HORIZON PHARMA, INC.
Form 10-K
March 23, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(MARK ONE)

x **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 001-35238

HORIZON PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**27-2179987**

(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
520 Lake Cook Road, Suite 520	
Deerfield, Illinois (Address of principal executive offices)	**60015** (Zip Code)

(224) 383-3000

(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 $0.0001 per share	The NASDAQ Global Market

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x.

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x.

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 x 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 x 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 the 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.

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

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

As of June 30, 2011, the last business day of the registrant s most recently completed second fiscal quarter, the registrant s common stock was not publicly traded. The registrant s common stock began trading on The NASDAQ Global Market on July 28, 2011. As of December 31, 2011, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $25.8 million, based on the closing price of the registrant s common stock on The NASDAQ Global Market on December 31, 2011.

As of March 15, 2012, the registrant had outstanding 33,703,370 shares of its common stock.

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HORIZON PHARMA, INC.

FORM 10-K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2011

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PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that is, statements related to future, not past, events as defined in Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), that reflect our current expectations regarding our future growth, results of operations, financial condition, cash flows, performance and business prospects, and opportunities, as well as assumptions made by, and information currently available to, our management. Forward-looking statements include any statement that does not directly relate to a current or historical fact. The Company has tried to identify forward-looking statements by using words such as believe, may, could, will, estimate, continue, anticipate, intend, seek, plan, expect, should, or would. Among the factors that could cause actual res materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the rate and degree of market acceptance of, and our ability and our distribution and marketing partners ability to obtain reimbursement for, any approved products; our ability to successfully execute our sales and marketing strategy, including to continue to successfully recruit and retain sales and marketing personnel in the U.S., and to successfully launch DUEXIS® in the U.S.; our ability to obtain additional financing; our ability to maintain regulatory approvals for DUEXIS and LODOTRA®, known as RAYOS® in the U.S.; the accuracy of our estimates regarding expenses, future revenues and capital requirements; our ability to manage our anticipated future growth; the ability of our products to compete with generic products, especially those representing the active pharmaceutical ingredients in DUEXIS and LODOTRA/RAYOS, as well as new products that may be developed by our competitors; our ability and our distribution and marketing partners ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products and product candidates; the performance of our third-party distribution partners and manufacturers, over which we have limited control; our ability to obtain and maintain intellectual property protection for our products and our product candidates; our ability to operate our business without infringing the intellectual property rights of others; the success and timing of our clinical development efforts; the loss of key scientific or management personnel; regulatory developments in the U.S. and foreign countries; our ability to either acquire or develop and commercialize other product candidates in addition to DUEXIS and LODOTRA/RAYOS; and other risks detailed below in Part I Item 1A Risk Factors.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Item 1. Business
Overview

We are a biopharmaceutical company that is developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases. On April 23, 2011, the U.S. Food and Drug Administration, or FDA, approved DUEXIS (formerly HZT-501), a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis, or RA, and osteoarthritis, or OA, and to decrease the risk of developing upper gastrointestinal, or GI, ulcers in patients who are taking ibuprofen for these indications. On November 14, 2011, we and sanofi-aventis U.S. LLC, or sanofi-aventis U.S., announced the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. In December 2011, Valeant Pharmaceuticals International, Inc., or Valeant, acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. We have hired our initial commercial organization and completed sales force training, and we began detailing DUEXIS to physicians in December 2011 and held our launch meeting for DUEXIS in the U.S. in January 2012. In October 2010, we

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submitted a Marketing Authorization Application, or MAA, for DUEXIS in the United Kingdom, or UK, the Reference Member State, or RMS, through the Decentralized Procedure. In February 2012, we modified the DUEXIS MAA submission to include the recently approved manufacturing site in Laval, Quebec through the National Procedure in the UK. We anticipate a decision on the MAA in the second half of 2012. Our other lead product, LODOTRA, known as RAYOS in the U.S., is a proprietary programmed release formulation of low-dose prednisone that is currently marketed in Europe by our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for the treatment of moderate to severe, active RA in adults when accompanied by morning stiffness. We have successfully completed two Phase 3 clinical trials of RAYOS and we submitted a new drug application, or NDA, for RAYOS to the FDA on September 26, 2011. As a result, we have a Prescription Drug User Fee Act, or PDUFA, goal date for RAYOS of July 26, 2012. We have worldwide marketing rights for DUEXIS and have retained exclusive marketing rights in the U.S. for all of our products. Our strategy is to commercialize our products in the U.S., to explore co-promotion opportunities for DUEXIS and RAYOS, if approved, in the U.S. and to enter into licensing or additional distribution agreements for commercialization of our products outside the U.S.

Our Strategy

Our strategy is to build a fully-integrated U.S.-focused biopharmaceutical company to successfully execute the commercial launches of DUEXIS and, if approved by the FDA, RAYOS in the U.S. market. We retain all U.S. commercialization rights for our products and have begun building an internal sales and marketing organization to market these products in the U.S. to top prescribing primary care physicians and to key specialists, such as rheumatologists, orthopedic surgeons and pain specialists. We plan to expand our sales force up to a total of approximately 160 sales representatives and explore other additional opportunities to expand the reach and frequency of our sales efforts such as co-promotion partnerships with companies that have commercial activity with similar physician targets and/or add sales representatives through a contract sales organization, or CSO. We intend to enter into licensing or additional distribution arrangements for commercialization of our products outside the U.S., such as our relationship with Mundipharma for the commercialization of LODOTRA in Europe, Asia and Latin America. As part of our longer-term strategy, we anticipate we will selectively in-license or acquire additional products and/or late stage product candidates that are synergistic with our commercial strategy.

We were incorporated as Horizon Pharma, Inc. in Delaware on March 23, 2010. We are a holding company that operates primarily through our two wholly-owned subsidiaries, Horizon Pharma USA, Inc., a Delaware corporation, and Horizon Pharma AG, a company organized under the laws of Switzerland. Horizon Pharma AG owns all of the outstanding share capital of its wholly-owned subsidiary, Horizon Pharma GmbH, a company organized under the laws of Germany through which Horizon Pharma AG conducts most of its European operations.

Our principal executive offices are located at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015 and our telephone number is (224) 383-3000. Our website address is *www.horizonpharma.com*. The information contained in or that can be accessed through our website is not part of this report.

Unless the context indicates otherwise, as used in this report, the terms Horizon, Horizon Pharma, we, us and our refer to Horizon Pharma, I a Delaware corporation, and its subsidiaries taken as a whole. Also, unless the context indicates otherwise, for historical periods prior to April 1, 2010, the terms Horizon, Horizon Pharma USA, we, us and our refer to Horizon Therapeutics, Inc.

