential drug treatment for a specific indication does not warrant approval. For example, in February 2010, safety concerns related to a preclinical finding of pancreatic acinar cell tumors in rats precluded FDA approval of the *Horizant* NDA in RLS in its form at that time. Although there were similar findings of rat pancreatic acinar cell tumors following treatment with gabapentin, the parent drug of *Horizant*, the FDA has, to date, not prevented the use of gabapentin. In the February 2010 Complete Response letter, the FDA noted that they had concluded that the seriousness and severity of refractory epilepsy and the benefit to patients provided by gabapentin justified the potential risk at that time. Thus, although the parent drug for one of our product candidates may be approved by the FDA in a particular indication, the FDA may conclude that our product candidate's risk/benefit profile does not warrant approval in a different indication, and the FDA may refuse to approve our product candidate. Such conclusion and refusal would prevent us from developing and commercializing our product candidates and severely harm our business and financial condition.

Horizant, Regnite and our product candidates are engineered to be broken down by the body's natural metabolic processes and to release the parent drug and other substances. While these breakdown products are generally regarded as safe, it is possible that there could be unexpected toxicity associated with these breakdown products that will cause any or all of *Horizant/Regnite*/gabapentin enacarbil, AP and XP21279 to be poorly tolerated by, or toxic to, humans. Any unexpected toxicity of, or suboptimal tolerance to, our Transported Prodrugs would delay or prevent commercialization of *Horizant, Regnite* or these product candidates.

Additionally, problems with approved products marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as the parent drug of *Horizant, Regnite* or our product candidates could adversely affect the commercialization of *Horizant* or *Regnite* or the development of our product candidates. For example, the product withdrawals of Vioxx from Merck & Co., Inc. and Bextra from Pfizer in 2005 due to safety issues have caused other drugs that have the same therapeutic target, such as Celebrex from Pfizer, to receive additional scrutiny from regulatory authorities. If either gabapentin or pregabalin, drugs from Pfizer that are marketed as Neurontin and Lyrica, respectively, encounters unexpected toxicity problems in humans, the FDA may restrict the use of *Horizant* since it is believed to share the same therapeutic target as gabapentin and pregabalin. In 2005, the FDA requested that all makers of epilepsy drugs analyze their clinical trial data to determine whether these drugs increase the risk of suicide in patients. In December 2008, the FDA added warnings to 11 antiepileptic drugs, including gabapentin, regarding an increased risk of suicide or suicidal thoughts. In April 2009, the FDA approved safety label changes for all approved antiepileptic drugs, except those indicated only for short-term use, to include a warning about an increased risk of suicidal thoughts or actions. In addition, in 2011, the FDA added warnings to the labels of antiepileptic drugs regarding an increased risk of drug reaction with Eosinophilia and Systemic Symptoms, or DRESS, also known as multiorgan hypersensitivity, which has been reported in patients taking antiepileptic drugs. *Horizant*, as a compound that is believed to share the same therapeutic target as antiepileptic drugs such as gabapentin and pregabalin, has similar warnings regarding suicidality and DRESS in its label. In September 2010, the FDA released draft guidance recommending that prospective suicidality assessments be performed in clinical trials of any drug with central nervous system activity. We expect that the FDA will follow this guidance, and we will be required to perform suicidality assessments in all of our clinical trials, including Phase 1 trials, of any of our product candidates with central nervous system activity. Finally, if the FDA determines that a drug may present a risk of substance abuse, it can recommend to the DEA that the drug be scheduled under the Controlled Substances Act. While gabapentin is not a scheduled drug at the present time, pregabalin has been scheduled as a controlled substance. Since pregabalin is a scheduled drug, it is possible that the FDA may require additional testing of *Horizant* in the future, the results of which could lead the FDA to conclude that *Horizant* should be

[Table of Contents](#)

scheduled as well. Scheduled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, and the DEA regulates the amount of a scheduled substance that is available for clinical trials and commercial distribution. Accordingly, any scheduling action that the FDA or DEA may take with respect to *Horizant* may delay further development or limit *Horizant's* marketing approval. Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for our product candidates would delay commercialization of our product candidates, and severely harm our business and financial condition.

We may not be successful in our efforts to develop additional Transported Prodrug candidates.

An important element of our strategy is to develop and commercialize Transported Prodrugs that improve upon the absorption, distribution and/or metabolism of drugs that have already received regulatory approval. Programs to develop and commercialize new product candidates require substantial technical, financial and human resources. These programs may initially show promise with respect to potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the methodology used may not be successful in identifying potential product candidates for development; or
- potential product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal pharmaceutical profile or other characteristics suggesting that they are unlikely to be effective products.

As part of our restructuring in March 2010, we eliminated our discovery research department, which will prevent our ability to discover additional product candidates at this time. If we are unable to develop suitable product candidates from our current preclinical pipeline, we may pursue additional product candidates through in-licensing. Any growth through in-licensing would depend upon the availability of suitable product candidates at favorable prices and upon advantageous terms and conditions. To obtain additional product candidates, we may also reconstitute our discovery research department, which would require the expenditure of significant resources and the identification and hiring of a number of highly-skilled employees. Such efforts could divert the time and resources from the later-stage development or commercialization of our product candidates.

If we are unable to develop or obtain suitable product candidates, we will not be able to increase our revenues in future periods, which could result in significant harm to our financial position and adversely impact our stock price.

Horizant and Regnite remain, and our product candidates, if they receive marketing approval, will remain, subject to ongoing regulatory review. If we or our collaborative partners fail to comply with continuing regulations, these approvals could be rescinded and the sale of our products could be suspended.

Any regulatory approval to market a product could be conditioned on conducting additional, costly, post-approval studies or implementing a risk evaluation and mitigation strategy or could contain strict limits on the indicated uses included in the labeling. For example, the FDA approval for *Horizant* for the treatment of RLS included requirements for GSK to conduct a program of PMCs and post-marketing requirements, or PMRs, in adults, including a 12-week, double-blind, placebo-controlled efficacy study, two simulated driving studies, a drug-drug interaction study with morphine and a QTc study. As part of this program, the FDA also requested an evaluation of 300 mg and 450 mg tablets of *Horizant*, dosed once per day. GSK will also conduct a pediatric program for subjects 13 years and older. The pediatric clinical program, which is scheduled to commence after requested adult data is obtained and reviewed by the FDA, includes a pharmacokinetics, or PK, study, a parallel, fixed-dose response efficacy study, a long-term safety study and a simulated driving study. The specific protocol submission and trial completion dates for these PMCs/PMRs range from April 2011 through July 2024. In the event that our collaboration agreement with GSK terminates and rights to *Horizant* revert to us, we may be responsible for fulfilling these post-marketing study requirements, which could increase our costs and divert management time and resources away from our commercialization efforts or the development of our product candidates. In addition, *Horizant* has certain warnings and precautions in the label, including information that *Horizant* causes significant driving impairment.

[Table of Contents](#)

A medication guide, which contains information about the labeling intended for the patient, is also required to be distributed with *Horizant*. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us or our collaborative partners to withdraw it from the market or impede or delay our or our collaborative partners' ability to obtain regulatory approvals in additional countries or indications. In addition, the manufacturer of the product and its facilities will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will remain subject to extensive regulatory requirements.

We are also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we may commercialize our products. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. These statutes and regulations include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical companies on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting identified common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid.

Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other health care companies have also been prosecuted on other legal theories of Medicare fraud. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and the reporting of gifts to individual physicians in the states. Other states require the posting of information relating to clinical studies. In addition, California requires pharmaceutical companies that engage in marketing to implement a comprehensive compliance program that includes a limit on expenditures for, or payments to, individual prescribers. Although we do not have a sales force and are not promoting *Horizant*, *Regnite* or any of our product candidates, we have adopted a comprehensive compliance program that we believe complies with California law. Several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

[Table of Contents](#)

If we or our collaborative partners fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities or previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we and our partners could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing processes;
- warning letters;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

Because we have a number of product candidates and are considering a variety of target indications, we may expend our limited resources to pursue a particular candidate or indication and fail to capitalize on candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on product candidates for the specific indications that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on product candidates for specific indications that ultimately do not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

Current healthcare laws and regulations and future legislative or regulatory reforms to the healthcare system may affect our ability to profitably sell any products that we may develop.

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

Table of Contents

- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers, effective March 30, 2013, and reporting any investment interests held by physicians and their immediate family members during the preceding calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;
- a licensure framework for follow-on biologic products; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The United States Supreme Court has accepted petitions to hear a constitutional challenge to the PPACA in 2012. If the Supreme Court rules that the PPACA is unconstitutional, our expenditures in preparation for the PPACA could go unused, we could require new expenditures to adjust to the new competitive environment and new legislation could later become law that could adversely affect the pharmaceutical industry. We anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Insurers may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse for newly-approved drugs, which in turn will put pressure on the pricing of drugs.

We also cannot be certain that *Horizant* or any other products that may result from our product candidates will successfully be placed on the list of drugs covered by particular health plan formularies, nor can we predict the negotiated price for such products, which will be determined by market factors. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If *Horizant* or other products that may result from our product candidates are not included on these preferred drug lists, physicians may not be inclined to prescribe it to their patients, thereby diminishing the potential market for such products. Astellas will face similar pricing and reimbursement restrictions in Japan for *Regnite*, and further efforts to reform the Japanese healthcare system may increase such restrictions.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading

[Table of Contents](#)

clinicians. If we are not able to retain Drs. Ronald Barrett, Kenneth Cundy and David Savello, we may not be able to successfully develop or commercialize our product candidates. Competition for experienced scientists and development staff may limit our ability to hire and retain highly qualified personnel on acceptable terms. In addition, none of our employees have employment commitments for any fixed period of time and could leave our employment at will. We do not carry "key person" insurance covering members of senior management or key scientific personnel. If we fail to identify, attract and retain qualified personnel, we may be unable to continue our development and commercialization activities.

If we use biological and hazardous materials in a manner that causes contamination or injury or violates laws, we may be liable for damages.

Our development activities involve the use of potentially harmful biological materials as well as hazardous materials, chemicals and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for damages that result, and any liability could exceed our resources. We, the third parties that conduct clinical trials on our behalf and the third parties that manufacture our product candidates are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and waste products. The cost of compliance with these laws and regulations could be significant. The failure to comply with these laws and regulations could result in significant fines and work stoppages and may harm our business.

Our facility is located in California's Silicon Valley, in an area with a long history of industrial activity and use of hazardous substances, including chlorinated solvents. Environmental studies conducted prior to our leasing of the site found levels of metals and volatile organic compounds in the soils and groundwater at our site. While these constituents of concern predated our occupancy, certain environmental laws, including the U.S. Comprehensive, Environmental Response, Compensation and Liability Act of 1980, impose strict, joint and several liability on current operators of real property for the cost of removal or remediation of hazardous substances. These laws often impose liability even if the owner or operator did not know of, or was not responsible for, the release of such hazardous substances. As a result, while we have not been, we cannot rule out the possibility that we could in the future be held liable for costs to address contamination at the property beneath our facility, which costs could be material.

Our facility is located near known earthquake fault zones, and the occurrence of an earthquake, extremist attack or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.

Our facility is located near known earthquake fault zones and, therefore, is vulnerable to damage from earthquakes. In October 1989, a major earthquake struck this area and caused significant property damage and a number of fatalities. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

Risks Related to Ownership of our Common Stock

Our stock price is volatile, and purchasers of our common stock could incur substantial losses.

The market prices for securities of biopharmaceutical companies in general have been highly volatile. The market price of our common stock may be influenced by many factors, including:

- the commercial sales of *Horizant*, *Regnite* or any of our other products approved by the FDA or its foreign counterparts;

Table of Contents

- developments with respect to our litigation proceedings with GSK, including any termination of the collaboration agreement and the ultimate terms on which the collaboration agreement may be terminated;
- developments in our relationship with Astellas, including potential disputes or the termination or modification of our agreement with Astellas;
- adverse results or delays in our or our collaborative partners' clinical trials;
- the timing of achievement of our clinical, regulatory, partnering and other milestones, such as the commencement of clinical development, the completion of a clinical trial, the filing for regulatory approval or the establishment of commercial partnerships for one or more of our product candidates;
- announcement of FDA approvability, approval or non-approval of our product candidates, and the timing of the FDA review process;
- actions taken by regulatory agencies with respect to *Horizant*, *Regnite* or our product candidates, our clinical trials or our sales and marketing activities;
- actions taken by regulatory agencies with respect to products or drug classes related to *Horizant*, *Regnite* or our product candidates;
- changes in our collaborators' business strategies;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- any intellectual property matter involving us, including infringement lawsuits;
- actions taken by regulatory agencies with respect to our or our partners' compliance with regulatory requirements;
- announcements of technological innovations or new products by us or our competitors;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders;
- restatements of our financial results and/or material weaknesses in our internal controls; and
- the loss of any of our key scientific or management personnel.

The stock markets in general and the markets for biotechnology stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, purported class action lawsuits have often been instituted against companies, including our company, whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations, divert management's attention and resources and possibly delay our clinical trials or commercialization efforts.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our stock price.

Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission, or SEC, require annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm attesting to,

[Table of Contents](#)

and reporting on, the effectiveness of our internal control over financial reporting. If we fail to maintain the adequacy of our internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. If we cannot favorably assess, or our independent registered public accounting firm is unable to provide an unqualified attestation report on, the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

Fluctuations in our operating results could cause our stock price to decline.

The following factors are likely to result in fluctuations of our operating results from quarter to quarter and year to year:

- the commercial sales of *Horizant*, *Regnite* or any of our other products approved by the FDA or its foreign counterparts;
- developments with respect to our litigation proceedings with GSK, including any termination of the collaboration agreement and the ultimate terms on which the collaboration agreement may be terminated;
- developments in our relationship with Astellas, including potential disputes or the termination or modification of our agreement with Astellas;
- adverse results or delays in our or our collaborative partners' clinical trials;
- the timing and achievement of our clinical, regulatory, partnering and other milestones, such as the commencement of clinical development, the completion of a clinical trial, the filing for regulatory approval or the establishment of a commercial partnership for one or more of our product candidates;
- announcement of FDA approvability, approval or non-approval of our product candidates and the timing of the FDA review process;
- actions taken by regulatory agencies with respect to *Horizant*, *Regnite* or our product candidates, our clinical trials or our sales and marketing activities;
- actions taken by regulatory agencies with respect to products or drug classes related to *Horizant*, *Regnite* or our product candidates;
- changes in our collaborators' business strategies;
- actions taken by regulatory agencies with respect to our or our partners' compliance with regulatory requirements;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- any intellectual property matter involving us, including patent infringement lawsuits; and
- announcements of technological innovations or new products by us or our competitors.

Due to these fluctuations in our operating results, a period-to-period comparison of our results of operations may not be a good predictor of our future performance. For example, due primarily to the recognition of revenues from up-front and milestone payments from our collaborations with Astellas and GSK, we were profitable in the three-month periods ended June 30, September 30 and December 31, 2007, for the year ended December 31, 2007 and in the three months ended June 30, 2011. However, while recognition of these revenues resulted in a

[Table of Contents](#)

profitable year for 2007 and profitability in the three months ended June 30, 2011, we incurred net losses in 2008, 2009, 2010 and 2011. In any particular financial period, the actual or anticipated fluctuations could be below the expectations of securities analysts or investors and our stock price could decline.

Because a small number of existing stockholders own a large percentage of our voting stock, they may be able to exercise significant influence over our affairs, acting in their best interests and not necessarily those of other stockholders.

As of February 1, 2012, our executive officers, directors and holders of 5% or more of our outstanding common stock, based upon information known to us and derived from Schedules 13G filed with the SEC, beneficially owned approximately 46.9% of our common stock. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquiror from attempting to obtain control of us, which in turn could reduce the price of our common stock.

Our stockholder rights plan and anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and bylaws may delay or prevent an acquisition of us, a change in our management or other changes that stockholders may consider favorable. These provisions include:

- a classified board of directors;
- a prohibition on actions by our stockholders by written consent;
- the ability of our board of directors to issue preferred stock without stockholder approval, which could be used to make it difficult for a third party to acquire us;
- notice requirements for nominations for election to the board of directors; and
- limitations on the removal of directors.

Moreover, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

We have adopted a rights agreement under which certain stockholders have the right to purchase shares of a new series of preferred stock, at an exercise price of \$140.00 per one one-hundredth of a share, if a person acquires more than 15% of our common stock. The rights plan could make it more difficult for a person to acquire a majority of our outstanding voting stock. The rights plan could also reduce the price that investors might be willing to pay for shares of our common stock and result in the market price being lower than it would be without the rights plan. In addition, the existence of the rights plan itself may deter a potential acquiror from acquiring us. As a result, either by operation of the rights plan or by its potential deterrent effect, mergers and acquisitions of us that our stockholders may consider in their best interests may not occur.

If there are large sales of our common stock, the market price of our common stock could drop substantially.

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell shares of our common stock, the market price of our common stock could decline significantly. As of February 1, 2012, we had 35,627,913 outstanding shares of common stock. Of these shares, 1,251,037 shares are held by our directors and executive officers and their affiliates and are subject to volume limitations and manner of sale requirements under Rule 144 under the Securities Act of 1933, as amended.

[Table of Contents](#)

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We lease approximately 162,000 square feet of office and laboratory space in two adjacent buildings in Santa Clara, California. We conduct our operations in one of the buildings and the other is vacant. The leases expire concurrently in August 2013, although we have the option to extend both leases for two additional terms of five years each. The 2011 aggregate annual rental amount payable under the leases was approximately \$5.5 million.

Item 3. Legal Proceedings.

In July 2010, a purported securities class action lawsuit was filed in the United States District Court for the Northern District of California, naming us and certain of our officers and directors as defendants. The lawsuit alleged violations of the Securities Exchange Act of 1934, as amended, in connection with allegedly false, misleading and incomplete statements issued by the defendants related to our product candidate, *Horizant* (gabapentin enacarbil) Extended-Release Tablets, as a potential treatment of moderate-to-severe primary restless legs syndrome, or RLS, which allegedly made it impossible for investors to meaningfully understand the drug's potential for U.S. Food and Drug Administration approval. The plaintiff sought damages, an award of its costs and injunctive and/or equitable relief on behalf of a purported class of stockholders who purchased our common stock during the period between May 5, 2009 and February 17, 2010. Another lawsuit was filed in September 2010 in the United States District Court for the Northern District of California making substantially similar allegations, on behalf of a purported class of stockholders who purchased our common stock during the period between March 16, 2009 and May 5, 2010. In November 2010, a motion to consolidate the complaints and appoint a lead plaintiff was granted. In January 2011, the lead plaintiff filed a consolidated complaint. In February 2011, we responded to the complaint with a motion to dismiss. In May 2011, the court granted our motion and dismissed the complaint with leave to amend. An amended complaint was filed in June 2011. In the amended complaint, the plaintiff sought damages, an award of its costs and injunctive and/or equitable relief on behalf of a purported class of stockholders who purchased our common stock during the period between May 7, 2008 and February 17, 2010. In July 2011, we filed a motion to dismiss, which was granted on December 12, 2011, without leave to amend the complaint. A judgment dismissing all claims in their entirety was entered the same day. Plaintiffs did not appeal and the judgment has become final.

In January 2012, we provided a notice of dispute and notice of breach and termination, or the Notice, to Glaxo Group Limited, or GSK, pursuant to the Amended and Restated Development and Commercialization Agreement, dated November 7, 2010, between us and GSK. Pursuant to the Notice, we provided notice to GSK that, among other matters, GSK has materially breached its contractual obligation to use commercially reasonable efforts to (i) maximize the sales of *Horizant* (gabapentin enacarbil) Extended-Release Tablets in an expeditious manner and (ii) achieve the sales milestones set forth in the agreement. The collaboration agreement provides that disputes arising with respect to certain matters related to the agreement shall, prior to initiating legal proceedings, first be presented to our Chief Executive Officer and the Chief Operating Officer of GSK, or their respective designees, for resolution during a contractually specified period of time. The collaboration agreement also provides that we may terminate the agreement in the event that GSK shall have materially breached or defaulted in the performance of any of its material obligations under the agreement, and such default shall have continued for 90 days after the date of GSK's receipt of written notice of the breach. The Notice provides that any such termination would become effective at the end of such 90-day period, which will expire on April 24, 2012, unless GSK has cured any such breach or default prior to such date.

On February 23, 2012, GSK filed a complaint, or the GSK Complaint, in the United States District Court for the District of Delaware naming us and other unspecified individuals as defendants. Pursuant to the GSK Complaint, GSK is seeking declaratory judgment that GSK is not in breach of the collaboration agreement and that we do not have the right to terminate the collaboration agreement as a result of GSK's performance under the agreement to date.

[Table of Contents](#)

Following the expiration of the contractually specified period of time for resolution of the dispute by the requisite officers of the parties, on February 24, 2012, we filed a complaint, or the XenoPort Complaint, in the Superior Court of the State of California in the County of Santa Clara against GSK and its affiliates, GlaxoSmithKline LLC and GlaxoSmithKline Holdings (Americas) Inc., for breach of contract, fraud, breach of fiduciary duty, breach of the covenant of good faith and fair dealing and unfair competition. Pursuant to the XenoPort Complaint, in addition to injunctive and equitable relief, we are seeking damages for lost profits, damage to the value of *Horizant* and unattained royalties and milestone payments in an amount to be proven at trial, as well as punitive damages and restitution.

We believe that we have meritorious defenses and intend to defend the GSK Complaint, and prosecute the XenoPort Complaint, vigorously. These lawsuits are subject to inherent uncertainties, including with respect to the timing and ultimate outcome of any resolution thereof, and the actual cost of pursuing or defending these lawsuits will depend on many unknown factors. Pursuing or defending these legal proceedings will also be time-consuming for our management and will detract from our ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with this litigation, and may not prevail in either of these legal proceedings.

From time to time, we may be involved in additional litigation relating to claims arising out of our ordinary course of business.

Item 4. *Mine Safety Disclosures.*

Not applicable.

PART II.

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

Market for Registrant's Common Equity

Our common stock is traded on The NASDAQ Global Select Market under the symbol "XNPT." As of February 1, 2012, there were approximately 80 holders of record of our common stock. No cash dividends have been paid on our common stock to date, and we intend to utilize any earnings for development of our business. The following table sets forth, for the periods indicated, the range of high and low intraday sales prices of our common stock as quoted on The NASDAQ Global Select Market for the two most recent fiscal years.

	<u>High</u>	<u>Low</u>
2011		
4th Quarter	\$ 6.43	\$ 3.46
3rd Quarter	7.90	5.63
2nd Quarter	11.34	5.85
1st Quarter	9.69	5.79
2010		
4th Quarter	\$ 9.33	\$ 6.93
3rd Quarter	9.80	5.66
2nd Quarter	11.82	8.70
1st Quarter	20.97	6.39

The closing price for our common stock as reported by The NASDAQ Global Select Market on February 1, 2012 was \$4.43 per share.

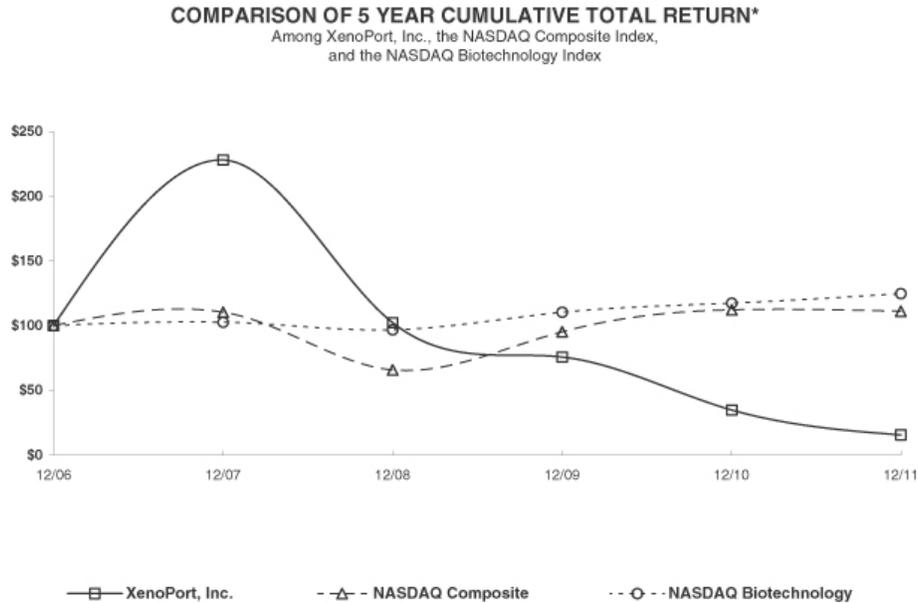
Issuer Purchases of Equity Securities

None.

[Table of Contents](#)

Performance Measurement Comparison(1)

The following graph shows the total stockholder return of an investment of \$100 in cash on December 31, 2006 for: (i) our common stock; (ii) the NASDAQ Composite Index; and (iii) the NASDAQ Biotechnology Index for the five-year period ended December 31, 2011. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends; however, no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



*\$100 invested on 12/31/06 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

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

[Table of Contents](#)

Item 6. Selected Financial Data.

You should read the following selected financial data together with our audited financial statements and related notes and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information included in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2011	2010	2009	2008	2007
(In thousands, except per share amounts)					
Statement of Operations Data:					
Revenues:					
Net revenue from unconsolidated joint operating activities	\$ 35,000	\$ 1,364	\$ 24,758	\$ 28,981	\$ 104,898
Collaboration revenue	8,515	1,515	9,515	13,015	8,924
Total revenues	43,515	2,879	34,273	41,996	113,822
Operating expenses:					
Research and development	43,788	52,546	70,747	83,172	74,397
Selling, general and administrative	30,427	28,323	31,807	26,391	18,755
Restructuring charges	2,923	5,275	—	—	—
Total operating expenses	77,138	86,144	102,554	109,563	93,152
Income (loss) from operations	(33,623)	(83,265)	(68,281)	(67,567)	20,670
Interest and other income	243	796	1,229	4,640	8,198
Interest and other expense	—	—	(4)	(19)	(53)
Income (loss) before income taxes	(33,380)	(82,469)	(67,056)	(62,946)	28,815
Income tax provision (benefit)	—	—	(722)	(406)	622
Net income (loss)	\$ (33,380)	\$ (82,469)	\$ (66,334)	\$ (62,540)	\$ 28,193
Basic net income (loss) per share	\$ (0.94)	\$ (2.68)	\$ (2.31)	\$ (2.48)	\$ 1.14
Diluted net income (loss) per share	\$ (0.94)	\$ (2.68)	\$ (2.31)	\$ (2.48)	\$ 1.08
Shares used to compute basic net income (loss) per share	35,400	30,813	28,766	25,180	24,773
Shares used to compute diluted net income (loss) per share	35,400	30,813	28,766	25,180	25,992
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 94,442	\$ 108,595	\$ 143,668	\$ 152,783	\$ 160,141
Working capital	83,922	99,314	131,749	128,835	138,685
Restricted investments	1,954	1,948	1,933	1,824	1,771
Total assets	104,036	121,229	160,212	169,097	172,877
Current portion of equipment financing obligations	—	—	—	—	176
Noncurrent portion of equipment financing obligations	—	—	—	—	5
Accumulated deficit	420,786	387,406	304,937	238,603	176,063
Total stockholders' equity	75,135	93,959	127,276	121,974	125,537

[Table of Contents](#)

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

Overview

We are a biopharmaceutical company focused on developing and commercializing a portfolio of internally discovered product candidates for the potential treatment of neurological disorders. Our innovative product candidates are prodrugs that are typically created by modifying the chemical structure of currently marketed drugs, referred to as parent drugs, and are designed to correct limitations in the oral absorption, distribution and/or metabolism of the parent drug. We intend to focus our development and commercialization efforts on potential treatments of diseases with significant unmet medical needs, with an emphasis on central nervous system disorders. Our marketed product and each of our product candidates is an orally available, patented or patentable new chemical entity that addresses potential markets with clear unmet medical needs.

In April 2011, the U.S. Food and Drug Administration, or FDA, approved our first product, known in the United States as *Horizant* (gabapentin enacarbil) Extended-Release Tablets, for the treatment of moderate-to-severe primary restless legs syndrome, or RLS, in adults. Restless legs syndrome is a neurological disorder characterized by an urge to move the legs, usually caused or accompanied by uncomfortable and unpleasant sensations in the legs.

Glaxo Group Limited, or GSK, holds commercialization rights and certain development rights for *Horizant* in the United States. In July 2011, GSK began promoting *Horizant* for the treatment of RLS in the United States and recorded net sales of \$2.0 million for the year ended December 31, 2011. Under our collaboration agreement with GSK, as currently in effect, all allowable expenses and sales of *Horizant* are accounted for using a joint profit and loss, or P&L, statement, in which we and GSK share in the resulting operating pre-tax profits and losses. Our share of losses from the joint P&L will be forgiven up to a maximum of \$10.0 million, of which approximately \$6.6 million had been forgiven through December 31, 2011. Our payment of additional losses, if any, would be deferred and payable without interest over a four-year period of time following the first quarter in which the joint P&L is profitable. GSK is responsible for the U.S. development of *Horizant* for RLS and postherpetic neuralgia, or PHN, a chronic type of neuropathic pain that can follow the resolution of shingles. In August 2011, GSK filed a supplemental new drug application, or sNDA, with the FDA under Section 505(b)(2) for *Horizant* for the potential management of PHN. In October 2011, the FDA accepted the sNDA for review and set a Prescription Drug User Fee Act, or PDUFA, date of June 9, 2012 as a goal for the completion of their review of the sNDA. Because June 9, 2012 is a Saturday, the effective action date is expected to be Friday, June 8, 2012. We are eligible to receive a \$10.0 million milestone payment from GSK associated with the possible approval of the PHN sNDA, assuming such approval occurs and the collaboration agreement with GSK is effective at the time of such approval.

In January 2012, we provided a notice of dispute and notice of breach and termination, or the Notice, to GSK that provided notice of our belief that, among other matters, GSK has materially breached its contractual obligation to use commercially reasonable efforts to (i) maximize the sales of *Horizant* in an expeditious manner and (ii) achieve the sales milestones set forth in our collaboration agreement. The Notice provides that the termination of the collaboration agreement would become effective at the end of the 90-day notice period provided under the agreement, which will expire on April 24, 2012, unless GSK has cured any such breach or default prior to such date.

However, on February 23, 2012, GSK filed a complaint, or the GSK Complaint, in the United States District Court for the District of Delaware naming us and other unspecified individuals as defendants. Pursuant to the GSK Complaint, GSK is seeking declaratory judgment that it is not in breach of the collaboration agreement and that we do not have the right to terminate the collaboration agreement as a result of GSK's performance under the agreement to date. Following the expiration of the contractually specified period of time for resolution of the dispute by the requisite officers of the parties, on February 24, 2012, we filed a complaint, or the XenoPort Complaint, in the Superior Court of the State of California in the County of Santa Clara against GSK and its affiliates, GlaxoSmithKline LLC and GlaxoSmithKline Holdings (Americas) Inc., for breach of contract, fraud, breach of fiduciary duty, breach of the covenant of good faith and fair dealing and unfair competition. Pursuant to the XenoPort Complaint, in addition to injunctive and equitable relief, we are seeking damages for lost profits, damage to the value of *Horizant* and unattained royalties and milestone payments in an amount to be proven at

[Table of Contents](#)

trial, as well as punitive damages and restitution. We believe that we have meritorious defenses and intend to defend the GSK Complaint, and prosecute the XenoPort Complaint, vigorously. We cannot predict the outcome of the litigation related to the GSK Complaint and the XenoPort Complaint or when or if the collaboration agreement will be terminated or the ultimate terms of any termination of the agreement. In addition, we may incur substantial legal fees and costs in connection with this litigation, and may not prevail in either of these legal proceedings. If our collaboration agreement with GSK is terminated, we may not be entitled to any further milestone payments, royalties or joint P&L loss forgiveness or deferral, and we could be responsible for the cost of additional *Horizant* commercialization and development activities, including post-marketing commitments, which could accelerate our need for additional capital.

Gabapentin enacarbil is licensed to Astellas Pharma Inc. in Japan and five other Asian countries. In January 2012, the Japanese Ministry of Health, Labor and Welfare approved Astellas' NDA for the use of gabapentin enacarbil, which will be known as *Regnite* in Japan, as a treatment for patients with RLS.

We are evaluating our second product candidate, arbaclofen placarbil, or AP, as a potential treatment for patients with spasticity. We are conducting a pivotal Phase 3 clinical trial under a Special Protocol Assessment, or SPA, with the FDA, for AP as a potential treatment for spasticity in patients with multiple sclerosis, or MS. Provided a positive outcome from this trial is achieved, along with supportive data from certain additional planned studies, we intend to file an NDA under Section 505(b)(2). Section 505(b)(2) allows reference to published literature and the FDA's previous finding of safety and effectiveness for baclofen, a drug that has been approved by the FDA for the alleviation of signs and symptoms of spasticity in individuals with MS and may also be of some value in patients with spinal cord injuries and other spinal cord diseases. We anticipate reporting top-line results from this trial near the end of 2012.

We also evaluated AP for the potential adjunctive treatment of gastroesophageal reflux disease, or GERD. Following the results in March 2011 of a Phase 2 clinical trial of AP as adjunctive therapy in patients with GERD who do not experience complete relief of GERD symptoms while being treated with proton pump inhibitors, we determined that the efficacy results of this trial, which did not meet the primary endpoint, did not warrant our investment in further development for AP in GERD at the present time.

We have evaluated our third product candidate, XP21279, for the potential treatment of patients with Parkinson's disease who experience motor fluctuations. In December 2011, we reported preliminary top-line results of a Phase 2 clinical trial of patient-optimized doses of our new bi-layer tablet of XP21279/carbidopa compared to patient-optimized doses of Sinemet (levodopa/carbidopa). Results of the study indicated that XP21279/carbidopa dosed three times per day reduced mean daily "off time" by 46% compared to baseline when the patients were taking their pre-trial Sinemet dosing regimen. However, in the primary analysis of the trial, the improvement with XP21279/carbidopa was not statistically better than the improvement seen with optimized Sinemet dosed four or five times per day during the double-blind phase of the trial. At this time, we plan to defer further investment in this program pending the outcome of additional data analysis and discussions with Parkinson's disease experts and possibly with regulatory authorities.

In August 2011, we announced plans to accelerate the development of our preclinical product candidate, XP23829, as a potential treatment for relapsing-remitting MS, or RRMS, with a goal of filing an investigational new drug application, or IND, in the second quarter of 2012. XP23829 is a new chemical entity that is a prodrug of monomethyl fumarate, or MMF, a molecule that appears to have anti-inflammatory properties and the potential to modulate cellular responses to oxidative stress.

In addition to our development and commercialization agreements with GSK for *Horizant* and with Astellas for *Regnite*, we plan to enter into other agreements with pharmaceutical companies for our product candidates: (1) when access to a primary care physician sales force is necessary to maximize the commercial potential of our product candidates in the United States; (2) for the development and commercialization of our product candidates outside the United States; or (3) to develop and commercialize product candidates that fall outside our core focus.

We believe that our existing capital resources and anticipated milestone payments, together with interest thereon, will be sufficient to meet our projected operating requirements into the third quarter of 2013. This estimate assumes receipt of a potential \$10.0 million milestone payment from GSK associated with the possible approval of *Horizant* for the management of PHN, assuming such approval occurs and the collaboration agreement with GSK is effective at the time of such approval.

[Table of Contents](#)

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to each of our critical accounting areas. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition

We currently have collaboration agreements with Astellas and GSK, each of which contains multiple elements. We account for these agreements entered into, or materially modified, through December 31, 2010 in accordance with the provisions of the *Revenue Recognition-Multiple-Element Arrangements* topic of the Financial Accounting Standards Board Accounting Standards Codification, or the Codification. We considered a variety of factors in determining the appropriate method of revenue recognition under these arrangements, such as whether the various elements could be considered separate units of accounting, whether there was objective and reliable evidence of fair value for these elements and whether there was a separate earnings process associated with a particular element of an agreement.

Effective January 1, 2011, we adopted the provisions of Accounting Standards Update, or ASU, 2009-13, *Multiple-Deliverable Revenue Arrangements*, or ASU 2009-13, which is included within the Codification as *Revenue Recognition-Multiple Element Arrangements*, on a prospective basis. Under the provisions of ASU 2009-13, we will no longer rely on objective and reliable evidence of the fair value of the elements in a revenue arrangement in order to separate a deliverable into a separate unit of accounting, and the use of the residual method has been eliminated. We will instead use a selling price hierarchy for determining the selling price of a deliverable, which will be used to determine the allocation of consideration to each unit of accounting under an arrangement. The selling price used for each deliverable will be based on vendor-specific objective evidence if available, third-party evidence if vendor-specific objective evidence is not available or estimated selling price if neither vendor-specific objective evidence nor third-party evidence is available. The provisions of ASU 2009-13 are applied by us to revenue arrangements entered into, or materially modified, beginning January 1, 2011. As of December 31, 2011, we had not applied the provisions of ASU 2009-13 to any of our revenue arrangements as we had not entered into any new, or materially modified any of our existing, revenue arrangements in 2011. Therefore, there was no material impact on our financial position or results of operations from adopting ASU 2009-13. However, the provisions of ASU 2009-13 could have a material impact on the revenue recognized from any collaboration agreements that we enter into, or materially modify, in future periods.

Effective January 1, 2011, we also adopted the provisions of ASU 2010-17, *Milestone Method of Revenue Recognition*, or ASU 2010-17, which is included within the Codification as *Revenue Recognition-Milestone Method*. The provisions of ASU 2010-17 are being applied on a prospective basis for milestones achieved starting in 2011. The adoption of ASU 2010-17 did not have a material impact on our financial position or results of operations in the year ended December 31, 2011, and the provisions of ASU 2010-17 are not expected to have a material impact on the revenue recognized from any existing collaboration agreements.

Where there are multiple deliverables combined as a single unit of accounting, revenues are deferred and recognized over the period that we remain obligated to perform services. The specific methodology for the recognition of the revenue (e.g., straight-line or according to specific performance criteria) is determined on a case-by-case basis according to the facts and circumstances applicable to a given agreement.