Horizon Pharma, Horizon Therapeutics, a stylized letter H, DUEXIS , LODOTRA and RAYOS are registered trademarks in the U.S. and/ certain other countries. This report also includes references to trademarks and service marks of other entities and those trademarks and service marks are the property of their respective owners.

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Our Strategic Partnerships

We have entered into several strategic partnerships with respect to the manufacturing, distribution and marketing of LODOTRA. We entered into separate transfer, license and supply agreements with Merck Serono GmbH and Merck GesmbH for the commercialization of LODOTRA in each of Germany and Austria, respectively, and we subsequently consented to assignment of the agreements with respect to Germany and Austria to Mundipharma Laboratories GmbH. We also entered into distribution agreements with Mundipharma for the exclusive distribution and marketing rights pertaining to LODOTRA for Europe (excluding Germany and Austria) and certain Asian, Latin American and other countries and a manufacturing and supply agreement with Mundipharma Medical Company, pursuant to which we supply LODOTRA to Mundipharma Medical Company. We have also entered into a manufacturing and supply agreement with Jagotec AG, an affiliate of SkyePharma AG, from whom we purchase LODOTRA. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to Aenova France SAS, or Aenova, with our consent to allow Jagotec to subcontract the manufacture of LODOTRA to Aenova.

Our Products and Product Candidates

We believe that our products and product candidates address unmet therapeutic needs in arthritis, pain and/or inflammatory diseases. We have developed DUEXIS and LODOTRA/RAYOS to provide significant advantages over existing therapies.

Our current product portfolio consists of the following:

Products and Product Candidates	Disease	Phase of Development	Marketing Rights	Territory
DUEXIS	Signs and symptoms of osteoarthritis and rheumatoid arthritis	NDA approved April 23, 2011; MAA submitted October 2010 and modified in February 2012	Horizon	Worldwide
LODOTRA/RAYOS	Rheumatoid arthritis	Approved and marketed in Europe; NDA submitted September 26, 2011	Horizon	Worldwide, excluding Europe and certain Asian, Latin American and other countries
			Mundipharma	Europe and certain Asian, Latin American and other countries
	Polymyalgia Rheumatica	Phase 2	Horizon	Worldwide, excluding Europe and certain Asian, Latin American and other countries
	Severe asthma	Phase 2a**	Horizon	Worldwide, excluding Europe and certain Asian, Latin American and other countries

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Products and Product Candidates	Disease	Phase of Development	Marketing Rights	Territory
TRUNOC	Pain-related diseases	Preclinical*, **	Horizon	Worldwide
HZN-602	Mild to moderate pain and arthritis	Preclinical**	Horizon	Worldwide

* A description of prior clinical trials conducted by third parties is provided under the heading Other Product Candidates.
** At the present time, we have no plans to further develop these indications or assets on our own.

Market Overview

Pain is a serious and costly public health concern affecting more people in the U.S. than diabetes, heart disease and cancer combined. In 2010, the U.S. National Center for Health Statistics reported that approximately 30% of U.S. adults 18 years of age and over reported recent symptoms of pain, aching or swelling around a joint within the past 30 days.

Some of the most common and debilitating chronic inflammation and pain-related diseases are OA, RA and acute and chronic pain. According to National Health Interview Survey data analyzed by the Centers for Disease Control and Prevention, 50 million U.S. adults 18 years of age and over had reported being diagnosed with some form of arthritis. With the aging of the U.S. population, the prevalence of arthritis is expected to rise by approximately 40% by 2030, impacting 67 million people in the U.S. People with these diseases may become increasingly debilitated as the disease progresses, experiencing not only significant pain but also loss of mobility, independence and the ability to work, thereby potentially placing a significant burden on family caregivers and healthcare and social services. In addition, patients suffering from chronic inflammatory diseases tend to have shortened life expectancies as a direct result of these diseases. According to the American Pain Foundation Fact Sheet and the U.S. Centers for Disease Control and Prevention:

- the annual cost of chronic pain in the U.S., including healthcare expenses, lost income and lost productivity is estimated to be $100 billion;
- arthritis and related conditions, such as OA, cost the U.S. economy nearly $128 billion per year in medical care and indirect expenses, including lost wages and productivity; and
- pain is the second leading cause of medically related work absenteeism, resulting in more than 50 million lost workdays each year.

In addition, the Arthritis Foundation reports 992,000 hospitalizations and 44 million office visits in the U.S. annually for arthritis alone.

Osteoarthritis

OA is a type of arthritis that is caused by the breakdown and eventual loss of the cartilage of one or more joints. Cartilage is a protein substance that serves as a cushion between the bones of the joints. OA is also known as degenerative arthritis. Among the over 100 different types of arthritis conditions, OA is the most common and occurs more frequently with age. Before age 45, OA occurs more frequently in males. After age 50, it occurs more frequently in females. OA commonly affects the hands, feet, spine and large weight-bearing joints, such as the hips and knees. Most cases of OA have no known cause and are referred to as primary OA.

Symptoms of OA manifest in patients as joint pain, tenderness, stiffness, limited joint movement, joint cracking or creaking (crepitation), locking of joints and local inflammation. OA can also lead to joint deformity in later stages of the disease. Many drugs are now used to treat the inflammation and pain associated with OA, including aspirin and other NSAIDs, such as ibuprofen and naproxen, that have a rapid analgesic and anti-inflammatory response.

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Rheumatoid Arthritis

RA is a chronic disease that causes pain, stiffness and swelling, primarily in the joints. According to DataMonitor, 3.0 million people in the U.S. suffer from RA, of which 1.7 million are diagnosed and treated with various drugs. RA has no known cause, but unlike OA, RA is not associated with factors such as aging. RA occurs when the body s immune system malfunctions, attacking healthy tissue and causing inflammation, which leads to pain and swelling in the joints and may eventually cause permanent joint damage and painful disability. The primary symptoms of RA include progressive immobility and pain, especially in the morning, with long-term sufferers experiencing continual joint destruction for the remainder of their lives. There is no known cure for RA. Once the disease is diagnosed, treatment is prescribed for life to alleviate symptoms and/or to slow or stop disease progression.