We account for our revenue-related activities as follows:

- *Up-front, licensing-type fees.* To date, these types of fees have been classified within the collaboration agreements as license fees, access fees, rights fees and initial licensing fees, and each of them was

[Table of Contents](#)

non-refundable and payable in connection with the execution of the contract. Up-front, licensing-type payments are assessed to determine whether or not the licensee is able to obtain any stand-alone value from the license. Where this is not the case, we do not consider the license deliverable to be a separate unit of accounting, and we defer the revenue with revenue recognition for the license fee being assessed in conjunction with the other deliverables that constitute the combined unit of accounting.

- *Milestones.* Prior to our adoption of ASU 2010-17 on January 1, 2011, we assessed milestones on an individual basis, and revenue was recognized from these milestones when earned, as evidenced by acknowledgment from our collaborator, provided that (i) the milestone event was substantive and its achievability was not reasonably assured at the inception of the agreement, (ii) the milestone represented the culmination, or progress towards the culmination, of an earnings process and (iii) the milestone payment was non-refundable. Milestones that were received after all substantive deliverables had occurred were considered to be bonus payments and were recognized when earned, assuming all of the other revenue recognition criteria were met. Where separate milestones did not meet these criteria, we used a performance-based model, with revenue recognition following delivery of effort as compared to an estimate of total expected effort.

Effective January 1, 2011, under the provisions of ASU 2010-17, consideration that is contingent upon achievement of a milestone can be recognized in its entirety as revenue in the period in which the milestone is achieved only if the consideration earned from the achievement of a milestone meets all the criteria for the milestone to be considered substantive at the inception of the arrangement. For a milestone to be considered substantive, the consideration earned by achieving the milestone should (i) be commensurate with either our performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relate solely to past performance and (iii) be reasonable relative to all deliverables and payment terms in the arrangement.

For events for which the occurrences are contingent solely upon the passage of time or are the result of the collaborative partner's performance, the contingent payments will not be accounted for in accordance with the provisions of ASU 2010-17 and will be recognized as revenue when payments are earned, the amounts are fixed or determinable and collectability is reasonably assured.

We will assess the nature of and appropriate accounting for these payments on a case-by-case basis in accordance with the provisions of the *Revenue Recognition* topic of the Codification.

- *Profit and loss sharing.* This represents our share of the profits and losses from the co-promotion of *Horizant* with GSK. Amounts are recognized in the period in which the related activities occur, and their financial statement classification is based on our assessment that these activities constitute part of our ongoing central operations.

Our current collaboration agreements also include potential payments for product royalties and detail reimbursements. To date, we have not received any revenue from these activities.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with selected service providers and make adjustments, if necessary. To date, we have not adjusted our estimate at any particular balance sheet date by any material amount. Examples of estimated accrued expenses include:

- fees paid to contract research organizations in connection with preclinical and toxicology studies and clinical trials;

[Table of Contents](#)

- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of clinical trial materials; and
- professional service fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Fair Value Measurements

We account for the fair value of our financial instruments in accordance with the provisions of the *Fair Value Measurement* topic of the Codification. The carrying amounts of certain of our financial instruments, including cash equivalents and short-term investments, continue to be valued at fair value on a recurring basis.

As defined in the *Fair Value Measurement* topic of the Codification, fair value is the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. We utilize market data or assumptions that we believe market participants would use in pricing assets or liabilities, including assumptions about risk and the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market corroborated or generally unobservable. We apply the market approach valuation technique for fair value measurements on a recurring basis and attempt to maximize the use of observable inputs and minimize the use of unobservable inputs. All of our cash equivalents and short-term investments are valued using quoted prices in active markets and are classified at Level 1 or Level 2 within the fair value hierarchy.

Stock-Based Compensation

The provisions of the *Compensation — Stock Compensation* topic of the Codification establish accounting for stock-based awards exchanged for employee services. In accordance with the topic, for stock options, awards and stock purchase rights granted under the 2005 Employee Stock Purchase Plan, stock-based compensation cost is measured on the grant date, based on the fair value of the award, and is recognized as expense over the requisite employee service period.

We estimate the fair value of stock options and stock purchase rights using a Black-Scholes valuation model. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option valuation model, and the resulting charge is expensed using the straight-line attribution method over the vesting period. Restricted stock units are measured at the fair value of our common stock on the date of grant and expensed over the period of vesting using the straight-line attribution approach. The *Compensation — Stock Compensation* topic of the Codification requires the use of option-pricing models that were not developed for use in valuing employee stock options. The Black-Scholes option-pricing model was developed for use in estimating the fair value of short-lived, exchange-traded options that have no vesting restrictions and are fully transferable. In addition, option-pricing models require the input of highly subjective assumptions, including the option's expected life and the price volatility of the underlying stock. Historically, we derived both the expected life and the expected stock price volatility assumptions using data obtained from similar entities, taking into consideration factors such as industry, stage of life cycle, size and financial leverage. On a prospective basis, beginning in the first quarter of 2011, we have determined that our historical volatility can be used as a reasonable basis to derive the expected stock price volatility assumption and have applied our historical volatility when valuing employee stock options granted beginning in the first quarter of 2011.

We account for stock compensation arrangements to non-employees in accordance with the *Equity-Based Payments to Non-Employees* topic of the Codification, using a fair value approach. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

[Table of Contents](#)

Research and Development Expenses

Research and development expenses consisted of costs associated with both partnered and unpartnered research activities, as well as costs associated with our drug discovery efforts, conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings. Research and development expenses are comprised of: external research and development expenses incurred under agreements with (i) third-party contract research organizations and investigative sites, where a substantial portion of our preclinical studies and all of our clinical trials are conducted, (ii) third-party manufacturing organizations, where a substantial portion of our preclinical supplies and all of our clinical supplies are produced and (iii) consultants; employee-related expenses, which include salaries and benefits; and facilities, depreciation and amortization and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment and laboratory and other supplies. We use our employee and infrastructure resources across multiple research projects, including our drug development programs. We do not allocate our employee and infrastructure costs on a project-by-project basis.

Our current portfolio of marketed products and proprietary product candidates includes the marketed product and product candidates summarized in the table below. The table summarizes development initiatives, including the related stages of development for each product candidate in development and the direct, third-party research and development expenses recognized in connection with our marketed product and each product candidate. The information in the column labeled "Estimated Completion of Current Phase" is our current estimate of the timing of completion of the current phase of development. The actual timing of completion could differ materially from the estimates provided in the table. For a discussion of the risks and uncertainties associated with the timing of completing a product development phase, see the "Our success also depends substantially on our advanced product candidates that are still under development. If we or our collaborative partners are unable to bring any of these product candidates to market, or experience significant delays in doing so, our ability to generate product revenue and our likelihood of success will be reduced;" "If we or our partners are not able to obtain or maintain required regulatory approvals, we or our partners will not be able to commercialize *Horizant*, *Regnite* or our product candidates, our ability to generate revenue will be materially impaired and our business will not be successful;" "We depend on collaborations to complete the development and commercialization of some of our product candidates. These collaborations may place the development of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us;" "If we do not establish collaborations for our product candidates, we will have to alter our development and commercialization plans;" "If our preclinical studies do not produce successful results or our clinical trials do not demonstrate safety and efficacy in humans, we will not be able to commercialize our product candidates;" "Any failure or delay in commencing or completing clinical trials for our product candidates could severely harm our business;" "We rely on third parties to conduct our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for, or commercialize, our product candidates;" "If third parties do not manufacture *Horizant*, *Regnite* or our product candidates in sufficient quantities or at an acceptable cost, commercialization of *Horizant*, *Regnite* and clinical development and commercialization of our product candidates would be harmed or delayed;" "If we are required to obtain alternate third-party manufacturers, it could delay or prevent the clinical development and commercialization of our product candidates;" and "Use of third-party manufacturers may increase the risk that we or our partners will not have adequate supplies of our product candidates" sections of "Risk Factors."

[Table of Contents](#)

Marketed Product and Product Candidate	Description	Phase of Development	Estimated Completion of Current Phase	Related R&D Expenses		
				Year Ended December 31,		
				2011	2010	2009
(In thousands)						
Preclinical and clinical development						
Gabapentin enacarbil*	RLS	Approved in the United States and in Japan	N/A	\$ 137	\$ 310	\$ 2,988
AP**	Spasticity	Phase 3	2013	10,673	15,729	15,602
	GERD	Discontinued	N/A			
XP21279	Parkinson's disease	On hold	Unknown	2,547	2,580	4,024
XP23829	RRMS	Preclinical	IND planned to be filed in the second quarter of 2012	2,743	—	—
Other(1)				<u>27,688</u>	<u>24,384</u>	<u>27,686</u>
Total preclinical and clinical development				43,788	43,003	50,300
Research(2)				<u>—</u>	<u>9,543</u>	<u>20,447</u>
Total research and development				<u>\$43,788</u>	<u>\$52,546</u>	<u>\$70,747</u>

* Known as *Horizant* in the United States and *Regnite* in Japan.

** Arbaclofen placarbil, previously known as XP19986. Related R&D expenses included costs for both the spasticity and GERD indications.

- (1) "Other" constitutes preclinical and clinical development costs for our marketed product and product candidates that are not directly allocated to gabapentin enacarbil, AP, XP21279 or XP23829. For the year ended December 31, 2011, "other" expenses consisted primarily of personnel costs of \$17.7 million and office and facilities overhead costs of \$7.3 million.
- (2) "Research" expenses for the year ended December 31, 2010 and 2009 consisted primarily of personnel costs and office and facilities overhead costs. As a result of our focus on advancement of our later-stage product candidates and to reduce expenses, we eliminated our discovery research efforts in 2010. The remaining office and facilities overhead costs were reclassified to the "preclinical and clinical development" other expenses for the year ended December 31, 2011.

The largest component of our total operating expenses is our ongoing investment in our research and development activities, including the clinical development of our product candidate pipeline. The process of conducting the clinical research necessary to obtain FDA approval is costly and time consuming. We consider the active management and development of our clinical pipeline to be critical to our long-term success. The actual probability of success for each product candidate and clinical program may be impacted by a variety of factors, including, among others, the quality of the product candidate, early clinical data, investment in the program, competition, manufacturing capability and commercial viability. Furthermore, our strategy includes entering into additional collaborations with third parties to participate in the development and commercialization of at least some of our product candidates. In situations in which third parties have control over the preclinical development or clinical trial process for a product candidate, the estimated completion date is largely under the control of that third party and not under our control. We cannot forecast with any degree of certainty which of our product candidates, if any, will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements.

[Table of Contents](#)

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates.

Results of Operations

Years Ended December 31, 2011, 2010 and 2009

Revenues

Our collaboration revenue consisted of the recognition of revenues from up-front and milestone payments from our collaboration with Astellas. Our net revenue from unconsolidated joint operating activities consisted of the recognition of revenues from up-front and milestone payments and the recognition of our share of operating losses resulting from our election to co-promote *Horizant* in the United States with GSK. In connection with the amendment and restatement of our collaboration agreement with GSK in November 2010, our share of operating losses is forgiven up to a maximum of \$10.0 million, of which approximately \$6.6 million had been forgiven through December 31, 2011. Pursuant to the agreement, GSK is responsible for recording sales of *Horizant* in the United States. For the year ended December 31, 2011, net sales in the United States of *Horizant* as recorded by GSK were \$2.0 million.

	Year Ended December 31,			2010 to 2011		2009 to 2010	
	2011	2010	2009	Change	Change	Change	Change
				\$	%	\$	%
	(In thousands, except percentages)						
Net revenue from unconsolidated joint operating activities	\$ 35,000	\$ 1,364	\$ 24,758	\$ 33,636	2,466%	\$ (23,394)	(94)%
Collaboration revenue	8,515	1,515	9,515	7,000	462%	(8,000)	(84)%
Total revenues	<u>\$ 43,515</u>	<u>\$ 2,879</u>	<u>\$ 34,273</u>	<u>\$ 40,636</u>	1,411%	<u>\$ (31,394)</u>	(92)%

The increase in net revenue from unconsolidated joint operating activities in 2011 compared to 2010 was primarily due to the receipt and recognition of a \$30.0 million milestone payment from GSK in connection with the first shipment of *Horizant* to a wholesaler and a \$5.0 million milestone payment from GSK in connection with the FDA's acceptance for review of the sNDA under Section 505(b)(2) requesting approval of *Horizant* for the potential management of PHN.

The decrease in net revenue from unconsolidated joint operating activities in 2010 compared to 2009 was primarily due to the receipt and recognition of a significant portion of milestone payments in the aggregate of \$20.0 million from GSK related to the FDA's acceptance for review of the *Horizant* NDA in 2009. As a result of our amended and restated collaboration agreement with GSK in November 2010, as currently in effect, our share of losses from the joint profit and loss is forgiven up to a maximum of \$10.0 million leading to the reversal in 2010 of the \$1.1 million loss recognized in 2009.

The increase in collaboration revenue in 2011 compared to 2010 was due to the recognition of a \$7.0 million milestone payment from Astellas in connection with FDA approval of the *Horizant* NDA for RLS.

The decrease in collaboration revenue in 2010 compared to 2009 was the result of an \$8.0 million decrease in revenues recognized in 2009 under our Astellas agreement from milestone payments related to the FDA's acceptance for review of the NDA for *Horizant* in the United States and the acceptance of filing of the NDA for *Regnite* with the Pharmaceuticals and Medical Device Agency in Japan.

We expect revenues to fluctuate in the future primarily depending upon the commercialization and potential further development of *Horizant/Regnite/gabapentin enacarbil*, the timing of milestone-related activities under our Astellas and GSK collaborations and the extent to which we enter into new, or modify existing, collaborative agreements. In the event our collaboration agreement with GSK terminates and commercialization rights to *Horizant* reverts to us, we expect revenues to fluctuate in our efforts to market and sell *Horizant* or enter into agreements with third parties to do so.

[Table of Contents](#)

Research and Development Expenses

Of the total research and development expenses for the years ended December 31, 2011, 2010 and 2009, the costs associated with research and preclinical and clinical development activities approximated the following:

	Year Ended December 31,			2010 to 2011 Change		2009 to 2010 Change	
	2011	2010	2009	\$	%	\$	%
	(In thousands, except percentages)						
Research	\$ —	\$ 9,543	\$ 20,447	\$ (9,543)	(100)%	\$ (10,904)	(53)%
Preclinical and clinical development	43,788	43,003	50,300	785	2%	(7,297)	(15)%
Total research and development	\$ 43,788	\$ 52,546	\$ 70,747	\$ (8,758)	(17)%	\$ (18,201)	(26)%

The decrease in research and development expenses for 2011 compared to 2010 was principally due to the following:

- decreased net costs for AP of \$5.1 million primarily due to decreased clinical costs;
- decreased personnel costs of \$4.7 million primarily due to decreased headcount and decreased non-cash stock-based compensation of \$2.7 million;
- decreased supplies and services costs of \$0.7 million;
- decreased office and facilities overhead costs of \$0.6 million; partially offset by
- increased net costs for XP23829 of \$2.7 million primarily due to increased toxicology costs.

The decrease in research and development expenses for 2010 compared to 2009 was principally due to the following:

- decreased net costs for *Horizant/Regnite/gabapentin enacarbil* of \$2.7 million primarily due to decreased manufacturing and clinical costs;
- decreased net costs for XP21279 of \$1.4 million primarily due to decreased toxicology costs; and
- decreased personnel costs of \$12.6 million primarily due to decreased headcount, including decreased non-cash stock-based compensation of \$2.2 million; partially offset by
- a credit in 2009 of \$2.0 million from Astellas for manufacturing costs under the supply arrangement.

We expect our research and development expenses to increase in 2012 primarily due to the AP Phase 3 spasticity program. The timing and amount of research and development expenses incurred will primarily depend upon the extent of current or future clinical trials for AP, as well as the related expenses associated with our development organization, regulatory requirements, advancement of our preclinical program and product candidate manufacturing costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted principally of salaries and other related costs for personnel in executive, finance, accounting, business development, information technology, legal, sales, marketing and human resources functions. Other selling, general and administrative expenses included facility costs not otherwise included in research and development expenses, patent-related costs and professional fees for legal, consulting and accounting services.

	Year Ended December 31,			2010 to 2011 Change		2009 to 2010 Change	
	2011	2010	2009	\$	%	\$	%
	(In thousands, except percentages)						
Selling, general and administrative	\$ 30,427	\$ 28,323	\$ 31,807	\$ 2,104	7%	\$ (3,484)	(11)%

[Table of Contents](#)

The increase in selling, general and administrative expenses in 2011 compared to 2010 was principally due to increased personnel costs of \$0.8 million, consulting costs of \$0.8 million and market research costs of \$0.6 million.

The decrease in selling, general and administrative expenses in 2010 compared to 2009 was principally due to decreased personnel costs of \$2.8 million primarily due to decreased headcount.

We expect moderate increases in selling, general and administrative expenses compared to 2011 levels. Pursuant to our amended and restated collaboration agreement with GSK, we have up to three years to deploy a sales force following the April 2011 approval of *Horizant* in the United States. The timing and amount of selling, general and administrative expenses incurred will primarily depend upon if or when we deploy such sales force in support of the commercialization of *Horizant* for RLS.

Restructuring Charges

As a result of the implementation of our March 2010 restructuring plan that resulted in a reduction in force of 107 employees, or approximately 50% of our workforce at the time, we recorded restructuring charges of \$5.3 million in the year ended December 31, 2010. The restructuring charges consisted primarily of \$3.9 million of leave of absence pay, severance and healthcare benefits, \$0.9 million of non-cash stock-based compensation and \$0.4 million of property and equipment write-offs. As of December 31, 2010, we had made all cash payments in association with this restructuring plan.

In December 2011, as part of our ongoing evaluation of our facilities requirements in light of future plans, we recorded restructuring charges of \$2.9 million in the fourth quarter of 2011 in connection with the permanent cease use of the office space in a building at 3400 Central Expressway, Santa Clara, California. The restructuring charges consisted of \$2.5 million of facility-related charges and \$0.4 million of property and equipment write-offs. As of December 31, 2011, we expect to make all cash payments associated with this action by August 2013, which coincides with the end of the lease term for the office space.

Interest and Other Income and Interest and Other Expense

	Year Ended December 31,			2010 to 2011		2009 to 2010	
	2011	2010	2009	Change		Change	
				\$	%	\$	%
	(In thousands, except percentages)						
Interest and other income	\$ 243	\$ 796	\$ 1,229	\$ (553)	(69)%	\$ (433)	(35)%
Interest and other expense	—	—	4	—	0%	(4)	(100)%

The decrease in interest and other income in 2011 compared to 2010 resulted primarily from awards that totaled \$0.5 million received and recognized in 2010 through the Qualifying Therapeutic Discovery Project program under section 48D of the Internal Revenue Code of 1986, as amended, which was enacted as part of the *Patient Protection and Affordable Care Act of 2010*, and, to a lesser extent, earnings on cash equivalents and short-term investments. The decrease in interest income in 2010 compared to 2009 was primarily due to lower interest rates.

Income Taxes

We recorded \$0, \$0 and \$0.7 million of current income tax benefit for the years ended December 31, 2011, 2010 and 2009, respectively. In the year ended December 31, 2009, \$0.4 million of current income tax benefit recognized was due to the adoption of a provision in the *Worker, Homeownership, and Business Assistance Act of 2009* that allows businesses with net operating losses in 2008 or 2009 to carry back those losses for up to five-years and \$0.3 million of current income tax benefit recognized was due to the adoption of a provision in the *American Recovery and Reinvestment Tax Act of 2009* that allows corporations to convert carry-forward research and development and Alternative Minimum Tax credits into a refundable credit amount, which we claimed and received as a refund in cash in 2010.

[Table of Contents](#)

Liquidity and Capital Resources

	Year Ended December 31,		
	2011	2010	2009
	(In thousands)		
Cash provided by (used in):			
Operating activities	\$ (13,413)	\$ (64,481)	\$ (57,680)
Investing activities	15,429	20,227	(25,631)
Financing activities	178	31,191	53,516
Capital expenditures (included in investing activities above)	(225)	(646)	(2,891)

Due to our significant research and development expenditures, we have generated cumulative operating losses since we incorporated in 1999. As such, we have funded our research and development operations primarily through sales of our equity securities, non-equity payments from our collaborators and interest earned on investments. At December 31, 2011, we had available cash and cash equivalents and short-term investments of \$94.4 million. Our cash and investment balances are held in a variety of interest-bearing instruments, including corporate debt securities, investments backed by U.S. government-sponsored agencies and money market accounts. Cash in excess of immediate requirements is invested with regard to liquidity and capital preservation, and we seek to minimize the potential effects of concentration and degrees of risk.

Net cash used in operating activities was \$13.4 million, \$64.5 million and \$57.7 million in the years ended December 31, 2011, 2010 and 2009, respectively. The net cash used in operating activities in 2011 primarily reflected our net loss, partially offset by non-cash stock-based compensation. The net cash used in operating activities in 2010 and 2009 primarily reflected our net loss and, to a lesser extent, changes in operating assets and liabilities, partially offset by non-cash stock-based compensation. Additionally, we recorded restructuring charges of \$2.9 million and \$5.3 million in the years ended December 31, 2011 and 2010, respectively, which included approximately \$0 and \$4.0 million of cash expenditures, all of which was paid in the year ended December 31, 2010.

Net cash provided by (used in) investing activities primarily reflected the timing of purchases of investments and proceeds from maturities of investments.

Net cash provided by financing activities was \$0.2 million, \$31.2 million and \$53.5 million in the years ended December 31, 2011, 2010 and 2009, respectively. The net cash provided by financing activities in 2011, 2010 and 2009 primarily reflected the net proceeds from the issuance of common stock and the exercise of stock options.

We believe that our existing capital resources and anticipated milestone payments, together with interest thereon, will be sufficient to meet our projected operating requirements into the third quarter of 2013. This estimate assumes receipt of a potential \$10.0 million milestone payment from GSK associated with the possible approval of *Horizant* for the management of PHN, assuming such approval occurs and the collaboration agreement with GSK is effective at the time of such approval. We have based our estimate of cash sufficiency on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We have no credit facility or committed sources of capital other than potential milestones and contingent payments receivable under our collaborations. If our collaboration with GSK is terminated, we may not be entitled to any further milestone payments or royalties from GSK with respect to the development and commercialization of *Horizant*, which could accelerate our need for additional capital. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in "Risk Factors." Because of the numerous risks and uncertainties associated with the development and commercialization of our marketed product and product candidates, and the extent to which we enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including:

[Table of Contents](#)

- the scope, rate of progress, results and cost of our preclinical testing, clinical trials and other research and development activities;
- the timing and amount of our share of operating losses from our GSK collaboration;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from *Horizant*, *Regnite* and our other potential products;
- the timing of any milestone and contingent payments under our collaborative arrangements;
- the costs and expenses associated with the litigation proceedings related to the XenoPort Complaint, the GSK Complaint and the notice of termination of the collaboration agreement with GSK;
- if our collaboration with GSK is not terminated, the timing and costs of our establishment of a sales force to support our co-promotion of *Horizant* for the treatment of RLS, if we establish a sales force;
- if our collaboration with GSK is terminated and rights to *Horizant* revert to us, the timing and costs of establishing third party arrangements to market and sell *Horizant* if we choose or are unable to establish sufficient sales, marketing and distribution capabilities on our own;
- the cost of manufacturing clinical, and establishing commercial, supplies of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue, including rights related to *Horizant* that we obtained pursuant to our amended and restated collaboration agreement with GSK or that we may obtain if the collaboration with GSK is terminated;
- the cost, timing and outcomes of regulatory approvals, if any;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish or modify;
- the cost and expenses associated with any potential litigation, including any further litigation arising from our collaboration agreement with GSK;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the extent of product development funding under our current collaborative arrangements; and
- the extent to which we acquire or invest in businesses, products or technologies that complement our business, although we have no commitments or agreements relating to any of these types of transactions.

If we need to raise additional money to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are, or anticipate that we may be, unable to raise additional funds when needed, we may terminate or delay clinical trials for one or more of our product candidates, we may delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates or we may curtail significant drug development programs for our product candidates. In addition, if our collaboration agreement with GSK does not terminate, at any time upon advance notice to GSK, we may exercise the right to revert to a net sales royalty-based compensation structure and forego the right to co-promote *Horizant* in the United States. We may seek to raise any necessary additional funds through equity or debt financings, collaborative arrangements with corporate partners or other sources. To the extent that we raise additional capital through licensing arrangements or arrangements with collaborative partners, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize ourselves. To the extent that we raise additional capital through equity financings, dilution to our stockholders would result. Any debt financing or additional equity that we raise may contain terms that are not favorable to our stockholders or us. Our ability to raise additional funds and the terms upon which we are able to raise such funds may be adversely impacted by the uncertainty regarding our financial condition, the outcome of the litigation proceedings with GSK, including whether our collaboration with GSK will terminate and on what terms, and/or current economic conditions,

[Table of Contents](#)

including the effects of disruptions to and volatility in the credit and financial markets in the United States, the European Union and other regions of the world, including those resulting from or associated with rising government debt levels.

Off-Balance Sheet Arrangements

We have no material off-balance sheet arrangements as defined in Regulation S-K 303(a)(4)(ii).

Contractual Obligations

Our future contractual obligations at December 31, 2011 were as follows (in thousands):

Contractual Obligations	Total	Less Than 1 Year	1-3 Years	3-5 Years	Greater Than 5 Years
Operating lease obligations	\$ 6,363	\$ 3,723	\$ 2,640	\$ —	\$ —

Operating lease obligations do not assume the exercise by us of any termination or extension options.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities of high-credit quality. As of December 31, 2011, we had cash and cash equivalents and short-term investments of \$94.4 million consisting of cash and highly liquid investments deposited in highly rated financial institutions in the United States. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

We contract for the conduct of certain manufacturing activities with a contract manufacturer in Europe. We made payments in the aggregate amount of \$0.1 million, \$1.1 million and \$3.5 million during the years ended December 31, 2011, 2010 and 2009, respectively, to this European contract manufacturer. We are subject to exposure to fluctuations in foreign exchange rates in connection with agreements with this European contract manufacturer. To date, the effect of the exposure to these fluctuations in foreign exchange rates has not been material, and we do not expect it to be material in the foreseeable future. We do not hedge our foreign currency exposures. We have not used derivative financial instruments for speculation or trading purposes.

Item 8. Financial Statements and Supplementary Data.

The information required by this item is incorporated herein by reference to the financial statements and schedule listed in Item 15 (1) and (2) of Part IV of this Annual Report on Form 10-K.

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

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

[Table of Contents](#)

Based on their evaluation as required by paragraph (b) of Rules 13a-15 or 15d-15 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of December 31, 2011, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) or 15d-15(e)) were effective.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our chief executive officer and chief financial officer have concluded, based on their evaluation as of December 31, 2011, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework*. Based on our evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2011.

Ernst & Young LLP, an independent registered public accounting firm, has audited our financial statements included herein and has issued an audit report on the effectiveness of our internal control over financial reporting, which report is included below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of XenoPort, Inc.

We have audited XenoPort, Inc.'s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). XenoPort, 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. 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, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, XenoPort, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of XenoPort, Inc. as of December 31, 2011 and 2010, and the related statements of comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011 of XenoPort, Inc., and our report dated February 29, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California
February 29, 2012

[Table of Contents](#)

Changes in Internal Controls Over Financial Reporting

There were no significant changes in our internal controls over financial reporting during the fourth quarter of 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

At our 2011 annual meeting of stockholders held in May 2011, our stockholders did not indicate a majority preference for how frequently we will include a non-binding "say-on-pay" stockholder advisory vote on the compensation of our named executive officers in our proxy materials. Our board of directors initially decided to include such non-binding say-on-pay stockholder advisory votes every three years until such time as the next advisory vote is submitted to stockholders regarding the frequency of such advisory votes or until our board of directors otherwise determines that a different frequency for such advisory votes is in the best interests of our stockholders. Upon a review of recent proxy voting guidance and guidelines, our board of directors has determined that it would be in the best interests of our stockholders to include an advisory vote on the compensation of our named executive officers in our proxy materials in connection with the 2012 annual meeting of stockholders.

PART III.

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we intend to file our definitive proxy statement for our 2012 annual meeting of stockholders, or the Proxy Statement, pursuant to Regulation 14A of the Exchange Act, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item with respect to our executive officers may be found under the caption, "Executive Officers of the Registrant" in Item 1 of this Annual Report on Form 10-K. The information required by this item relating to our directors and nominees, including information with respect to our audit committee, audit committee financial experts and procedures by which stockholders may recommend nominees to our board of directors, may be found under the section entitled "Proposal 1 — Election of Directors" appearing in the Proxy Statement. Such information is incorporated herein by reference. Information regarding compliance with Section 16(a) of the Exchange Act may be found under the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" appearing in our Proxy Statement. Such information is incorporated herein by reference.

We have adopted a code of ethics that applies to our employees, officers and directors and incorporates guidelines designed to deter wrongdoing and to promote honest and ethical conduct and compliance with applicable laws and regulations. In addition, the code of ethics incorporates our guidelines pertaining to topics such as conflicts of interest and workplace behavior. We have posted the text of our code of ethics on our Web site at www.XenoPort.com in connection with "Investor Relations/Corporate Governance" materials. In addition, we intend to promptly disclose (1) the nature of any amendment to our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our Web site in the future.

Item 11. Executive Compensation.

The information required by this item is included in our Proxy Statement under the sections entitled "Executive Compensation," "Director Compensation," "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" and is incorporated herein by reference.

[Table of Contents](#)

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

Equity Compensation Plan Information

The following table provides certain information regarding our equity compensation plans in effect as of December 31, 2011:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by security holders:			
1999 Stock Plan(1)	434,261	\$ 4.36	—
2005 Equity Incentive Plan(2)	4,710,424	\$ 18.67	879,674
2005 Non-Employee Directors' Stock Option Plan(3)	397,500	\$ 21.58	144,166
2005 Employee Stock Purchase Plan(4)	—	—	333,306
Equity compensation plans not approved by security holders:			
New Hire Option Agreement with Vincent J. Angotti(5)	140,612	\$ 42.59	—
New Hire Stock Unit Award Agreement with Vincent J. Angotti(6)	2,500	—	—
2010 Inducement Award Plan(7)	317,674	\$ 6.24	655,516
Total	6,002,971	\$ 17.69	2,012,662

- (1) In December 1999, we adopted the 1999 Stock Plan, or the 1999 Plan, which was terminated in June 2005 in connection with our initial public offering so that no further awards may be granted under the 1999 Plan. Although the 1999 Plan has terminated, all outstanding options under the 1999 Plan will continue to be governed by their existing terms.
- (2) In January 2005, we adopted the 2005 Equity Incentive Plan, or the 2005 Incentive Plan, which became effective in June 2005 in connection with our initial public offering. A total of 2,000,000 shares of common stock were initially authorized for issuance under the 2005 Incentive Plan. Our board of directors may increase the share reserve of the 2005 Incentive Plan as of each January 1, from January 1, 2006 through January 1, 2015, by an amount determined by our board; provided, however that the increase for any year may not exceed the lesser of (1) 2.5% of the total number of shares of our common stock outstanding on the December 31st of the preceding calendar year or (2) 2,000,000 shares. During the year ended December 31, 2011, the annual increase to the 2005 Incentive Plan reserve was 880,669 shares. Restricted stock unit awards and a performance stock unit award have been granted under the 2005 Incentive Plan and are included in column (a). The outstanding performance stock unit award has a variable amount of securities that may be issued under it depending on certain performance measures. The maximum number of shares of common stock that may be issued under such award, 200,000, has been included in column (a). The weighted-average exercise price in column (b) does not take the performance stock unit award into account, but does include the effect of the restricted stock unit awards under the 2005 Incentive Plan, which awards do not carry an exercise price. At December 31, 2011, the weighted-average exercise price of outstanding options under the 2005 Incentive Plan was \$24.80, excluding the restricted stock unit awards.
- (3) In January 2005, we adopted the 2005 Non-Employee Directors' Stock Option Plan, or the Directors' Plan, which became effective in June 2005 in connection with our initial public offering. The Directors' Plan provides for the automatic grant of options to purchase shares of our common stock to non-employee

[Table of Contents](#)

directors. A total of 150,000 shares of our common stock were initially authorized for issuance under the Directors' Plan. Our board of directors may increase the share reserve of the Directors' Plan as of each January 1, from January 1, 2006 through January 1, 2015, by an amount determined by our board; provided, however that the increase for any year may not exceed the excess of (1) the number of shares of our common stock subject to options granted under the Directors' Plan during the preceding calendar year over (2) the number of shares added back to the share reserve of the Directors' Plan during the preceding calendar year from cancellations. During the year ended December 31, 2011, the annual increase to the Directors' Plan reserve was 27,083 shares.

- (4) In January 2005, we adopted the 2005 Employee Stock Purchase Plan, or ESPP, which became effective in June 2005 in connection with our initial public offering. The ESPP allows for qualified employees (as defined in the ESPP) to purchase shares of our common stock at a price equal to the lower of 85% of the closing price of our common stock at the beginning of the offering period or 85% of the closing price of our common stock on the date of purchase. A total of 250,000 shares of our common stock were initially authorized for issuance under the ESPP. Our board of directors may increase the share reserve of the ESPP as of each January 1, from January 1, 2006 through January 1, 2015, by an amount determined by our board; provided, however that the increase for any year may not exceed the lesser of (1) 1% of the total number of shares of our common stock outstanding on the December 31st of the preceding calendar year or (2) 250,000 shares. During the year ended December 31, 2011, our board determined that the share reserve of the ESPP was sufficient and did not require an annual increase.
- (5) On May 1, 2008, Mr. Angotti was granted a new employee inducement stock award outside of our stockholder approved equity plans consisting of nonqualified stock options to purchase 140,612 shares of our common stock. The stock options have a per share exercise price of \$42.59, the closing trading price of our common stock on the NASDAQ Global Market on May 1, 2008. The stock options have a ten-year term and vest over four years, with 25% cliff vesting on the first anniversary of the May 1, 2008 grant date, and 1/48th of the shares subject to the options vesting monthly thereafter.
- (6) On May 1, 2008, Mr. Angotti was granted a new employee inducement stock award outside of our stockholder approved equity plans consisting of restricted stock units for 10,000 shares of our common stock. The restricted stock units vest in four equal annual installments on each anniversary of the May 1, 2008 grant date. The restricted stock units have no exercise price.
- (7) In May 2010, the 2010 Inducement Award Plan, or the 2010 Inducement Plan, was adopted by our board and became effective. We intend to grant awards under the 2010 Inducement Plan to persons not previously employees or directors of ours (or following *bona fide* periods of non-employment by us and our affiliates) as inducements material to such individuals entering into employment with us and to provide incentives for such persons to exert maximum efforts for our success. A total of 350,000 shares of common stock were initially authorized for issuance under the 2010 Inducement Plan and an additional 625,000 shares were authorized for issuance in 2011. The 2010 Inducement Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock awards. Restricted stock unit awards have been granted under the 2010 Inducement Plan and are included in column (a). The weighted-average exercise price in column (b) includes the effect of the restricted stock unit awards under the 2010 Inducement Plan, which awards do not carry an exercise price. At December 31, 2011, the weighted-average exercise price of outstanding options under the 2010 Inducement Plan was \$6.83, excluding the restricted stock unit awards.

Security Ownership of Certain Beneficial Owners and Management

The information required by this item relating to security ownership of certain beneficial owners and management is included in our Proxy Statement under the section entitled "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference.

[Table of Contents](#)

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

The information required by this item is included in our Proxy Statement under the sections entitled "Transactions with Related Persons" and "Proposal 1 — Election of Directors" and is incorporated herein by reference.

Item 14. *Principal Accountant Fees and Services.*

The information required by this item is incorporated herein by reference to the information included in our Proxy Statement under the section entitled "Proposal 3 — Ratification of Selection of Independent Registered Public Accounting Firm."

PART IV.

Item 15. *Exhibits, Financial Statement Schedules.*

1. *Index to Financial Statements*

The following Financial Statements are included herein:

	<u>Page Number</u>
Report of Independent Registered Public Accounting Firm	92
Balance Sheets as of December 31, 2011 and 2010	93
Statements of Comprehensive Loss for each of the three years ended December 31, 2011, 2010 and 2009	94
Statements of Stockholders' Equity for each of the three years ended December 31, 2011, 2010 and 2009	95
Statements of Cash Flows for each of the three years ended December 31, 2011, 2010 and 2009	96
Notes to Financial Statements	97

2. *Index to Financial Statement Schedules*

None.

All other schedules are omitted because they are not applicable, or not required, or because the required information is included in the financial statements or notes thereto.

[Table of Contents](#)

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

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation(1)
3.2	Amended and Restated Bylaws(1)
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock(2)
4.1	Specimen Common Stock Certificate(3)
4.2	Form of Right Certificate(4)
4.3	Form of Registered Direct Common Warrant(5)
10.1*	Form of Indemnification Agreement between the Company and its officers and directors(6)
10.2*	Form of Employee Proprietary Information Agreement between the Company and its executive officers(7)
10.3	Lease Agreement, dated September 24, 2001, by and between the Company and Sobrato Interests(7)
10.3.1	First Amendment to Lease Agreement, dated February 29, 2008, by and between the Company and Sobrato Interests(8)
10.4	Lease, dated February 29, 2008, by and between the Company and Sobrato Interests(9)
10.5*	1999 Stock Plan(7)
10.6*	Form of Stock Option Agreement under the 1999 Stock Plan(7)
10.7*	2005 Equity Incentive Plan(6)
10.8*	Form of Option Agreement under the 2005 Equity Incentive Plan(6)
10.9*	Form of Stock Unit Award Agreement under the 2005 Equity Incentive Plan(10)
10.10*	2005 Non-Employee Directors' Stock Option Plan(11)
10.11*	Form of Stock Option Agreement under the 2005 Non-Employee Directors' Stock Option Plan(12)
10.12*	2005 Employee Stock Purchase Plan(13)
10.13*	Form of 2005 Employee Stock Purchase Plan Offering Document(14)
10.14*	2010 Inducement Award Plan, as amended effective August 1, 2011(15)
10.15*	Form of Option Agreement under the 2010 Inducement Award Plan(16)
10.16*	Form of Stock Unit Award Agreement under the 2010 Inducement Award Plan(17)
10.17*	New Hire Option Agreement between Vincent J. Angotti and the Company(18)
10.18*	New Hire Stock Unit Award Agreement between Vincent J. Angotti and the Company(19)
10.19*	Performance Stock Unit Agreement, dated May 13, 2010, between the Company and Ronald W. Barrett, Ph.D.(20)
10.20*	Severance Rights Agreement, dated February 9, 2012, between the Company and Ronald W. Barrett, Ph.D.(21)
10.21*	Form of Severance Rights Agreement, dated February 9, 2012, between the Company and each of Vincent J. Angotti, Gianna M. Bosko, William G. Harris and David R. Savello, Ph.D.(22)
10.22*	Form of Change of Control Agreement between the Company and certain of its officers(23)
10.23*	Change of Control Agreement, dated November 7, 2007, between the Company and Kenneth C. Cundy, Ph.D.(24)

Table of Contents

Exhibit Number	Description of Document
10.24*	Amended and Restated Change of Control Agreement, dated February 25, 2011, between the Company and Gianna M. Bosko(25)
10.25*	Consulting Letter Agreement, dated August 26, 2010, between the Company and William J. Rieflin(26)
10.26*	XenoPort, Inc. Corporate Bonus Plan(27)
10.27*	Term Sheet for Director Cash Compensation(28)
10.28*	2011 Executive Compensation Information(29)
10.29*	2012 Executive Compensation Information(30)
10.30†	Amended and Restated Distribution and License Agreement, dated as of October 31, 2009, between the Company and Astellas Pharma Inc.(31)
10.31†	Amended and Restated Development and Commercialization Agreement, dated November 7, 2010, by and between the Company and Glaxo Group Limited
10.32	Rights Agreement, dated as of December 15, 2005, by and between the Company and Mellon Investor Services LLC(32)
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included in the signature page hereto)
31.1	Certification of the Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)(33)
101.INS	XBRL Instance Document(34)
101.SCH	XBRL Taxonomy Extension Schema Document(34)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document(34)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document(34)
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document(34)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document(34)

* Represents a management contract or compensation plan or arrangement.

† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

- (1) Incorporated herein by reference to the same numbered exhibit of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended June 30, 2005, as filed with the SEC on August 11, 2005.
- (2) Incorporated herein by reference to Exhibit 3.1 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on December 16, 2005.
- (3) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on April 13, 2005.
- (4) Incorporated herein by reference to Exhibit 4.1 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on December 16, 2005.

Table of Contents

- (5) Incorporated herein by reference to Exhibit 4.1 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on December 30, 2008.
- (6) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on March 2, 2005.
- (7) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-122156), as filed with the SEC on January 19, 2005.
- (8) Incorporated herein by reference to the same numbered exhibit of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended March 31, 2008, as filed with the SEC on May 8, 2008.
- (9) Incorporated herein by reference to Exhibit 10.32 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended March 31, 2008, as filed with the SEC on May 8, 2008.
- (10) Incorporated herein by reference to the same numbered exhibit of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended June 30, 2008, as filed with the SEC on August 7, 2008.
- (11) Incorporated herein by reference to Exhibit 10.9 of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on April 13, 2005.
- (12) Incorporated herein by reference to Exhibit 10.10 of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on April 13, 2005.
- (13) Incorporated herein by reference to Exhibit 10.11 of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on March 2, 2005.
- (14) Incorporated herein by reference to Exhibit 10.12 of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on March 2, 2005.
- (15) Incorporated herein by reference to Exhibit 10.17 of our quarterly report on Form 10-Q (File No. 000-51329), as filed with the SEC on August 5, 2011.
- (16) Incorporated herein by reference to Exhibit 99.3.2 of our registration statement on Form S-8 (File No. 333-166760), as filed with the SEC on May 12, 2010.
- (17) Incorporated herein by reference to Exhibit 99.3.3 of our registration statement on Form S-8 (File No. 333-166760), as filed with the SEC on May 12, 2010.
- (18) Incorporated herein by reference to Exhibit 99.4 of our registration statement on Form S-8 (File No. 333-150730), as filed with the SEC on May 8, 2008.
- (19) Incorporated herein by reference to Exhibit 99.5 of our registration statement on Form S-8 (File No. 333-150730), as filed with the SEC on May 8, 2008.
- (20) Incorporated herein by reference to Exhibit 10.41 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended June 30, 2010, as filed with the SEC on August 6, 2010.
- (21) Incorporated herein by reference to Exhibit 10.39 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on February 10, 2012.
- (22) Incorporated herein by reference to Exhibit 10.40 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on February 10, 2012.
- (23) Incorporated herein by reference to Exhibit 10.13 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended September 30, 2007, as filed with the SEC on November 9, 2007.
- (24) Incorporated herein by reference to Exhibit 10.31 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended September 30, 2007, as filed with the SEC on November 9, 2007.
- (25) Incorporated herein by reference to Exhibit 10.28 of our annual report on Form 10-K (File No. 000-51329) for the period ended December 31, 2010, as filed with the SEC on March 1, 2011.
- (26) Incorporated herein by reference to Exhibit 10.43 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended September 30, 2010, as filed with the SEC on November 9, 2010.
- (27) Incorporated herein by reference to Exhibit 10.24 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on February 2, 2007.
- (28) Incorporated herein by reference to Exhibit 10.25 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on August 4, 2006.

Table of Contents

- (29) Incorporated herein by reference to Exhibit 10.45 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on January 14, 2011.
- (30) Incorporated herein by reference to Exhibit 10.38 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on January 17, 2012.
- (31) Incorporated herein by reference to Exhibit 10.35 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended September 30, 2009, as filed with the SEC on November 4, 2009.
- (32) Incorporated herein by reference to Exhibit 4.2 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on December 16, 2005.
- (33) This certification accompanies the annual report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.
- (34) Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. In accordance with Rule 406T of Regulation S-T, the information in these exhibits is furnished and deemed not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

[Table of Contents](#)

SIGNATURES

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

February 29, 2012	XenoPort, Inc. <i>(Registrant)</i> /s/ Ronald W. Barrett
February 29, 2012	_____ Ronald W. Barrett Chief Executive Officer and Director /s/ William G. Harris
	_____ William G. Harris Senior Vice President of Finance and Chief Financial Officer (Principal Financial and Accounting Officer)

[Table of Contents](#)

POWER OF ATTORNEY

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Ronald W. Barrett</u> Ronald W. Barrett	Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	February 29, 2012
<u>/s/ William G. Harris</u> William G. Harris	Senior Vice President of Finance and Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	February 29, 2012
<u>/s/ Paul L. Berns</u> Paul L. Berns	Director	February 29, 2012
<u>/s/ Dennis M. Fenton</u> Dennis M. Fenton	Director	February 29, 2012
<u>/s/ John G. Freund</u> John G. Freund	Director	February 29, 2012
<u>/s/ Catherine J. Friedman</u> Catherine J. Friedman	Director	February 29, 2012
<u>/s/ Jeryl L. Hilleman</u> Jeryl L. Hilleman	Director	February 29, 2012
<u>/s/ William J. Rieflin</u> William J. Rieflin	Director	February 29, 2012
<u>/s/ Wendell Wierenga</u> Wendell Wierenga	Director	February 29, 2012

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation(1)
3.2	Amended and Restated Bylaws(1)
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock(2)
4.1	Specimen Common Stock Certificate(3)
4.2	Form of Right Certificate(4)
4.3	Form of Registered Direct Common Warrant(5)
10.1*	Form of Indemnification Agreement between the Company and its officers and directors(6)
10.2*	Form of Employee Proprietary Information Agreement between the Company and its executive officers(7)
10.3	Lease Agreement, dated September 24, 2001, by and between the Company and Sobrato Interests(7)
10.3.1	First Amendment to Lease Agreement, dated February 29, 2008, by and between the Company and Sobrato Interests(8)
10.4	Lease, dated February 29, 2008, by and between the Company and Sobrato Interests(9)
10.5*	1999 Stock Plan(7)
10.6*	Form of Stock Option Agreement under the 1999 Stock Plan(7)
10.7*	2005 Equity Incentive Plan(6)
10.8*	Form of Option Agreement under the 2005 Equity Incentive Plan(6)
10.9*	Form of Stock Unit Award Agreement under the 2005 Equity Incentive Plan(10)
10.10*	2005 Non-Employee Directors' Stock Option Plan(11)
10.11*	Form of Stock Option Agreement under the 2005 Non-Employee Directors' Stock Option Plan(12)
10.12*	2005 Employee Stock Purchase Plan(13)
10.13*	Form of 2005 Employee Stock Purchase Plan Offering Document(14)
10.14*	2010 Inducement Award Plan, as amended effective August 1, 2011(15)
10.15*	Form of Option Agreement under the 2010 Inducement Award Plan(16)
10.16*	Form of Stock Unit Award Agreement under the 2010 Inducement Award Plan(17)
10.17*	New Hire Option Agreement between Vincent J. Angotti and the Company(18)
10.18*	New Hire Stock Unit Award Agreement between Vincent J. Angotti and the Company(19)
10.19*	Performance Stock Unit Agreement, dated May 13, 2010, between the Company and Ronald W. Barrett, Ph.D.(20)
10.20*	Severance Rights Agreement, dated February 9, 2012, between the Company and Ronald W. Barrett, Ph.D.(21)
10.21*	Form of Severance Rights Agreement, dated February 9, 2012, between the Company and each of Vincent J. Angotti, Gianna M. Bosko, William G. Harris and David R. Savello, Ph.D.(22)
10.22*	Form of Change of Control Agreement between the Company and certain of its officers(23)
10.23*	Change of Control Agreement, dated November 7, 2007, between the Company and Kenneth C. Cundy, Ph.D.(24)

Table of Contents

Exhibit Number	Description of Document
10.24*	Amended and Restated Change of Control Agreement, dated February 25, 2011, between the Company and Gianna M. Bosko(25)
10.25*	Consulting Letter Agreement, dated August 26, 2010, between the Company and William J. Rieflin(26)
10.26*	XenoPort, Inc. Corporate Bonus Plan(27)
10.27*	Term Sheet for Director Cash Compensation(28)
10.28*	2011 Executive Compensation Information(29)
10.29*	2012 Executive Compensation Information(30)
10.30†	Amended and Restated Distribution and License Agreement, dated as of October 31, 2009, between the Company and Astellas Pharma Inc. (31)
10.31†	Amended and Restated Development and Commercialization Agreement, dated November 7, 2010, by and between the Company and Glaxo Group Limited
10.32	Rights Agreement, dated as of December 15, 2005, by and between the Company and Mellon Investor Services LLC(32)
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included in the signature page hereto)
31.1	Certification of the Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)(33)
101.INS	XBRL Instance Document(34)
101.SCH	XBRL Taxonomy Extension Schema Document(34)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document(34)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document(34)
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document(34)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document(34)

* Represents a management contract or compensation plan or arrangement.

† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

- (1) Incorporated herein by reference to the same numbered exhibit of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended June 30, 2005, as filed with the SEC on August 11, 2005.
- (2) Incorporated herein by reference to Exhibit 3.1 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on December 16, 2005.
- (3) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on April 13, 2005.
- (4) Incorporated herein by reference to Exhibit 4.1 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on December 16, 2005.

Table of Contents

- (5) Incorporated herein by reference to Exhibit 4.1 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on December 30, 2008.
- (6) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on March 2, 2005.
- (7) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-122156), as filed with the SEC on January 19, 2005.
- (8) Incorporated herein by reference to the same numbered exhibit of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended March 31, 2008, as filed with the SEC on May 8, 2008.
- (9) Incorporated herein by reference to Exhibit 10.32 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended March 31, 2008, as filed with the SEC on May 8, 2008.
- (10) Incorporated herein by reference to the same numbered exhibit of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended June 30, 2008, as filed with the SEC on August 7, 2008.
- (11) Incorporated herein by reference to Exhibit 10.9 of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on April 13, 2005.
- (12) Incorporated herein by reference to Exhibit 10.10 of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on April 13, 2005.
- (13) Incorporated herein by reference to Exhibit 10.11 of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on March 2, 2005.
- (14) Incorporated herein by reference to Exhibit 10.12 of our registration statement on Form S-1, as amended (File No. 333-122156), as filed with the SEC on March 2, 2005.
- (15) Incorporated herein by reference to Exhibit 10.17 of our quarterly report on Form 10-Q (File No. 000-51329), as filed with the SEC on August 5, 2011.
- (16) Incorporated herein by reference to Exhibit 99.3.2 of our registration statement on Form S-8 (File No. 333-166760), as filed with the SEC on May 12, 2010.
- (17) Incorporated herein by reference to Exhibit 99.3.3 of our registration statement on Form S-8 (File No. 333-166760), as filed with the SEC on May 12, 2010.
- (18) Incorporated herein by reference to Exhibit 99.4 of our registration statement on Form S-8 (File No. 333-150730), as filed with the SEC on May 8, 2008.
- (19) Incorporated herein by reference to Exhibit 99.5 of our registration statement on Form S-8 (File No. 333-150730), as filed with the SEC on May 8, 2008.
- (20) Incorporated herein by reference to Exhibit 10.41 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended June 30, 2010, as filed with the SEC on August 6, 2010.
- (21) Incorporated herein by reference to Exhibit 10.39 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on February 10, 2012.
- (22) Incorporated herein by reference to Exhibit 10.40 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on February 10, 2012.
- (23) Incorporated herein by reference to Exhibit 10.13 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended September 30, 2007, as filed with the SEC on November 9, 2007.
- (24) Incorporated herein by reference to Exhibit 10.31 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended September 30, 2007, as filed with the SEC on November 9, 2007.
- (25) Incorporated herein by reference to Exhibit 10.28 of our annual report on Form 10-K (File No. 000-51329) for the period ended December 31, 2010, as filed with the SEC on March 1, 2011.
- (26) Incorporated herein by reference to Exhibit 10.43 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended September 30, 2010, as filed with the SEC on November 9, 2010.
- (27) Incorporated herein by reference to Exhibit 10.24 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on February 2, 2007.
- (28) Incorporated herein by reference to Exhibit 10.25 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on August 4, 2006.

[Table of Contents](#)

- (29) Incorporated herein by reference to Exhibit 10.45 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on January 14, 2011.
- (30) Incorporated herein by reference to Exhibit 10.38 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on January 17, 2012.
- (31) Incorporated herein by reference to Exhibit 10.35 of our quarterly report on Form 10-Q (File No. 000-51329) for the period ended September 30, 2009, as filed with the SEC on November 4, 2009.
- (32) Incorporated herein by reference to Exhibit 4.2 of our current report on Form 8-K (File No. 000-51329), filed with the SEC on December 16, 2005.
- (33) This certification accompanies the annual report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.
- (34) Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. In accordance with Rule 406T of Regulation S-T, the information in these exhibits is furnished and deemed not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of XenoPort, Inc.

We have audited the accompanying balance sheets of XenoPort, Inc. as of December 31, 2011 and 2010, and the related statements of comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of XenoPort, Inc. at December 31, 2011 and 2010, and the results of its comprehensive loss and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), XenoPort, Inc.'s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 29, 2012, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California
February 29, 2012

[Table of Contents](#)

XENOPORT, INC.
BALANCE SHEETS

	<u>December 31,</u>	
	<u>2011</u>	<u>2010</u>
	(In thousands, except per share amount)	
Current assets:		
Cash and cash equivalents	\$ 25,386	\$ 23,192
Short-term investments	69,056	85,403
Prepays and other current assets	3,010	2,206
Total current assets	<u>97,452</u>	<u>110,801</u>
Property and equipment, net	3,921	7,209
Restricted investments and other assets	2,663	3,219
Total assets	<u>\$ 104,036</u>	<u>\$ 121,229</u>
Current liabilities:		
Accounts payable	\$ 1,032	\$ 515
Accrued compensation	4,176	2,493
Accrued restructuring charges	1,627	—
Accrued preclinical and clinical costs	4,433	4,884
Other accrued liabilities	747	976
Deferred rent	—	1,104
Deferred revenue	1,515	1,515
Total current liabilities	<u>13,530</u>	<u>11,487</u>
Accrued restructuring charges	1,103	—
Deferred revenue	14,268	15,783
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 60,000 shares authorized; 35,515 and 35,227 shares issued and outstanding at December 31, 2011 and 2010, respectively	35	35
Additional paid-in capital	495,902	481,336
Accumulated other comprehensive loss	(16)	(6)
Accumulated deficit	<u>(420,786)</u>	<u>(387,406)</u>
Total stockholders' equity	<u>75,135</u>	<u>93,959</u>
Total liabilities and stockholders' equity	<u>\$ 104,036</u>	<u>\$ 121,229</u>

The accompanying notes are an integral part of these financial statements.

[Table of Contents](#)

XENOPORT, INC.
STATEMENTS OF COMPREHENSIVE LOSS

	<u>Year Ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
	(In thousands, except per share amounts)		
Revenues:			
Net revenue from unconsolidated joint operating activities	\$ 35,000	\$ 1,364	\$ 24,758
Collaboration revenue	8,515	1,515	9,515
Total revenues	<u>43,515</u>	<u>2,879</u>	<u>34,273</u>
Operating expenses:			
Research and development	43,788	52,546	70,747
Selling, general and administrative	30,427	28,323	31,807
Restructuring charges	2,923	5,275	—
Total operating expenses	<u>77,138</u>	<u>86,144</u>	<u>102,554</u>
Loss from operations	(33,623)	(83,265)	(68,281)
Interest and other income	243	796	1,229
Interest and other expense	—	—	(4)
Loss before income taxes	(33,380)	(82,469)	(67,056)
Income tax benefit	—	—	(722)
Net loss	(33,380)	(82,469)	(66,334)
Other comprehensive loss:			
Unrealized gains (losses) on available-for sale securities	(10)	(32)	(513)
Comprehensive loss	<u>\$ (33,390)</u>	<u>\$ (82,501)</u>	<u>\$ (66,847)</u>
Basic and diluted net loss per share	<u>\$ (0.94)</u>	<u>\$ (2.68)</u>	<u>\$ (2.31)</u>
Shares used to compute basic and diluted net loss per share	<u>35,400</u>	<u>30,813</u>	<u>28,766</u>

The accompanying notes are an integral part of these financial statements.

XENOPORT, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>				
	(In thousands, except share amounts)					
Balance at December 31, 2008	27,247,088	\$ 27	\$360,011	\$ 539	\$ (238,603)	\$ 121,974
Issuance of common stock upon exercise of options and vesting of restricted stock units	160,930	—	587	—	—	587
Issuance of common stock in connection with Employee Stock Purchase Plan	120,039	—	1,714	—	—	1,714
Employees stock-based compensation expense	—	—	18,633	—	—	18,633
Proceeds from common stock issued upon public offering, net of offering costs	2,875,000	3	51,212	—	—	51,215
Change in unrealized gains (losses) on investments	—	—	—	(513)	—	(513)
Net loss	—	—	—	—	(66,334)	(66,334)
Balance at December 31, 2009	30,403,057	30	432,157	26	(304,937)	127,276
Issuance of common stock upon exercise of options and vesting of restricted stock units	119,605	—	(358)	—	—	(358)
Issuance of common stock in connection with Employee Stock Purchase Plan	104,100	—	859	—	—	859
Employees stock-based compensation expense	—	—	17,993	—	—	17,993
Proceeds from common stock issued upon public offering, net of offering costs	4,600,000	5	30,685	—	—	30,690
Change in unrealized gains (losses) on investments	—	—	—	(32)	—	(32)
Net loss	—	—	—	—	(82,469)	(82,469)
Balance at December 31, 2010	35,226,762	35	481,336	(6)	(387,406)	93,959
Issuance of common stock upon exercise of options and vesting of restricted stock units	143,969	—	(624)	—	—	(624)
Issuance of common stock in connection with Employee Stock Purchase Plan	143,905	—	802	—	—	802
Employees stock-based compensation expense	—	—	14,388	—	—	14,388
Change in unrealized gains (losses) on investments	—	—	—	(10)	—	(10)
Net loss	—	—	—	—	(33,380)	(33,380)
Balance at December 31, 2011	<u>35,514,636</u>	<u>\$ 35</u>	<u>\$495,902</u>	<u>\$ (16)</u>	<u>\$ (420,786)</u>	<u>\$ 75,135</u>

The accompanying notes are an integral part of these financial statements.

[Table of Contents](#)

XENOPORT, INC.
STATEMENTS OF CASH FLOWS

	<u>Year Ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
	(In thousands)		
Operating activities			
Net loss	\$ (33,380)	\$ (82,469)	\$ (66,334)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,513	4,163	3,635
Accretion of investment discounts and amortization of investment premiums, net	677	1,090	1,438
Stock-based compensation expense	14,388	17,993	18,633
Changes in assets and liabilities:			
Prepays and other current and noncurrent assets	127	1,513	(799)
Accounts payable	517	(1,516)	(230)
Accrued compensation	1,683	(3,160)	821
Accrued restructuring charges	2,730	—	—
Accrued preclinical and clinical costs	(451)	1,775	(6,598)
Accrued unconsolidated joint operating activities	—	(1,095)	1,095
Other accrued liabilities	(229)	65	(1,090)
Deferred revenue	(1,515)	(1,784)	(7,368)
Deferred rent	(1,473)	(1,056)	(883)
Net cash used in operating activities	<u>(13,413)</u>	<u>(64,481)</u>	<u>(57,680)</u>
Investing activities			
Purchases of investments	(141,357)	(144,085)	(231,650)
Proceeds from maturities of investments	157,017	164,973	209,019
Change in restricted investments	(6)	(15)	(109)
Purchases of property and equipment	(225)	(646)	(2,891)
Net cash provided by (used in) investing activities	<u>15,429</u>	<u>20,227</u>	<u>(25,631)</u>
Financing activities			
Net proceeds from issuance of common stock and exercise of stock options	178	31,191	53,516
Net cash provided by financing activities	<u>178</u>	<u>31,191</u>	<u>53,516</u>
Net increase (decrease) in cash and cash equivalents	2,194	(13,063)	(29,795)
Cash and cash equivalents at beginning of period	23,192	36,255	66,050
Cash and cash equivalents at end of period	<u>\$ 25,386</u>	<u>\$ 23,192</u>	<u>\$ 36,255</u>
Supplemental disclosure of cash flow information			
Income taxes refunded	<u>\$ —</u>	<u>\$ 722</u>	<u>\$ 388</u>

The accompanying notes are an integral part of these financial statements.

XENOPORT, INC.
NOTES TO FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Nature of Operations

XenoPort, Inc., or the Company, was incorporated in the state of Delaware on May 19, 1999. The Company is a biopharmaceutical company focused on developing and commercializing a portfolio of internally discovered product candidates for the potential treatment of neurological disorders. The Company's innovative product candidates are prodrugs that are typically created by modifying the chemical structure of currently marketed drugs, referred to as parent drugs, and are designed to correct limitations in the oral absorption, distribution and/or metabolism of the parent drug. The Company intends to focus its development and commercialization efforts on potential treatments of diseases with significant unmet medical needs, with an emphasis on central nervous system disorders. The Company's marketed product and each of its product candidates is an orally available, patented or patentable new chemical entity that addresses potential markets with clear unmet medical needs. The Company's facilities are located in Santa Clara, California.

Basis of Preparation

The Company's financial statements are prepared in accordance with the Financial Accounting Standards Board Accounting Standards Codification, or the Codification, which is the single source for all authoritative U.S. generally accepted accounting principles, or GAAP.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from these estimates.

Fair Value of Financial Instruments

The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents and short-term investments, approximate fair value due to their short maturities. The Company accounts for the fair value of its financial instruments in accordance with the provisions of the *Fair Value Measurement* topic of the Codification.

Fair value is the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. The Company utilizes market data or assumptions that the Company believes market participants would use in pricing assets or liabilities, including assumptions about risk and the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market corroborated or generally unobservable. The Company applies the market approach valuation technique for fair value measurements on a recurring basis and attempts to maximize the use of observable inputs and minimize the use of unobservable inputs. All of the Company's cash equivalents and short-term investments are valued using quoted prices in active markets and are classified at Level 1 or Level 2 within the fair value hierarchy.

Cash Equivalents and Short-Term Investments

The Company considers all highly liquid investments with original maturities of 90 days or less at the time of purchase to be cash equivalents, which primarily consist of money market funds, U.S. government-sponsored agencies and corporate debt securities.

Management determines the appropriate classification of securities at the time of purchase. All investments have been designated as available-for-sale. The Company views its available-for-sale portfolio as available for

[Table of Contents](#)

use in current operations. Accordingly, the Company has classified all investments as short-term, even though the stated maturity may be one year or more beyond the current balance sheet date. Available-for-sale securities are carried at estimated fair value with unrealized gains and losses reported as a component of other comprehensive loss in the statements of comprehensive loss.

The cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, if any, are recorded in interest income and expense. The cost of securities sold is based on the specific-identification method. Interest and dividends are included in interest income.

Restricted Investments

Under a facilities operating lease agreement, the Company is required to secure a letter of credit with cash or securities. At December 31, 2011 and 2010, the Company recorded \$1,704,000 and \$1,699,000, respectively, of restricted investments related to the letter of credit (see Note 6).

In connection with the Company's license to use radioactive materials in its research facilities, it must maintain a \$225,000 letter of credit with the Radiological Health Branch of the State of California. This requirement has been fulfilled through certificates of deposit with a financial institution. The fair value of the secured amount of \$250,000 and \$249,000 was classified as restricted investments in the accompanying balance sheets at December 31, 2011 and 2010, respectively.

Concentrations of Risk

The Company invests cash that is not being used for operational purposes. This exposes the Company to credit risk in the event of default by the institutions holding the cash and cash equivalents and available-for-sale securities. The credit risk is mitigated by the Company's investment policy, which allows for the purchase of low risk debt securities issued by the U.S. government, U.S. government-sponsored agencies and highly rated banks and corporations, subject to certain concentration limits. The maturities of these securities are maintained at no longer than 18 months. The Company believes its established guidelines for investment of its excess cash enhances safety and liquidity through its policies on diversification and investment maturity.

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and available-for-sale investment securities in high-credit quality debt securities issued by the U.S. government, U.S. government-sponsored enterprises and highly rated banks and corporations. The carrying amounts of cash equivalents and available-for-sale investment securities approximate fair value due to their short-term nature.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the respective assets, which is generally five years for the Company's laboratory equipment and furniture and fixtures and generally three years for the Company's computer equipment and software. Leasehold improvements are amortized over their estimated useful lives or the remaining lease term, whichever is shorter.

Revenue Recognition

Revenue arrangements entered into, or materially modified, through December 31, 2010 are accounted for in accordance with the provisions of the *Revenue Recognition-Multiple-Element Arrangements* topic of the Codification. A variety of factors were considered in determining the appropriate method of revenue recognition under these arrangements, such as whether the various elements could be considered separate units of accounting, whether there was objective and reliable evidence of fair value for these elements and whether there was a separate earnings process associated with a particular element of an agreement.

[Table of Contents](#)

Effective January 1, 2011, the Company adopted the provisions of Accounting Standards Update, or ASU, 2009-13, *Multiple-Deliverable Revenue Arrangements*, or ASU 2009-13, which is included within the Codification as *Revenue Recognition-Multiple Element Arrangements*, on a prospective basis. Under the provisions of ASU 2009-13, the Company will no longer rely on objective and reliable evidence of the fair value of the elements in a revenue arrangement in order to separate a deliverable into a separate unit of accounting, and the use of the residual method has been eliminated. The Company will instead use a selling price hierarchy for determining the selling price of a deliverable, which will be used to determine the allocation of consideration to each unit of accounting under an arrangement. The selling price used for each deliverable will be based on vendor-specific objective evidence if available, third-party evidence if vendor-specific objective evidence is not available or estimated selling price if neither vendor-specific objective evidence nor third-party evidence is available. The provisions of ASU 2009-13 will be applied by the Company to revenue arrangements entered into, or materially modified, beginning January 1, 2011. As of December 31, 2011, the Company had not applied the provisions of ASU 2009-13 to any of its revenue arrangements as the Company had not entered into any new, or materially modified any of its existing, revenue arrangements in 2011. Therefore, there was no material impact on the Company's financial position or results of operations from adopting ASU 2009-13. However, the provisions of ASU 2009-13 could have a material impact on the revenue recognized from any collaboration agreements that the Company enters into, or materially modifies, in future periods.

Effective January 1, 2011, the Company also adopted the provisions of ASU 2010-17, *Milestone Method of Revenue Recognition*, or ASU 2010-17, which is included within the Codification as *Revenue Recognition-Milestone Method*. The provisions of ASU 2010-17 are being applied by the Company on a prospective basis for milestones achieved starting in 2011. The adoption of ASU 2010-17 did not have a material impact on the Company's financial position or results of operations as of December 31, 2011, and the provisions of ASU 2010-17 are not expected to have a material impact on the revenue recognized from any existing collaboration agreements.

Where there are multiple deliverables combined as a single unit of accounting, revenues are deferred and recognized over the period during which the Company remains obligated to perform services. The specific methodology for the recognition of the revenue (e.g., straight-line or according to specific performance criteria) is determined on a case-by-case basis according to the facts and circumstances applicable to a given agreement. For contracts with specific performance criteria, the Company utilizes the performance-based expected revenue method of revenue recognition, which requires that the Company estimate the total amount of costs to be expended for a given unit of accounting and then recognize revenue equal to the portion of costs expended to date. The estimated total costs to be expended are subject to revision from time-to-time as the underlying facts and circumstances change.

Payments received in excess of revenues recognized are recorded as deferred revenue until such time as the revenue recognition criteria have been met.

Collaboration revenue includes revenue from the Company's current collaboration agreement with Astellas Pharma Inc. Net revenue from unconsolidated joint operating activities includes all revenue that results solely from the Company's current collaboration agreement with Glaxo Group Limited, or GSK. The Company accounts for the revenue-related activities of these collaboration agreements as follows:

- *Up-front, licensing-type payments.* Up-front, licensing-type payments are assessed to determine whether or not the licensee is able to obtain any stand-alone value from the license. Where this is not the case, the Company does not consider the license deliverable to be a separate unit of accounting, and the revenue is deferred with revenue recognition for the license fee being assessed in conjunction with the other deliverables that constitute the combined unit of accounting.
- *Milestones.* Prior to the Company's adoption of ASU 2010-17 on January 1, 2011, milestones were assessed on an individual basis, and revenue was recognized from these milestones when earned, as evidenced by acknowledgment from collaborators, provided that (i) the milestone event was substantive and its achievability was not reasonably assured at the inception of the agreement, (ii) the milestone

[Table of Contents](#)

represented the culmination, or progress towards the culmination, of an earnings process and (iii) the milestone payment was non-refundable. Milestones that were received after all substantive deliverables had occurred were considered to be bonus payments and were recognized when earned, assuming all of the other revenue recognition criteria were met. Where separate milestones did not meet these criteria, the Company used a performance-based model, with revenue recognition following delivery of effort as compared to an estimate of total expected effort.

Effective January 1, 2011, under the provisions of ASU 2010-17, consideration that is contingent upon achievement of a milestone can be recognized in its entirety as revenue in the period in which the milestone is achieved. Recognition will occur only if the consideration earned from the achievement of a milestone meets all the criteria for the milestone to be considered substantive at the inception of the arrangement, such that it: (i) is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Company's performance to achieve the milestone; (ii) relates solely to past performance; and (iii) is reasonable relative to all deliverables and payment terms in the arrangement.

The provisions of ASU 2010-17 do not apply to contingent payments for which payment is either contingent solely upon the passage of time or the result of a collaborative partner's performance. The Company will assess the nature of, and appropriate accounting for, these payments on a case-by-case basis in accordance with the provisions of the *Revenue Recognition* topic of the Codification.

- *Profit and loss sharing.* This represents the Company's share of the profits and losses from the co-promotion of *Horizant* with GSK. Amounts are recognized in the period in which the related activities occur, and their financial statement classification is based on the Company's assessment that these activities constitute part of the Company's ongoing central operations.

The Company's current collaboration agreements also include potential payments for product royalties and detail reimbursements. To date, the Company has not received any revenue from these activities.

Research and Development

All research and development costs, including those funded by third parties, are expensed as incurred. Research and development costs consist of salaries, employee benefits, laboratory supplies, costs associated with clinical trials, including amounts paid to clinical research organizations, other professional services and facility costs.

Clinical Trials

The Company accrues and expenses the costs for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with contract research organizations and clinical trial sites. The Company determines the estimates through discussions with internal clinical personnel and external service providers as to progress or stage of completion of trials or services and the agreed upon fee to be paid for such services. Costs of setting up clinical trial sites for participation in the trials are expensed immediately as research and development expenses. Clinical trial site costs related to patient visits are accrued as patients progress through the trial and are reduced by any payments made to the clinical trial site. Non-refundable advance payments for research and development goods or services are recognized as expense as the related goods are delivered or the related services are provided in accordance with the provisions of the *Research and Development Arrangements* topic of the Codification.

Stock-Based Compensation

The *Compensation — Stock Compensation* topic of the Codification establishes accounting for stock-based awards exchanged for employee services. In accordance with this topic, for stock options, awards and stock purchase rights granted under the 2005 Employee Stock Purchase Plan, or ESPP, stock-based compensation cost is measured at grant date, based on the fair value of the award, and is recognized as expense over the requisite employee service period.

[Table of Contents](#)

The effect of recording stock-based compensation under the *Compensation — Stock Compensation* topic was as follows:

	Year Ended December 31,		
	2011	2010	2009
	(In thousands, except per share amounts)		
Stock-based compensation by type of award:			
Employee stock options and awards	\$ 14,044	\$ 17,347	\$ 17,835
ESPP	344	646	798
Total stock-based compensation	\$ 14,388	\$ 17,993	\$ 18,633
Effect on basic and diluted net loss per share	\$ (0.41)	\$ (0.58)	\$ (0.65)

The Company's employee non-cash stock-based compensation, excluding non-cash stock-based compensation resulting from the Company's 2010 restructuring plan, was reported as follows:

	Year Ended December 31,		
	2011	2010	2009
	(In thousands)		
Research and development	\$ 5,208	\$ 7,930	\$ 10,101
Selling, general and administrative	9,180	9,210	8,532
	\$ 14,388	\$ 17,140	\$ 18,633

Valuation Assumptions

The Company estimates the fair value of all of its stock options and stock purchase rights on the date of grant using a Black-Scholes valuation model, and the Company expenses the resulting charge using the straight-line attribution method over the vesting period. Restricted stock units are measured at the fair value of the Company's common stock on the date of grant and expensed over the period of vesting using the straight-line attribution approach. The calculation of the Black-Scholes valuations used the following weighted-average assumptions:

	Year Ended December 31,		
	2011	2010	2009
Dividend yield	0%	0%	0%
Volatility for options	0.77	0.74	0.72
Volatility for ESPP	0.73	1.18	0.80
Weighted-average expected life of options (years)	5.34	5.26	5.36
Weighted-average expected life of ESPP rights (years)	0.5	0.5	0.5
Risk-free interest rate for options	0.90-2.26%	1.18-2.58%	1.60-2.71%
Risk-free interest rate for ESPP rights	0.07-0.19%	0.19-0.24%	0.24-1.74%

The *Compensation — Stock Compensation* topic of the Codification requires the use of option-pricing models that were not developed for use in valuing employee stock options. The Black-Scholes option-pricing model was developed for use in estimating the fair value of short-lived, exchange-traded options that have no vesting restrictions and are fully transferable. In addition, option-pricing models require the input of highly subjective assumptions, including the option's expected life and the price volatility of the underlying stock. Historically, the Company derived both the expected life and the expected stock price volatility assumptions using data obtained from similar entities, taking into consideration factors such as industry, stage of life cycle, size and financial leverage. On a prospective basis, beginning in the first quarter of 2011, the Company has determined that its historical volatility can be used as a reasonable basis to derive the expected stock price volatility assumption and has applied its historical volatility when valuing employee stock options granted beginning in the first quarter of 2011.

[Table of Contents](#)

Income Taxes

Income taxes are accounted for in accordance with the *Income Taxes* topic of the Codification using the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities as measured by the enacted tax rates that will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets if, based upon the available evidence, it is more-likely-than-not that the deferred tax assets will not be realized.

The recognition, derecognition and measurement of a tax position is based on management's best judgment given the facts, circumstances and information available at the reporting date.

As of December 31, 2011, the Company continued to have no unrecognized tax benefits and expected no significant changes in unrecognized tax benefits in the next 12 months.

The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense. To date, there have been no interest or penalties charged to the Company in relation to the underpayment of income taxes.

Comprehensive Loss

Beginning in the third quarter of 2011, the Company early adopted the provisions of ASU 2011-05, an amendment of the Codification Topic 220, *Comprehensive Income*, or ASU 2011-05. ASU 2011-05 eliminates the option to present components of other comprehensive income (loss) as part of the statement of changes in stockholders' equity. Under the provisions of ASU 2011-05, the Company presented all non-owner changes in stockholders' equity in a single continuous statement of comprehensive loss. The Company presented: (i) each component of net loss along with total net loss; (ii) each component of other comprehensive loss along with a total for other comprehensive loss; and (iii) a total amount for comprehensive loss. The Company's other comprehensive loss is comprised of unrealized gains (losses) on available-for-sale securities.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period without consideration for potential common shares. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period plus any dilutive potential common shares for the period determined using the treasury-stock method. For purposes of this calculation, restricted stock units, options to purchase stock and warrants are considered to be potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive.

	Year Ended December 31,		
	2011	2010	2009
	(In thousands, except per share amounts)		
Numerator:			
Net loss	<u>\$ (33,380)</u>	<u>\$ (82,469)</u>	<u>\$ (66,334)</u>
Denominator:			
Weighted-average common shares outstanding	<u>35,400</u>	<u>30,813</u>	<u>28,766</u>
Basic and diluted net loss per share	<u>\$ (0.94)</u>	<u>\$ (2.68)</u>	<u>\$ (2.31)</u>
Outstanding securities at period end not included in the computation of diluted net loss per share as they had an anti-dilutive effect:			
Restricted stock units and options to purchase common stock	5,903	5,168	4,206
Warrants outstanding	<u>305</u>	<u>305</u>	<u>305</u>
	<u>6,208</u>	<u>5,473</u>	<u>4,511</u>

[Table of Contents](#)

2. Collaboration Agreements

Astellas Pharma Inc.