RA treatments include medications, physical therapy, exercise, education and sometimes surgery. Early, aggressive treatment of RA can delay joint destruction. Treatment of RA usually includes multiple drug therapies taken concurrently. Disease modifying antirheumatic drugs, or DMARDs, are the current standard of care for the treatment of RA, in addition to rest, exercise and anti-inflammatory drugs such as NSAIDs. Methotrexate is the most commonly prescribed DMARD for the treatment of RA. Other common agents for the treatment of RA include corticosteroids and biologic agents. Corticosteroids, such as prednisone, effectively reduce joint swelling and inflammation and have been shown to slow the progression of RA, but at high doses are associated with potential for significant long-term adverse side effects such as osteoporosis, cardiovascular disease and weight gain. Over the last decade, the advent of biologic agents has transformed the treatment of RA. Tumor necrosis factor, or TNF, inhibitors are the primary biologic agents used today to treat RA. Although effective for treatment of RA, these agents are costly and, because they are very potent immunosuppressants, may increase the risk of infection.

RA has the potential to cause serious damage to joints and bones and, as such, physicians typically treat patients aggressively, including with combination therapies to reduce pain and inflammation and to slow the progression of the disease. Recent research sponsored by Mundipharma and conducted by Ipsos MORI involving 750 RA patients from 11 European countries found that 60% of surveyed patients with RA indicated that pain and morning stiffness controls their lives. Additionally, 74% of people with pain and morning stiffness as a result of their RA indicated that they are either unemployed, retired early or are on sick leave as a result of RA and 58% say they are frustrated emotionally because they find it difficult to do everyday tasks due to morning stiffness caused by their RA.

Mild to Moderate Pain

Mild to moderate pain is generally characterized as either acute or chronic. Acute pain often results from tissue damage, such as a broken bone. Acute pain can also be associated with headaches or muscle cramps. This type of pain usually decreases as the injury heals or the cause of the pain is removed. Pain is generally considered acute if it dissipates within six months of onset. Chronic pain includes pain that persists after an injury heals, pain related to a persistent or degenerative disease and long-term pain from an unidentifiable cause. Chronic pain may be caused by the body s response to acute pain or may have unknown causes. According to the American Pain Foundation, 44% of pain sufferers 20 years of age and over in the U.S. report pain that lasts up to three months (over 30 million people), 14% report pain lasting for three months to one year (approximately 11 million people) and 42% report pain lasting more than one year (approximately 32 million people). About one-third of people who report pain indicate that their pain is disabling, which is defined as both severe and having a high impact on functions of daily life.

However, even if the underlying disorder can be treated, analgesics such as NSAIDs may still be needed to manage the pain. Physicians choose an analgesic based on the type and duration of pain and on the likely benefits and risks. Most analgesics are effective for treatment of pain due to ordinary injury of tissues (nociceptive pain) but are less effective for treatment of pain due to damage or dysfunction of the nerves, spinal cord, or brain (neuropathic pain). Common analgesics to treat acute and chronic pain are opioid (narcotic) analgesics and non-opioid analgesics, such as acetaminophen and NSAIDs.

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DUEXIS

DUEXIS is a proprietary single tablet formulation containing a fixed-dose combination of ibuprofen, one of the most widely prescribed NSAIDs, and famotidine, a well-established GI agent used to treat dyspepsia, GERD and active ulcers, in one pill. Ibuprofen has proven anti-inflammatory and analgesic properties and famotidine reduces the stomach acid secretion that can cause upper GI ulcers. Both ibuprofen and famotidine have well-documented and excellent long-term safety profiles and both products have been used for many years by millions of patients worldwide. Based on our clinical study results, DUEXIS has been shown to provide effective pain relief and decrease stomach acidity, thus reducing the risk of NSAID-induced upper GI ulcers.

Market Opportunity and Limitations of Existing Treatments

NSAIDs are very effective at providing pain relief, including pain associated with OA and RA; however, there are significant upper GI-associated adverse events that can result from the use of NSAIDs. As a result, COX-2 inhibitor drugs (i.e., Vioxx™, Merck & Co., Inc.; Celebrex/Bextra™, Pfizer Inc.) were introduced to the market in order to provide pain and arthritis relief with reduced risk of significant upper GI-associated adverse events. The COX-2 drugs generated approximately $6.3 billion in sales at their peak in 2004. However, safety concerns associated with COX-2 inhibitor drugs led to the withdrawal of Vioxx and Bextra from the market in 2004 and a significant decline in the use of Celebrex. In the U.S. alone, over $3 billion in sales of COX-2 inhibitor drugs were lost. As a result, demand for traditional prescription NSAIDs, such as ibuprofen and meloxicam, has increased dramatically.

U.S. Total Prescriptions Major NSAIDs and COX-2 Products

Source: IMS National Prescription Audit and Wolters Kluwer Pharmaceutical Audit Suite Total Rx s 2002-2011 (National Level Retail and Institutional, Source Healthcare Analytics is a source of data only and does not endorse the views, opinions and/or findings expressed or otherwise published by Horizon)

According to a 2004 article published in Aliment Pharmacology & Therapeutics, significant GI side effects, including serious ulcers, afflict up to approximately 25% of all chronic arthritis patients treated with NSAIDs for three months and OA and RA patients are two to five times more likely than the general population to be hospitalized for NSAID-related GI complications. It is estimated that NSAID-induced GI toxicity causes over 16,500 related deaths in OA and RA patients alone and over 107,000 hospitalizations for serious GI complications each year. In more than 80% of patients with these serious GI complications, there are no prior symptoms.

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Despite the fact that GI ulcers are one of the most prevalent adverse events resulting from the use of NSAIDs in the U.S., according to a 2006 article published in BMC Muskoskeletal Disorders, eleven observational studies indicated that physicians do not commonly co-prescribe GI protective agents to high-risk patients. Physicians prescribe concomitant therapy to only 24% of NSAID users, and studies show sub-optimal patient compliance with concomitant prophylaxis therapy. According to a 2003 article published in Aliment Pharmacology & Therapeutics, in a study of 784 patients, 37% of patients were non-compliant, a rate increasing to 61% in patients treated with three or more drugs. This noncompliance results in a substantial unmet clinical need, which we believe can be appropriately addressed with DUEXIS, creating a simple solution for both patients and physicians.

DUEXIS Solution

Ibuprofen: One of the World s Most Widely Prescribed NSAIDs

Ibuprofen continues to be one of the most widely prescribed NSAIDs worldwide. According to Wolters Kluwer, in the U.S. alone, there were over 31 million prescriptions written for ibuprofen in 2011. Ibuprofen prescription volumes in Europe approximately equal those in the U.S. In the U.S., both the 600 mg and 800 mg doses together account for approximately 90% of total ibuprofen prescriptions. In addition, ibuprofen s flexible three times daily dosing allows it to be used for both chronic conditions such as arthritis and chronic back pain, and acute conditions such as sprains and strains.