In December 2005, the Company entered into an agreement in which it licensed to Astellas exclusive rights to develop and commercialize gabapentin enacarbil, to be marketed in Japan under the trade name *Regnite*, in Japan, Korea, the Philippines, Indonesia, Thailand and Taiwan. The Company received an initial license payment of \$25,000,000 in December 2005, which has been deferred and is being recognized on a straight-line basis over the period that the Company expects to remain obligated to provide services. In addition, as of December 31, 2011, the Company was eligible to receive potential total payments of \$60,000,000 upon the occurrence of additional clinical and regulatory events, of which \$30,000,000 has been received and recognized through December 31, 2011. Of the remaining \$30,000,000, the Company was eligible to receive a payment of \$10,000,000 following the achievement of product marketing approval of *Regnite* in Japan. In January 2012, the Japanese Ministry of Health, Labor and Welfare, or MHLW, approved Astellas' new drug application, or NDA, for the use of *Regnite* in Japan as a treatment for patients with moderate-to-severe primary restless legs syndrome, or RLS. The achievement of the milestone associated with the approval is based in whole or in part on the Company's past performance. For revenue recognition purposes, the Company has determined this milestone to be substantive, and, therefore, the payment will be recognized in its entirety as revenue in the first quarter of 2012. The remaining \$20,000,000 of potential payments payable under this agreement entail no performance obligation on the part of the Company and are tied solely to the regulatory success of additional indications, and, accordingly, these payments will not be accounted for under the provisions of ASU 2010-17. The Company is also entitled to receive mid-teen royalties on net sales of *Regnite* and gabapentin enacarbil in the Astellas territory, if any. In each of the years ended December 31, 2011, 2010 and 2009, the Company recognized revenue of \$1,515,000 representing amortization of the up-front license payment under this agreement. In the year ended December 31, 2011, the Company recognized a \$7,000,000 milestone payment in connection with the U.S. Food and Drug Administration, or FDA, approval of *Horizant* for the treatment of RLS. In the year ended December 31, 2009, the Company recognized a total of \$8,000,000 in milestone payments related to the FDA's acceptance for review of the NDA for *Horizant* in the United States and the acceptance of filing of the NDA for *Regnite* with the Pharmaceuticals and Medical Device Agency in Japan. As of December 31, 2011, the Company had recognized an aggregate of \$39,217,000 of revenue pursuant to this agreement. At December 31, 2011, \$15,783,000 of revenue was deferred under this agreement, of which \$1,515,000 was classified within current liabilities and the remaining \$14,268,000 was recorded as a noncurrent liability. In addition, the agreement allows Astellas to request that the Company conduct development activities and required Astellas to source all drug product and both clinical and commercial supplies of the active pharmaceutical ingredient, or API, form of *Regnite*/gabapentin enacarbil from the Company under a specified supply agreement. In October 2009, all of the Company's remaining manufacturing or supply obligations to Astellas for *Regnite*/gabapentin enacarbil API or finished drug product ceased. The Company remains obligated to provide certain services as originally specified in the December 2005 arrangement.

Glaxo Group Limited

In February 2007, the Company entered into an exclusive collaboration agreement with GSK to develop and commercialize gabapentin enacarbil, known in the United States by the trade name *Horizant* (gabapentin enacarbil) Extended-Release Tablets, in all countries of the world excluding the Astellas territory. In November 2010, the Company amended and restated its collaboration agreement with GSK, pursuant to which the Company reacquired all rights to gabapentin enacarbil outside of the United States previously granted to GSK (which excludes the Astellas territory) and obtained the right, but not the obligation, to pursue development of *Horizant* for: (i) the potential treatment of diabetic peripheral neuropathy; (ii) the potential treatment of postherpetic neuralgia, or PHN, to the extent that a product label would reflect a superiority claim over a currently approved drug; and (iii) any additional indications in the United States. In April 2011, the FDA approved *Horizant* for the treatment of RLS in adults. Shipments of *Horizant* to wholesalers commenced in June 2011, and *Horizant* was commercially launched in July 2011. Under the Company's collaboration agreement, as currently in effect, GSK remains responsible for further development and regulatory matters with respect to *Horizant* for the potential management of PHN and manufacturing and commercialization of *Horizant* in the United States for all

[Table of Contents](#)

indications. In January 2012, the Company provided a notice of dispute and notice of breach and termination, or the Notice, to GSK and, in February 2012, both GSK and the Company initiated legal proceedings related to the collaboration agreement (see Note 11 for more information).

In March 2007, GSK made an up-front, non-refundable license payment of \$75,000,000. Under the terms of the amended and restated collaboration agreement, as currently in effect, the Company is eligible to receive a total of \$312,500,000 in aggregate clinical and regulatory event-based potential payments, of which \$120,000,000 has been received and fully recognized through December 31, 2011, including \$30,000,000 received and fully recognized in June 2011 in connection with the first shipment of *Horizant* to a wholesaler and \$5,000,000 received and fully recognized in October 2011 in connection with the FDA's acceptance for review the supplemental new drug application, or sNDA, under Section 505(b)(2) requesting approval of *Horizant* for the potential management for PHN. Of the remaining \$192,500,000, the Company has determined that payments aggregating \$67,500,000 relate to events that, for revenue recognition purposes, are considered substantive milestones, and each of these payments will therefore be recognized as revenue in its entirety if, and when, the events are achieved. These potential payments consist of \$10,000,000 relating to achievement of positive results from clinical trials and \$57,500,000 relating to the achievement of certain regulatory milestones, such as the first filing of an NDA for product approval for a given indication in the United States. The remaining potential payments payable under this collaboration agreement entail no performance obligations on the part of the Company and, accordingly, these payments will not be accounted for under the provisions of ASU 2010-17. The Company remains eligible to receive up to \$290,000,000 upon the achievement of specified sales levels. The Company concluded that the up-front license payment did not have value to GSK on a stand-alone basis without the benefit of the specified development activities that the Company performed in connection with *Horizant* and that the \$85,000,000 of milestones paid for clinical trial and pre-clinical activities were either not sufficiently substantive or not sufficiently at risk to be accounted for using the "when-earned" model. Accordingly, these milestones and the up-front payment were combined into one unit of accounting that was recognized over the best estimate of the development period to commercialization of the product, during which time delivery of substantially all of the efforts required for the completion of the Company's contractual responsibilities under the GSK agreement has occurred, and the Company has determined that no additional performance obligations resulted from the amended agreement. As of December 31, 2011, the Company had recognized an aggregate of \$195,000,000 of up-front license and milestone payments pursuant to this agreement and no revenue was deferred under this agreement.

The Company exercised its right to the co-promotion arrangement in April 2009, under which all allowable expenses and sales of *Horizant* are accounted for using a joint profit and loss, or P&L, statement, in which the Company and GSK share in the resulting operating pre-tax profits and losses. Under the amended and restated collaboration agreement, as currently in effect, the Company's participation in the co-promotion and joint P&L arrangements remains unchanged, except that the Company can delay the deployment of its sales force for up to three years following the April 2011 approval of *Horizant* in the United States and the Company's share of losses from the joint P&L will be forgiven up to a maximum of \$10,000,000. The Company's payment of additional losses, if any, would be deferred and payable without interest over a four-year period following the first quarter in which the joint P&L is profitable. GSK is responsible for: establishing pricing and reimbursement; creating promotional and advertising materials; managed care contracting; receiving, accepting and filling orders; distributing; controlling invoicing, order processing and collecting accounts receivable; and recording sales of *Horizant* in the United States. Expenses that can be charged to the joint P&L statement are the cost of goods and certain costs directly related to *Horizant* marketing and sales. Sales and marketing expenses of *Horizant* that the Company incurs that are not charged to the joint P&L statement are classified as selling, general and administrative operating expenses within the Company's statements of comprehensive loss. The Company has concluded that under the original and amended agreements, the potential detail of *Horizant* and the amount from the joint P&L statement together constitute one unit of accounting separate from the previously established milestone and up-front payment unit of accounting. The Company also has determined the commercialization of its portfolio of product candidates to be part of its core operations, and accordingly concluded that all revenue resulting from the Company's GSK collaboration agreement is presented in the net revenue from unconsolidated joint operating activities line item in the revenues section of the statements of comprehensive loss in the period the related activities occur. The Company began recording its share of pre-launch operating losses from the joint

[Table of Contents](#)

P&L statement of Horizant in the second quarter of 2009, and the total pre-launch operating losses of \$1,095,000 recorded as of December 31, 2009 were forgiven and therefore reversed in the fourth quarter of 2010 as a result of the amended and restated development and commercialization agreement in November 2010. No detailing activities occurred and no detail reimbursements were recognized in the years ended December 31, 2011, 2010 and 2009.

The Company shares any profits or losses on sales of *Horizant* in the United States at tiered rates that escalate as a function of annual net sales levels, from a low of 20% to a maximum of 50%. For example (and for illustrative purposes only), if the annual net sales of *Horizant* reach \$250,000,000, \$500,000,000 and \$1,000,000,000, the Company would be entitled to blended profit share rates of 25%, 34% and 42%, respectively. The Company may terminate its co-promotion right and participation in the profit share arrangement at any time upon notice to GSK with no penalty to the Company, resulting in a royalty-based compensation structure, whereby the Company would receive royalties on annual net sales in the United States at tiered rates that escalate as a function of net sales levels from a low of 15% to a maximum of 30%. For example (and for illustrative purposes only), if the annual net sales of *Horizant* reach \$250,000,000, \$500,000,000 and \$1,000,000,000, the Company would be entitled to blended royalty rates of 17%, 21% and 25%, respectively. GSK may terminate the Company's co-promotion right for the Company not meeting a minimum sales requirement, for the Company's uncured material breach in conducting co-promotional activities or upon the Company's change of control in certain circumstances. GSK may terminate the collaboration agreement in its entirety for any reason and at any time. In such event, certain *Horizant* product rights would revert to the Company, and the Company would be entitled to specified transition assistance from GSK.

The Company's net revenue from unconsolidated joint operating activities from the GSK collaboration agreement was comprised of the following:

	Year Ended December 31,		
	2011	2010	2009
	(In thousands)		
Up-front license and development milestone revenue	\$ —	\$ 269	\$ 25,853
XenoPort's share of pre-launch operating losses	—	1,095	(1,095)
Milestone payments	35,000	—	—
Net revenue from unconsolidated joint operating activities	<u>\$ 35,000</u>	<u>\$ 1,364</u>	<u>\$ 24,758</u>

The following table presents the Company's total revenues that have been recognized pursuant to its current collaboration agreements (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Astellas	\$ 8,515	\$ 1,515	\$ 9,515
GSK	35,000	1,364	24,758
	<u>\$ 43,515</u>	<u>\$ 2,879</u>	<u>\$ 34,273</u>

[Table of Contents](#)

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

The following are summaries of cash and cash equivalents, short-term investments and restricted investments (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2011:				
Cash	\$ 2,941	\$ —	\$ —	\$ 2,941
Money market funds	18,027	—	—	18,027
U.S. government-sponsored agencies	28,909	3	(1)	28,911
Corporate debt securities	44,581	10	(28)	44,563
Certificates of deposit	1,954	—	—	1,954
	<u>\$ 96,412</u>	<u>\$ 13</u>	<u>\$ (29)</u>	<u>\$ 96,396</u>
Reported as:				
Cash and cash equivalents				\$ 25,386
Short-term investments				69,056
Restricted investments				1,954
				<u>\$ 96,396</u>
As of December 31, 2010:				
Cash	\$ 915	\$ —	\$ —	\$ 915
Money market funds	9,917	—	—	9,917
U.S. treasury securities	5,515	1	—	5,516
U.S. government-sponsored agencies	38,552	2	(11)	38,543
Corporate debt securities	53,702	10	(8)	53,704
Certificates of deposit	1,948	—	—	1,948
	<u>\$ 110,549</u>	<u>\$ 13</u>	<u>\$ (19)</u>	<u>\$ 110,543</u>
Reported as:				
Cash and cash equivalents				\$ 23,192
Short-term investments				85,403
Restricted investments				1,948
				<u>\$ 110,543</u>

At December 31, 2011 and 2010, the contractual maturities of all investments held were less than one year.

No gross realized gains or losses were recognized in 2011, 2010 and 2009.

[Table of Contents](#)

The Company's available-for-sale investments, which include cash equivalents and short-term investments, are measured at fair value using the following inputs (in thousands):

Description	Total As of December 31, 2011	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 18,027	\$ 18,027	\$ —	\$ —
U.S. government-sponsored agencies	28,911	—	28,911	—
Corporate debt securities	44,563	—	44,563	—
Total	\$ 91,501	\$ 18,027	\$ 73,474	\$ —

Description	Total As of December 31, 2010	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 9,917	\$ 9,917	\$ —	\$ —
U.S. treasury securities	5,516	—	5,516	—
U.S. government-sponsored agencies	38,543	—	38,543	—
Corporate debt securities	53,704	—	53,704	—
Total	\$ 107,680	\$ 9,917	\$ 97,763	\$ —

4. Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2011	2010
Laboratory equipment	\$ 11,687	\$ 11,836
Furniture and fixtures	1,287	1,287
Computer equipment and software	5,676	5,345
Leasehold improvements	4,596	4,596
Construction in-progress	78	198
	23,324	23,262
Less: Accumulated depreciation and amortization	(19,403)	(16,053)
Property and equipment, net	\$ 3,921	\$ 7,209

5. Restructuring

On March 5, 2010, due to a significant delay in the regulatory review of *Horizant*, the Company implemented a restructuring plan to reduce expenses, focus the Company's resources on advancement of its later-stage product candidates and eliminate the Company's discovery research efforts. The restructuring plan resulted in a reduction in force of 107 employees, or approximately 50% of the Company's workforce at the time. The Company provided affected employees with up to 60 days of leave of absence pay in accordance with the *Worker Adjustment and Retraining Notification Act*, and provided 60 days of employee benefits and continued vesting of stock options and awards. Qualified affected employees were also eligible to receive severance payments, transition pay, continuation of medical insurance under COBRA, a two-year extension of exercisability of stock options vested as of May 4, 2010 and outplacement services.

[Table of Contents](#)

As a result of this restructuring, the Company recorded restructuring charges of \$5,275,000 in the three months ended March 31, 2010, which were included on a separate line in the Company's statements of comprehensive loss, in accordance with the *Exit or Disposal Cost Obligations* topic of the Codification. The restructuring components are summarized in the following table (in thousands):

	Paid Leave, Severance and Other Benefits	Non-Cash Stock-Based Compensation	Property and Equipment	Legal and Other	Total
Net restructuring charges	\$ 3,910	\$ 853	\$ 437	\$ 75	\$ 5,275
Cash payments	(966)	—	—	(16)	(982)
Non-cash charges	—	(853)	(437)	(19)	(1,309)
Ending liability balance at March 31, 2010	2,944	—	—	40	2,984
Cash payments	(2,692)	—	—	(40)	(2,732)
Ending liability balance at June 30, 2010	252	—	—	—	252
Cash payments	(252)	—	—	—	(252)
Ending liability balance at September 30 and December 31, 2010 and December 31, 2011	\$ —	\$ —	\$ —	\$ —	\$ —

In December 2011, as part of the Company's ongoing evaluation of its facilities requirements in light of future plans, the Company recorded restructuring charges of \$2,923,000 in the fourth quarter of 2011, in accordance with the *Exit or Disposal Cost Obligations* topic of the Codification, which were included on a separate line in the Company's statements of comprehensive loss, in connection with the permanent cease use of the office space in a building at 3400 Central Expressway, Santa Clara, California, or the 3400 Lease. The restructuring charges consisted of \$2,476,000 of facility-related charges and \$447,000 of property and equipment write-offs. As of December 31, 2011, the Company expected to make all cash payments associated with this action by August 2013, which coincides with the end of the lease term for the office space. At December 31, 2011, the liability balance, included as "Accrued restructuring charges" on the balance sheets, was \$2,730,000, of which \$1,627,000 was classified within current liabilities and the remaining \$1,103,000 was recorded as a noncurrent liability.

6. Commitments and Contingencies

Operating Leases

In February 2008, the Company entered into a lease for approximately 59,000 square feet of office space at the 3400 Lease. The term of the 3400 Lease runs until August 2013, which is 60 months from the date the premises were considered ready for occupation by the Company.

Also in February 2008, the Company amended its lease with respect to the Company's current office space at 3410 Central Expressway, Santa Clara, California, or, as amended, the 3410 Lease, that commenced in December 2001. This amendment extended the term of the 3410 Lease for approximately two years from the original expiration date of December 10, 2011, so that the 3410 Lease will expire in August 2013, on the same date as the 3400 Lease.

The Company has the option to extend both the 3410 Lease and 3400 Lease for two additional terms of five years each.

In connection with the 3410 Lease, the Company entered into a letter of credit agreement of \$1,500,000 in December 2006. The fair value of the certificate of deposit is presented as restricted investments on the balance sheet at \$1,704,000 and \$1,699,000 at December 31, 2011 and 2010, respectively. This letter of credit is required until the termination of the lease.

The Company is recognizing rent expense on a straight-line basis over the applicable lease terms. The Company began recognizing rent expense on the 3400 Lease in May 2008. Rent expense, excluding rent expense recognized as part of the restructuring charges recorded in 2011, was \$4,347,000, \$4,443,000 and \$4,443,000 for the years ended December 31, 2011, 2010 and 2009. Net deferred rent asset of \$1,540,000 and \$67,000 at December 31, 2011 and 2010, respectively, represented the difference between rent expense recognized and

[Table of Contents](#)

actual cash payments related to the Company's operating leases. At December 31, 2011, net deferred rent was comprised of a current deferred rent asset of \$931,000 and a noncurrent deferred rent asset of \$609,000. At December 31, 2010, net deferred rent was comprised of a current deferred rent liability of \$1,104,000 and a noncurrent deferred rent asset of \$1,171,000.

At December 31, 2011, future minimum payments under all non-cancelable operating leases were as follows (in thousands):

Year ending December 31:	
2012	\$ 3,723
2013	2,640
Total minimum lease payments	<u>\$ 6,363</u>

At December 31, 2011, the portion of the total future minimum lease payments that was related to the 3400 Lease was recorded as part of "Accrued restructuring charges" on the balance sheets (see Note 5 for more information).

Guarantees and Indemnifications

The Company, as permitted under Delaware law and in accordance with its bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The Company may terminate the indemnification agreements with its officers and directors upon 90 days' written notice, but termination will not affect claims for indemnification relating to events occurring prior to the effective date of termination. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that limits its exposure and may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company had not recorded any liabilities for these agreements as of December 31, 2011.

Contingencies

In July 2010, a purported securities class action lawsuit was filed in the United States District Court for the Northern District of California, naming the Company and certain of its officers and directors as defendants. The lawsuit alleged violations of the Securities Exchange Act of 1934, as amended, in connection with allegedly false, misleading and incomplete statements issued by the defendants related to the Company's product candidate, *Horizant* (gabapentin enacarbil) Extended-Release Tablets, as a potential treatment of moderate-to-severe primary restless legs syndrome, or RLS, which allegedly made it impossible for investors to meaningfully understand the drug's potential for U.S. Food and Drug Administration approval. The plaintiff sought damages, an award of its costs and injunctive and/or equitable relief on behalf of a purported class of stockholders who purchased the Company's common stock during the period between May 5, 2009 and February 17, 2010. Another lawsuit was filed in September 2010 in the United States District Court for the Northern District of California making substantially similar allegations, on behalf of a purported class of stockholders who purchased the Company's common stock during the period between March 16, 2009 and May 5, 2010. In November 2010, a motion to consolidate the complaints and appoint a lead plaintiff was granted. In January 2011, the lead plaintiff filed a consolidated complaint. In February 2011, the Company responded to the complaint with a motion to dismiss. In May 2011, the court granted the Company's motion and dismissed the complaint with leave to amend. An amended complaint was filed in June 2011. In the amended complaint, the plaintiff sought damages, an award of its costs and injunctive and/or equitable relief on behalf of a purported class of stockholders who purchased the Company's common stock during the period between May 7, 2008 and February 17, 2010. In July 2011, the Company filed a motion to dismiss, which was granted on December 12, 2011, without leave to amend the complaint. A judgment dismissing all claims in their entirety was entered the same day. Plaintiffs did not appeal and the judgment has become final.

The Company has not established any reserves for any potential liability relating to this lawsuit.

[Table of Contents](#)

7. Stockholders' Equity

Common Stock

At December 31, 2011 and 2010, the Company was authorized to issue 60,000,000 shares of common stock.

Stockholders' Rights Plan

On December 16, 2005, the Company adopted a preferred stock rights plan pursuant to which each share of common stock outstanding on January 13, 2006, and each subsequently issued share, will receive a non-taxable dividend. The dividend will confer the purchase right, or a right, that confers the right to purchase one one-hundredth of a share of a new class of preferred stock and will be exercisable only if a person or group acquires 15% or more of the Company's common stock or announces a tender offer for 15% or more of the Company's common stock. If such a person acquires 15% or more of the Company's common stock, all rights holders, except the 15% acquiror, will be entitled to acquire the Company's common stock at a discount through the exercise of the preferred stock. The rights plan has been designed to discourage acquisitions of more than 15% of the Company's common stock without negotiations with the board of directors. The rights expire on January 13, 2016. The rights will trade with the Company's common stock, unless and until they are separated upon the occurrence of certain future events. The board of directors may terminate the rights plan at any time or redeem the rights prior to the time the rights are triggered.

Equity Incentive Plans

1999 Stock Plan

Under the terms of the 1999 Stock Plan, or the 1999 Plan, options or stock purchase rights were granted by the board of directors to employees, directors and consultants. Options granted were either incentive stock options or non-statutory stock options. Incentive stock options were granted to employees with exercise prices of no less than the fair value, and non-statutory options were granted to employees, directors or consultants at exercise prices of no less than 85% of the fair value, of the common stock on the grant date as determined by the board of directors. Options vest as determined by the board of directors, generally at the rate of 25% at the end of the first year, with the remaining balance vesting ratably over the next three years for initial employee grants and ratably over four years for subsequent grants. Options granted under the 1999 Plan expire no more than ten years after the date of grant. All options granted under the 1999 Plan have vested.

2005 Equity Incentive Plan

In January 2005, the Company's board of directors adopted the 2005 Equity Incentive Plan, or the 2005 Plan. Under the terms of the 2005 Plan, options, stock purchase rights, stock bonus rights, stock appreciation rights and other stock awards and rights may be granted by the board of directors to employees, directors and consultants. Options granted may be either incentive stock options or non-statutory stock options. Incentive stock options may be granted to employees with exercise prices of no less than the fair value, and non-statutory options may be granted to employees, directors or consultants at exercise prices of no less than 85% of the fair value, of the common stock on the grant date. Options vest as determined by the board of directors, generally at the rate of 25% at the end of the first year, with the remaining balance vesting ratably over the next three years for initial employee grants and ratably over four years for subsequent grants. Options granted under the 2005 Plan expire no more than ten years after the date of grant.

In January 2007, the Company's board of directors approved the use of grants of restricted stock units to employees under the 2005 Plan as part of the Company's long-term incentive compensation program. Restricted stock units have no exercise price, are valued using the closing market price on the date of grant and vest as determined by the board of directors, typically either: (i) in annual tranches over a four-year period at the rate of 25% at the end of each year; or (ii) in annual tranches over a three-year period at the rate of 25, 25 and 50%, respectively, at the end of each year. Employees can elect to have the Company withhold a portion of shares to pay for their payroll taxes in connection with the vesting of restricted stock units, where the Company would then make a cash payment for the associated payroll taxes on behalf of the employees, or employees can elect to make the cash payment for the associated payroll taxes.

[Table of Contents](#)

In May 2010, the Company granted performance stock unit awards to two executive employees. Each performance stock unit award is scheduled to vest three years from the grant date, with the actual number of shares of common stock of the Company subject to issuance to be between 0% and 200% of the target amount, based on the performance of the Company's total shareholder return as compared to the total shareholder returns of a group of pre-selected pharmaceutical companies over a performance period ending on the third anniversary of the grant date. The target amount of shares of common stock of the Company that were subject to issuance under the performance stock unit awards was 140,000, and the grant date fair value using a lattice valuation model of these performance stock unit awards was \$2,675,000. In 2010, a performance stock unit award representing a target amount of 40,000 shares was cancelled due to the departure of one of the two executive employees. At December 31, 2011 and 2010, a performance stock unit award representing a target amount of 100,000 shares was outstanding, and the associated expense recognized in the year ended December 31, 2011 and 2010 was \$636,000 and \$405,000, respectively.

Stock purchase rights, stock bonus rights, stock appreciation rights and other stock awards and rights may be granted by the board of directors to employees, directors and consultants and may be subject to such terms and conditions as the board of directors deems appropriate, although such awards may not be granted with a purchase price below the par value of the stock. Under the terms of the 2005 Plan, the maximum number of shares that may be issued shall not exceed the total of 2,000,000, plus any shares issuable from options previously granted from the 1999 Plan at the date of the Company's initial public offering, plus an annual increase equal to the lesser of (i) 2.5% of the total number of common shares outstanding at the end of the preceding calendar year and (ii) 2,000,000 common shares. During the year ended December 31, 2011, the annual increase to the 2005 Plan reserve was 880,669 shares. At December 31, 2011 and 2010, there were 979,674 and 902,596 shares, respectively, remaining and available for future grant under the 2005 Plan.

New Employee Inducement Stock Awards

In May 2008, the Company's Senior Vice President and Chief Commercialization Officer was granted a new employee inducement stock award outside of the Company's stockholder-approved equity plans consisting of nonqualified stock options to purchase 140,612 shares of the Company's common stock. The stock options have a per share exercise price of \$42.59, the closing trading price of the Company's common stock on the NASDAQ Global Market on the May 1, 2008 grant date. The stock options have a ten-year term and vest over four years, with 25% cliff vesting on the first anniversary of the May 1, 2008 grant date, and 1/48th of the shares subject to the options vesting monthly thereafter. The Company also granted to the Company's Senior Vice President and Chief Commercialization Officer a new employee inducement stock award outside of the Company's stockholder-approved equity plans consisting of restricted stock units for 10,000 shares of the Company's common stock. The restricted stock units shall vest in four equal annual installments on each anniversary of the May 1, 2008 grant date.

2010 Inducement Award Plan

In May 2010, the Company's board of directors adopted the 2010 Inducement Award Plan, or the 2010 Inducement Plan. Under the terms of the 2010 Inducement Plan, options, stock purchase awards, stock bonus awards, stock appreciation rights, stock unit awards and other stock awards may be granted by the board of directors or the independent compensation committee of the board of directors to persons entering into employment with the Company and not previously employees or directors of the Company (or following *bona fide* periods of non-employment with the Company) as an inducement material to the new employees entering into employment with the Company in accordance with NASDAQ Market Place Rule 5635(c)(4). Options granted may be non-statutory stock options with exercise prices of no less than 100% of the fair value of the Company's common stock on the grant date. Options vest as determined by the board of directors or the compensation committee of the board of directors, generally at the rate of 25% at the end of the first year, with the remaining balance vesting ratably over the next three years. Options granted under the 2010 Inducement Plan expire no more than ten years after the date of grant. Restricted stock units have no exercise price, are valued using the closing market price on the date of grant and vest as determined by the board of directors or the compensation committee of the board of directors, typically in annual tranches over a four-year period at the rate of 25% at the end of each year.

[Table of Contents](#)

A total of 350,000 shares of common stock were initially authorized for issuance under the 2010 Inducement Plan and an additional 625,000 shares were authorized for issuance in 2011. Under the terms of the 2010 Inducement Plan, the maximum number of shares that may be issued shall not exceed the total of 975,000. At December 31, 2011, there were 655,516 shares remaining and available for future grant under the 2010 Inducement Plan.

2005 Non-Employee Directors' Stock Option Plan

In January 2005, the Company's board of directors adopted the 2005 Non-Employee Directors' Stock Option Plan, or the 2005 Directors' Plan, under which non-statutory options are automatically granted to non-employee directors. Any individual who first becomes a non-employee director automatically receives an option to purchase 25,000 shares subject to vesting in four equal successive annual installments. Non-employee directors serving on the date of each annual meeting of stockholders receive an option to purchase 10,000 shares subject to vesting in 12 successive equal monthly installments measured from the grant date. Stock options may be granted at exercise prices no less than the fair value on the grant date and may expire no more than ten years after the date of grant. Under the terms of the 2005 Directors' Plan, the maximum number of shares that may be issued shall not exceed the total of 150,000, plus an annual increase equal to the excess of (i) the number of shares subject to options granted in the preceding calendar year, over (ii) the number of shares added back to the share reserve from cancellations, provided that such increase shall not exceed 150,000 shares. During the year ended December 31, 2011, the annual increase to the 2005 Directors' Plan reserve was 27,083 shares. At December 31, 2011 and 2010, there were 144,166 and 122,917 shares, respectively, remaining and available for future grant under the 2005 Directors' Plan.

A summary of option activity as of December 31, 2011 is presented below:

	Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2011	4,220,042	\$ 25.08		
Options granted	829,500	\$ 8.18		
Options cancelled	(387,870)	\$ 25.72		
Options exercised	(3,350)	\$ 1.53		
Outstanding at December 31, 2011	<u>4,658,322</u>	<u>\$ 22.04</u>	<u>5.89</u>	<u>\$ (84,910)</u>
Exercisable at December 31, 2011	<u>3,425,888</u>	<u>\$ 24.83</u>	<u>4.95</u>	<u>\$ (72,019)</u>

A summary of restricted stock and performance stock unit activity as of December 31, 2011 is presented below:

	Shares	Weighted- Average Grant Date Fair Value
Outstanding at January 1, 2011	948,024	\$ 13.02
Awards granted	593,225	\$ 9.04
Awards cancelled	(72,417)	\$ 11.45
Awards vested	(224,183)	\$ 15.19
Outstanding at December 31, 2011	<u>1,244,649</u>	<u>\$ 10.82</u>

The Company expected that the number of options, restricted stock and performance stock units that will ultimately vest will be materially similar to the number of options, restricted stock and performance stock units outstanding at December 31, 2011.

[Table of Contents](#)

The aggregate intrinsic value of all options outstanding and exercisable at December 31, 2011 was based on a closing stock price of \$3.81.

The weighted-average grant date fair values of options granted in the years ended December 31, 2011, 2010 and 2009 were \$5.26, \$10.45 and \$14.09 per share, respectively. The weighted-average grant date fair values of restricted stock units and performance stock units granted in the years ended December 31, 2011, 2010 and 2009 were \$9.04, \$11.81 and \$25.01 per share, respectively.

The total intrinsic value of options exercised in the years ended December 31, 2011, 2010 and 2009 was \$20,000, \$271,000 and \$1,450,000, respectively. The total fair value of restricted stock units that vested in the year ended December 31, 2011, 2010 and 2009 was \$3,406,000, \$3,826,000 and \$3,528,000, respectively.

As of December 31, 2011, the total compensation cost related to 1,232,434 unvested options and unvested awards covering 1,244,649 shares not yet recognized was \$18,153,000. This amount will be recognized over an estimated weighted-average amortization period of 2.07 years.

Employee Stock Purchase Plan

As of December 31, 2011, the Company had reserved a total of 945,555 shares of common stock for issuance under the ESPP. In addition, the board of directors may increase the share reserve as of each January 1 through January 1, 2015, by an amount not to exceed the lesser of (i) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year or (ii) 250,000 shares. The ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. The price at which the stock is purchased is equal to the lower of 85% of the fair market value of the common stock at the beginning of an offering period or after a purchase period ends. During the years ended December 31, 2011 and 2010, 143,905 shares and 104,100 shares, respectively, were purchased under the ESPP. At December 31, 2011 and 2010, there were 333,306 and 477,211 shares, respectively, remaining and available for future grant under the ESPP.

Warrants

At December 31, 2011, 304,752 warrants were outstanding, of which 21,332 were exercisable for shares of common stock at \$15.00 per share and 283,420 were exercisable for shares of common stock at \$25.40 per share. The warrants expire at various dates from June 2012 to December 2013.

8. Preferred Stock

At December 31, 2011 and 2010, the Company was authorized to issue 5,000,000 shares of preferred stock.

9. Income Taxes

The Company recorded \$0, \$0 and \$722,000 of current income tax benefit for the years ended December 31, 2011, 2010 and 2009, respectively. In the year ended December 31, 2009, \$444,000 of current income tax benefit recognized was due to the adoption of a provision in the *Worker, Homeownership, and Business Assistance Act of 2009* that allows businesses with net operating loss, or NOLs, in 2008 or 2009 to carry back those losses for up to five years, and \$278,000 of current income tax benefit recognized was due to the adoption of a provision in the *American Recovery and Reinvestment Tax Act of 2009* that allows corporations to convert carry-forward research and development and Alternative Minimum Tax, or AMT, credits into a separate refundable amount, which the Company claimed and received as a refund in cash in 2010.

[Table of Contents](#)

Deferred income taxes reflect the net tax effects of NOL and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets were as follows (in thousands):

	December 31,	
	2011	2010
Net operating loss carryforwards	\$ 118,735	\$ 108,753
Research credit carryforwards	29,113	26,924
Capitalized research and development	11,605	14,259
Deferred revenue	6,431	7,048
Stock options	15,981	14,648
Other	2,996	928
Total net deferred tax assets	184,861	172,560
Valuation allowance	(184,861)	(172,560)
Net deferred tax assets	\$ —	\$ —

Realization of net deferred tax assets is dependent upon the Company generating future taxable income, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$12,301,000, \$33,324,000 and \$27,686,000 during 2011, 2010 and 2009, respectively.

As of December 31, 2011, the Company had NOL carryforwards for federal income tax purposes of \$295,803,000, which expire in the years 2022 through 2031, and federal research and development tax credits of \$21,086,000, which expire in the years 2021 through 2031.

As of December 31, 2011, the Company had NOL carryforwards for state income tax purposes of \$294,658,000, which expire in the years 2013 through 2031, and state research and development tax credits of \$12,511,000, which do not expire.

Approximately \$529,000 of the valuation allowance for net deferred tax assets relates to benefits of stock option deductions that, when recognized, will be allocated directly to additional paid-in capital.

The Company files income tax returns in the U.S. federal jurisdiction and the California state jurisdiction. To date, the Company has not been audited by the Internal Revenue Service or any state income tax jurisdiction. Tax years 2002 to 2011 remain subject to examination by the U.S. federal jurisdiction and the California state jurisdiction.

Utilization of the Company's NOL and credit carryforwards may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such annual limitation could result in the expiration of the net operating loss and credit carryforwards before utilization. As of December 31, 2011, based on the analyses performed on annual limitation as a result of ownership changes that may have occurred from inception through December 2010, the Company expects to be able to use all of the NOL and tax credit carryforwards before their respective expiration periods.

10. Related-Party Transaction

In May 2011, the Company engaged McKinsey & Company, Inc. to provide consulting services to the Company. Jon R. Duane, a director of McKinsey, is the spouse of Catherine J. Friedman, a member of the Company's Board of Directors. The Company expensed \$1,011,000 through December 31, 2011 in connection with this engagement.

[Table of Contents](#)**11. Subsequent Events**

In January 2012, the Japanese MHLW approved Astellas' NDA for the use of gabapentin enacarbil, which will be known as *Regnite* in Japan, as a treatment for patients with RLS. The approval triggered a \$10,000,000 milestone payment from Astellas that was received by the Company in February 2012. This milestone payment from Astellas will be recognized in its entirety as revenue in the first quarter of 2012 in accordance with the provisions of ASU 2010-17.

In January 2012, the Company provided the Notice to GSK that provided notice of the Company's belief that, among other matters, GSK has materially breached its contractual obligation to use commercially reasonable efforts to (i) maximize the sales of *Horizant* in an expeditious manner and (ii) achieve the sales milestones set forth in the collaboration agreement. The Notice provides that the termination of the collaboration agreement would become effective at the end of the 90-day notice period provided under the agreement, which will expire on April 24, 2012, unless GSK has cured any such breach or default prior to such date.

However, on February 23, 2012, GSK filed a complaint, or the GSK Complaint, in the United States District Court for the District of Delaware naming the Company and other unspecified individuals as defendants. Pursuant to the GSK Complaint, GSK is seeking declaratory judgment that GSK is not in breach of the collaboration agreement and that the Company does not have the right to terminate the collaboration agreement as a result of GSK's performance under the collaboration agreement to date. On February 24, 2012, the Company filed a complaint, or the XenoPort Complaint, in the Superior Court of the State of California in the County of Santa Clara against GSK and its affiliates, GlaxoSmithKline LLC and GlaxoSmithKline Holdings (Americas) Inc., for breach of contract, fraud, breach of fiduciary duty, breach of the covenant of good faith and fair dealing and unfair competition. Pursuant to the XenoPort Complaint, in addition to injunctive and equitable relief, the Company is seeking damages for lost profits, damage to the value of *Horizant* and unattained royalties and milestone payments in an amount to be proven at trial, as well as punitive damages and restitution. The Company cannot predict the outcome of the litigation related to the GSK Complaint and the XenoPort Complaint or when or if the collaboration agreement will be terminated or the ultimate terms of any termination of the agreement. Additionally, the Company cannot predict whether the Company will be successful in obtaining injunctive or other equitable relief, damages or the amount of such damages, if any. The Company is not currently able to estimate the impact of the Notice, the GSK Complaint or the XenoPort Complaint on its financial position or results of operations.

12. Quarterly Financial Data (Unaudited)

The following table summarizes the unaudited quarterly financial data for the last two fiscal years (in thousands, except per share data):

	Quarter Ended							
	Dec. 31, 2011	Sept. 30, 2011	June 30, 2011	March 31, 2011	Dec. 31, 2010	Sept. 30, 2010	June 30, 2010	March 31, 2010
Selected Quarterly Data:								
Total revenues	\$ 5,378	\$ 379	\$ 37,379	\$ 379	\$ 1,906	\$ 389	\$ 491	\$ 93
Net income (loss)	\$ (16,886)	\$ (18,793)	\$ 19,455	\$ (17,156)	\$ (14,823)	\$ (19,899)	\$ (19,522)	\$ (28,225)
Basic and diluted net income (loss) per share	\$ (0.48)	\$ (0.53)	\$ 0.55	\$ (0.49)	\$ (0.47)	\$ (0.65)	\$ (0.64)	\$ (0.93)

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

AMENDED AND RESTATED DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

THIS AMENDED AND RESTATED DEVELOPMENT AND COMMERCIALIZATION AGREEMENT ("Restated Agreement"), dated as of November 7, 2010 ("Restatement Effective Date"), is entered into between XenoPort, Inc., a Delaware corporation having its principal place of business at 3410 Central Expressway, Santa Clara, CA 95051 ("XenoPort") and Glaxo Group Limited, a company existing under the laws of England and Wales, having its registered office at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, England ("GSK"). As of the Restatement Effective Date, this Restated Agreement amends and restates the Development and Commercialization Agreement between XenoPort and GSK, dated as of February 7, 2007, as amended by that certain First Amendment to Development and Commercialization Agreement between XenoPort and GSK, dated as of May 4, 2007 ("First Amendment"), and as further amended by that certain Second Amendment to Development and Commercialization Agreement between XenoPort and GSK, dated as of February 13, 2009 ("Second Amendment") (together with the First Amendment and the Second Amendment, the "Original Agreement").

BACKGROUND

A. XenoPort has developed a Transported Prodrug of gabapentin (as further defined below, the "Product") for the treatment of restless legs syndrome ("RLS") and the management of neuropathic pain (which includes post-herpetic neuralgia and diabetic peripheral neuropathy);

B. The Parties (as hereinafter defined) previously entered into the Original Agreement, pursuant to which XenoPort granted to GSK certain rights for the Product worldwide except for the Asian Territory (as hereinafter defined), and pursuant to which GSK and XenoPort were to co-develop and, in certain cases, co-commercialize the Product in the United States, all in accordance with the Original Agreement; and

C. The Parties now desire to amend certain terms of the Original Agreement to provide, among other matters, XenoPort the reversion of all rights for the development and commercialization of the Product in all countries other than the United States and the right to conduct and control activities relating to the development of the Product for Other Indications (as hereinafter defined) in the United States, all on the terms and conditions set forth in this Restated Agreement; and to restate the Original Agreement in its entirety in this Restated Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I

DEFINITIONS

As used in this Restated Agreement, the following capitalized terms will have the meanings set forth in this Article 1 when used in this Restated Agreement.

1.1 "Affiliate" of a Party shall mean any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party, as the case may be, for as long as such control exists. As used in this Section 1.1, "control" shall mean: (a) to possess, directly or indirectly, the power to direct the management and policies of such Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of at least fifty percent (50%) (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital in such Person. A "Controlled Affiliate" is an Affiliate that [*].

1.2 "Agreement" shall mean the Original Agreement, as in effect from the Effective Date until the Restatement Effective Date, together with the Restated Agreement, which pursuant to Section 20.1 below replaces the Original Agreement in its entirety as of the Restatement Effective Date.

1.3 "Annual Net Sales" shall mean total Net Sales in the Territory in a particular calendar year.

1.4 "Anti-Kickback Statute" means the Medicare and Medicaid Anti-Kickback Statute set forth at 42 U.S.C. §1320a-7b(b).

1.5 "Applicable Commercial Practices Policies" means the portions as identified by GSK of the Commercial Practices Policies of GSK applicable (and as applied generally to GSK's own personnel) to the marketing, sale, promotion and detailing of pharmaceutical products, as amended or supplemented by GSK from time to time, a copy of which will be delivered to XenoPort prior to XenoPort Co-Promoting and Detailing the Product in the United States and updated copies will thereafter be delivered to XenoPort as and when amended or supplemented.

1.6 "Applicable Laws" means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidances, ordinances, judgments, decrees, directives, injunctions, orders, permits (including Marketing Approvals) of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE * COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

1.7 "Asian Territory" shall mean Indonesia, Japan, Korea, Philippines, Taiwan and Thailand.

1.8 "Astellas" shall mean Astellas Pharma Inc. and its Affiliates, and any other Third Parties to whom Astellas or XenoPort has granted a right to sell, market, distribute and/or promote a Product in a country in the Asian Territory. To the extent Astellas' rights in the Asian Territory terminate and XenoPort grants rights to a Third Party, references herein to Astellas shall be deemed to reference such Third Party.

1.9 "Astellas Agreement" shall mean the Distribution and License Agreement, dated December 1, 2005, between XenoPort and Astellas, as amended and in effect from December 1, 2005 until October 31, 2009, together with the Amended and Restated Distribution and License Agreement, dated October 31, 2009, between XenoPort and Astellas.

1.10 "Astellas Know-How" shall mean any scientific, medical, technical, marketing, regulatory and/or other information, data and materials (including, preclinical data, clinical data, clinical pharmacology data and regulatory filings and approvals submitted or obtained, together with its supporting data and regulatory correspondence and rights to reference the same) primarily relating to the Compound and/or any Product, which is Controlled by Astellas as of the Effective Date or during the Term; provided, however, that [*].

1.11 "Call" shall mean a face-to-face meeting in an individual, hospital or group setting between a Sales Representative and one or more members of the Target Audience.

1.12 "Change of Control" shall mean either: (a) a sale of all or substantially all of the assets of a Party in one or a series of integrated transactions not in the ordinary course of business to a Third Party; or (b) the acquisition of a Party by a Third Party by means of any transaction or series of related transactions to which such Party is a party (including, any stock acquisition, merger or consolidation). For clarity, a Change of Control would not include any transaction or series of transactions in which the holders of voting securities of a Party outstanding immediately prior to such transaction continue to retain (either by such voting securities remaining outstanding or by such voting securities being converted into voting securities of the surviving entity), as a result of shares in the Party held by such holders prior to such transaction, fifty percent (50%) or more of the total voting power represented by the voting securities of the acquiring entity outstanding immediately after such transaction or series of transactions.

1.13 "Closing Date" shall mean March 2, 2007.

1.14 "Commercially Reasonable Efforts" shall mean that level of efforts and resources consistent with the usual practice followed by a Party in the exercise of reasonable business discretion relating to other pharmaceutical products owned by it or to which it has exclusive rights, which is of similar market potential and at a similar stage in development or product life, taking into

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

account issues of patent coverage, safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the profitability of the products (including, without limitation, pricing and reimbursement status achieved), and other relevant factors, including without limitation technical, legal, scientific, and/or medical factors.

1.15 "Compound" shall mean that certain compound, referred to internally at XenoPort as XP13512, the structure of which is set forth on Exhibit 1.15, and all esters, hydrates, metabolites [*], salts, solvates, isomers and/or mixtures of isomers thereof.

1.16 "Control" (including any variations such as "Controlled" and "Controlling"), in the context of intellectual property rights of a Party, shall mean that such Party or its Controlled Affiliate owns or possesses rights to intellectual property sufficient to grant the applicable license under this Agreement, without violating the terms of an agreement with a Third Party.

1.17 "Co-Promotion" (including any variations such as "Co-Promote") shall mean those promotional and sales activities undertaken by a pharmaceutical company's sales force in concert with at least one other pharmaceutical company's sales force in a single territory to implement the marketing and/or sales plans with respect to a particular prescription pharmaceutical product under the same trademark in such territory.

1.18 "Data" shall mean any and all research data, pharmacology data, preclinical data, clinical data and/or all regulatory documentation, information and submissions pertaining to, or made in association with, an IND, Marketing Approval Application, Marketing Approval or the like for the Product, in each case that are Controlled by a Party or its Controlled Affiliates as of the Effective Date or during the Term.

1.19 "Data Package" for a clinical trial shall mean the audited and statistically validated data tables, listings and figures from the applicable clinical trial, together with written summaries (including patient accountability, demographics, baseline characteristics and the primary and second endpoints (including safety)) of the study outcomes of such clinical trial.

1.20 "Detail" (including any variations such as "Detailing") shall mean that part of the activity undertaken by a Sales Representative during a Call whereby a Sales Representative, who has been trained with respect to the Product in accordance with Section 5.4(c), makes a face-to-face presentation: (a) describing [*] (b) which may also include [*]; and (c) in accordance with the [*]. [*], shall not constitute a Detail. [*] shall not constitute a Detail. [*] As used herein, a [*] in which [*] (as consistent with industry norms) [*], and a [*] in which [*]

1.21 [*] shall mean: [*].

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

1.22 "Effective Date" shall mean February 7, 2007, the effective date of the Original Agreement.

1.23 "Existing Phase III Studies" shall mean those certain Phase III clinical studies being conducted by XenoPort as of the Effective Date and described on Exhibit 4.3(a) as follows: (a) Study No. XP052, "Pivotal Study in RLS"; (b) Study No. XP053, "Pivotal Study in RLS" and (c) Study No. XP060, "Maintenance of Effect Study in RLS."

1.24 "FDA" shall mean the United States Food and Drug Administration, or any successor entity thereto performing similar functions.

1.25 "FD&C Act" means the federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder from time to time.

1.26 "Field" shall mean the diagnosis, palliation, treatment and/or prevention of any disease or health condition in humans.

1.27 "Filing" of an NDA shall be deemed to occur on the date of receipt of written notice of acceptance from the FDA in the United States of such NDA for substantive review.

1.28 "First Commercial Sale" shall mean, on a Product-by-Product basis, the first *bona fide*, arm's length sale of a Product in the Territory following receipt of Marketing Approval of such Product in such country for use or consumption by the general public of such Product in such country; provided that the First Commercial Sale of the Product in the Territory for a particular indication shall be deemed to occur upon the First Commercial Sale of a Product with labeling for such indication. Sales of a Product for registration samples, compassionate use sales, named patient use, inter-company transfers to Affiliates of a Party and the like will not constitute a First Commercial Sale.

1.29 "GSK Know-How" shall mean all scientific, medical, technical, marketing, regulatory and other information primarily relating to the Product (including Data), which are Controlled by GSK or its Controlled Affiliates during the Term, that are needed by or reasonably useful to XenoPort in order for XenoPort to exercise its rights (including the conduct of activities directed towards developing Products for commercialization outside the Territory and/or the commercialization of Products outside the Territory) or perform its obligations under this Agreement and the Astellas Agreement; provided, however, that [*].

1.30 "GSK Trademarks" shall mean the Trademarks Controlled by GSK or its Controlled Affiliates as of the Effective Date or during the Term, which are used with the Products in the Field in the Territory.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

1.31 "IND" shall mean any Investigational New Drug Application (including any amendments thereto) filed with the FDA pursuant to 21 C.F.R. §321 before the commencement of clinical trials of a Product, or any comparable filings with any Regulatory Authority in any other jurisdiction.

1.32 "Major Pharmaceutical Company" shall mean a company that is engaged in the business of selling pharmaceutical products, whose revenues from such sales (on a consolidated basis in the last full fiscal year prior to the closing of any Change of Control) was in excess of [*]. Any Affiliate of such company shall be deemed to be a Major Pharmaceutical Company.

1.33 "Marketing Approval" shall mean all approvals, licenses, registrations or authorizations of the Regulatory Authority in a country, necessary for the manufacture, use, storage, import, marketing and sale of a Product in such country. For countries where governmental or other similar approval of pricing and/or reimbursement is required for marketing in such country, Marketing Approval shall not be deemed to occur until such pricing or reimbursement approval is obtained. Notwithstanding the foregoing, Marketing Approval shall be deemed to have occurred for a particular indication for a Product in such jurisdiction upon the First Commercial Sale of such Product in such jurisdiction with labeling for such indication.

1.34 "Marketing Approval Application" (or "MAA") shall mean a NDA submitted to the FDA in the United States or a corresponding application for Marketing Approval that has been submitted to a Regulatory Authority in any other country.

1.35 "NDA" shall mean a New Drug Application or supplemental New Drug Application as defined in Title 21 of the U.S. Code of Federal Regulations, Section 314.50, et seq., which is filed with the FDA in order to gain the FDA's approval to commercialize a pharmaceutical product in the United States for the indications set forth in the New Drug Application or supplemental New Drug Application.

1.36 "Net Sales" shall mean the gross invoice price by GSK or its Affiliates or Sublicensees, as the case may be, for all Products sold by GSK, its Affiliates or Sublicensees ("Selling Party") under this Agreement in the Territory in arm's length sales to Third Parties less the following deductions that are actually incurred, allowed, paid, accrued or specifically allocated to the extent that such amounts are deducted from gross invoiced sales amounts as reported by the Selling Party in its financial statements in accordance with the International Financial Reporting Standards ("IFRS"), applied on a consistent basis:

(a) trade, quantity and cash discounts and allowances;

(b) credits, rebates and charge backs or equivalents thereof (including those to managed-care entities, national, state/provincial, local and other governments, their agencies and purchasers, and to trade customers);

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(c) allowances or credits to customers on account of rejection or returns (including wholesaler and retailer returns), retroactive price reductions affecting such Product or billing errors;

(d) freight, postage and duties, and transportation charges relating to such Product (including handling and insurance thereto) separately identified on the invoice or other documentation maintained in the ordinary course of business;

(e) sales (such as value-added tax or its equivalent) and excise taxes, other consumption taxes, customs duties and compulsory payments to governmental authorities and any other governmental charges imposed upon the sale of a Product to Third Parties;

(f) commissions allowed or paid to Third Party wholesalers, or other similar Third Party distributors, in each case who do not engage in marketing or promotion of the Product;

(g) [*] bad debt reported [*] in which [*] or [*] or [*] in which [*]; and

(h) any other items actually deducted from (and therefore not included as) gross invoiced sales amounts in determining revenue, and not otherwise included as an item of income or the like, as reported by a Selling Party in its financial statements in accordance with the IFRS, applied on a consistent basis.

Sales between GSK and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, and no payments will be payable on such sales except where such Affiliates or Sublicensees are end users. If a Product is sold or transferred for consideration other than cash, the Net Sales from such sale or transfer shall be deemed the then fair market value of such Product. [*]

In the event that [*] the Net Sales [*] shall be [*] during the applicable reporting period [*] in which [*]. If [*], then Net Sales for purposes of [*] shall be [*] on the [*] shall not [*]. If [*] as provided in this paragraph, the matter shall be resolved in accordance with Section 18.2 below.

1.37 "Neuropathic Pain Indication" shall mean an indication for the Product involving [*].

1.38 "Other Indication(s)" shall mean any indication for the Product other than RLS or PHN, but only to the extent [*]. For clarity, [*] shall be deemed an Other Indication.

1.39 "Party" shall mean XenoPort or GSK individually, and "Parties" shall mean XenoPort and GSK collectively.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

1.40 "Patent(s)" shall mean any patents and patent applications, together with all additions, divisions, continuations, continuations-in-part, substitutions, reissues, re-examinations, extensions, registrations, patent term extensions, supplemental protection certificates and renewals of any of the foregoing.

1.41 "PDMA" means the federal Prescription Drug Marketing Act of 1987, as amended, and the regulations promulgated thereunder from time to time.

1.42 "Person" means any individual, corporation, partnership, firm, association, joint venture, joint stock company, trust or other entity, or any government or regulatory administrative or political subdivision or agency, department or instrumentality thereof.

1.43 "Phase I" shall mean a human clinical trial, the principal purpose of which is to demonstrate safety, tolerability and pharmacokinetics of the Product in volunteer or patient subjects, as further described in 21 C.F.R. §312.21(a) (including, any such clinical study in any country other than the United States).

1.44 "Phase III" shall mean a human clinical trial, the principal purpose of which is to establish safety and efficacy of the Product in patients with the disease being studied, as further described in 21 C.F.R. §312.21(c) (including, any such clinical study in any country other than the United States), which is designed and intended to be of a size and statistical power sufficient to serve as a pivotal study to support the filing of an MAA for the indication being studied.

1.45 "Phase IV" shall mean a human clinical trial conducted with respect to a Product: (a) after [*]; (b) within the [*]; and (c) intended as [*]. Phase IV studies may include, for example, [*], and the like. Except [*], Phase IV studies shall not include any human clinical trials: (i) [*]; and/or (ii) from which [*] for the purposes of: [*] or [*] provided that in the case of paragraph (ii), [*].

1.46 "PhRMA Code" means the PhRMA Code on Interactions with Health Care Professionals, as amended.

1.47 "Product" shall mean any pharmaceutical product containing the Compound, alone or in combination with one or more other active pharmaceutical ingredients, in any dosage form or formulation.

1.48 "Promotional Materials" means all written, printed, video or graphic advertising, promotional, educational and communication materials [*] for marketing, advertising, promotion and sale of the Product for use in the United States (a) [*].

1.49 "Regulatory Authority" shall mean the FDA, or a regulatory body with similar regulatory authority in any other jurisdiction.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

1.50 "Regulatory Filing" means all approvals, licenses, registrations, submissions and authorizations made to or received from a Regulatory Authority in a country necessary for the development, manufacture and/or commercialization of a pharmaceutical product, including any INDs, Marketing Approval Applications and Marketing Approvals.

1.51 "RLS Indication" shall mean an indication for the Product involving RLS.

1.52 "ROW Licensee" shall mean any Third Party to whom XenoPort has granted a right to sell, market, distribute and/or promote a Product in a country or countries outside the Territory after the Restatement Effective Date.

1.53 "Sales Representative" shall mean a professional pharmaceutical sales representative engaged or employed by either Party to conduct sales activities and other promotional efforts with respect to the Product.

1.54 "Samples" shall mean individual physician sample units of the Product.

1.55 "Sublicensee" shall mean a Third Party to whom GSK has granted a right to sell, market, distribute and/or promote a Product in the Territory pursuant to Section 2.2 and "Sublicense" shall mean an agreement or arrangement between GSK and a Sublicensee granting such rights. As used in this Agreement, "Sublicensee" shall not include a wholesaler or reseller of a Product who does not market or promote such Product.

1.56 "Target Audience" means those health care professionals legally permitted to prescribe the Product, or issue hospital orders for the Product, in each case in the United States, or those other allied professionals that are part of the treatment team and who are recognized for this purpose in the Co-Promotion Plan.

1.57 "Territory" shall mean the United States.

1.58 "Third Party" shall mean any Person other than XenoPort, GSK and their respective Affiliates.

1.59 "Trademarks" means registered and unregistered trademarks, including words and logos, and any applications for registrations thereof, and intellectual property rights residing in such trademarks, including copyrights and design rights.

1.60 "United States" or "U.S." means the fifty (50) states of the United States of America and the District of Columbia and the territories of the United States of America.

1.61 "XenoPort Know-How" shall mean, subject to Section 4.8(b)(iii), all scientific, medical, technical, regulatory and other information primarily relating to the Compound and the Product (including the Data), which are Controlled by XenoPort or its Controlled Affiliates as of the

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Effective Date or during the Term, that were generated or utilized by XenoPort or its Controlled Affiliates in developing or producing the Product or are otherwise reasonably necessary for GSK to exercise its rights or perform its obligations under this Agreement; provided, however, that [*].

1.62 "XenoPort Patents" shall mean: (a) the Patents Controlled by XenoPort or its Controlled Affiliates listed on Exhibit 1.62, together with all additions, divisions, continuations, substitutions, re-issues, re-examinations, extensions, registrations, patent term extensions, supplemental protection certificates and renewals of any such Patents; and (b) all [*], subject to Section 4.8(b)(iii).

1.63 "XenoPort Trademarks" shall mean the Trademarks Controlled by XenoPort or its Controlled Affiliates and reflected in Exhibit 1.63 hereto, the applications for which have been filed in the name of XenoPort, or another mutually agreed Trademark Controlled by XenoPort or its Affiliates, in each case for use with the Products in the Field in the Territory.

1.64 Additional Definitions. Each of the following terms shall have the meaning described in the corresponding section of this Agreement indicated below:

<u>Term</u>	<u>Section Defined</u>
Acquired Party	9.1(c)
[*]	Exhibit 6.5
[*]	4.4(a)(ii)
Additional Post-Approval Trial	4.4(c)
[*]	5.2(e)
Aggregate Loss Carry Forward	6.5(d)
Alliance Manager	3.7
Auditor	7.4(a) / 7.4(b)
Clinical Materials	10.3(a)
[*]	1.36
Commercialization Party	12.7(a)
Commercialization Plan	5.1(b)
Committee	3.4(a)
[*]	6.2(c)(i)
Competitive Compound	12.3(a)
[*]	6.2(c)(ii)
Confidential Information	11.1
Continuing Party	9.1(c)
Controlled Affiliate	1.1
Cooperating Party	11.5
Co-Promotion Agreement	5.5

<u>Term</u>	<u>Section Defined</u>
Co-Promotion	5.2(a)
Commencement Date	
Co-Promotion	5.2(a)
Commencement Date Notice	
Co-Promotion Option	5.2(a)
Co-Promotion Plan	5.2(b)
Co-Promotion Year	5.2(d)(i)
[*]	Exhibit 6.5
Damages	12.4
Development Plan	4.1(a)
[*]	6.2(c)(iii) /
	6.2(c)(iv)
[*]	4.4(e)
Dispute	18.1
[*]	1.37
[*]	3.6
Executive Steering Committee / ESC	3.1(a)
First Amendment	Introduction
First Profitable Quarter	6.5(d)
Generic Competition	6.4(c)
Generic Product	6.4(c)

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Term	Section Defined
GSK	Introduction
GSK Indemnitees	17.2
[*]	4.8(b)(iii)
GSK Operating Expenses	6.5(c)
GSK Prosecuted XP Patents	12.2(a)
IFRS	1.36
[*]	12.1
[*]	12.1
Indemnitee	17.3
Indemnitor	17.3
Independent Trial	2.4(a)
Independent Trial Notice	2.4(a)
[*]	Exhibit 5
Infringement	12.3(a)
Infringement Actions	12.4
Initial Clinical Studies and Activities	4.3(a)
[*]	6.2(c)(v)
JAMS	18.2
Joint Commercialization Committee / JCC	3.3(a)
Joint Development Committee / JDC	3.2(a)
Joint P&L	6.5(c)
[*]	6.2(c)(vi)
Liabilities	17.1
[*]	Exhibit 6.5
[*]	5.2(d)(ii)
[*]	5.2(e)
New Technology Election Notice	12.7(a)
[*]	2.4(a)
Operating Profit or Loss	Exhibit 6.5
Operating Profits/Loss Percentage	6.5(c)
Option Exercise Date	5.2(a)
Original Agreement	Introduction
Other Indication NDAs	4.6(b)
Other Indication Regulatory Filings	4.6(a)(ii)
[*]	Exhibit 6.5
Parties	1.39
Payment Report	6.3(b)
Personnel	5.4(h)

Term	Section Defined
Pharmacovigilance Agreement	4.12(c)
[*]	1.37
[*]	4.4(a)(i)
[*]	6.2(c)(vii)
Pre-Co-Promotion Period	5.2(a)
[*]	1.20
Product	Background
Product Materials	15.2(g)
Prosecute and Maintain	12.2(a)
Prosecution and Maintenance	12.2(a)
Requesting Party	11.5
Responsible Party	4.7(c)
Restated Agreement	Introduction
Restatement Effective Date	Introduction
RLS	Background
[*]	Exhibit 6.5
Second Amendment	Introduction
[*]	1.20
Selling Party	1.36
[*]	3.6
Specifications	10.3(e)
Subcommittee	3.1(c)
Sublicense	1.55
Sublicensing Party	12.7
[*]	14.1

Third Party Claim	17.1
[*]	4.8(b)(iii)
Third Party Royalties	6.4(a)
Third Party Technology	12.7
[*]	10.3(a)
[*]	1.37
[*]	2.4(b)
Wind-down Period	15.2(a)(ii)
Withdrawal Notice	3.4(b)
[*]	6.2(c)(viii)
XenoPort	Introduction
XenoPort House Marks	13.3
XenoPort Indemnitees	17.1
XenoPort Operating Expenses	6.5(c)
[*]	12.2(b)

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

<u>Term</u>	<u>Section Defined</u>
XenoPort Trademarks Option	13.2

ARTICLE II

GRANT OF LICENSE

2.1 License; Reversion.

(a) License. Subject to the terms and conditions of this Agreement, XenoPort hereby grants to GSK an exclusive license, with the right to grant sublicenses as provided in Section 2.2, under the XenoPort Patents and XenoPort Know-How to develop, use, make, have made, offer for sale, sell, import, market, distribute and promote the Compound and Products, in each case solely in the Field in the Territory. In addition, XenoPort hereby grants to GSK a non-exclusive license, with the right to sublicense as provided in Section 2.2, under the XenoPort Patents and XenoPort Know-How to make and have made the Compound and Products in countries outside the Territory, other than the Asian Territory, solely for commercialization, sale and/or use of the Product within the Territory in the Field. The rights and licenses granted to GSK in the first sentence of this Section 2.1(a) shall be exclusive even as to XenoPort, except that XenoPort retains the right: (i) [*] or, [*]; (ii) [*]; and (iii) [*].

(b) Reversion of Rights. It is understood that as of the Effective Date, XenoPort granted to GSK certain licenses and rights to develop and commercialize the Compound and all Products in all countries worldwide except for the Asian Territory under the Original Agreement. As of the Restatement Effective Date, except as expressly provided in Section 2.1(a) above, all licenses and rights granted by XenoPort to GSK under the Original Agreement (including the licenses and rights granted by XenoPort to GSK pursuant to Sections 2.1 and 2.2 of the Original Agreement) with respect to the Compound and all Products in all countries other than the United States shall terminate immediately and all such licenses and rights with respect to the Compound and Product shall revert back to XenoPort. In connection with such termination and reversion, the provisions set forth in Exhibit 2.1 attached to this Agreement are hereby incorporated by reference and shall be deemed to be part of the body of this Agreement as if such provisions were set forth herein in their entirety.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

2.2 Sublicensees.

(a) GSK shall have the right to sublicense its rights under this Agreement: (i) in the Territory to its Affiliates; and (ii) to Third Parties to permit such Third Parties to provide services to and on behalf of GSK relating to the manufacturing or development of the Product; in each case of (i) and (ii), without the consent of XenoPort. GSK may sublicense its rights as provided in this Section 2.2(a) to such Affiliates solely for so long as such Person remains an Affiliate.

(b) Except as otherwise provided in Section 2.2(a), GSK may engage Sublicensees and grant Sublicenses in the Territory [*]. To the extent [*]. In addition, [*]. Promptly following the execution of each Sublicense as provided in this Section 2.2(b), [*].

2.3 Activities Outside the Territory.

(a) GSK agrees that neither it, nor any of its Controlled Affiliates, will sell or provide the Compound or the Products to any Third Party if GSK or its relevant Controlled Affiliate knows, or has reason to believe, that the Compound and/or the Products, as the case may be, sold or provided to such Third Party would be sold or transferred, directly or indirectly, for use outside the Territory.

(b) XenoPort agrees that it and its Affiliates will not, and that it will use Commercially Reasonable Efforts to exercise its rights under any agreements with Astellas (including the Astellas Agreement) and any ROW Licensees to cause Astellas and such ROW Licensee(s) not to, sell or provide the Compound or the Product to any Third Party if XenoPort, its relevant Affiliate or Astellas or such ROW Licensee knows, or has reason to believe, that the Compound and/or the Products, as the case may be, sold or provided to such Third Party would be sold or transferred, directly or indirectly, for use in the Territory; provided, however, that nothing in this Agreement (including this Section 2.3(b)) shall be deemed [*]

(c) Subject to [*] with respect to [*], XenoPort agrees to keep GSK reasonably informed through the JDC of [*] directed to [*] to the extent XenoPort [*].

2.4 Independent Trials.

(a) If XenoPort, Astellas and/or any ROW Licensee proposes to conduct a human clinical trial with respect to a Product [*] that is directed to [*] (an "Independent Trial"), then XenoPort shall [*] to the initiation of such Independent Trial (such notice, an "Independent Trial Notice") and provide to GSK, together with such Independent Trial Notice [*] for such Independent Trial. If GSK [*], then GSK may [*]. If GSK delivers to XenoPort such [*], XenoPort, Astellas or such ROW Licensee (respectively) shall [*]. For clarity, it is understood that [*] shall not apply with respect to [*].

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(b) Notwithstanding the foregoing, it is understood and agreed that [*] shall not apply with respect to any clinical trial to be conducted [*] by XenoPort or [*]. Nonetheless, XenoPort represents to GSK that XenoPort [*]. Subject to the first sentence of this Section 2.4(b), XenoPort agrees to [*] or the [*].

2.5 No Other Rights. Except for the rights and licenses expressly granted in this Agreement, XenoPort retains all rights under its intellectual property, and no additional rights shall be deemed granted to GSK by implication, estoppel or otherwise. For clarity, the licenses and rights granted in this Agreement shall not be construed to convey any licenses or rights under the XenoPort Patents with respect to any active pharmaceutical ingredient other than the Compound.

ARTICLE III GOVERNANCE

3.1 Executive Steering Committee.

(a) Establishment. Within thirty (30) days following the Closing Date, XenoPort and GSK shall establish an Executive Steering Committee ("Executive Steering Committee" or "ESC") to oversee, review and coordinate the activities of the Parties under this Agreement, including, the development of the Product for registration, and the marketing, commercialization and distribution of Products, in the Field in the Territory, as set forth in and subject to the provisions of this Article 3.

(b) Duties. The ESC shall:

- (i) Review and approve material changes to the Development Plan;
- (ii) Review and, in the event XenoPort has exercised the Co-Promotion Option as provided in Section 5.2(a), approve material changes to the Commercialization Plan for the United States;
- (iii) Intentionally Omitted;
- (iv) Provide a forum for the Parties to exchange information and coordinate their respective activities with respect to matters pertaining to the development, manufacture, marketing and distribution of the Products for the Territory, and matters pertaining to Regulatory Filings for the Product in the Territory;
- (v) Provide a forum for resolving matters to be decided by the JDC or JCC under this Agreement;

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(vi) Provide a forum to review with XenoPort decisions by GSK regarding material development, regulatory, manufacturing and commercial matters pertaining to the Product for the Territory that are not decided by the JDC or the JCC; and

(vii) Perform such other duties as are specifically assigned to the ESC in this Agreement.

(c) Subcommittees. From time to time, the ESC may establish subcommittees to oversee particular projects or activities within the scope of authority of the ESC, as it deems necessary or advisable (each, a "Subcommittee"). Each Subcommittee shall consist of such number of representatives of each Party as the ESC determines is appropriate from time to time. Each Subcommittee shall meet with such frequency as the ESC shall determine. Each Subcommittee shall operate by unanimous vote in all decisions, with each Party having one (1) vote and with at least one (1) representative from each Party participating in such vote. If, with respect to a matter that is subject to a Subcommittee's decision-making authority, the Subcommittee cannot reach unanimity, the matter shall be referred to the ESC, which shall resolve such matter in accordance with Section 3.6.

3.2 Joint Development Committee.

(a) Establishment. Within thirty (30) days following the Closing Date, GSK and XenoPort shall establish a joint development committee ("Joint Development Committee" or "JDC") to plan, oversee and coordinate the conduct of the development activities for the Product in the Territory, as set forth in and subject to the provisions of this Article 3.

(b) Duties. The JDC shall:

(i) Subject to oversight by the ESC, determine the Development Plan in accordance with Section 4.1;

(ii) Subject to and within the parameters of the Development Plan:

(A) Oversee the implementation of the Development Plan, allocate responsibilities to each Party in connection with executing the Development Plan and review each Party's execution of its responsibilities under the Development Plan (including review of the clinical trials conducted by each Party pursuant to the Development Plan); and

(B) Approve certain regulatory matters as provided in Section 4.7 below;

(iii) Present any proposed revisions or amendments to the Development Plan, and the results of development efforts, to the ESC as needed, but no less frequently than once each calendar half-year;

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(iv) Determine [*];

(v) Oversee XenoPort's conduct of the Initial Clinical Studies and Activities and XenoPort's development activities for the Product for any Other Indication in the Territory; and

(vi) Perform such other duties as are specifically assigned to the JDC in this Agreement or delegated to the JDC by the ESC.

3.3 Joint Commercialization Committee.

(a) Establishment. From and after the Restatement Effective Date, GSK and XenoPort shall maintain a joint commercialization committee ("Joint Commercialization Committee" or "JCC") to oversee the conduct of the commercialization, marketing and Co-Promotion activities for Products in the United States.

(b) Duties. The JCC shall:

(i) Subject to oversight by the ESC, review and approve the Commercialization Plan for the United States developed by GSK in accordance with Section 5.1(b);

(ii) Review and approve the Co-Promotion Plan developed in accordance with Sections 5.2(b) and 5.2(c); and

(iii) Perform such other duties as are specifically assigned to the JCC in this Agreement or delegated to the JCC by the ESC.

3.4 Committee Membership.

(a) Membership. Subject to Section 3.4(b), the ESC, JDC and JCC (each, a "Committee") shall each be composed of an equal number of representatives from each of GSK and XenoPort, selected by such Party. Unless the Parties otherwise agree, the exact number of representatives for each of GSK and XenoPort shall be: (a) with respect to the ESC, subject to Section 3.4(b), two (2) representatives, at least one (1) of whom shall be [*], or a delegate of such [*] (or representative of [*]); provided that such delegate shall [*]; and (b) with respect to the JDC and the JCC, three (3) representatives, at least one (1) of whom shall [*], or a delegate of such [*] (or representative of [*]); provided that such delegate shall be [*]. Either Party may replace its respective Committee representatives at any time with prior written notice to the other Party; provided that the criteria for composition of each Committee set forth in the preceding sentence continues to be satisfied following any such replacement of a Party's representative on any such Committee. Each Committee will be chaired by a GSK representative and GSK may, from time to time and in its sole discretion, change the representative who serves as the chairperson on any Committee with prior written notice to XenoPort.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(b) Withdrawal from Committees. At any time during the Term and for any reason, XenoPort shall have the right to withdraw from participation in the Committees upon written notice to GSK, which notice shall be effective immediately upon receipt ("Withdrawal Notice"). Following the issuance of a Withdrawal Notice and subject to this Section 3.4(b), XenoPort's representatives to the Committees shall not participate in any meetings of the Committees, nor shall XenoPort have any right to vote on decisions within the authority of the Committees. If, at any time, following the issuance of a Withdrawal Notice, XenoPort wishes to resume participation in the Committees, XenoPort shall notify GSK in writing and, thereafter, XenoPort's representatives to the Committees shall be entitled to attend any subsequent meeting of the Committees and to participate in the activities of, and decision-making by, the Committees as provided in this Article 3 as if a Withdrawal Notice had not been issued by XenoPort pursuant to this Section 3.4(b). Following XenoPort's issuance of a Withdrawal Notice pursuant to this Section 3.4(b), unless and until XenoPort resumes participation in the Committees in accordance with this Section 3.4(b): (i) all meetings of the Committees shall be held at GSK's facilities; (ii) GSK shall have the right to make the final decision on all matters within the scope of authority of the Committees [*]; (iii) XenoPort shall have the right to continue to receive the minutes of Committee meetings, but shall not have the right to approve the minutes for any Committee meeting held after XenoPort's issuance of a Withdrawal Notice.

3.5 Committee Meetings. The ESC shall meet at least once each calendar half-year, or more or less often as otherwise agreed to by the Parties. The JDC and, from and after such time as is appropriate, the JCC shall meet at least once each calendar quarter, or more or less often as otherwise agreed to by the Parties. All Committee meetings may be conducted by telephone, video-conference or in person as determined by the applicable Committee; provided, however, that each Committee shall meet in person at least twice each calendar year, unless the Parties mutually agree to meet by alternative means. Unless otherwise agreed by the Parties, all in-person meetings for each Committee shall be held on an alternating basis between XenoPort's facilities and GSK's facilities. Each Party shall bear its own personnel and travel costs and expenses relating to Committee meetings. With the consent of the Parties (not to be unreasonably withheld or delayed), other employee representatives of the Parties may attend any Committee meeting as non-voting observers. Minutes of each Committee meeting will be prepared by the chairperson and distributed to the members of the applicable Committee for review and comment within twenty (20) days after each meeting of the applicable Committee, and will be approved as the first order of business at the immediately succeeding Committee meeting.

3.6 Decision-Making. Subject to Section 3.4(b), decisions of each Committee shall be [*]. In the event the JDC or the JCC [*] with respect to a particular matter within its authority, then upon request by either Party, such matter shall be referred to the ESC for resolution. In the event that the ESC [*] with respect to a particular matter [*] as requested by [*]. The Parties' [*] to resolve such matter; provided, however that with respect to [*]. If, [*] are unable to resolve such matter [*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(a) Subject to [*], the [*] and (ii) subject to sub-clause (i) of clause (b) below, [*]; and

(b) the [*] and (ii) any matter to the extent such matter relates to any issue to be decided by the ESC [*]. For clarity, [*].

In each case, [*]. [*]. Notwithstanding the foregoing, [*] under clause (a) or (b) above in a manner [*].

3.7 Alliance Managers. Within thirty (30) days following the Closing Date, each Party shall appoint a representative ("Alliance Manager") to facilitate communications between the Parties (including coordinating the exchange of Data and Know-How of each Party as required under this Agreement) and to act as a liaison between the Parties with respect to such other matters as the Parties may mutually agree in order to maximize the efficiency of the collaboration. Each Party may replace its Alliance Manager with an alternative representative satisfying the requirements of this Section 3.7 at any time with prior written notice to the other Party.

3.8 Scope of Governance. Notwithstanding the creation of the ESC, JDC and JCC, each Party shall retain the rights, powers and discretion granted to it hereunder, and no Committee shall be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. No Committee shall have the power to amend or modify this Agreement, and no decision of any Committee shall be in contravention of any terms and conditions of this Agreement. It is understood and agreed that issues to be formally decided by the ESC, JDC and JCC, as applicable, are only those specific issues that are expressly provided in this Agreement to be decided by the ESC, JDC and JCC, as applicable. For clarity but in any event [*], it is understood that the ESC, JDC and JCC shall not have authority over activities of XenoPort that are directed to the development and/or commercialization of the Compound or Products for use outside the Territory or that are conducted pursuant to an agreement with Astellas or an ROW Licensee.

ARTICLE IV

DEVELOPMENT AND REGULATORY ACTIVITIES

4.1 Development Plans.

(a) Initial Development Plan. An initial development plan for the collaboration as of the Effective Date is attached to this Agreement as Exhibit 4.1 ("Development Plan") and sets out separately the development activities to be conducted by each Party under this Agreement. Within [*] the Closing Date, the JDC shall review and finalize the details of the Development Plan, which shall be consistent with the Development Plan in Exhibit 4.1.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(b) Scope of Development Plan Following Restatement Effective Date. From and after the Restatement Effective Date, the Development Plan will reflect: (i) [*]; and (ii) [*].