Famotidine: A Safe and Effective GI Agent

Famotidine, the most potent marketed drug in the class of histamine-2 receptor antagonists, a class of drugs used to block the action of histamine on the cells in the stomach that secrete gastric acid, was chosen as the ideal GI protectant to be combined with ibuprofen as it is a well-studied compound with an estimated 18.8 million patients treated worldwide that provides distinct advantages including:

- rapid onset of action;
- significant reduction in gastric acid levels in the GI tract for the treatment of dyspepsia, GERD and NSAID-induced upper GI ulcers;

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well tolerated with a low incidence of adverse drug reactions and a demonstrated safety margin of up to eight times the approved prescription dose for an extended period of greater than 12 months; and

lower incidence of long-term adverse events, such as bone fracture, *Clostridium difficile* diarrhea and drug-drug interactions, reported recently with another class of GI agents referred to as proton pump inhibitors, or PPIs.

Despite these advantages, famotidine had not yet been approved to reduce the incidence of NSAID-induced upper GI ulcers in patients taking NSAIDs. As a result, we conducted two pivotal Phase 3 clinical trials demonstrating that treatment with DUEXIS significantly reduced the incidence of NSAID-induced upper GI ulcers in patients with mild to moderate pain or arthritis compared to ibuprofen alone. Based on the data from our Phase 3 clinical trials of DUEXIS, in March 2010 we submitted an NDA requesting approval to market DUEXIS in the U.S. On April 23, 2011, the FDA approved DUEXIS for the relief of signs and symptoms of RA and OA and to decrease the risk of developing upper GI ulcers in patients who are taking ibuprofen for these indications.

Benefits of a Fixed-Dose Combination Therapy

Numerous studies have demonstrated that fixed-dose combination therapy provides significant advantages over taking multiple pills. Specifically, fixed-dose combinations can reduce the number of pills, ensure that the correct dosage of each component is taken at the correct time and improve compliance, often associated with better treatment outcomes. DUEXIS has been formulated to provide an optimal dosing regimen of ibuprofen and famotidine together in the convenience of a single pill.

Phase 3 Clinical Trial Results

We have completed two large-scale Phase 3 clinical trials of DUEXIS. We received scientific advice from the European Medicines Agency, or EMA, with respect to certain questions concerning the quality, and preclinical and clinical development of DUEXIS as part of our MAA submission plans. These trials, named the Registration Endoscopic Study to Determine Ulcer Formation of DUEXIS (HZT-501) Compared to Ibuprofen: Efficacy and Safety Study, or REDUCE-1 and REDUCE-2, were randomized, double-blind, controlled trials that enrolled 1,533 patients in the U.S. with chronic pain or arthritis. Patients were randomly assigned, in approximately a 2:1 ratio, to receive DUEXIS (800 mg ibuprofen and 26.6 mg famotidine in a single pill) or ibuprofen (800 mg) alone, orally three times daily for a 24-week treatment period or until patients developed either an endoscopically diagnosed upper GI ulcer and/or prohibitive toxicity.

REDUCE-1 and REDUCE-2

The primary endpoint of REDUCE-1 was to show a reduction in the cumulative incidence of gastric ulcers during the six month treatment period. The primary endpoint of REDUCE-2 was to show a reduction in the cumulative incidence of upper GI (defined as gastric and/or duodenal) ulcers during the six month treatment period. In REDUCE-1, DUEXIS demonstrated a statistically significant reduction in the incidence of gastric ulcers versus treatment with ibuprofen alone (8.7% versus 17.6%, p-value = 0.0004). In REDUCE-2, DUEXIS demonstrated a statistically significant reduction in the incidence of upper GI ulcers versus treatment with ibuprofen alone (10.5% versus 20.0%, p-value = 0.002). The overall relative risk reduction of upper GI ulcers with DUEXIS versus ibuprofen was consistent across key subgroups including: age (under and over 65), history of prior ulcer, low dose aspirin use, gender and presence of baseline upper GI erosions although the studies were not powered for those individual subgroups.

In the REDUCE-1 and REDUCE-2 combined patient population, the most common adverse reactions (at least 1% and greater than ibuprofen alone) were nausea, diarrhea, constipation, upper abdominal pain and headache. The incidence of dyspepsia with DUEXIS was statistically significantly lower than ibuprofen alone (4.7% vs. 8%, p-value = 0.009). Overall, the discontinuation rate in the REDUCE-1 and REDUCE-2 studies due to adverse events for patients receiving DUEXIS and ibuprofen alone were similar.

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Commercial and Regulatory Status

On April 23, 2011, the FDA approved DUEXIS, and we began the initial commercial sale of DUEXIS in the U.S. in December 2011. We held our national launch meeting in late January 2012. We have evaluated a number of metrics to assess the effectiveness of the DUEXIS commercial launch to date. These metrics looked at key messages, managed care access and field force execution on reach and frequency. We have evaluated key messages at launch through a message recall tool that surveys prescribers that have been seen by our sales representatives. We believe the data to date has shown strong brand and message awareness among target physicians who have been seen by our sales representatives.

In October 2010, we submitted an MAA for DUEXIS to the Medicines and Healthcare products Regulatory Agency, or MHRA, in the UK, the RMS, through the Decentralized Procedure in the European Economic Area, or EAA. In February 2012, we modified the DUEXIS MAA submission to include the recently approved manufacturing site in Laval, Quebec through the National Procedure in the UK. In connection with our MAA for DUEXIS, and consistent with an identical request we made in our NDA for DUEXIS, we are requesting that the MHRA approve a formulation that is different from the formulation in our Phase 3 clinical trials, which we determined had inadequate stability characteristics to be suitable for commercialization. As a result, we were required to demonstrate the bioequivalence of famotidine between the new and old formulations of DUEXIS and the reference labeled drug ibuprofen as part of the MAA submission. See Government Regulation for a description of the regulatory approval process in the EAA. We expect that a determination with respect to the MAA will be made in the second half of 2012.

LODOTRA/RAYOS

LODOTRA, known as RAYOS in the U.S., is a proprietary programmed release formulation of low-dose prednisone and has received regulatory approval in Europe for reduction in morning stiffness associated with RA.

Market Opportunity and Limitations of Existing Treatments

According to DataMonitor, there are approximately 4.5 million RA patients in the U.S., Japan, France, Italy, Spain, Germany and the United Kingdom, of which approximately 3.0 million are diagnosed. Common agents for the treatment of RA include NSAIDs, DMARDs, biologic agents and corticosteroids such as prednisone. Physicians are increasingly supportive of prescribing multiple therapies as some RA patients are able to achieve a clinical remission with a multiple treatments. A Medical Marketing Economics May 2008 study of 150 RA patients in the U.S., which we sponsored, showed that despite the use of a combination of currently available treatments for RA, over 90% of the patients reported suffering from morning stiffness, pain and immobility.