(c) Changes to a Development Plan. The JDC shall review the Development Plan on an ongoing basis, and in no event less frequently than [*]. The JDC may propose to the ESC revisions to the then-current Development Plan; provided, however, the [*].

(d) Conduct of Activities. Each Party shall conduct those activities allocated to such Party under the Development Plan [*]. On and from the Restatement Effective Date, each Party shall also use Commercially Reasonable Efforts to comply [*] in conducting activities allocated to it hereunder, [*]; provided that, in any event, XenoPort's obligations under this Section 4.1(d) [*] shall be limited to the extent that [*].

4.2 Development Activities of GSK

(a) Conduct of Development Activities. Except as provided in Sections 4.3 and 4.4 below, GSK shall, at its expense, use Commercially Reasonable Efforts to carry out all clinical development and other activities required to obtain Marketing Approvals for the Product in the Territory. GSK shall carry out all such activities for the RLS Indications and the Undifferentiated PHN Indications in accordance with the then-current Development Plan and the provisions of this Agreement. For the avoidance of doubt and with the exception of providing Clinical Materials as provided in Section 10.3 below, neither GSK nor any of its Affiliates shall have any obligation under this Agreement to carry out any development activities required to obtain Marketing Approvals for the Product with respect to any Other Indications.

(b) Diligence. Except as provided in Sections 4.3, 4.4(b) and 4.4(e) below, GSK shall use Commercially Reasonable Efforts to achieve the goals of the then-current Development Plan in accordance with the timelines specified therein and to realize the commercial opportunity for the Product in other indications.

4.3 Development Activities of XenoPort

(a) Existing Phase III Studies; Initial Clinical Studies and Activities. Except as otherwise mutually agreed, XenoPort shall, at its expense and with oversight by the JDC, continue to conduct the Existing Phase III Studies and those other clinical studies and activities listed on Exhibit 4.3(a) to this Agreement (collectively, the "Initial Clinical Studies and Activities"). XenoPort shall make reasonable modifications to the protocols for such Initial Clinical Studies and Activities, as requested by GSK from time to time; provided, however, that [*]. Notwithstanding the foregoing, [*] Existing Phase III Study [*] of such modifications. In addition, XenoPort shall [*] the Initial Clinical Studies and Activities but excluding the Existing Phase III Studies, [*].

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(b) Diligence. XenoPort shall use Commercially Reasonable Efforts to conduct and complete the Initial Clinical Studies and Activities in order to achieve the goals of the then-current Development Plan in accordance with the timelines specified therein.

4.4 PHN; Other Indications.

(a) PHN.

(i) GSK shall [*]; provided that [*]. Notwithstanding the foregoing, [*].

(ii) Notwithstanding Section 4.4(a)(i) above, if: (A) [*] prior to granting Marketing Approval for the Product for PHN in the United States, or (B) [*], then, [*]. It is understood that, [*].

(b) Other Indications. From and after the Restatement Effective Date, XenoPort shall have the right to conduct, at its expense with oversight of the JDC and pursuant to the Development Plan, any further development and other activities required to obtain Marketing Approvals in the Territory for a Product with respect to any Other Indication(s); provided, however, that [*]. [*]

(c) Certain Additional Post-Approval Trials. Notwithstanding Section 4.4(b) above, [*] the conduct of any clinical and/or preclinical studies after Marketing Approval of the Product in the United States for PHN or an Other Indication (such as preclinical studies to establish pediatric dosing and the like) (each, an "Additional Post-Approval Trial"), then the Development Plan shall be amended accordingly pursuant to Section 4.1(c) above and, as between the Parties, GSK shall be responsible for the conduct of such trials and studies, in accordance with the Development Plan; provided that [*].

(d) Costs of [*] Additional Post-Approval Trials. Notwithstanding [*] Additional Post-Approval Trials shall be [*] incurred by the Parties in connection with any [*]; provided that [*].

(e) Differentiated Profile Trials. It is understood that XenoPort shall have the right, at its option and expense, to conduct clinical trial(s) directed to establishing a Differentiated Profile for a Neuropathic Pain Indication. Notwithstanding the foregoing, [*] XenoPort shall [*]. In such case, [*]. For clarity, it is understood that [*].

4.5 Change in Formulation. Before [*], GSK shall discuss the proposed [*] with XenoPort at the ESC and [*]. Subject to the foregoing, XenoPort agrees that GSK may [*] that were so discussed [*] by the ESC.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

4.6 Regulatory Matters.

(a) Assignment of Regulatory Filings.

(i) At a reasonable time [*], XenoPort shall assign or cause to be assigned to GSK all Regulatory Filings for the Compound in the Territory; provided, however, that, [*] XenoPort shall maintain [*]. Notwithstanding the foregoing, it is understood that XenoPort may [*] and/or [*] provided that, [*] For such purposes, [*] at which XenoPort [*].

(ii) Notwithstanding Section 4.6(a)(i) above, at a reasonable time after the Restatement Effective Date, but in any case no later than [*], GSK shall assign (or cause to be assigned) any and all INDs and/or other Regulatory Filings pertaining to the Product for any Other Indication filed by GSK, or any of its Affiliates or Sublicensees in the Territory (together with any Regulatory Filings filed, or authorized to be filed, by XenoPort in the Territory with respect to Other Indications collectively, the "Other Indication Regulatory Filings"); provided, however, [*]; and provided further, that [*]. Further, it is understood that, following the Restatement Effective Date: (A) XenoPort may file (or authorize the filing of) additional INDs and other Regulatory Filings to conduct the clinical trials and other activities pertaining to the Product for any Other Indication set out in the then-current Development Plan, or that XenoPort is otherwise permitted to conduct pursuant to Section 4.4(b) or 2.1(a); and (B) without limiting the last sentence of this Section 4.6(a)(ii), Section 4.6(b) or Section 4.9 below, GSK shall not be obligated to file (or authorize the filing of) additional INDs or other Regulatory Filings to support the clinical trials and other activities described in the preceding clause (A). Notwithstanding the foregoing and without limiting Section 4.9 below, GSK shall cooperate with and assist XenoPort (or its designee) and shall take those actions reasonably necessary to allow XenoPort to conduct clinical trials and other activities in the Territory [*].

(iii) Except to the extent required or, if agreed to by the Parties [*] useful, for XenoPort to continue to conduct development activities for Other Indications [*], upon GSK's written request, XenoPort shall assign (or cause to be assigned) to GSK the Regulatory Filings with respect to an Other Indication in the Territory in connection with the filing of an NDA for the Product for such Other Indication in the Territory in accordance with Section 4.6(b) below.

(b) Responsibility for Regulatory Filings. Except for [*] or [*], GSK shall be responsible, [*] for publishing, submitting, obtaining, and maintaining all Regulatory Filings (including any Other Indication NDAs for each Other Indication [*]) for the Compound and Products in the Territory. Notwithstanding the foregoing sentence, [*] for such Other Indication and with respect to any Regulatory Filings or activities [*]. XenoPort shall be responsible for [*] of each NDA for Other Indications (collectively, the "Other Indication NDAs") in accordance with [*]. In addition, XenoPort shall be responsible for: [*]. It is understood that GSK shall have the right to [*], and to file in GSK's name each Other Indication NDA. After such Other Indication NDA is filed, [*] with respect to such

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Other Indication NDA and [*] Other Indication and [*] in the Territory. GSK [*], [*].

4.7 Regulatory Cooperation. [*], GSK shall be responsible for liaising with and managing all interactions with Regulatory Authorities in the Territory, including with respect to all Regulatory Filings for Product in the Territory, other than [*], and XenoPort shall be entitled to participate in such interactions as provided in Section 4.7(a) below. With respect to [*], XenoPort shall [*]; provided that [*].

(a) Involvement of XenoPort. With respect to those interactions with the Regulatory Authorities in the Territory [*], and to the extent relating to the Product within the Territory, GSK shall provide XenoPort with:

(i) reasonable advanced notice [*] of substantive meetings with [*], that are either scheduled with, or initiated by or under the authority of, GSK or its Affiliates;

(ii) an opportunity to have [*] representatives attend, and [*], all substantive meetings with [*]; and in any case, GSK shall keep the JDC informed as to all material interactions with Regulatory Authorities in the Territory; and

(iii) a copy of any material documents, information and correspondence submitted to a [*] relating to Regulatory Filings for the Product in the Territory as soon as reasonably practicable.

The JDC shall approve the overall strategy and positioning of all [*] Regulatory Filings with such [*], based upon reasonably detailed reports and summaries of such submissions and filings presented to the JDC by GSK. In connection with such review, [*]

(b) Involvement by GSK. With respect to the Regulatory Filings in the Territory maintained by XenoPort under Section 4.6(a), Regulatory Filings relating to the trials permitted to be conducted by XenoPort in the Territory under Section 2.1(a) and Section 4.4 above and any regulatory matters (including regulatory strategy) within the Territory as described in Section 4.6(b) for which XenoPort is the lead party, XenoPort shall provide GSK with:

(i) reasonable advanced notice [*] of substantive meetings with a [*] that are either scheduled with, or initiated by or under the authority of, XenoPort or its Affiliates relating to such Regulatory Filings;

(ii) an opportunity to have [*] representatives attend, and [*], all substantive meetings with such [*] relating to such Regulatory Filings; and in any case, XenoPort shall keep the JDC informed as to all material interactions with such Regulatory Authority relating to such Regulatory Filings in the Territory; and

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(iii) a copy of any material documents, information and correspondence submitted to such [*] relating to such Regulatory Filings in the Territory as soon as reasonably practicable.

(c) Cooperation and Assistance. With respect to those interactions with Regulatory Authorities in the Territory for which a Party (the "Responsible Party") is primarily responsible, the other Party will provide reasonable cooperation and assistance to the Responsible Party in the event that the Responsible Party must respond to questions from Regulatory Authorities in the Territory concerning development activities conducted by or on behalf of the other Party with the Compound or Product.

(d) Other Regulatory Matters. Each Party will promptly provide the other Party with copies of all material documents, information and correspondence received from a Regulatory Authority (including a written summary of any material communications in which such other Party did not participate) within the Territory and, upon reasonable request, with copies of any other documents, reports and communications from or to any Regulatory Authority within the Territory relating to the Compound, the Product and/or activities under this Agreement.

4.8 Exchange of Data and Know-How.

(a) By XenoPort. Promptly following the Closing Date, XenoPort will make available to GSK, at no cost or expense to GSK, all XenoPort Know-How that is necessary, or materially useful, for GSK to develop and/or commercialize the Compound and Products in the Territory, including all Data from any and all clinical trials (including the Initial Clinical Studies and Activities) and preclinical studies and non-clinical development work for the Compound and Products that have been obtained by XenoPort as of the Effective Date.

(b) By Either Party.

(i) During the Term, each Party shall provide to the other Party all such Party's Know-How (i.e., in case of XenoPort, XenoPort Know-How, and in the case of GSK, all GSK Know-How) and that has not previously been provided hereunder, in each case promptly upon request by the other Party. The Party providing such Party's Know-How shall provide the same in electronic form to the extent the same exists in electronic form, and shall provide copies as reasonably requested and an opportunity for the other Party or its designee to inspect (and copy) all other materials comprising such Know-How (including for example, original patient report forms and other original source data). The Parties will cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of the XenoPort Know-How and the GSK Know-How.

(ii) [*]; provided that [*] or [*] For the avoidance of doubt, [*]. Accordingly, and consistent with the proviso in the first sentence of this Section 4.8(b)(ii), XenoPort shall [*].

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(iii) [*], XenoPort may [*] in accordance with this Section 4.8(b)(iii). [*]; provided that [*]. If requested, [*]. Except as provided in this Section 4.8(b)(iii), [*]. For clarity, it is understood that [*].

(c) Provision of Data to JDC. Upon request by the JDC, each Party shall promptly provide the JDC with summaries in reasonable detail of all Data generated or obtained in the course of such Party's performance of activities under a Development Plan.

4.9 Sharing of Regulatory Filings. Without limiting Section 4.8 above, each Party shall permit the other to access, and shall provide the other Party with sufficient rights to reference and use in association with exercising its rights and performing its obligations under this Agreement [*], all of such Party's, and its Affiliates' (and, to the extent it has the right to do so, its Sublicensees'), Data, Regulatory Filings and regulatory communications associated with any submissions of MAAs or other approvals for the Product in the Territory. Without limiting the foregoing, each Party shall permit the other to access and shall provide such other Party with sufficient rights to reference and use, in support of MAAs filed and Marketing Approvals received by or on behalf of the other Party, any Regulatory Filings relating to the Compound or a Product in the Territory and/or, upon the other Party's request, shall obtain from a Regulatory Authority any certificate or other documentation (including, a Certificate of Pharmaceutical Product) that may be requested or required by a Regulatory Authority for such purposes. Notwithstanding the foregoing, and excluding any Regulatory Filings made available to XenoPort pursuant to Section 2.1(b) and Exhibit 2.1, GSK shall be obligated to [*]

4.10 Inspection Right.

(a) Inspection by Astellas or ROW Licensee.

(i) To the extent any Regulatory Authority [*] requests an audit of the clinical trial sites and/or manufacturing sites in the Territory [*], GSK shall permit such Regulatory Authority and XenoPort [*] to enter the relevant clinical trial sites and, if applicable, manufacturing sites of GSK and its Affiliates during normal business hours and upon reasonable advance notice to inspect and verify compliance with applicable regulatory requirements. GSK shall, at XenoPort's expense, provide reasonable assistance for a full and correct carrying out of the inspection. Such inspection shall not relieve GSK of any of its obligations under this Agreement.

(ii) Diligence. GSK shall use Commercially Reasonable Efforts to secure the rights set forth in Section 4.10(a)(i) from GSK's Sublicensees, trial sites and other contractors for the Product. In the event GSK is unable to secure such inspection rights from any of its Sublicensees, trial sites or contractors, GSK agrees to secure such rights for itself and, [*] GSK shall exercise such rights [*] and fully report the results thereof to XenoPort and as applicable, Astellas and such ROW Licensee.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(b) Inspection by GSK.

(i) To the extent any Regulatory Authority [*] requests an audit of the clinical trial sites and/or manufacturing sites outside the Territory [*], XenoPort shall permit such Regulatory Authority to enter the relevant clinical trial sites and, if applicable, manufacturing sites of XenoPort and its Affiliates during normal business hours and upon reasonable advance notice to inspect and verify compliance with applicable regulatory requirements. XenoPort shall, at GSK's expense, provide reasonable assistance for a full and correct carrying out of the inspection. Such inspection shall not relieve XenoPort of any of its obligations under this Agreement.

(ii) Diligence. XenoPort shall use Commercially Reasonable Efforts to secure the rights set forth in Section 4.10(b)(i) from ROW Licensees, trial sites and other contractors for the Product. In the event XenoPort is unable to secure such inspection rights from any of its ROW Licensees, trial sites or contractors, XenoPort agrees to secure such rights for itself and, [*] XenoPort shall exercise such rights [*] and fully report the results thereof to GSK.

4.11 Clinical Trial Register. Notwithstanding anything in this Agreement to the contrary, including Article XI, GSK shall have the right to publish in its clinical trial register the results or summaries of the results of all clinical trials for the Compound and Products conducted: (a) by either Party in the Territory pursuant to this Agreement (including any clinical trials conducted by XenoPort to support an application for Marketing Approval in the Territory for the Product for an Other Indication); and (b) by [*] provided, however, that [*]. The Parties will discuss the process for [*]. Further, notwithstanding anything in this Agreement to contrary, including Article XI, each Party shall have the right to submit and publish information pertaining to any clinical trials involving the Product as necessary to meet such Party's obligations under Applicable Law as the sponsor of such clinical trials, including publication of any such clinical studies and the results thereof on clinicaltrials.gov (or any substitute website established by the FDA or another Regulatory Authority for similar purposes).

4.12 Reporting.

(a) Initial Pharmacovigilance Agreement. The Parties acknowledge that certain Safety Data Exchange Agreement, dated May 30, 2007, by and between the Parties, which was entered into pursuant to the terms of Section 4.12(a) of the Original Agreement, and that such Agreement expired by its terms upon the transfer of all INDs relating to the Compound and the Products from XenoPort to GSK pursuant to Section 4.6(a)(i).

(b) Adverse Event Reporting. Effective as of the Restatement Effective Date, as between the Parties: (i) XenoPort shall be responsible for [*] (ii) GSK shall continue to be responsible for [*] and (iii) GSK shall be responsible for [*]. For the purposes of clarity only, GSK shall be responsible for [*].

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(c) Pharmacovigilance Agreement. Within ninety (90) days after the Restatement Effective Date, the Parties shall enter into a pharmacovigilance agreement (the "Pharmacovigilance Agreement") on terms no less stringent than those required by ICH guidelines, including: (i) providing detailed procedures regarding the maintenance of core safety information and the exchange of safety data relating to the Compound and the Products within and outside the Territory within appropriate timeframes and in an appropriate format to enable each Party to meet both its expedited and periodic regulatory reporting requirements; and (ii) ensuring compliance with the reporting requirements of all applicable Regulatory Authorities where XenoPort expects to conduct development activities for the Product as set forth in Section 4.4 (or other development activities in the Territory pursuant to Section 2.1(a)) for the reporting of safety data in accordance with standards stipulated in the Applicable Law (including FDA and ICH Guidelines), and all applicable regulatory and legal requirements regarding the management of safety data. Upon request by either Party from time to time, the Parties shall reasonably amend such Pharmacovigilance Agreement to comply with any such Applicable law, including such regulatory and legal requirements.

(d) Global Safety Database. GSK shall maintain the global safety database with respect to the Product [*] The Parties agree to [*] enable GSK to maintain such global safety database for [*].

ARTICLE V

COMMERCIALIZATION AND PROMOTION

5.1 GSK Commercialization of Product.

(a) GSK's Responsibility. Except as provided below, GSK shall have sole responsibility for the commercialization, distribution, marketing and promotion of the Products in the Field in the Territory. Further, regardless of whether XenoPort exercises the Co-Promotion Option as provided in Section 5.2 below, during the Term, GSK will have the exclusive right and responsibility in the Territory for the following:

- (i) establishing pricing and reimbursement for Product;
- (ii) managed care contracting for Product;
- (iii) receiving, accepting and filling orders for Product from customers;
- (iv) distributing Product to customers;
- (v) controlling invoicing, order processing and collecting accounts receivable for sales of Product; and
- (vi) recording sales of Product in the Territory in its books of account for sales.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(b) Commercialization Plan. At least [*], GSK shall prepare [*] a plan setting forth the strategic plan for the marketing, promotion and commercialization of the Products in [*], which plan shall be in reasonable scope and detail (the "Commercialization Plan"); provided, however, that the [*]; provided further that [*] with respect thereto, [*]. The Commercialization Plan (and any revisions thereto) shall be presented by GSK to the ESC or the JCC [*], as applicable. The ESC and the JCC [*] shall review and revise the Commercialization Plan on an ongoing basis, and in no event less frequently than once each calendar year. Subject to Section 5.2, GSK shall carry out all marketing, promotion and commercialization of the Products in the Territory in accordance with the then-current Commercialization Plan and the provisions of this Agreement.

5.2 Co-Promotion Option of XenoPort.

(a) Exercise of Co-Promotion Option. The Parties acknowledge that on April 13, 2009 (the "Option Exercise Date"), XenoPort exercised its non-sublicensable option to Co-Promote the Product with GSK in the United States ("Co-Promotion Option") in accordance with the terms and conditions of this Article 5. Accordingly, XenoPort will have an exclusive right to Co-Promote and Detail the Product with GSK in the United States until [*]. Notwithstanding the foregoing, XenoPort shall have a period of three (3) years from the date of GSK's receipt of the first (1st) Marketing Approval for the Product in the Territory for the RLS Indication (the "Pre-Co-Promotion Period") to commence the Co-Promotion and Detailing of the Product with GSK in the Territory as provided herein. XenoPort shall notify GSK in writing [*] (such written notice, the "Co-Promotion Commencement Date Notice" and such date, the "Co-Promotion Commencement Date"), which Co-Promotion Commencement Date must be prior to the expiration of the Pre- Co-Promotion Period. In the event that XenoPort does not provide written notice to GSK of the Co-Promotion Commencement Date as provided in this Section 5.2(a) or if XenoPort does not - commence the Co-Promotion and Detailing of the Product in the Territory as provided herein by the Co-Promotion Commencement Date, XenoPort will have no right to Co-Promote or Detail the Product with GSK in the United States, and GSK will have no further obligation with respect to the Co-Promotion Option.

(b) Co-Promotion Plan. The Parties acknowledge that, as XenoPort has exercised its Co-Promotion Option on the Option Exercise Date, [*] consistent with the Commercialization Plan for the United States ("Co-Promotion Plan"), which set out in reasonable detail: (i) [*] in connection with the Co-Promotion [*] (ii) [*] (iii) [*] and (iv) [*]

(c) Changes to the Co-Promotion Plan. After the approval of the initial Co-Promotion Plan, the JCC shall review and amend if necessary the Co-Promotion Plan on an ongoing basis and in no event less frequently than [*].

(d) Sales Efforts.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(i) During each Co-Promotion Year, the Parties shall each use Commercially Reasonable Efforts to Co-Promote and Detail the Product in the United States pursuant to the terms and conditions hereof and the then-current Co-Promotion Plan. The JCC will agree upon and monitor each Party's Co-Promotion and Detailing activities for each Co-Promotion Year. "Co-Promotion Year" shall mean, for the calendar year in which the Parties are first engaged in Co-Promotion, the portion of the calendar year remaining after (and including) the Co-Promotion Commencement Date, and shall mean the relevant January 1 through December 31 calendar year, or pro rata portion thereof, for all subsequent calendar years until the expiration or earlier termination of XenoPort's right to Co-Promote the Product as provided herein.

(ii) During any Co-Promotion Year, XenoPort shall use Commercially Reasonable Efforts to [*] the Co-Promotion Plan approved by the JCC [*].

(iii) The Co-Promotion Plan approved by the JCC for each Co-Promotion Year shall: (A) specify [*] to be provided [*] the number of Sales Representatives [*] (B) [*] in a manner that ensures [*] to be provided [*] and (C) to the extent [*] Sales Representatives that [*].

(e) Sales Efforts of XenoPort. In the event that XenoPort provides a Co-Promotion Commencement Date Notice to GSK as provided in Section 5.2(a), then together with such Co-Promotion Commencement Date Notice, XenoPort shall notify GSK of the number of Sales Representatives that XenoPort elects to deploy from and after the Co-Promotion Commencement Date for the Product, provided that [*]. Promptly after the Co-Promotion Commencement Date, XenoPort will [*] of Sales Representatives that XenoPort so elects; provided that upon written request to GSK by XenoPort, it may take [*] of Sales Representatives to provide Details of the Product in accordance with the Co-Promotion Plan. XenoPort shall, as requested by GSK, within [*] provided that, subject to [*] Sales Representatives that XenoPort deploys [*]. In the event that XenoPort desires to increase the number of XenoPort Sales Representatives who Detail and Co-Promote Product [*] in accordance with the Co-Promotion Plan, [*] Co-Promoting and Detailing the Product as provided herein [*]. In the event that GSK does not agree to using such Additional Sales Representatives in the Co-Promotion and Detailing of the Product, XenoPort will [*].

(f) Costs of Co-Promotion. The Parties acknowledge that because XenoPort has exercised its Co-Promotion Option on the Option Exercise Date as provided in Section 5.2(a), then as of the Option Exercise Date and continuing until [*], the Parties shall [*], notwithstanding that the Co-Promotion Commencement Date did not occur as of the Option Exercise Date or Restatement Effective Date and may not occur prior to the First Commercial Sale. If XenoPort commences the Co-Promotion and Detailing of the Product by the Co-Promotion Commencement Date, GSK shall [*] in accordance with the Co-Promotion Plan [*]. Such [*].

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(g) Co-Promotion Coordination. GSK shall be responsible for developing the strategies and programs to carry out the Co-Promotion activities, including the assignment of sales activities in accordance with the Commercialization Plan for the United States and Co-Promotion Plan.

5.3 [Intentionally Omitted.]

5.4 XenoPort Sales Representatives.

(a) Qualifications. All XenoPort Sales Representatives Co-Promoting and Detailing Product shall be required to have comparable educational qualifications and experience as GSK requires for its own Sales Representatives. Such XenoPort Sales Representatives shall be subject to a reasonable proficiency examination relevant to the Product in the same manner as GSK's Sales Representatives.

(b) No Contract Sales Force. XenoPort shall not be permitted to use a contract sales force to fulfill its Co-Promotion and Detailing responsibilities with respect to the Product under this Agreement.

(c) Training. GSK shall provide the same sales training on the Product for XenoPort Sales Representatives who will be Co-Promoting and Detailing the Product as the training on the Product that GSK provides to its own Sales Representatives who promote and Detail the Product in the United States. XenoPort shall be responsible for causing its Sales Representatives to attend and successfully complete the GSK training program prior to such Sales Representatives Co-Promoting and Detailing Product in the United States. The Parties acknowledge and agree that in order for a XenoPort Sales Representative to be deemed to have successfully completed the training, such XenoPort Sales Representative must demonstrate thorough knowledge of the medical and technical aspects of the Product and the Applicable Commercial Practices Policies and must achieve scores on certifications for the Product at similar rates to those required for GSK sales representatives who are Co-Promoting and Detailing the Product. XenoPort Sales Representatives will be entitled to attend those sections of national and regional sales or plan of action meetings for GSK Sales Representatives, except [*]. The costs of such sales training for XenoPort Sales Representatives for the Product and attendance at meetings shall be included as a Marketing Expense; provided, however, that each Party shall [*].

(d) Timing. XenoPort and GSK shall cooperate to have the XenoPort Sales Representatives hired and trained as provided in this Agreement [*].

(e) Compensation and Bonus System for Sales Representatives. The Parties acknowledge that in order to attract and retain professional Sales Representatives, there may be a degree of discrepancy between the compensation and bonus incentive structure for GSK's Sales Representatives and the compensation and bonus incentive structure for XenoPort's Sales Representatives. To ensure consistency of efforts between the Sales Representatives of the Parties,

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

each Party agrees that in designing such Party's compensation and bonus incentive structure, each Party will give due consideration to the effect that such Party's compensation and bonus structure may have on the other Party's sales force, provided however, that [*].

(f) XenoPort Salaries and Wages. XenoPort acknowledges and agrees that it will be solely responsible for paying all salaries, wages, benefits and other compensation that its employees, including XenoPort Sales Representatives, may be entitled to receive in connection with providing services under this Agreement.

(g) Support. Except as otherwise agreed, XenoPort shall be solely responsible for providing its own equipment, automobiles, offices and fixtures, working facilities, and such other facilities, services and support as may be required for XenoPort Sales Representatives Co-Promoting and Detailing Product as provided in this Agreement and pursuant to the Co-Promotion Plan.

(h) No Employment by GSK. For the avoidance of doubt, XenoPort Sales Representatives will not be, and will not be considered or deemed to be, employees of GSK for any purpose. GSK is engaging XenoPort hereunder, and XenoPort will perform its obligations hereunder, strictly as an "independent contractor." Sales Representatives and any other employee or agent that is involved in performing XenoPort's obligations under this Agreement (collectively, "Personnel") will not be, and will not be considered or deemed to be, employees of GSK for any purpose. GSK will not have any responsibility for the hiring, termination, compensation, benefits or other conditions of employment or engagement of the Personnel of XenoPort.

(i) GSK Benefit Plans. Personnel of XenoPort are not eligible to participate in any benefit programs offered by GSK to its employees, or in any pension plans, profit sharing plans, insurance plans or any other employee benefit plans offered from time to time by GSK to its employees. XenoPort acknowledges and agrees that GSK does not, and will not, maintain or procure any workers' compensation or unemployment compensation insurance for or on behalf of the XenoPort's employees, including, without limitation, XenoPort Sales Representatives.

(j) Management of Sales Representatives. XenoPort will be responsible for supervising its Sales Representatives. In connection therewith, at all times that XenoPort is Co-Promoting and Detailing the Product, XenoPort will provide a sufficient number of full time employees to serve as district managers. XenoPort may, but will not be obligated to, designate one (1) or more full time employees to serve as regional directors having the responsibility for supervising a group of its district managers in a particular geographic region of the United States. XenoPort will provide GSK with contact information for its district managers and regional directors, and will update that information periodically or as requested by GSK from time to time. XenoPort acknowledges and agrees that it will comply with this Section 5.4 in the hiring and employment of all district managers and regional directors, and that the provisions in this Section 5.4 will apply to all such district managers and regional directors.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

5.5 Co-Promotion Agreement. Promptly following GSK's receipt of the Co-Promotion Commencement Date Notice from XenoPort in accordance with Section 5.2(a), for the purposes of permitting GSK to comply with its obligations under Applicable Law, GSK and XenoPort shall enter into a co-promotion agreement setting out such obligations of XenoPort, including with respect to the activities of its Sales Representatives, in the Co-Promotion and Detailing of the Product and containing terms substantially similar to the terms set out on Exhibit 5 and which is consistent with the terms and conditions of this Agreement ("Co-Promotion Agreement"). Notwithstanding the foregoing, the obligations imposed on XenoPort, including with respect to the activities of its Sales Representatives, in the Co-Promotion and Detailing of the Product, including the terms of the Co-Promotion Agreement to be executed by GSK and XenoPort as provided in this Section 5.5, shall be [*]. It is understood that XenoPort may continue to exercise its rights under this Article 5 pending completion of such Co-Promotion Agreement, provided however, that [*].

5.6 Promotional Materials.

(a) Subject to Article XIII, GSK will own all right, title and interest in and to all Promotional Materials during and after the Term, including any intellectual property rights (including Trademarks) in the Promotional Materials other than the XenoPort Trademarks.

(b) The determination of the content of the Promotional Materials shall be the sole responsibility of GSK. The quantity and method of distribution of the Promotional Materials in the United States for the XenoPort Sales Representatives shall be as set forth in the Co-Promotion Plan.

(c) With respect to the Co-Promotion of the Product in the Territory, XenoPort will cause its Sales Representatives to utilize only the Promotional Materials relating to Product provided to them by GSK, and will not utilize any other promotional, advertising, educational or communication materials or other materials relating to or referring to the Product. XenoPort Sales Representatives will conduct only those promotional and other sales activities in the Territory relating to the Product that have been approved in advance in accordance with the Co-Promotion Plan. XenoPort Sales Representatives shall not modify, change or alter the Promotional Materials provided by GSK in any way whatsoever, without the express prior written consent of GSK. XenoPort Sales Representatives shall use such Promotional Materials solely for the purpose of performing their obligations under this Agreement.

5.7 Reports and Audit Rights.

(a) XenoPort will keep accurate records in sufficient detail of the XenoPort's Sales Representatives' Detailing activities relating to the Product to determine the amounts owed by GSK to XenoPort hereunder. XenoPort shall keep such records regarding such Sales Representatives' Detailing activities during the period during which XenoPort is Co-Promoting the Product and for a period of [*].

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(b) During normal business hours and with not less than [*] advance written notice to XenoPort, XenoPort will permit GSK or its authorized representatives to (i) have access to the records of XenoPort Sales Representative Detailing activities maintained by XenoPort for purposes of verifying the accuracy of the invoices presented by XenoPort hereunder, and (ii) audit such records; provided, however that [*]. Any and all audits undertaken by GSK pursuant to this Section shall be performed [*].

5.8 Reimbursement. Within [*], XenoPort shall submit to GSK a report containing an accounting of the Sales Representatives deployed by XenoPort in Co-Promoting and Detailing the Product in the United States and [*]. Such reimbursements shall be made to XenoPort [*]. The amount of such reimbursement shall be as specified in Section 5.2(f).

5.9 XenoPort and GSK Right to Terminate.

(a) XenoPort Termination Right. After XenoPort has exercised the Co-Promotion Option, XenoPort shall have the right to terminate its Co-Promotion of the Product and the sharing of Operating Profit or Loss under Section 6.5 below, upon [*].

(b) GSK Termination Right.

(i) As to the Product. After XenoPort has commenced its Detailing of the Product, GSK shall have the right to terminate XenoPort's right to Co-Promote and Detail the Product: (A) [*] in accordance with the Co-Promotion Plan) [*] and/or (B) [*].

(ii) [Intentionally Omitted.]

(iii) Sole Remedy. GSK's rights under this Section 5.9(b) to terminate XenoPort's right to Co-Promote and Detail the Product shall be GSK's sole remedy with respect to [*]. In addition, termination of the Co-Promotion Agreement by GSK for XenoPort's material breach of such agreement will not constitute grounds for GSK to terminate this Agreement pursuant to Section 14.2.

(c) Intentionally Omitted.

(d) Mutual Termination. The Parties may mutually agree to terminate XenoPort's right to Co-Promote and Detail the Product, respectively, at any time.

(e) Consequences of Termination of Product. Upon termination of XenoPort's right to Co-Promote the Product pursuant to Section 5.9(a), Section 5.9(b)(i), Section 5.9(d) or Section 9.1(a): (i) XenoPort shall [*] (ii) [*] with respect to the Product [*] in accordance with [*] in accordance with [*] and (iii) XenoPort shall [*] with respect to Product [*].

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

ARTICLE VI

PAYMENTS

6.1 Initial License Fee. GSK shall pay to XenoPort an initial license fee in the amount of Seventy Five Million Dollars (\$75,000,000) within five (5) days following the Closing Date in accordance with the payment provisions of Article 7. The initial license fee set forth in this Section shall not be refundable or creditable against any future milestone payments, royalties or other payments by GSK to XenoPort under this Agreement.

6.2 Milestone Payments.

(a) Milestone Payments. In addition, GSK shall pay to XenoPort the milestone payments set out below following the first achievement by a Party, or, in the case of GSK, any of its Affiliates or Sublicensees, of the corresponding milestone set out below, in accordance with this Section 6.2 and the payment provisions in Article 7:

<u>Milestone Event</u>	<u>Milestone Payment</u>	
[*]	\$	10,000,000
[*]	\$	11,000,000
[*]	\$	11,000,000
[*]	\$	8,000,000
[*]	\$	25,000,000
[*]	\$	10,000,000
[*]	\$	10,000,000
[*]	\$	30,000,000
[*]		[*]
[*]		[*]
[*]	\$	5,000,000
[*]		[*]
[*]		[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Milestone Event	Milestone Payment
[*]	[*]
[*]	\$ 10,000,000
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

(b) Certain Terms Regarding Milestone Payments.

(i) If the first achievement of [*] achievement of [*] shall be [*]. In addition: (A) if the first achievement of [*] shall not [*] achievement of [*] to achievement of [*] Section 6.2 [*] achievement of [*] shall not [*].

(ii) Subject to Section 6.2(b)(i), if, upon the [*] set out in Section 6.2(a), the amount corresponding [*] as described in Section 6.2(a)[*]. In addition, if, upon the [*] as described in Section 6.2(a) [*].

(c) Definitions. For the purposes of the milestone payments due under Section 6.2(a):

(i) [*]: (A) any of the following, [*] in the context of [*] as applicable: [*] mutually agreed by the Parties; provided that, [*] of the [*] as applicable, and [*] of such [*] and in the event [*] other than [*] this Section 6.2, [*] until the Parties mutually agree [*].

(ii) [*] as provided in [*] shall be [*] of the [*] together with [*].

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(iii) [*] as to [*] above, the achievement of [*] against which [*] in the [*] and/or [*] that is [*] than such [*].

(iv) [*] as to [*] above, receipt [*] the Product [*] that would [*] that is [*] than such [*].

(v) [*] shall mean [*].

(vi) [*] as required by the protocol for such trial, by the [*] in such [*].

(vii) [*] as provided in [*] above, shall mean achievement of [*] the Product [*] and/or [*] than such [*] for which [*] by the Parties and will be included in the Development Plan.

(viii) [*] as provided in [*] above, shall mean [*] the Product [*] of the [*].

(d) **Reports and Payments.** Except as described below, GSK shall notify XenoPort in writing promptly, but [*] the achievement of [*] provided that, [*] Any milestone payable by GSK pursuant to this Section 6.2 shall be made no more than once with respect to the achievement of each milestone set out in Section 6.2(a) by GSK, its Affiliates or Sublicensees, and in no event shall the aggregate amount to be paid by GSK under this Section 6.2 exceed Six Hundred and Two Million Five Hundred Thousand Dollars (\$602,500,000.00). For clarity, in no event shall the aggregate amount to be paid by GSK [*]. For the avoidance of doubt, the milestone payments set forth in this Section 6.2 shall not be refundable and shall not be creditable against future milestone payments, royalties or other payments to XenoPort under this Agreement.

6.3 Royalty Payments.

(a) **U.S. Royalty Rate.** Subject to the terms and conditions of this Agreement (including Section 6.4), in further consideration of the rights granted to GSK under this Agreement, GSK shall pay to XenoPort royalties at the rate(s) set out below on Annual Net Sales of Products in the United States in the event that XenoPort shall not elect the Co-Promotion Option in the United States or in the event that XenoPort's rights to Co-Promote the Product are terminated for any reason:

<u>Annual Net Sales of Product in the United States</u>	<u>Royalty Rate</u>
[*]	[*]
[*]	[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(b) Reports and Royalty Payment. Within [*], GSK shall send to XenoPort a written report with respect to the preceding calendar quarter, stating the gross invoiced sales for Product, a top-line summary of the deductions specified in Section 1.36 taken from gross sales and the Net Sales in the Territory during such calendar quarter in United States dollars (each, a "Payment Report"). Royalties will be calculated based on the Payment Report. GSK shall pay the appropriate royalties set forth in the Payment Report within [*]

(c) No Separate Patent Royalties. It is understood that the royalties to be paid under this Section 6.3 are in consideration of the XenoPort Know-How, commercial opportunities and other undertakings of XenoPort provided in this Agreement, and that no separate royalty is due with respect to the XenoPort Patents.

6.4 Certain Reductions to Royalties.

(a) Third Party Royalties. In the event GSK or its Affiliates pays to a Third Party royalties under agreements for patent rights that cover the composition of matter or therapeutic use of the Compound, or that cover all feasible methods to manufacture the Compound ("Third Party Royalties"), which GSK reasonably believes [*] then GSK [*] with respect to the [*] pursuant to [*]. For such purposes, [*].

(b) Patent Litigation Expenses. XenoPort acknowledges and agrees that GSK may [*] as provided in [*] pursuant to [*] (i) [*] as a result of [*] or [*] in connection therewith; and (ii) [*] XenoPort shall [*].