In addition, according to DataMonitor, approximately 50% of RA patients in the U.S., Japan, France, Italy, Spain, Germany and the United Kingdom are prescribed combination therapy which often includes corticosteroids, with prednisone being one of the most common. Corticosteroids, including prednisone, are used to suppress various autoimmune, inflammatory and allergic disorders by inhibiting the production of various pro-inflammatory cytokines, such as interleukin 6, or IL-6, and TNF-alpha. Joint inflammation in RA is driven by excessive production of inflammatory mediators and cytokines such as IL-6 and TNF-alpha. While corticosteroids are potent and effective agents to treat patients with RA, they are often used at high doses to treat RA flares or significant inflammation. High-dose oral corticosteroid treatment is not a viable long-term treatment option due to adverse side effects such as osteoporosis, cardiovascular disease and weight gain. However, clinical studies have shown that the long-term use of low-dose prednisone (<10 mg per day) does not dramatically increase total adverse events. In addition, low-doses, typically less than 10 mg daily, of corticosteroids such as prednisone have been shown to treat the symptoms of RA while slowing the overall progression of the disease.

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An additional limitation of RA treatment with corticosteroids is related to the time at which patients pro-inflammatory cytokines are at peak levels. Increased levels of pro-inflammatory cytokines during the early morning hours are a known cause of morning stiffness and decreased mobility of RA. IL-6 levels are substantially increased in patients with RA in general and show a significant circadian variation in these levels. As reflected in the chart below, peak IL-6 levels tend to occur in the early morning hours and low levels typically occur in the afternoon and evening. Therefore, we believe an optimal treatment would reduce IL-6 levels in the early morning hours.

LODOTRA/RAYOS Solution

The proprietary formulation technology of LODOTRA/RAYOS enables a programmed release of prednisone approximately four hours after administration. As reflected in the chart below, LODOTRA/RAYOS proprietary delivery system synchronizes the prednisone delivery time with the patient s elevated cytokine levels, thereby taking effect at a physiologically optimal point to inhibit cytokine production, and thus significantly reduces the signs and symptoms of RA.

LODOTRA/RAYOS was developed utilizing SkyePharma s proprietary GeoClock and GeoMatrix technologies, for which we hold an exclusive worldwide license for the delivery of corticosteroids. LODOTRA/RAYOS is comprised of an active core containing prednisone, which is encapsulated by an inactive porous shell. The inactive shell acts as a barrier between the product s active core and a patient s GI fluids. LODOTRA/RAYOS is intended to be administered at bedtime. At approximately four hours following bedtime administration of LODOTRA/RAYOS, water in the digestive tract diffuses through the shell, causing the active core to expand, which leads to a weakening and breakage of the shell and allows the release of prednisone from the active core.

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Our pharmacokinetic studies have shown that the blood concentration of prednisone from LODOTRA/RAYOS is similar to immediate release prednisone except for the intended time delay. The administration of LODOTRA/RAYOS (5 mg) provides equivalent exposure, or area under curve, and maximum blood concentration to an immediate release prednisone 5 mg formulation. The following chart shows mean plasma levels of prednisone after a single dose of LODOTRA/RAYOS (5 mg) compared to an immediate release prednisone 5 mg tablet.

Clinical Trial Results

We have successfully completed two pivotal Phase 3 clinical trials evaluating LODOTRA/RAYOS for the treatment of RA. The Circadian Administration of Prednisone in Rheumatoid Arthritis-1, or CAPRA-1 trial, investigating the efficacy of LODOTRA/RAYOS in the treatment of RA, supported MAA approval in Europe. The second pivotal Phase 3 clinical trial, Circadian Administration of Prednisone in Rheumatoid Arthritis-2, or CAPRA-2 trial, along with the CAPRA-1 study, supports the NDA submission for U.S. marketing approval.

CAPRA-1

The primary endpoint of CAPRA-1 was reduction of the duration of morning stiffness associated with RA. CAPRA-1 was a 12-week, randomized, double-blind, placebo-controlled trial that enrolled 288 RA patients comparing bedtime administration of LODOTRA/RAYOS with morning administration of immediate release prednisone at the same individual dose (an average dose of 6.7 mg). All patients continued on existing DMARD and NSAID treatment at stable doses. At the conclusion of the 12-week period, patients taking LODOTRA/RAYOS were permitted to continue LODOTRA/RAYOS treatment and patients taking immediate release prednisone were permitted to switch to LODOTRA/RAYOS for a nine-month open label extension study for a total of twelve-months. There were a total of 219 patients who completed the open label extension study.

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The trial results demonstrated that bedtime administration of LODOTRA/RAYOS was superior to immediate release prednisone in reducing the duration of morning stiffness associated with RA. As shown in the chart below, the duration of morning stiffness was significantly reduced in the LODOTRA/RAYOS treatment group compared to the group treated with immediate release prednisone, where no change in morning stiffness was shown. The mean relative change in duration of morning stiffness of joints from baseline was approximately 23% in patients taking LODOTRA/RAYOS compared to approximately 0.4% for patients taking immediate release prednisone (p-value = 0.045) after 12 weeks.

LODOTRA/RAYOS reduced IL-6 levels by approximately 29% (relative median change), which was statistically significant (p-value < 0.0001), while corresponding IL-6 levels following treatment with immediate release prednisone remained constant. In addition, LODOTRA/RAYOS was as effective as treatment with immediate release prednisone for other markers of disease activity, including disease activity scores in 28 joints typically impacted by RA, and American College of Rheumatology 20, or ACR20, response rate, which measures the percentage of patients who have achieved a 20% improvement in tender or swollen joint counts as well as a 20% improvement in three of five other criteria of disease activity and all other efficacy parameters investigated. In the initial 12-week period of the study, the most commonly reported treatment-emergent adverse events were a flare in RA-related symptoms (7.6% for LODOTRA/RAYOS compared to 9.0% for immediate release prednisone), abdominal pain (3.5% for LODOTRA/RAYOS compared to 5.6% for immediate release prednisone), nasopharyngitis, or inflammation of the nasal passages (2.8% for LODOTRA/RAYOS compared to 5.6% for immediate release prednisone), headache (4.2% for LODOTRA compared to 2.8% for immediate release prednisone), and flushing (2.8% for LODOTRA/RAYOS compared to 4.2% for immediate release prednisone).