(c) Generic Competition. On a Product-by-Product basis, if: (A) one or more Generic Products are being marketed for an approved indication of the Product in the Territory; and (B) such Generic Product(s) represent a total unit volume of [*] in any calendar quarter determined by [*] in such calendar quarter [*] ("Generic Competition"), and GSK reasonably determines that it is not likely to recover such lost market share, then the royalties payable pursuant to Sections 6.3(a) with respect to such Product sold in the Territory for such quarter shall thereafter be reduced by [*]; provided however that if such Generic Competition continues for a period of [*], then upon the date that is on the [*] of the initiation of such Generic Competition, GSK shall no longer be required to pay royalties to XenoPort with respect to such Product in the Territory. "Generic Product" shall mean a [*] being sold hereunder in the Territory [*].

6.5 Cost-Profit Sharing in the United States. The Parties acknowledge that because XenoPort has exercised the Co-Promotion Option for the Product in the United States as provided in

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Section 5.2 on the Option Exercise Date, then in lieu of the royalties specified in Section 6.3(a) with respect to Net Sales in the United States, and notwithstanding that the Co-Promotion Commencement Date has not occurred as of the Option Exercise Date and the Restatement Effective Date, the Parties shall, subject to Section 6.5(d) below, share Operating Profit or Loss (as defined in Exhibit 6.5) in the United States as provided in this Section 6.5 as of the Option Exercise Date. The Parties acknowledge that in the event XenoPort's right to Co-Promote and Detail the Product as provided herein are terminated pursuant to Section 5.2(a) or 5.9, the Parties shall not share Operating Profit or Loss (as defined in Exhibit 6.5) in the United States and any sales of Product in the Territory by GSK, its Affiliates and Sublicensees shall be subject to royalty payments under Section 6.3 above.

(a) Co-Promotion Expenses. After XenoPort's exercise of the Co-Promotion Option, those expenses outlined in Exhibit 6.5 shall be allocated to the Joint P&L calculated under Section 6.5(c).

(b) Allocation of Operating Profit or Loss. In consideration for each Party's efforts pursuant to the Co-Promotion Plan in the United States, for each calendar quarter, GSK shall be entitled to the following percentage of the Operating Profit or Loss for such quarter and XenoPort shall be entitled to the following percentage of the Operating Profit or Loss for such quarter, such amounts to be distributed to the Parties pursuant to Section 6.5(c):

	GSK's Share of Operating Profit or Loss	XenoPort's Share of Operating Profit or Loss
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

(c) Joint P&L. Within [*], XenoPort shall furnish to GSK a statement setting forth its year-to-date [*] (collectively, "XenoPort Operating Expenses") for such quarter in the United States, as defined in Exhibit 6.5. Within [*], GSK shall furnish to XenoPort a statement (the "Joint P&L") setting forth the year-to-date Net Sales in the United States during such quarter, and GSK's year to date [*] (collectively, "GSK Operating Expenses") for such quarter in the United States, as defined in Exhibit 6.5. Whenever GSK provides XenoPort with a statement of GSK Operating Expenses, or XenoPort provides GSK with a statement of XenoPort Operating Expenses, the providing Party shall provide such supporting documentation as the receiving Party may reasonably request. Such Joint P&L will also include the amount of the Operating Profits or Loss for the quarter and year-to-date and the percentage of such Operating Profits or Loss to Net Sales (the "Operating Profits/Loss Percentage"). GSK will calculate each Party's share of the Operating Profit or Loss as follows: [*] In the event that the calculation

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

of XenoPort's share of the Operating Profits or Loss is a positive number, GSK shall pay to XenoPort, [*] receipt of an invoice therefor from XenoPort as provided in Section 7.1, the difference between the amount owed to XenoPort under the then-current Joint P&L and any amounts already paid to or received from XenoPort pursuant to this Section 6.5(c) with respect to prior Joint P&Ls for the same year. In the event that the calculation of XenoPort's share of the Operating Profits or Loss is a negative number, then subject to Section 6.5(d) below, XenoPort shall, [*] its receipt of an invoice provided by GSK together with, or after providing, such a Joint P&L, pay to GSK the difference between the amount owed to GSK under the then current Joint P&L and any amounts already paid to or received from GSK pursuant to this Section 6.5(c) with respect to prior Joint P&Ls for the same year. For clarity, it is understood that XenoPort is [*] with respect to [*] in accordance with [*] Examples of the calculation of each Party's share of the Operating Profits or Loss is provided in Exhibit 6.5. In the event that the foregoing procedure does not permit one or both of the Parties to comply with reporting requirements under applicable United States securities laws, rules and regulations, the JCC will modify the foregoing procedure to permit the Parties to comply with such reporting requirements, consistent with the general approach set forth in this Section 6.5(c).

(d) Operating Losses. It is understood that the calculation of Marketing Costs shall commence as of the Option Exercise Date in accordance with Section 5.2(a) above and shall include only those Marketing Costs incurred after such Option Exercise Date. However, XenoPort shall not be required to pay to GSK its portion of any Operating Loss prior to the calendar quarter immediately following the first full calendar quarter after the First Commercial Sale of the Product in the United States in which the Joint P&L achieves an Operating Profit ("First Profitable Quarter"); provided that [*]; provided, further, that XenoPort's portion of any such Operating Loss up to the amount of Ten Million Dollars (\$10,000,000) shall be forgiven in full by GSK (i.e., XenoPort shall not be responsible for any Operating Losses until the share of the Operating Losses that would otherwise be payable by XenoPort exceeds Ten Million Dollars (\$10,000,000)). In addition, to the extent that XenoPort's portion of any Operating Losses incurred prior to the First Profitable Quarter exceeds Ten Million Dollars (\$10,000,000) (such excess amount, the "Aggregate Loss Carry Forward") shall be carried forward and reimbursed [*]

(e) Financial Reporting. To facilitate financial reporting, including earnings forecasts, each Party agrees to keep the other Party fully informed as to its forecasts of Net Sales, Operating Expenses and Operating Profit or Loss.

ARTICLE VII

PAYMENTS; BOOKS AND RECORDS

7.1 Payment Method; Invoices. All milestone payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated in an invoice from the Party to which such payments are due, which invoice should include bank details, the contact name for any issue resolution and be marked for the attention of the Alliance Manager of the

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Party to whom such payment is due. Any payments or portions thereof due under this Agreement that are not paid by the date such payments are due under this Agreement shall bear interest at a rate equal to: (i) the prime rate as reported by Citibank N.A., [*] or (ii) if lower, the maximum rate permitted by law; calculated on the number of days such payment is delinquent, compounded annually and computed on the basis of a three hundred sixty five (365) day year. This Section 7.1 shall in no way limit any other remedies available to the Parties. All amounts owed by GSK to XenoPort hereunder shall be paid by an entity resident in the United Kingdom from a bank account located in the United Kingdom.

7.2 Currency Conversion. With respect to sales of the Product invoiced in United States dollars, the Net Sales and the amounts due hereunder will be expressed in United States dollars. With respect to sales of the Product invoiced in a currency other than United States dollars, the Net Sales and amounts due hereunder will be reported in United States dollars, calculated using the average exchange rates as calculated and utilized by GSK's group reporting system and published accounts. As of the Effective Date, [*]

7.3 Withholding Taxes; Taxes Generally.

(a) If taxes are required under Applicable Law in the United Kingdom to be withheld by GSK on any payment on behalf of XenoPort, GSK will (a) deduct those taxes from the payment and (b) pay the taxes to the proper taxing authority. In the event such taxing authorities routinely provide a tax receipt upon payment, GSK will procure such receipt for any such withholding evidencing payment of such taxes, which will be forwarded to XenoPort. XenoPort represents and warrants that it is resident for tax purposes in the United States and that it is entitled to relief from the United Kingdom income tax under the terms of the double tax agreement between the United Kingdom and the United States. [*] GSK shall [*] GSK shall [*] the United Kingdom and the United States. [*] withholding tax [*]

(b) Each Party shall be responsible for paying taxes imposed by any taxing authority on any income earned by such Party under this Agreement.

7.4 Records; Inspection.

(a) GSK. GSK shall keep, and require its Affiliates and Sublicensees to keep, complete, true and accurate books of accounts and records for the purpose of determining the amounts payable to XenoPort pursuant to this Agreement. Such books and records shall be kept for at least [*] following the end of the calendar quarter to which they pertain and shall be open for inspection and audit by XenoPort during such [*] period on the terms of this Section 7.4(a). Upon not less than [*] prior written notice, GSK shall permit an independent, certified public accountant selected by XenoPort and reasonably acceptable to GSK, which acceptance will not be unreasonably withheld or delayed (for the purposes of this Section 7.4(a), the "Auditor"), to audit or inspect those books or records of GSK that relate to Net Sales and Payment Reports, and/or Joint P&L (including the components thereof) for the sole purpose of verifying the:

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(i) royalties and other payments payable hereunder in respect of Net Sales or Operating Profit or Loss for such annual period under review; (ii) withholding taxes, if any, required by Applicable Law to be deducted as a payment by GSK in respect of such Net Sales; and (iii) exchange rates used in determining the amount of United States dollars. The Auditor will disclose to XenoPort only the amount and accuracy of payments reported and actually paid or otherwise payable under this Agreement. The Auditor will send a copy of the report to GSK at the same time it is sent to XenoPort. Such inspections may be made no more than once each calendar year and during normal business hours. Such records for any particular calendar quarter shall be subject to no more than one inspection. The Auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. Inspections conducted under this Section 7.4(a) shall be at the expense of XenoPort, unless a variation or error producing an underpayment in amounts payable exceeding [*] of the amount paid for a period covered by the inspection is established, in which case all reasonable costs relating to the inspection for such period and any unpaid amounts that are discovered shall be paid by GSK, together with interest on such unpaid amounts at the rate set forth in Section 7.1 above. The Parties will endeavor in such inspection to minimize disruption of GSK's normal business activities to the extent reasonably practicable.

(b) XenoPort. XenoPort shall keep complete, true and accurate books of accounts and records for the purpose of determining payments due from GSK pursuant to this Agreement. Such books and records shall be kept for at least [*] following the end of the calendar quarter to which they pertain and shall be open for inspection and audit by GSK during such [*] period on the terms of this Section 7.4(b). Upon not less than [*] prior written notice, XenoPort shall permit an independent, certified public accountant selected by GSK and reasonably acceptable to XenoPort, which acceptance will not be unreasonably withheld or delayed (for the purposes of this Section 7.4(b), the "Auditor"), to audit or inspect those books or records of XenoPort that relate to XenoPort Operating Expenses and Sales Costs, for the sole purpose of verifying the amounts payable hereunder. The Auditor will disclose to GSK only the amount and accuracy of payments reported and actually paid or otherwise payable under this Agreement. The Auditor will send a copy of the report to XenoPort at the same time it is sent to GSK. Such inspections may be made no more than once each calendar year and during normal business hours. Such records for any particular calendar quarter shall be subject to no more than one inspection. Auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. Inspections conducted under this Section 7.4(b) shall be at the expense of GSK, unless a variation or error producing an overpayment in amounts payable exceeding [*] of the amount paid for a period covered by the inspection is established, in which case all reasonable costs relating to the inspection for such period and any overpaid amounts that are discovered shall be paid by XenoPort, together with interest on such overpaid amounts at the rate set forth in Section 7.1 above. The Parties will endeavor in such inspection to minimize disruption of XenoPort's normal business activities to the extent reasonably practicable.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

ARTICLE VIII

CERTAIN COVENANTS

8.1 Diligent Efforts of GSK. GSK shall use Commercially Reasonable Efforts to [*] maximize the sales of at least one (1) Product in the Territory in an expeditious manner. Without limiting the foregoing and excluding [*] GSK agrees to use Commercially Reasonable Efforts to achieve [*] milestones set forth in section 6.2.

8.2 Diligent Efforts of XenoPort. XenoPort shall use Commercially Reasonable Efforts to conduct the Initial Clinical Studies and Activities and all development activities for the Other Indications allocated to XenoPort in the then-current Development Plan and, in the event that XenoPort Co-Promotes and Details the Product as provided in this Agreement, use Commercially Reasonable Efforts in its Co-Promotion and Detailing of the Product following the Marketing Approval of the Product in the United States.

8.3 General Communications. Each Party shall keep the other Party fully and promptly informed as to its progress and activities relating to the development, commercialization, marketing and promotion of the Product in the Territory, including with respect to regulatory matters and meetings with Regulatory Authorities, by way of updates to appropriate Committees at their meetings and as otherwise specified in this Agreement, or as reasonably requested by the other Party. In connection therewith, XenoPort and GSK shall provide each other with such information regarding such progress and activities under the Development Plan, the Commercialization Plan and/or any Co-Promotion Plan, or otherwise relating to the development of the Product for, or commercialization of the Product in, the Territory, as the other Party may request from time to time. In order to facilitate the Parties' exercise of their rights and fulfillment of their obligations hereunder, each Party agrees to give due consideration to any comments provided by the other Party with respect to such development, commercialization, marketing and promotion of the Compound and/or any Product for the Territory.

8.4 Managed Care Contracting. [*]

ARTICLE IX

CHANGE OF CONTROL

9.1 Change of Control of XenoPort. XenoPort shall notify GSK in writing within [*] Following any Change of Control of XenoPort:

(a) During a [*] commencing on [*], and upon at least [*] days prior written notice to XenoPort, GSK shall have the right to terminate XenoPort's right to Co-Promote and Detail the Product as provided in Article 5 above if such Change of Control involves a Major Pharmaceutical Company; provided that [*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(b) Any material changes to the Development Plan in effect as of the date of such notice of a Change of Control of XenoPort [*]; subject to the foregoing, [*].

(c) If as a result of a Change of Control of a Party (the "Acquired Party"), such Acquired Party becomes obligated to divest rights to the Compound and Products in the Territory, such Party shall notify the other Party (the "Continuing Party") in writing. Within [*], the Continuing Party shall notify the Acquired Party in writing whether it is interested in acquiring all of the Acquired Party's rights to the Compound and Products in the Territory. If the Continuing Party so notifies the Acquired Party, the Parties shall discuss mutually acceptable terms upon which the Continuing Party may acquire all of the Acquired Party's rights to the Compound and Products in the Territory. In such case, if the Parties do not agree on such terms then prior to divesting such rights, the Acquired Party shall notify the Continuing Party in writing, together with the full set of terms and conditions under which the Acquired Party proposes to divest such rights, and the Continuing Party shall have the right, exercisable within [*], to acquire such rights on such terms and conditions.

(d) For the avoidance of doubt, except as set out in this Section 9.1, a Change of Control of XenoPort shall not otherwise affect the rights or obligations of the Parties with respect to the Compound and Products in the Territory under this Agreement, and shall not be deemed to modify or expand the scope of GSK's rights under Section 2.1 or 2.2 above.

ARTICLE X

MANUFACTURING AND SUPPLY

10.1 Transfer of Manufacturing and Supply Responsibilities. The Parties acknowledge that, pursuant to Section 10.1 of the Original Agreement, XenoPort transitioned the manufacture and supply of the Compound and Products to GSK. Such transition included the transfer by XenoPort to GSK of the items contained in Exhibit 10.1.

10.2 Activities After the Supply Transition. As between the Parties and subject to the terms and conditions of this Agreement, GSK shall have the exclusive right to manufacture the Compound and the Products for distribution in the Territory; except that [*] the Compound and Products [*] the Territory [*] It is understood that [*] with respect to [*] manufacture of the Compound and Products for distribution [*]

10.3 Supply of Clinical Materials.

(a) To the extent that XenoPort will conduct any clinical trials, preclinical studies and other research and development activities involving the Product for any Other Indication as provided in a Development Plan, GSK shall supply XenoPort with such quantities of Compound, Product and matching placebo, in each case, in bulk finished form [*] as are reasonably requested by XenoPort for it to conduct such clinical trials, preclinical studies and other research and

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

development activities ("Clinical Materials") [*]. The price of Clinical Materials supplied by GSK to XenoPort pursuant to this Section 10.3(a) and/or pursuant to Section 10.3 (b) below shall be [*]; provided, however, that, [*]. If XenoPort orders, and GSK delivers to XenoPort pursuant to this Section 10.3(a), quantities of Clinical Materials such that [*], XenoPort shall pay to GSK [*]. Any such amounts payable by XenoPort shall be paid [*] in arrears within [*] after XenoPort's receipt from GSK of an invoice for the quantities of Clinical Materials delivered by GSK to XenoPort in accordance with this Section 10.3 during such calendar quarter. It is understood and agreed that the Clinical Materials supplied by GSK to XenoPort pursuant to this Section 10.3(a) or Section 10.3(b) below shall not include [*] for the conduct of such clinical trials, preclinical studies and other research and development activities.

(b) In the event that XenoPort requests Clinical Materials for use in conducting development activities solely for the purpose of [*], or otherwise solely for purposes directed to the development of such Product for commercialization, in each case [*], GSK shall supply such Clinical Materials to XenoPort [*]. In the event that XenoPort requests Clinical Materials for use in conducting development activities solely for the purpose of [*], or otherwise solely for purposes directed to the development of such Product for commercialization, in each case [*], GSK shall supply such Clinical Materials to XenoPort [*]. In the event XenoPort requests [*] for use in the manufacture of Product for [*], GSK shall supply such [*]: (i) [*]; or (ii) [*]. The Parties shall enter into a separate supply agreement, within [*] following a request by either Party to do so, covering the foregoing supply by GSK to XenoPort of Clinical Materials and/or [*], which agreement shall reflect the terms specified in this Section 10.3(b), and such other terms and conditions as are reasonable and customary for pharmaceutical supply arrangements. Without limiting the foregoing, [*], GSK shall [*] to cooperate [*].

(c) GSK shall deliver to XenoPort Clinical Materials ordered by XenoPort promptly, to the extent that GSK has available supplies of Product, but in any event, [*]. XenoPort shall provide to GSK, upon GSK's reasonable request, good faith, non-binding estimates of XenoPort's anticipated requirements of Clinical Materials [*] and, in any event, XenoPort shall provide to GSK an order for its anticipated requirements of Clinical Materials [*] prior to the commencement of the trial, study or activity in which such Clinical Materials are intended to be used.

(d) Any Clinical Materials provided by GSK to XenoPort pursuant to this Section 10.3 shall be delivered [*]. Prior to shipment, GSK shall provide to XenoPort a certificate of analysis, in a form reasonably agreed by the Parties, demonstrating that the relevant Clinical Materials to be shipped conform to the applicable specifications therefor.

(e) GSK shall supply to XenoPort the Clinical Materials ordered by XenoPort pursuant to this Section 10.3 in bulk finished dosage form. The Clinical Materials shall conform to the specifications for the Product included in the NDA for the Product for RLS in the United States

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

as of the Restatement Effective Date (as amended from time to time as provided in this Section 10.3(e) below, the "Specifications"). GSK shall [*].

(f) GSK warrants that all Clinical Materials supplied to XenoPort under this Agreement shall: [*] (ii) [*]; (iii) [*]; and (iv) have at least [*] of remaining shelf life at the time of delivery of such Clinical Materials by GSK to XenoPort.

(g) Subject to Section 10.3(a) above, any amounts payable by XenoPort with respect to Clinical Materials ordered by XenoPort, and delivered by GSK, in accordance with this Section 10.3 shall be paid quarterly in arrears within [*] after XenoPort's receipt from GSK of an invoice for the quantities of Clinical Materials delivered by GSK to XenoPort in accordance with this Section 10.3 during such calendar quarter.

ARTICLE XI

CONFIDENTIALITY

11.1 Confidential Information. Except as expressly provided in this Agreement, the Parties agree that the receiving Party shall not publish or otherwise disclose and shall not use for any purpose any information furnished to it by the other Party hereto pursuant to this Agreement (collectively, "Confidential Information"). Notwithstanding the foregoing, Confidential Information shall not include information that, in each case as demonstrated by written documentation:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure or, as shown by written documentation, was developed by the receiving Party prior to its disclosure by the disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was subsequently lawfully disclosed to the receiving Party by a person other than the disclosing Party, and who did not directly or indirectly receive such information from disclosing Party; or

(e) is developed by the receiving Party without use of or reference to any Confidential Information disclosed by the disclosing Party.

11.2 Permitted Disclosures. Notwithstanding the provisions of Section 11.1 above and subject to Sections 11.3 and 11.4 below, each Party hereto may use and disclose the other Party's Confidential Information to its Affiliates, licensees, permitted Sublicensees, contractors and any

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

other Third Parties to the extent such use and/or disclosure is reasonably necessary to exercise the rights granted to it, or reserved by it, under this Agreement, prosecuting or defending litigation, complying with Applicable Laws, submitting information to tax or other governmental authorities or conducting clinical trials hereunder with respect to any Product. If a Party is required by Applicable Law to make any such disclosure of the other Party's Confidential Information, to the extent it may legally do so, it will give reasonable advance notice to the latter Party of such disclosure and, save to the extent inappropriate in the case of patent applications or otherwise, will use its good faith efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise). For any other disclosures of the other Party's Confidential Information, including to Affiliates, licensees, permitted Sublicensees, contractors and other Third Parties, a Party shall ensure that the recipient thereof is bound by a written confidentiality agreement as materially protective of such Confidential Information as this Article 11.

11.3 Confidential Terms. Each Party agrees not to disclose to any Third Party [*] except each Party may disclose [*] (a) [*] or (b) [*] to the extent allowable by Applicable Law, [*] that is required [*] Notwithstanding the foregoing, [*] of which [*] thereafter, [*]

11.4 Publication of Product Information. Prior to its publishing, publicly presenting and/or submitting for written or oral publication a manuscript, abstract or the like in the Territory with respect to GSK and with respect to XenoPort (to the extent XenoPort has the right to do so) outside the Territory, that includes Data or other information relating to the Compound or any Product that has not previously published, a Party shall provide the other Party a copy thereof for its clinical review for at least [*] (unless such Party is required by Applicable Law to publish such information sooner). Such Party shall consider in good faith any comments provided by the other Party during such [*] period. In addition, the publishing Party shall, at the request of the other Party, remove any Confidential Information of the other Party therefrom, except each Party shall have the right to publicly disclose any information, including Confidential Information, pertaining to safety of a Product that such Party believes in good faith it is obligated or appropriate to disclose. Without limiting the foregoing, it is understood that the principles to be observed in any disclosures described in this Section 11.4 shall be accuracy, compliance with Applicable Law, reasonable sensitivity to potential negative reactions of the FDA (and its foreign counterparts) and the need to keep investors informed regarding the publishing Party's business. Accordingly, any comments provided by the other Party on a disclosure submitted to it by the publishing Party pursuant to this Section and/or any requests for any Confidential Information to be removed from any such disclosure shall comply with such principles. The contribution of each Party shall be noted in all publications or presentations by acknowledgment or co-authorship, whichever is appropriate. Notwithstanding the foregoing, XenoPort will not be permitted, without the prior written consent of GSK, which consent will not be unreasonably withheld, to publish, publicly present and/or submit for written or oral publication a manuscript, abstract or the like in the Territory relating to any clinical studies involving the Product for: [*]; it being understood that the foregoing shall not limit XenoPort's ability to submit and publish information pertaining to [*] any such

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

disclosures as described in this Section 11.4. Nothing in this Section 11.4 shall, however, be deemed to limit Astellas' or a ROW Licensee's rights to publish, publicly present and/or submit for publication a manuscript, abstract or the like that includes data or other information relating to the Compound or any Product under development or being commercialized by or under the authority of Astellas or such ROW Licensee for use outside the Territory.

11.5 Publicity Review. The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding the Product and other activities in connection with this Agreement that may reflect the terms of this Agreement or information that is not otherwise permitted to be disclosed under this Article 11, beyond what is required by Applicable Law, and each Party may make such disclosures from time to time with the approval of the other Party, which approval shall not be unreasonably withheld or delayed. Such disclosures may include, without limitation, achievement of milestones, significant events in the development and regulatory process, commercialization activities and the like. When a Party (the "Requesting Party") elects to make any such public disclosure under this Section 11.5, it will give the other Party (the "Cooperating Party") at [*] notice to review and comment on such statement, it being understood that if the Cooperating Party does not notify the Requesting Party in writing within such [*] period of any reasonable objections, as contemplated in this Section 11.5, such disclosure shall be deemed approved, and in any event the Cooperating Party shall work diligently and reasonably to agree on the text of any proposed disclosure in an expeditious manner. The principles to be observed in such disclosures shall be accuracy, compliance with Applicable Law, reasonable sensitivity to potential negative reactions of the FDA (and its foreign counterparts) and the need to keep investors informed regarding the Requesting Party's business. Accordingly, the Cooperating Party shall not withhold its approval of a proposed disclosure that complies with such principles.

11.6 Prior Non-Disclosure Agreements. Upon execution of this Restated Agreement, the terms of this Article 11 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties, including the non-disclosure and confidentiality obligations of the Parties under Article 11 of the Original Agreement. Any information disclosed under such prior agreements shall be deemed disclosed under this Agreement.

ARTICLE XII

PATENT PROSECUTION AND ENFORCEMENT

12.1 Ownership of Inventions. Title to all inventions and other intellectual property (other than XenoPort Trademarks) made solely by GSK personnel in connection with this Agreement shall be owned by GSK. Title to all inventions and other intellectual property (other than GSK Trademarks) made solely by XenoPort personnel in connection with this Agreement shall be owned by XenoPort. Title to all inventions and other intellectual property (other than Trademarks) made jointly by personnel of XenoPort and GSK in connection with this Agreement shall be jointly owned by XenoPort and GSK. Prosecution of any Patent with respect to such jointly-owned inventions and

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

intellectual property shall be solely as mutually agreed. Except as expressly provided in this Agreement, it is understood that neither Party shall have any obligation to obtain any approval of, nor pay a share of the proceeds to, the other Party to practice, enforce, license, assign or otherwise exploit such jointly-owned inventions or intellectual property, and each Party hereby waives any right it may have under the Applicable Laws of any jurisdiction to require such approval or accounting. GSK hereby grants to XenoPort [*]

12.2 Prosecution and Maintenance of XenoPort Patents.

(a) GSK Control of Prosecution. [*] GSK shall have the right, at its expense, to control the Prosecution and Maintenance of Patents in the Territory included in the XenoPort Patents as of the Effective Date, or which may be filed in the Territory after the Effective Date, to the extent the same are directed to the Compound or any Product, and/or manufacturing and/or use thereof, in the Field in the Territory (such XenoPort Patents, [*], are referred to below as the "GSK Prosecuted XP Patents"). GSK shall diligently Prosecute and Maintain the GSK Prosecuted XP Patents; shall consult with XenoPort in good faith regarding the Prosecution and Maintenance of such GSK Prosecuted XP Patents; and shall take into account XenoPort's reasonable comments related to such matters. If GSK determines not to file any Patent, or to abandon any Patent within the GSK Prosecuted XP Patents, with respect to any subject matter described in this Section 12.2(a), as applicable, GSK shall provide XenoPort with at least [*] written notice of such decision, prior to the deadline for filing any such Patent or the date on which such abandonment would become effective. In such event, XenoPort shall have the right, at its option, to control the Prosecution and Maintenance of such Patent. For the purposes of this Section 12.2, "Prosecution and Maintenance" (including variations such as "Prosecute and Maintain") shall mean, with respect to a Patent, the preparing, filing, prosecuting and maintenance of such Patent, as well as re-examinations, reissues and requests for Patent term extensions and the like with respect to such Patent, together with the conduct of interferences, the defense of oppositions and other similar proceedings with respect to a Patent. Also, as used in this Section 12.2, to "abandon" a Patent shall include deciding not to defend against an opposition, not to defend an interference or similar proceeding or not to pursue an appeal of an adverse decision, in each case with respect to such Patent in the United States Patent & Trademark Office.

(b) XenoPort Prosecuted Patents. XenoPort shall have the right, at its expense, to control the Prosecution and Maintenance of the XenoPort Patents in the Territory [*] and shall diligently Prosecute and Maintain the XenoPort Prosecuted Patents in the Territory. [*] If XenoPort determines not to file, or to abandon, any such Patent within such XenoPort Prosecuted Patents, [*] XenoPort shall [*] to the extent of [*] In addition, [*] XenoPort shall [*]

(c) XenoPort Patents Outside the Territory. It is understood that as between the Parties, XenoPort shall control the Prosecution and Maintenance of XenoPort Patents outside the Territory and that Section 12.2(b) above shall not apply to such XenoPort Patents. However, to the extent XenoPort may do so under the Astellas Agreement and agreements with ROW Licensees,

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

XenoPort shall consult with GSK in good faith upon request regarding the Prosecution and Maintenance of XenoPort Patents outside the Territory and shall take into account GSK's reasonable comments related to such matters.

(d) Cooperation. Each Party shall cooperate with the other Party in connection with all activities relating to the Prosecution and Maintenance of the XenoPort Patents in the Territory undertaken by such other Party pursuant to this Section 12.2, including: (i) making available in a timely manner any documents or information such other Party reasonably requests to facilitate such other Party's Prosecution and Maintenance of the XenoPort Patents pursuant to this Section 12.2; and (ii) if and as appropriate, signing (or causing to have signed) all documents relating to the Prosecution and Maintenance of any XenoPort Patents by such other Party. Each Party shall also promptly provide to the other Party all information reasonably requested by such other Party with regard to such Party's activities pursuant to this Section 12.2, and if requested, permit such other Party to participate at its own expense in any opposition, interference, appeal or similar proceeding with respect to a XenoPort Patent in the Territory, to the extent the same are directed to the Compound or any Product, and/or manufacturing and/or use thereof, in the Field in the Territory. GSK shall hold all information disclosed to it under this Section 12.2 as Confidential Information.

12.3 Enforcement.

(a) Notice. In the event that XenoPort or GSK becomes aware of actual or threatened infringement or misappropriation of any XenoPort Patent or XenoPort Know-How by the manufacture, sale or use in the Territory of a product containing a Competitive Compound for the treatment of an indication that competes directly with a Product in the Field in the Territory, including the filing of an Abbreviated New Drug Application with the FDA (an "Infringement"), that Party shall promptly notify the other Party in writing. "Competitive Compound" shall mean [*]

(b) Initiating Enforcement Actions. GSK has the right to initiate infringement proceedings or take other appropriate actions against an Infringement in the Territory. If Applicable Law in the Territory does not permit an exclusive licensee to initiate such actions (i.e., such action may only be initiated by the owner of the patent being infringed), GSK would have the right to insist that XenoPort initiates such action on GSK's behalf and at GSK's expense. If GSK does not initiate proceedings or take other appropriate action within [*] of receipt of a request by XenoPort to do so, then XenoPort shall be entitled to initiate infringement proceedings or take other appropriate action against an Infringement at its own expense. The Party conducting such action shall have full control over the conduct of such action, including settlement thereof; provided, however, that the Party conducting such action may not settle any such action, or make any admissions or assert any position in such action, in a manner that would materially adversely affect the rights or interests of the other Party (including by making any admission or assertion of any position, that would materially adversely affect the validity, enforceability or scope of any XenoPort Patent within or outside the Territory), without the prior written consent of the other Party, which shall not be

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

unreasonably withheld or delayed. The Party conducting such action (except in the case of XenoPort, where XenoPort conducts such action at the request of GSK) will [*]. In any event, the Parties shall assist one another and cooperate in any such action at the other's reasonable request.

(c) Recovery. GSK and XenoPort shall [*] associated with any litigation against infringers undertaken pursuant to this Section 12.3 above or settlement thereof [*] to the extent [*].

(d) Cooperation. The Parties shall keep one another informed of the status of their respective activities regarding any litigation or settlement thereof concerning an Infringement and shall assist one another and cooperate in any such litigation at the other's reasonable request (including joining as a party plaintiff to the extent necessary and requested by the other Party).

12.4 Third Party Infringement Claims. If the production, sale or use of the Compound or any Product in the Territory pursuant to this Agreement results in a claim, suit or proceeding alleging patent infringement against XenoPort or GSK (or their respective Affiliates, licensees or Sublicensees) (collectively, "Infringement Actions"), such Party shall promptly notify the other Party hereto in writing. The Party subject to such Infringement Action shall have the first right, but not the obligation, to direct and control the defense thereof; provided, however, that the other Party may participate in the defense and/or settlement thereof at its own expense with counsel of its choice. In any event, the Party that is subject to the Infringement Action agrees to keep the other Party hereto reasonably informed of all material developments in connection with any such Infringement Action. The Party who is subject to the Infringement Action agrees not to settle such Infringement Action, or make any admissions or assert any position in such Infringement Action, in a manner that would adversely affect the Compound or the manufacture, use or sale of the Compound or any Product within or outside the Territory, without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed. GSK may [*]. As used herein, "Damages" shall mean out-of-pocket costs incurred by GSK, including reasonable attorney's fees, damages and other liabilities that are part of any final judgment awarded against GSK, and any amounts paid by GSK in a settlement of the action that is approved by XenoPort, such approval not to be unreasonably withheld or delayed. The Parties shall assist one another and cooperate in any such action at the other's reasonable request.

12.5 Patent Marking. GSK agrees to mark, and have its Affiliates and Sublicensees mark, all patented Products they sell or distribute pursuant to this Agreement in accordance with the applicable patent statutes or regulations in the country or countries of sale thereof.

12.6 Regulatory Data Protection

(a) To the extent required or permitted by Applicable Law, the Parties will use Commercially Reasonable Efforts to promptly, accurately and completely list, with the applicable

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Regulatory Authorities in the Territory during the Term all applicable XenoPort Patents, and/or any Patents that are Controlled by GSK or its Controlled Affiliates, for any Product and that the Parties intend, or have begun, to commercialize in the Territory and that have become the subject of an NDA submitted to FDA, such listings to include all so called "Orange Book" listings required under the Hatch-Waxman Act (regardless of which Party is the sponsor of record of the NDA at such time).

(b) In connection with such listings, the Parties will meet to evaluate and identify all applicable Patents in the Territory that are Controlled by each Party. GSK will retain final decision making authority as to the listing of all applicable Patents in the Territory for any Product regardless of which Party Controls such Patent.

(c) Patent Rights Certifications and Infringement Suits. Each Party will immediately give notice to the other Party of any certification received under the Hatch-Waxman Act with respect to a Product. Notwithstanding any provision herein to the contrary, the following provisions of this Section 12.6(c) will apply for certifications in the Territory claiming that any of the XenoPort Patents are invalid, unenforceable or that no infringement will arise from the manufacture, use or sale in the Territory of a Third Party's product containing a Competitive Compound (i.e., a Paragraph IV Certification under 21 U.S.C. Section 355 and 21 C.F.R. Part 314). With respect to any such certifications in the Territory, GSK has the first right, but not the obligation to bring suit against the Third Party that filed the certification. If GSK decides to bring suit, GSK has sole control of all decisions regarding all aspects of such litigation; provided that XenoPort will have the right to participate in such litigation and to share in recoveries from such litigation in the same manner as set forth in Section 12.3(c) with respect to infringement litigation brought by GSK thereunder. XenoPort will execute such legal papers necessary for the prosecution of such suit and cooperate with GSK as may be reasonably requested by GSK. If GSK decides not to bring infringement proceedings against the entity making such a certification with respect to any such XenoPort Patents, GSK will give notice to XenoPort of its decision not to bring suit within [*] after receipt of notice of such certification and XenoPort shall have the right, but not the obligation, to bring suit against the Third Party that filed the certification, in the same manner that XenoPort has the right to bring actions under Section 12.3(b) if GSK does not exercise its first right to bring suit thereunder. If XenoPort decides to bring suit, XenoPort will have sole control of such litigation and will, at GSK's request, execute an agreement confirming that the decision to sue was made despite GSK's objection and indemnifying GSK for all claims and losses suffered by GSK as a result of such suit. If XenoPort decides to sue, XenoPort is responsible for all litigation costs and shall have no right to obtain reimbursement for its litigation costs from GSK; provided, however, that [*].

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

ARTICLE XIII

TRADEMARKS

13.1 Non-Exclusive License. GSK shall have a non-exclusive, royalty-free license, with the right to grant sublicenses, to use the XenoPort Trademarks solely for market research and other similar activities to determine whether GSK will use the XenoPort Trademarks or GSK Trademarks in connection with the commercialization and promotion of the Product in the Field in the Territory.

13.2 Option for XenoPort Trademarks. For [*] the Closing Date, GSK shall have an exclusive option to obtain an exclusive, royalty-free license, with the right to grant sublicenses, to use the XenoPort Trademarks in each country in the Territory in connection with the developing, making, having made, use, sale, offering for sale, importation, distributing and promoting of the Product in the Field in the Territory (the "XenoPort Trademarks Option"). In the event that GSK notifies XenoPort in writing that GSK is exercising the XenoPort Trademarks Option within [*], XenoPort hereby grants to GSK an exclusive, royalty-free license, with the right to grant sublicenses as provided in Section 2.2, to use the XenoPort Trademarks in the Territory in connection with the developing, making, having made, use, sale, offering for sale, importation, distributing and promoting of the Product in the Field in the Territory. Such license under the XenoPort Trademarks would include a right to use the XenoPort Trademarks as part of a domain name. In the event that (a) GSK determines not to exercise the XenoPort Trademarks Option, (b) GSK determines to use the GSK Trademarks in connection with Products in the Field in the Territory, or (c) GSK fails to notify XenoPort that it wishes to exercise the XenoPort Trademarks Option within [*] the Closing Date, GSK's rights under the XenoPort Trademarks Option shall terminate and XenoPort shall have no further obligations to GSK under such XenoPort Trademarks Option.

13.3 XenoPort House Marks. All packaging, and package inserts for the Product in the Territory shall, along with the GSK brand name and logo, include the XenoPort brand name and logo (such XenoPort brand name and logo, collectively "XenoPort House Marks") (in such form as is reasonably requested by XenoPort) in reasonable size and prominence; it being understood that the exact size, placement and prominence of such XenoPort House Marks shall be determined by GSK in its reasonable discretion, and shall be subject to the approval of the ESC. XenoPort hereby grants to GSK a non-exclusive, royalty-free license, with the right to grant sublicenses as provided in Section 2.2, to use the XenoPort House Marks in connection with the developing making, having made, use, sale, offering for sale, importation, distributing and promotion of the Product in the Field in the Territory.

13.4 Use of XenoPort Trademarks. With respect to GSK's use of the XenoPort House Marks as provided in Section 13.3 above and GSK's use the XenoPort Trademarks, if GSK exercises the XenoPort Trademarks Option as provided in Section 13.2 above, the following shall apply, to the extent relevant:

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(a) Restriction on Use. XenoPort agrees that it will not, and will cause its Affiliates and Astellas not to, use the XenoPort Trademarks or any substantially identical or similar marks in the Territory for any reason without obtaining the prior written consent of GSK, which consent will not be unreasonably withheld.

(b) Display. All final packaging, labels and Promotional Materials for the Product shall display the XenoPort Trademarks. Further, GSK will clearly indicate on all such final packaging, labels and promotional materials for the Product that the XenoPort Trademarks are owned by XenoPort. The trade dress and style of packaging used for each Product in the Field in the Territory shall be determined by GSK in a manner that is consistent with GSK's then current standards for trade dress and style, and as part of GSK's updates to the ESC, GSK shall keep XenoPort informed of GSK's plans with respect to trade dress and style of packaging for the Product. For the avoidance of doubt, GSK may include the GSK logo and trade name on all final packaging, labels and promotional materials for the Product in the Territory.

(c) Registration of Trade Marks. GSK agrees to file, register and maintain, during the Term and at GSK's expense, appropriate trademark registrations for the XenoPort Trademarks in the Territory. Such registrations for the XenoPort Trademarks shall be obtained by GSK in XenoPort's name, to the extent permitted by Applicable Law in within the Territory. GSK shall promptly take all steps that may be reasonably necessary to transfer any such registration(s) for the Product Trade Marks in GSK's name to XenoPort.

(d) Ownership. As between the Parties, XenoPort shall own, and is hereby assigned, all right, title and interest in and to the XenoPort Trademarks and the XenoPort House Marks. The ownership and all goodwill from the use of the XenoPort Trademarks and the XenoPort House Marks shall vest in and inure to the benefit of XenoPort.

(e) Recordation of Licenses. In those countries where a trademark license must be recorded, XenoPort will provide to GSK, on GSK's written request, a separate trademark license for the XenoPort Trademarks and, if necessary, XenoPort House Marks on terms that are consistent with, and no broader or more onerous than, the terms of this Agreement and GSK will arrange for the recordation of such trade mark license with the appropriate governmental authority, at GSK's expense, promptly following receipt of such license from XenoPort. GSK shall cooperate in the preparation and execution of such documents.

13.5 Approval of Packaging and Promotional Materials. Solely to the extent necessary to preserve XenoPort's legal rights in the XenoPort House Marks and, if applicable, the XenoPort Trademarks, GSK shall submit to XenoPort, not less than [*] to XenoPort for XenoPort's review and approval solely with respect to GSK's use of the XenoPort House Marks and XenoPort Trademarks, as applicable, which approval will not be unreasonably withheld or delayed. If XenoPort has not responded within [*] XenoPort's approval to GSK's use of the XenoPort House Marks and XenoPort Trademarks, as applicable, on such promotional materials and packaging and will be deemed to have been received. GSK may make any subsequent changes to

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

promotional materials and packaging bearing the XenoPort House Marks, or an approved XenoPort Trademark, other than changes to the XenoPort House Marks or XenoPort Trademark, as applicable, without the subsequent approval from XenoPort.

13.6 Enforcement of XenoPort Trademarks.

(a) Notice. If, after GSK has exercised the XenoPort Trademark Option, XenoPort or GSK becomes aware of actual or threatened infringement or misappropriation of any XenoPort Trademark in the Territory, that Party shall promptly notify the other Party in writing.

(b) Initiating Enforcement Actions. GSK has the right to initiate infringement proceedings or take other appropriate actions against an infringement of the XenoPort Trademark in the Territory. If Applicable Law in a country in the Territory does not permit an exclusive licensee to initiate such actions (i.e., such action may only be initiated by the owner of the trademark being infringed), GSK would have the right to insist that XenoPort initiates such action on GSK's behalf and at GSK's expense. If GSK does not initiate proceedings or take other appropriate action within [*] then XenoPort shall be entitled to initiate infringement proceedings or take other appropriate action against an infringement of the XenoPort Trademark at its own expense. The Party conducting such action shall have full control over the conduct of such action, including settlement thereof; provided, however, that the Party conducting such action may not settle any such action, or make any admissions or assert any position in such action, in a manner that would materially adversely affect the rights or interests of the other Party, without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed. The Party conducting such action (except in the case of XenoPort, where XenoPort conducts such action at the request of GSK) will [*]. In any event, the Parties shall assist one another and cooperate in any such action at the other's reasonable request.

(c) Recovery. GSK and XenoPort shall [*] associated with any litigation against infringers undertaken pursuant to this Section 13.6 or settlement thereof [*] to the extent [*].

(d) Cooperation. The Parties shall keep one another informed of the status of their respective activities regarding any litigation or settlement thereof concerning an infringement of the XenoPort Trademark and shall assist one another and cooperate in any such litigation at the other's reasonable request (including joining as a party plaintiff to the extent necessary and requested by the other Party).

13.7 Enforcement of GSK Trademarks.

(a) Notice. If XenoPort becomes aware of actual or threatened infringement or misappropriation of any GSK Trademark in the Territory, XenoPort shall promptly notify GSK in writing.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(b) Initiating Enforcement Actions. GSK has the sole and exclusive right to initiate infringement proceedings or take other appropriate actions against an infringement of the GSK Trademarks in the Territory. GSK shall have full control over the conduct of such action, including settlement thereof. XenoPort shall assist GSK and cooperate in any such action at the other's reasonable request.

(c) Recovery. GSK shall [*].

(d) Cooperation. XenoPort shall provide any necessary assistance and cooperate in any such litigation concerning the infringement of the GSK Trademarks at GSK's reasonable request.

13.8 Use of Trademarks for Product Outside of the Territory. XenoPort acknowledges and agrees that it [*].

ARTICLE XIV

TERM AND TERMINATION

14.1 Term. This Agreement shall commence on the Effective Date, and unless terminated earlier as provided in this Article 14, shall continue in full force and effect on a Product-by-Product basis until [*]. Upon expiration (but not an earlier termination) of this Agreement in the Territory, GSK shall have a perpetual, non-exclusive, fully paid-up, royalty free license under the XenoPort Patents and XenoPort Know-How, and XenoPort Trademarks if GSK exercised the XenoPort Trademarks Option as provided in Article XIII to make, have made, use, sell, offer for sale and import such Product in the Territory.

14.2 Breach. Either Party to this Agreement may terminate this Agreement in the event the other Party shall have materially breached or defaulted in the performance of any of its material obligations hereunder, and such default shall have continued for ninety(90) days after written notice thereof was provided to the breaching Party by the non-breaching Party. Any such termination shall become effective at the end of such ninety (90) day period unless the breaching Party has cured any such breach or default prior to the expiration of the ninety (90) day period.

14.3 Termination For Convenience. GSK may terminate this Agreement in its entirety for any reason: (a) upon [*] prior written notice to XenoPort prior to [*]; and (b) upon [*] prior written notice to XenoPort following [*]; provided that GSK shall not [*].

14.4 Bankruptcy. Either Party may terminate this Agreement in its entirety at any time during the Term by giving written notice to the other Party if the other Party files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, or if the other Party is served with an involuntary petition against it, filed

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

in any insolvency proceeding, and such petition will not be dismissed with [*] after the filing thereof, or if the other Party makes a general assignment for the benefit of creditors.

ARTICLE XV

EFFECT OF TERMINATION

15.1 Accrued Obligations. The expiration or termination of this Agreement for any reason shall not release either Party from any liability that, at the time of such expiration or termination, has already accrued to the other Party or that is attributable to a period prior to such expiration or termination, nor will any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement.

15.2 Rights on Termination by XenoPort for Breach. This Section 15.2 shall apply upon any termination of GSK's rights under this Agreement in its entirety pursuant to Section 14.2 or pursuant to Section 14.3.

(a) Wind-down Period.

(i) Development. In the event there are any ongoing clinical trials of any Product in the Territory being conducted by or under the authority of GSK, at XenoPort's request, following the date a notice of termination has been issued pursuant to Section 14.2 or 14.3, GSK agrees to continue such trials in the normal course until [*].

(ii) Commercialization. To avoid a disruption in the supply of Product to patients, if the Agreement is terminated after the First Commercial Sale, GSK, its Affiliates and its Sublicensees shall continue to distribute the Product in the Territory, in accordance with the terms and conditions of this Agreement, until [*] the effective date of any termination of this Agreement (the "Wind-down Period"); provided that [*]. Notwithstanding any other provision of this Agreement, during the Wind-down Period, GSK's and its Affiliates' and Sublicensees' rights with respect to the Compound and the Products in the Territory shall be non-exclusive and, without limiting the foregoing, XenoPort shall have the right to engage one or more other distributor(s) and/or licensee(s) of any Product in all or part of the Territory. Any Product sold or disposed by GSK in the Territory during the Wind-down Period shall be subject to applicable payment obligations under Article 6 above. Within [*] GSK shall notify XenoPort of any quantity of the Products remaining in GSK's inventory and subject to the last sentence in Section 15.2(c) below, XenoPort shall have the option, upon notice to GSK, to repurchase any such quantities of the Products from GSK at [*].

(b) Assignment of Regulatory Filings and Marketing Approvals. At XenoPort's option, which shall be exercised by written notice to GSK, and to the extent permitted under Applicable Law, GSK shall assign or cause to be assigned to XenoPort or its designee (or to the

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

extent not so assignable, GSK shall take all reasonable actions to make available to XenoPort or its designee the benefits of) all Regulatory Filings for all Product in the Territory, including any such Regulatory Filings made or owned by GSK's Affiliates and/or Sublicensees. In each case, unless otherwise required by any Applicable Law, the foregoing assignment (or availability) shall be made [*] the effective date of such termination, [*]. In addition, GSK shall promptly provide to XenoPort a copy of all Data and GSK Know-How pertaining to all Products in the Territory to the extent not previously provided to XenoPort and XenoPort shall have the right to use and disclose all Data and GSK Know How pertaining to such Products following termination of this Agreement.

(c) Supply. In addition, GSK shall use Commercially Reasonable Efforts to transition to XenoPort upon XenoPort's request any arrangement with any contractor from which GSK had arranged to obtain a supply of the Compound or Products. In the event that such materials are manufactured by GSK, then, upon request by XenoPort, GSK shall continue to provide XenoPort with such materials [*]; provided that XenoPort shall use Commercially Reasonable Efforts to obtain such alternative source as soon as practicable; provided further that, Section 10.3 shall continue to apply during [*]. In addition, GSK shall promptly provide to XenoPort a copy of all Data pertaining to the manufacture of the Compound and the Products to the extent not previously provided to XenoPort, during the Term or pursuant to Section 15.2(b), and XenoPort shall have the right to use (and authorize the use of) and to disclose all such Data following termination of this Agreement. Notwithstanding the foregoing, if the Agreement is terminated by GSK prior to [*], then no later than the effective date of such termination, GSK shall [*] and shall cooperate fully with XenoPort to [*].

(d) Transition. Without limiting the foregoing, GSK shall use Commercially Reasonable Efforts to cooperate with XenoPort and/or its designee to effect a smooth and orderly transition in the development, sale and ongoing marketing, promotion and commercialization of the Products in the Territory during the Wind-down Period. Without limiting the foregoing, GSK shall use Commercially Reasonable Efforts to conduct in an expeditious manner any activities to be conducted under this Section 15.2.

(e) Licenses: Assignment of GSK Trademarks. Effective as of the date of any notice of termination of this Agreement pursuant to Section 14.2 or 14.3, to the extent requested by XenoPort, XenoPort shall have and is hereby granted by GSK a non-exclusive, worldwide license, with the right to grant sublicenses, under: (i) any Patents owned or Controlled by GSK that are reasonably necessary, for the purposes of making, having made, using, developing, importing, offering for sale, selling, distributing, marketing, promoting and otherwise exploiting the Compound and Products; (ii) the GSK Know How to make, have made, use, develop, import, offer for sale, sell, distribute, market, promote and otherwise exploit the Compound and Products, and (iii) solely to the extent that the Agreement is terminated after the First Commercial Sale, GSK's rights (including any copyrights) in the Promotional Materials, to use, reproduce, modify, distribute such Promotional Materials and derivatives thereof (provided that such license shall not include any rights with respect to the company trade name or logo of GSK and provided that such Promotion Materials would be provided "as is" and without any representations or warranties whatsoever with respect to the use of

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

such Promotional Materials). In addition, GSK shall assign to XenoPort all right, title and interest to the GSK Trademarks, and all Product-specific domain names, for the Products, including all registrations thereof.

(f) Royalty Back. In the event of a termination by GSK under Section 14.3 after GSK has obtained a Marketing Approval in the Territory for a Neuropathic Pain Indication and commercially launched the Product for such indication in the Territory, XenoPort shall pay to GSK royalties on Net Sales of such Product by XenoPort, its Affiliates and licenses of such Product in the Territory, as follows: (i) if GSK achieved Annual Net Sales for such Product in a calendar year prior to termination of [*] XenoPort shall pay to GSK a royalty of [*] of the Net Sales of such Product in the Territory; and (ii) if GSK achieved Annual Net Sales for such Product in a calendar year prior to termination of [*] then in lieu of the royalty specified in (i) above, XenoPort shall pay to GSK a royalty of [*] of the Net Sales of such Product. Such royalty shall continue for a period of ten years (10) from the date of such termination, or if longer, until the expiration of the last XenoPort Patent that would be infringed by the unlicensed sale of such Product in the Territory. For such purposes, the provisions of Sections 1.36, 6.3(b) and 6.4, and of Article 7, shall apply *mutatis mutandis*.

(g) Return of Materials. Within [*] after the end of the Wind-down Period upon request by XenoPort, GSK shall use Commercially Reasonable Efforts to either return to XenoPort or destroy all tangible items comprising, bearing or containing trademarks (including the XenoPort Trademarks), trade names, patents, copyrights, designs, drawings, formulas or other Data, photographs, samples, literature, sales and promotional aids ("Product Materials") and all Confidential Information of XenoPort, that is in GSK's possession. Effective upon the end of the Wind-down Period, GSK shall: (i) cease to use all trademarks and trade names of XenoPort (including the XenoPort Trademarks) in the Territory, and all rights granted to GSK hereunder with respect to the Compound and all Products in the Territory shall terminate; and (ii) assign to XenoPort all trademarks and trade names of XenoPort (including the XenoPort Trademarks).

(h) Sublicensees. Any contracts with Sublicensees of any Product in the Territory engaged by GSK other than GSK's Affiliates shall be assigned to XenoPort to the extent GSK has the right to do so and XenoPort so requests. In the event such assignment is not requested by XenoPort or GSK does not have the right to do so, then the rights of such Sublicensees shall terminate upon termination of GSK's rights with respect to the Product in the Territory. GSK shall contractually require that its Affiliates and such Sublicensees (if not assigned to XenoPort pursuant to this Section 15.2(h)) shall use Commercially Reasonable Efforts to transition all Products back to XenoPort in the manner set forth in this Section 15.2 as if such Affiliate or Sublicensee were named herein.

15.3 Rights Upon Termination for Bankruptcy. Notwithstanding the bankruptcy of XenoPort, or the impairment of performance by XenoPort of its obligations under this Agreement as a result of bankruptcy or insolvency of XenoPort, upon the termination of this Agreement by GSK pursuant to Section 14.4, GSK will be entitled to retain all rights and licenses granted to GSK by

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

XenoPort under this Agreement. All rights and licenses granted under or pursuant to this Agreement by XenoPort to GSK are, and will otherwise be deemed to be, for purposes of Article 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Article 101(52) of the Bankruptcy Code. The Parties agree that GSK, as a licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against XenoPort under the Bankruptcy Code, GSK will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in its possession, will be promptly delivered to GSK (i) upon any such commencement of a bankruptcy proceeding upon written request therefor by GSK, unless XenoPort elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of XenoPort, upon written request therefore by GSK.

15.4 Additional Rights. The expiration or termination of this Agreement for any reason shall not relieve the Parties of any obligation (including any payments) that accrued prior to such expiration or termination. Further, neither Party will be precluded from pursuing all rights and remedies that it may have hereunder at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

15.5 Survival. Upon the expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate except those described in the following provisions: [*] In addition: (a) [*] and (b) [*] shall survive with respect to [*].

ARTICLE XVI

REPRESENTATIONS, WARRANTIES AND COVENANTS

16.1 General Representations. Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

(a) Duly Organized. Such Party is a corporation duly organized, validly existing and is in good standing under the laws of the jurisdiction of its incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent such Party from performing its obligations under this Agreement.

(b) Due Execution; Binding Agreement. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary corporate action and do not and will not: (i) require any consent or approval of its stockholders; (ii) to such Party's knowledge, violate any Applicable Law, order, writ, judgment,

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over such Party; nor (iii) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which such Party is a party or by which it is bound.

(c) No Other Affiliates. As of the Effective Date, such Party does not have any Affiliates that are not Controlled Affiliates.

16.2 Representations and Warranties of XenoPort. XenoPort represents, warrants to GSK that, as of the Effective Date:

(a) it has the full right and authority to grant the rights and licenses as provided herein;

(b) it has not previously granted any right, license or interest in or to the XenoPort Patents or XenoPort Trademarks, or any portion thereof, that is in conflict with the rights or licenses granted to GSK under this Agreement;

(c) to its knowledge, there are no actual, pending, anticipated, alleged or threatened actions, suits, claims, interference or governmental investigations involving the Compound, the XenoPort Patents, the XenoPort Know-How or the XenoPort Trademarks by or against XenoPort, or any of its Affiliates; provided that no representation or warranty is made with respect to any Patent rights of a Third Party of which GSK is aware as of the Effective Date. In particular, to its best knowledge, there is no pending or threatened product liability action nor intellectual property right litigation in relation to the Compound;

(d) subject to Article 19, all necessary consents, approvals and authorizations of all Regulatory Authorities, other governmental authorities and other persons or entities required to be obtained by XenoPort in order to enter into this Agreement have been obtained; to its knowledge, there is no actual, pending, anticipated, alleged or threatened infringement by a Third Party of any of the XenoPort Patents, the XenoPort Know-How or the XenoPort Trademarks;

(e) to its knowledge, none of the issued XenoPort Patents or applications or registrations for the XenoPort Trademarks are invalid or unenforceable;

(f) it has not, up through and including the Effective Date, knowingly withheld any material information in its possession from GSK in response to GSK's reasonable inquiries in connection with GSK's due diligence relating to the Compound, this Agreement and the underlying transaction, and to the best of its knowledge, the information related to the Compound that XenoPort has provided to GSK prior to the Effective Date is up-to-date and accurate in all material respects; and

(g) [*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

16.3 Representations and Warranties of GSK. GSK represents and warrants to XenoPort that, as of the Effective Date:

(a) it has the full right and authority to grant the rights granted herein;

(b) subject to Article 19, all necessary consents, approvals and authorizations of all Regulatory Authorities, other governmental authorities and other persons or entities required to be obtained by GSK in order to enter into this Agreement have been obtained; and

(c) GSK does not have any knowledge that any of XenoPort's representations and warranties set forth in Sections 16.1 and 16.2 above are inaccurate.

16.4 DISCLAIMER. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OR VALIDITY OF ANY PATENTS ISSUED OR PENDING.

ARTICLE XVII

INDEMNIFICATION

17.1 Indemnification of XenoPort. GSK shall indemnify and hold harmless each of XenoPort, its Affiliates and the directors, officers, stockholders and employees of such entities and the successors and assigns of any of the foregoing (the "XenoPort Indemnitees"), from and against any and all liabilities, damages, penalties, fines, costs, expenses (including, reasonable attorneys' fees and other expenses of litigation) ("Liabilities") from any claims, actions, suits or proceedings brought by a Third Party (a "Third Party Claim") incurred by any XenoPort Indemnitee, arising from, or occurring as a result of: (a) the use, marketing, distribution, importation or sale of any Product by GSK, its Affiliates or Sublicensees in the Territory; (b) the manufacture of any Compound or Product by or on behalf of GSK, its Affiliates or Sublicensees for use and/or distribution in the Territory; (c) gross negligence or willful misconduct in the conduct of the research and development activities conducted by GSK, or any of its Affiliates or Sublicensees, related to the Compound and/or any Product; and (d) any material breach of any representations, warranties or covenants by GSK in Article 16 above; except to the extent such Third Party Claims fall within the scope of XenoPort's indemnification obligations set forth in Section 17.2 below or result from the gross negligence or fault of a XenoPort Indemnitee. In the event XenoPort exercises the Co-Promotion Option and is Co-Promoting Product, GSK's indemnification obligations set forth in this Section 17.1 shall [*]

17.2 Indemnification of GSK. XenoPort shall indemnify and hold harmless each of GSK, its Affiliates and Sublicensees and the directors, officers and employees of GSK, its Affiliates and Sublicensees and the successors and assigns of any of the foregoing (the "GSK Indemnitees"), from

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

and against any and all Liabilities from any Third Party Claims incurred by any GSK Indemnitee, arising from, or occurring as a result of (a) gross negligence or willful misconduct in the conduct of the research and development activities conducted by XenoPort or its Affiliates related to Compound and/or any Product, (b) the use, marketing, distribution, or sale of any Product by XenoPort, its Affiliates or licensees outside the Territory, (c) the manufacture of any Compound or Product by or on behalf of XenoPort, its Affiliates or licensees in the Territory for the purposes of use and/or distribution outside the Territory; or (d) any material breach of any representations, warranties or covenants by XenoPort in Article 16 above, except to the extent such Third Party Claims fall within the scope of GSK's indemnification obligations set forth in Section 17.1 above or result from the fault of an GSK Indemnitee.

17.3 Procedure. A Party that intends to claim indemnification under this Article 17 (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") in writing of the assertion or the commencement of Third Party Claim and will provide the Indemnitor such information with respect thereto that the Indemnitor may reasonably request. The Indemnitor shall be entitled to participate in the defense of any Third Party Claim and, subject to the limitations set forth in this Section 17.3, shall be entitled to control and appoint lead counsel for such defense, in each case at its expense. If the Indemnitor shall assume the control of the defense of any Third Party Claim in accordance with the provisions of this Section 17.3, the Indemnitor shall obtain the prior written consent of the Indemnitee (which shall not be unreasonably withheld) before entering into any settlement of such Third Party Claim. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Section 17.3, but the omission to so deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may have to any Indemnitee otherwise than under this Section 17.3. The Indemnitee under this Section 17.3 shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by this indemnification.

ARTICLE XVIII

DISPUTE RESOLUTION

18.1 Dispute Resolution. The Parties agree that with respect to any disputes that are not within the authority of the ESC, JDC or JCC as provided in Article 3 (all such disputes that are not within the authority of the ESC, JDC or JCC would include disputes arising with respect to the interpretation, enforcement, termination or invalidity of this Agreement, and for the purposes of this Article 18, each a "Dispute"), the Dispute shall first be presented to the Chief Executive Officer of XenoPort and the Chief Operating Officer of GSK, or their respective designees for resolution. If the Chief Executive Officers, or their respective designees, cannot resolve the Dispute within [*] of the request to do so, either Party may initiate legal proceedings with respect thereto. Notwithstanding anything in this Article 18 to the contrary, XenoPort and GSK shall each have the

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

right to apply to any court of competent jurisdiction for appropriate interim or provisional relief, as necessary to protect the rights or property of that Party.

18.2 Arbitration of Certain Limited Disputes. If: (i) the Parties do not agree upon [*] or (ii) the Parties otherwise mutually agree to the resolution of a dispute by binding arbitration; in each case, such dispute shall, upon written notice of either Party to the other, be resolved by final, binding arbitration in accordance with the provisions of this Section 18.2. The arbitration shall be conducted by the Judicial Arbitration and Mediation Services, Inc. (or any successor entity thereto) ("JAMS") under its rules of arbitration then in effect, except as modified in this Agreement. The arbitration shall be conducted in the English language, by a single arbitrator. If the Parties are unable to agree on an arbitrator, the arbitrator shall be selected in accordance with the JAMS rules, or if the JAMS Rules do not provide for such selection, by the chief executive of JAMS. At his or her election, the arbitrator may engage an independent expert with experience in the subject matter of the Dispute to advise the arbitrator.

(a) With respect to any dispute to be resolved under this Section 18.2, the Parties and the arbitrator shall use all reasonable efforts to complete any such arbitration within [*] from the issuance of notice of a referral of any such dispute to arbitration. The arbitrator shall determine what discovery will be permitted, consistent with the goal of limiting the cost and time that the Parties must expend for discovery; provided that the arbitrator shall permit such discovery as he or she deems necessary to permit an equitable resolution of the Dispute.

(b) The arbitration under this Section 18.2 with respect to the matter described in (i) above shall [*] Accordingly, [*] with respect to [*] the arbitrator shall [*].

(c) The Parties agree that the decision of the arbitrator shall be the binding remedy between them regarding the Dispute presented to the arbitrator. Any decision of the arbitrator may be entered in a court of competent jurisdiction for judicial recognition of the decision and an order of enforcement. The arbitration proceedings and the decision of the arbitrator shall not be made public without the joint consent of the Parties and each Party shall maintain the confidentiality of such proceedings and decision unless each Party otherwise agrees in writing; provided that either Party may make such disclosures as are permitted for Confidential Information of the other Party under Article 11 above.

(d) Unless otherwise mutually agreed upon by the Parties, the arbitration proceedings shall be conducted in New York, New York. The Parties agree that they shall share equally the cost of the arbitration filing and hearing fees, the cost of the independent expert retained by the arbitrator, and the cost of the arbitrator and administrative fees of JAMS. Each Party shall bear its own costs and attorneys' and witnesses' fees and associated costs and expenses.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

ARTICLE XIX

HART-SCOTT-RODINO

19.1 HSR Act Compliance. Notwithstanding anything to the contrary in this Agreement, this Agreement shall be binding upon the Parties as of the Effective Date; however, the provisions of Articles 2-7 shall not take effect, and commencement of the collaboration shall not occur, until the Closing Date.

19.2 Cooperation.

(a) The Parties shall use their Commercially Reasonable Efforts to obtain prompt clearance required under the HSR Act for the consummation of this Agreement and the transactions contemplated hereby and shall keep each other apprised of the status of any communications with, and any inquiries or requests for additional information from, the FTC and the DOJ and shall comply promptly with any such inquiry or request; provided, however, that neither Party shall be required to consent to the divestiture or other disposition of any of its or its Affiliates' assets or to consent to any other structural or conduct remedy, and each Party and its Affiliates shall have no obligation to contest, administratively or in court, any ruling, order or other action of the FTC or DOJ or any third party respecting the transactions contemplated by this Agreement.

(b) The Parties hereto commit to instruct their respective counsel to cooperate with each other and use Commercially Reasonable Efforts to facilitate and expedite the identification and resolution of any such issues and, consequently, the expiration of the applicable HSR Act waiting period. Said Commercially Reasonable Efforts and cooperation include, but are not limited to, counsel's undertaking: (i) to keep each other appropriately informed of communications from and to personnel of the reviewing antitrust authority; and (ii) to confer with each other regarding appropriate contacts with and response to personnel of the FTC or DOJ.

ARTICLE XX

GENERAL PROVISIONS

20.1 Effect of Restatement. It is understood that this Restated Agreement supersedes and replaces the Original Agreement from and after the Restatement Effective Date. Notwithstanding the foregoing, the terms of the Original Agreement shall continue to apply with respect to matters that occurred prior to the Restatement Effective Date.

20.2 Force Majeure. If the performance of any part of this Agreement (except for any payment obligation under this Agreement) by either Party is prevented, restricted, interfered with or delayed by reason of *force majeure* (including, fire, flood, embargo, power shortage or failure, acts of war, insurrection, riot, terrorism, strike, lockout or other labor disturbance or acts of God), the Party so affected shall, upon giving written notice to the other Party, be excused from such

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

performance to the extent of such prevention, restriction, interference or delay; provided that the affected Party shall use its reasonable efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed.

20.3 Governing Law. This Agreement and all questions regarding its validity or interpretation, or the breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without reference to conflict of law principles.

20.4 Waiver of Breach. Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. The delay or failure of either Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

20.5 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by a duly authorized representative of each Party. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by a duly authorized representative of each Party.

20.6 Severability. In the event any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction. In the event a Party seeks to avoid a provision of this Agreement by asserting that such provision is invalid, illegal or otherwise unenforceable, the other Party shall have the right to terminate this Agreement upon [*] prior written notice to the asserting Party, unless such assertion is eliminated and the effect of such assertion cured within such [*] period. Any termination in accordance with the foregoing shall be deemed a termination pursuant to Section 14.3 if the Party who made the assertion was GSK, and shall be deemed a termination under Section 14.2 by reason of a breach by XenoPort, if XenoPort is the Party who made such assertion.

20.7 Entire Agreement. This Agreement (including the Exhibits attached hereto), together with the pharmacovigilance agreement specified in Section 4.12(a), the Pharmacovigilance Agreement specified in Section 4.12(b), the Co-Promotion Agreement specified in Section 5.5 and the supply agreement specified in Section 10.3(b) (from and after the time that each such agreement is executed by the Parties), constitute the entire agreement between the Parties relating to its subject matter and supersede all prior or contemporaneous agreements, understandings or representations,

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

either written or oral, between XenoPort and GSK with respect to such subject matter, subject to Section 20.1.

20.8 Notices. Unless otherwise agreed by the Parties or specified in this Agreement, all communications between the Parties relating to, and all written documentation to be prepared and provided under, this Agreement shall be in the English language. Any notice required or permitted under this Agreement shall be in writing in the English language: (a) delivered personally; (b) sent by registered or certified mail (return receipt requested and postage prepaid); (c) sent by express courier service providing evidence of receipt, postage pre-paid where applicable; or (d) sent by facsimile (receipt verified and a copy promptly sent by another permissible method of providing notice described in paragraphs (b), (c) or (d) above), to the following addresses of the Parties or such other address for a Party as may be specified by like notice:

To XenoPort:

XenoPort, Inc.
3410 Central Expressway
Santa Clara, CA 95051
Telephone: (408) 616-7200
Facsimile: (408) 616-7211
Attention: Secretary

To GSK:

Glaxo Group Limited
Glaxo Wellcome House, Berkeley Avenue
Greenford, Middlesex, UB6 0NN, England
Telephone: 44 20 8 047 4501
Facsimile: 44 20 8 047 6904
Attention: Company Secretary

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

With a copy to:

Wilson, Sonsini, Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
Telephone: (650) 493-9300
Facsimile: (650) 493-6811
Attention: Kenneth A. Clark

With a copy to:

GlaxoSmithKline
709 Swedeland Road
P.O. Box 1539
King of Prussia, PA 19406-0939 USA
Telephone: (610) 270-5397
Facsimile: (610) 270-5880
Attention : Senior Vice President, Worldwide
Business Development

and

GlaxoSmithKline
2301 Renaissance Boulevard
Mailcode RN0220
King of Prussia, PA 19406-2772
Telephone: (610) 787-3626
Facsimile: (610) 787-7084
Attention: Vice President and Associate General
Counsel, Business Development Transactions

Any notice required or permitted to be given concerning this Agreement shall be effective upon receipt by the Party to whom it is addressed or within seven (7) days of dispatch whichever is earlier.

20.9 Assignment. This Agreement shall not be assignable by either Party to any Third Party hereto without the written consent of the other Party hereto; except either Party may assign this Agreement without the other Party's consent to an entity that acquires substantially all of the business or assets of the assigning Party, whether by merger, acquisition or otherwise, provided that the Party to whom this Agreement is assigned assumes this Agreement in writing or by operation of law. In addition, either Party shall have the right to assign this Agreement to an Affiliate upon written notice to the non-assigning Party; provided that the assigning Party guarantees the performance of this Agreement by such Affiliate; and further provided that if the non-assigning Party reasonably believes such assignment could result in material adverse tax consequences to the non-assigning Party, such assignment shall not be made without the non-assigning Party's consent. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 20.9 shall be null and void.

20.10 No Partnership or Joint Venture. Nothing in this Agreement is intended, or shall be deemed, to establish a joint venture or partnership between Xenoport and GSK. Neither Party to this

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

20.11 Interpretation. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under International Generally Accepted Accounting Principles. All references to a "business day" or "business days" in this Agreement means any day other than a day which is a Saturday, a Sunday or any day banks are authorized or required to be closed in the United States or in the United Kingdom.

20.12 Export Laws. Notwithstanding anything to the contrary contained herein, all obligations of XenoPort and GSK are subject to prior compliance with the export regulations of the United States, the European Union or any other relevant country and such other laws and regulations in effect in the United States, the European Union or any other relevant country as may be applicable, and to obtaining all necessary approvals required by the applicable agencies of the governments of the United States, the countries within the European Union and any other relevant countries. XenoPort and GSK shall cooperate with each other and shall provide assistance to the other as reasonably necessary to obtain any required approvals.

20.13 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument.

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

IN WITNESS WHEREOF, the Parties have executed this Development and Commercialization Agreement as of the Restatement Effective Date.

XENOPORT, INC.

BY: /s/ Ronald W. Barrett

NAME: Ronald W. Barrett

TITLE: Chief Executive Officer

GLAXO GROUP LIMITED

BY: /s/ Rosalind F. Cheetham

NAME: Rosalind F. Cheetham

TITLE: Attorney-In-Fact

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 1.15

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 1.62

XenoPort Patents

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 1.63

XenoPort Trademarks

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 2.1

Reversion of Rights

1. Further to Section 2.1(b) of the Restated Agreement, the Parties hereby agree as follows:

(a) To the extent permitted under Applicable Law, GSK shall assign (or cause to be assigned to) XenoPort all Regulatory Filings for all Products in the ROW Territory (including any such Regulatory Filings made or owned by GSK's Affiliates), or to the extent not so assignable, GSK shall take all reasonable actions to make available to XenoPort or its designee the benefits of such Regulatory Filings. In each case, the foregoing assignment (or availability) shall be made [*]

(b) Effective as of the Restatement Effective Date, [*] to the extent applicable, XenoPort shall have and is hereby granted by GSK a non-exclusive license, with the right to grant sublicenses, under any Patents owned or Controlled by GSK: (i) for the purposes of making, having made, using, developing, importing, offering for sale, selling, distributing, marketing, promoting and otherwise exploiting the Compound and Products in the ROW Territory; (ii) [*] of the Agreement, to conduct within the Territory research and development activities that are directed towards obtaining Marketing Approvals or otherwise developing Products for commercialization outside the Territory; and (iii) to manufacture the Compound and Product within the Territory solely for use in the foregoing research and development activities and/or solely for development, commercialization and exploitation outside the Territory.

(c) From and after the Restatement Effective Date, GSK shall: (A) cease to use all trademarks and trade names of XenoPort (including the XenoPort Trademarks) in the ROW Territory; and (ii) if applicable, assign to XenoPort all trademarks and trade names of XenoPort (including the XenoPort Trademarks) in the ROW Territory.

As used herein, "ROW Territory" shall mean all countries in the world other than the United States.

2. GSK represents and warrants that, [*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 2.3(b)

Phase I Activities

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 2.4(b)

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 4.1

Initial Development Plan for Restless Legs Syndrome

(See attached.)

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 4.1 (contd.)

Initial Development Plan for Neuropathic Pain

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 4.1(d)

GSK Policies

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 4.3(a)

Clinical Studies and Activities

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 5

Co-Promotion Agreement Terms

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 6.5

Financial Planning, Accounting and Reporting Methodologies

(Operating Profit or Loss)

This Exhibit 6.5 addresses the financial planning, accounting policies and procedures to be followed under the Agreement in determining sharing of revenue and expenses and related share of Operating Profit or Loss in the United States. Terms not defined in this Exhibit 6.5 shall have the meanings set forth in the Agreement.

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 10.1

Supply Transition – Technical Transfer Requirements

Documentation and materials to be supplied by XenoPort as part of technical transfer requirements include, but are not limited to, the follow:

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 11.3

Press Release

(See publicly filed press release.)

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXHIBIT 12.2

XenoPort Prosecuted Patents

[*]

* CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statements (Form S-8 Nos. 333-125518, 333-133357, 333-142844, 333-150730, 333-159021, 333-166760, 333-171626 and 333-178947) pertaining to the 1999 Stock Plan, the 2005 Equity Incentive Plan, the 2005 Non-Employee Directors' Stock Option Plan and the 2005 Employee Stock Purchase Plan of XenoPort, Inc., the New Hire Option Agreements between each of Vincent J. Angotti and David A. Stamler, M.D. and XenoPort, Inc., the New Hire Stock Unit Award Agreements between each of Vincent J. Angotti and David A. Stamler, M.D. and XenoPort, Inc. and the 2010 Inducement Award Plan, and
 - (2) Registration Statement (Form S-3 No. 333-167972) of XenoPort, Inc. and in the related Prospectus;
- of our reports dated February 29, 2012, with respect to the financial statements of XenoPort, Inc. and the effectiveness of internal control over financial reporting of XenoPort, Inc. included in this Annual Report (Form 10-K) of XenoPort, Inc. for the year ended December 31, 2011.

/s/ Ernst & Young LLP

Redwood City, California
February 29, 2012

CERTIFICATION

I, Ronald W. Barrett, certify that:

1. I have reviewed this annual report on Form 10-K of XenoPort, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Ronald W. Barrett

Ronald W. Barrett
Chief Executive Officer and Director
February 29, 2012

CERTIFICATION

I, William G. Harris, certify that:

1. I have reviewed this annual report on Form 10-K of XenoPort, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ William G. Harris

William G. Harris
Senior Vice President of Finance and Chief Financial Officer
February 29, 2012

CERTIFICATION(1)

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), Ronald W. Barrett, Chief Executive Officer of XenoPort, Inc. (the "Company"), and William G. Harris, Senior Vice President of Finance and Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2011 (the "Annual Report"), to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act, and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 29th day of February, 2012.

/s/ Ronald W. Barrett

Ronald W. Barrett
Chief Executive Officer and Director

/s/ William G. Harris

William G. Harris
*Senior Vice President of Finance and Chief
Financial Officer*

-
- (1) This certification accompanies the annual report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of XenoPort, Inc. under the Securities Act of 1933, as amended, or the Exchange Act, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to XenoPort, Inc. and will be retained by XenoPort, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.