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At the conclusion of the nine-month open label extension period, patients who continued treatment with LODOTRA/RAYOS experienced a 55% reduction in the duration of morning stiffness. In addition, patients who were newly assigned to LODOTRA/RAYOS exhibited a 45% reduction in the duration of morning stiffness over the nine-month course of this extension study. These patients also experienced a 50% median reduction in IL-6 levels which also corresponded to improvements in the duration of morning stiffness following daily administration of LODOTRA/RAYOS at bedtime. In the open label phase, the most commonly reported treatment-emergent adverse events were a flare in RA-related symptoms (14.5%), flushing (5.2%), upper respiratory tract infections (2.8%), back pain (2.8%) and weight increase (2.8%). Adverse events indicative of aggravated hypothalamic-pituitary-adrenal, or HPA, axis suppression, typical of high dose prednisone administration, were not observed.

CAPRA-2

The primary endpoint of CAPRA-2 was to show that LODOTRA/RAYOS significantly improved the ACR20 response rate in patients with RA as compared to placebo. This primary endpoint is the standard used in approval of RA products in the U.S. by the FDA. CAPRA-2 was a 12-week, randomized, double-blind, placebo-controlled Phase 3 clinical trial conducted in centers in both the U.S. and Europe involving 350 RA patients. All patients were inadequate responders to DMARD therapy and were randomized into one of two arms to receive either LODOTRA/RAYOS (5 mg) or placebo once daily at bedtime in addition to their existing therapy. Results showed that patients treated with LODOTRA/RAYOS experienced a statistically significant improvement in ACR20 response criteria compared to patients in the placebo group (48.5% vs. 28.6%; p-value = 0.0002), which met the primary endpoint.

In addition, patients taking LODOTRA/RAYOS experienced a statistically significant improvement in the more stringent American College of Rheumatology 50, or ACR50, response criteria (22.7% vs. 9.2%; p-value = 0.0027), which was the secondary endpoint. ACR50 response rate measures the percentage of patients who have achieved a 50% improvement in tender or swollen joint counts as well as a 50% improvement in three of five other criteria of disease activity. Patients taking LODOTRA/RAYOS also experienced an improvement in the more stringent American College of Rheumatology 70, or ACR70, response criteria (7.0% vs. 2.5%; p-value = 0.0955), which is another measure of treatment response. ACR70 response rate measures the percentage of patients who have achieved a 70% improvement in tender or swollen joint counts as well as a 70% improvement in three of five other criteria of disease activity. Importantly, patients treated with LODOTRA/RAYOS also experienced a statistically significant reduction in morning stiffness compared to patients in the placebo group (56.5% vs. 33.3%; p-value = 0.0008).

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In this study, the most commonly reported treatment-emergent adverse events were joint pain (10.4% for LODOTRA/RAYOS compared to 20.2% for placebo), RA flare (6.5% for LODOTRA/RAYOS compared to 9.2% for placebo), nasopharyngitis (4.8% for LODOTRA/RAYOS compared to 3.4% for placebo) and headache (3.9% for LODOTRA/RAYOS compared to 4.2% for placebo).

Regulatory and Commercial Status

LODOTRA received its first approval in Europe in March 2009 and is currently approved for marketing in 16 European countries and Israel where it is being commercialized by Mundipharma. We anticipate 2012 launches to occur in France, Spain, Australia and Korea. We submitted an NDA for RAYOS to the FDA on September 26, 2011 and, based on a standard 10-month FDA review, have a PDUFA goal date of July 26, 2012.

LODOTRA/RAYOS in Other Indications

We are in the process of investigating LODOTRA/RAYOS through an investigator-initiated Phase 2 clinical trial as a potential treatment for polymyalgia rheumatica, or PMR, an inflammatory disorder involving aching and stiffness in patients over the age of 50 typically affecting the shoulders and arms. Similar to RA, the symptoms associated with PMR such as stiffness are worse in the morning as compared to the rest of the day. However, unlike RA, glucocorticoid therapy is generally viewed as the most effective treatment currently available. The clinical trial is being conducted to assess whether LODOTRA/RAYOS compared to immediate-release prednisone will induce changes in the inflammatory cytokine, IL-6, and morning symptoms associated with PMR similar to those observed with LODOTRA/RAYOS in RA. Additionally, pursuant to a March 2011 letter agreement and in connection with our waiver of certain milestone payments, Mundipharma has agreed to conduct a separate clinical trial for LODOTRA/RAYOS for the potential treatment for PMR, which we expect will be a Phase 3 clinical trial, beginning in the second half of 2012.

We also conducted a small exploratory Phase 2a clinical trial to evaluate the potential use of LODOTRA/RAYOS to treat severe asthma. Severe asthma sufferers are frequently prescribed very high doses of oral corticosteroids. However, high-dose oral corticosteroid treatment is limited by side effects which include, among others, osteoporosis and its various negative effects. Data from seven patients who had been treated with 5 to 45 mg of daily immediate release prednisone in accordance with the study protocol showed improvements in nocturnal symptoms, asthma control and asthma-related quality of life when switched to an equivalent dose of LODOTRA/RAYOS. We currently do not have plans to pursue further clinical trials for LODOTRA/RAYOS for the treatment of severe asthma. This is primarily due to the higher doses of corticosteroids required and related increased potential for adverse events often seen in severe asthma patients.

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Other Product Candidates

In addition to DUEXIS and LODOTRA/RAYOS, we have several other potential product development candidates for the treatment of pain-related diseases and chronic inflammation. At this time, we are currently not expending any resources on these earlier stage product candidates as we instead focus all of our near term resources on DUEXIS and LODOTRA/RAYOS. As part of our longer-term strategy, we anticipate we will selectively in-license or acquire additional products and/or late stage product candidates that are synergistic with our commercial strategy.

TRUNOC, or tarenflurbil, is a focused inhibitor of certain well-characterized genes (NF-kB and AP-1), whose expression is known to lead to pain and inflammation. The compound is one of two enantiomers (chemically mirror-imaged compounds) that constitute flurbiprofen, an analgesic and anti-inflammatory pharmaceutical, which received marketing approval in the 1970s. Compared to the opposite enantiomer, tarenflurbil does not exhibit significant COX-1/2 inhibition, or its associated negative side-effects. Third parties have conducted multiple clinical trials of TRUNOC in other indications. HZN-602 is a novel fixed-dose combination product containing immediate release naproxen, commonly known as Naprosyn®, with famotidine. HZN-602 may potentially improve naproxen s GI safety profile of naproxen without altering its ability to reduce pain and inflammation.

Commercial Agreements

Merck Serono License Agreements (Assigned to Mundipharma)

In December 2006 and March 2009, we entered into separate transfer, license and supply agreements with Merck Serono and Merck GesmbH, an affiliate of Merck Serono, for the commercialization of LODOTRA in Germany and Austria, respectively. The agreement covering Germany was amended in December 2008 to allow co-promotion of LODOTRA in Germany. Under the agreements, we granted Merck Serono and Merck GesmbH exclusive distribution and marketing rights pertaining to LODOTRA for each of Germany and Austria, respectively, and an exclusive license to use the trademark for LODOTRA in Germany and Austria. The transfer, license and supply agreements related to Germany and Austria were assigned to Mundipharma from Merck Serono in April 2011 and September 2011, respectively, with our consent. Mundipharma Laboratories is obligated to commercialize LODOTRA in Germany and Austria, as applicable, exclusively under the LODOTRA trademark. Mundipharma Laboratories is obligated to use commercially reasonable efforts to market LODOTRA in Germany and Austria, and is prohibited from launching other oral corticosteroids for the treatment of RA for the first three years following the launch of LODOTRA. With respect to the agreement covering Germany, if Mundipharma Laboratories does not meet specified minimum sales targets over specified periods of time, the marketing rights to LODOTRA will become nonexclusive unless Mundipharma Laboratories pays us the shortfall. With respect to the agreement covering Austria, if Mundipharma Laboratories does not meet specified minimum sales targets over specified periods of time, after good faith discussions to modify the agreement, we have the right to terminate the agreement.

Mundipharma Laboratories has agreed to purchase LODOTRA commercial product exclusively from us. We supply LODOTRA to Mundipharma Laboratories at the price which is the higher of (1) a percentage of the list price of LODOTRA sold to final purchasers of LODOTRA from Mundipharma Laboratories (excluding any discounts) and (2) the costs we incur for the production and delivery of LODOTRA to a Mundipharma Laboratories supply depot, as applicable, plus a profit mark-up.

Subject to early termination, the terms of the agreements are 15 years from the launch of LODOTRA in Germany and 10 years from the launch of LODOTRA in Austria. Thereafter, the agreements automatically renew until terminated by a party by giving specified prior written notice to the other party to the agreement. Under both agreements a party may also terminate an agreement in the event of a bankruptcy of the other party, certain events beyond the parties control that impair performance under an agreement, or upon material uncured breach by a party.

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For the years ended December 31, 2011 and 2010, Merck Serono accounted for 20% and 98% of total revenues, respectively.

Mundipharma Agreements

In March 2009, we entered into a distribution agreement with Mundipharma for the commercialization of LODOTRA in Europe, excluding Germany and Austria, and a manufacturing and supply agreement with Mundipharma Medical Company, or Mundipharma Medical. The distribution agreement, which was amended in July 2009 and March 2011, provides for an upfront payment of 5.0 million Euros, all of which has been paid by Mundipharma, and aggregate potential milestone payments of up to an additional 11.0 million Euros, which includes a credit in the amount of 1.0 million Euros we agreed to provide to Mundipharma to be applied towards certain future milestone payments in connection with the March 2011 amendment. As of December 31, 2011, we had received an aggregate of 9.4 million Euros under the distribution agreement.

Under the distribution agreement, we granted Mundipharma the exclusive distribution and marketing rights pertaining to LODOTRA for: Albania, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Liechtenstein, Lithuania, Luxemburg, Macedonia, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, former Soviet Union countries, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom. We also granted to Mundipharma an exclusive license to use our trademark for LODOTRA in these countries, and Mundipharma is allowed to commercialize LODOTRA under the LODOTRA trademark. Mundipharma is obligated to use commercially reasonable efforts to market LODOTRA in the territory and is prohibited from launching other oral corticosteroids during the term of the distribution agreement. If Mundipharma does not meet specified minimum sales targets, which range from single digit millions of Euros to tens of millions of Euros on a country by country basis, over specified periods of time, the marketing rights granted under the distribution agreement will become nonexclusive with respect to the applicable country unless Mundipharma pays us the shortfall.

Under the manufacturing and supply agreement, which was subsequently amended in March 2011, Mundipharma Medical agreed to purchase LODOTRA exclusively from us with respect to the territory. We supply LODOTRA to Mundipharma Medical at the price which is a specified percentage of the average net selling price for sales in a given country.

Subject to early termination, the terms of both of the March 2009 agreements extend to March 2024. Thereafter, the agreements automatically renew until terminated by either party giving specified prior written notice to other party. Either party may also terminate either of the agreements in the event of a bankruptcy of the other party or upon an uncured material breach by the other party. In addition, Mundipharma has the right to terminate the distribution agreement in the event of material risk of personal injury to third parties or immediately by written notice with respect to any country if the market authorization for LODOTRA is cancelled in such country.

In November 2010, we entered into a second distribution agreement with Mundipharma for the commercialization of LODOTRA in several Asian countries, Australia, New Zealand and South Africa, and a second manufacturing and supply agreement with Mundipharma Medical. Under the distribution agreement, we received an upfront payment of $3.5 million and may be entitled to additional aggregate milestone payments of up to $4.4 million. In March 2012, we amended the distribution agreement to include certain Latin American countries. Under the amendment to the distribution agreement, we may receive aggregate up-front and milestone payments of up to $2.0 million.

Under the distribution agreement and the amendment, we granted Mundipharma the exclusive distribution and marketing rights pertaining to LODOTRA for: Australia, China, Hong Kong, Indonesia, Korea, Malaysia, New Zealand, the Philippines, Singapore, South Africa, Taiwan, Thailand, Vietnam, Mexico, Brazil, Argentina,

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Colombia, Venezuela, Peru, Chile, Ecuador, Dominican Republic, Guatemala, Costa Rica, Uruguay, Bolivia, Panama, Nicaragua, El Salvador and Honduras. Mundipharma will be responsible for obtaining regulatory approvals in these countries. We also granted to Mundipharma an exclusive license to use our trademark for LODOTRA in these countries, and Mundipharma is allowed to commercialize LODOTRA under the LODOTRA trademark. Mundipharma is obligated to use commercially reasonable efforts to obtain regulatory approval for and market LODOTRA and is prohibited from launching other oral corticosteroids in these countries during the term of the distribution agreement. If Mundipharma does not meet specified minimum volume targets, which range from thousands of Euros to millions of Euros on a country by country basis, over specified periods of time, the marketing rights granted under the distribution agreement will become nonexclusive with respect to the applicable country unless Mundipharma pays us the shortfall.

Under the manufacturing and supply agreement, Mundipharma Medical agreed to purchase LODOTRA exclusively from us with respect to the territory. We supply bulk product of LODOTRA to Mundipharma Medical at an adjustable price per tablet and Mundipharma is responsible for final packaging and distribution in the territory.

Subject to early termination, the terms of both of the November 2010 agreements are 15 years from the first product launch on a country by country basis. Thereafter, the agreements automatically renew until terminated by either party by giving specified prior written notice to other party. Either party may terminate either of the agreements early in the event of a change in control of the other party, bankruptcy of the other party, or upon an uncured material breach by the other party. Either party has the right to terminate the distribution agreement with respect to any country upon prior written notice if the volume target is not met in such country for reasons beyond its control. In addition, Mundipharma has the right to terminate the distribution agreement in the event of material risk of personal injury to third parties or immediately by written notice with respect to any country if the market authorization for LODOTRA is cancelled, withdrawn or suspended in such country. We also have the right, subject to certain conditions, to terminate the distribution agreement with respect to any country in the territory if within a specified period of time, Mundipharma fails to submit appropriate filings to obtain marketing authorization in the country or fails to initiate a clinical trial required for marketing authorization in the country.

For the year ended December 31, 2011, Mundipharma accounted for 79% of total revenues.

SkyePharma and Jagotec Agreements

Development and License Agreement

In August 2004, we entered into a development and license agreement with SkyePharma AG and Jagotec AG, a wholly-owned subsidiary of SkyePharma, regarding certain proprietary technology and know-how owned by SkyePharma for the delayed release of corticosteroids. The agreement replaced a similar agreement entered into between Merck and SkyePharma in 1998, which Merck assigned to us.

Under the agreement, which was amended in August 2007, we received an exclusive, sub-licensable worldwide license to the oral formulation of any corticosteroid, including prednisone, prednisolone, methylprednisolone and/or cortisone, with delayed release technology covered by intellectual property rights and know-how owned by SkyePharma. We were also granted an option to acquire a royalty-free, exclusive and sub-licensable right to license and manufacture LODOTRA/RAYOS which we can exercise any time upon specified prior written notice, expiring no earlier than five years after the first launch of LODOTRA/RAYOS.

In return for the grant of the license, Jagotec has the exclusive right to manufacture, package and supply LODOTRA/RAYOS to us in accordance with terms and conditions of a separate manufacturing and supply agreement we entered into with Jagotec. In addition, Jagotec is entitled to receive a single digit percentage royalty on net sales of LODOTRA/RAYOS and on any sub-licensing income, which includes any payments not calculated based on the net sales of LODOTRA/RAYOS, such as license fees, and lump sum and milestone payments.

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The agreement expires on the later of August 20, 2014 or, on a country-by-country basis, upon the expiration of the last patent rights for LODOTRA/RAYOS. In the event of expiration, the licenses under the agreement will be perpetual, fully paid-up and royalty-free. Either party may also terminate the agreement in the event of a liquidation or bankruptcy of the other party or upon an uncured breach by the other party.

Manufacturing and Supply Agreement

In August 2007, we entered into a manufacturing and supply agreement with Jagotec, an affiliate of SkyePharma AG, from whom we purchase LODOTRA/RAYOS. Under the agreement, which was amended in March 2011, Jagotec or its affiliates manufacture and supply LODOTRA/RAYOS exclusively to us in bulk. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to Aenova, a large contract manufacturing organization. As such, Aenova is now a subcontractor for Jagotec for the manufacture of LODOTRA/RAYOS, with our consent. We purchase LODOTRA/RAYOS exclusively from Jagotec. As of December 31, 2011 our total remaining minimum purchase commitment was approximately $3.2 million based on tablet pricing under the agreement as of that date, which amount is subject to volume and price adjustments due to, among other things, inflation, order quantities and launch and approval in certain European Union countries. We also supply the active pharmaceutical ingredient prednisone to Jagotec at our expense for use in the manufacture of LODOTRA/RAYOS.

We pay Jagotec, exclusive of any value added tax or similar governmental charges, a price for LODOTRA/RAYOS representing a negotiated mark-up over manufacturing costs. After a short initial period, the price will be adjusted annually to reflect changes in both manufacturing and materials costs as measured by the Ensemble price index.

If Jagotec makes a major capital expenditure during the contract term to fulfill increased orders forecast by us, the price per unit will increase if the actual order falls short of the forecast.

The agreement term extends until the end of the fifth year after the first launch of LODOTRA/RAYOS and automatically extends on a yearly basis unless terminated by either party upon prior written notice. Either party may also terminate the agreement in the event of insolvency, liquidation or bankruptcy of the other party or upon an uncured breach by the other party. We have the right to receive a continuing supply of LODOTRA/RAYOS from Jagotec for a period of 24 months after termination by Jagotec, regardless of the reason for termination.

sanofi-aventis U.S. LLC Agreements

Technical Transfer Agreement

In November 2009, we entered into a technical transfer agreement with sanofi-aventis U.S. to increase our commercial manufacturing capacity. Pursuant to the agreement, sanofi-aventis U.S. performed engineering studies of DUEXIS core tablets and finished product, performed installation qualification of equipment used in the manufacture of DUEXIS, produced validation batches of DUEXIS and conducted a stability study on the final validation batches. In order to allow sanofi-aventis U.S. to perform its obligations under the agreement, we provided sanofi-aventis U.S. certain pharmaceutical materials and process information relating to the production of DUEXIS tablets and granted sanofi-aventis U.S. a license to our related intellectual property.

We have paid for the purchase and installation of equipment necessary to manufacture DUEXIS tablets, and sanofi-aventis U.S. was obligated to pay the costs of routine maintenance of the equipment. We were also obligated to pay sanofi-aventis U.S. for any validation batches of DUEXIS.

The technical transfer activities have been completed and the agreement expired as of December 31, 2011.

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Manufacturing and Supply Agreement

In May 2011, we entered into a manufacturing and supply agreement with sanofi-aventis U.S. Pursuant to the agreement, sanofi-aventis U.S. is obligated to manufacture and supply DUEXIS to us in final, packaged form, and we are obligated to purchase DUEXIS exclusively from sanofi-aventis U.S. for our commercial requirements of DUEXIS in North America and certain countries and territories in Europe, including the European Union member states and Scandinavia, and South America. Sanofi-aventis U.S. is obligated to acquire the components necessary to manufacture DUEXIS, including the active pharmaceutical ingredients DC85, which is ibuprofen in a direct compression blend, and famotidine, and is obligated to acquire all DC85 under the terms of any agreements we may have with suppliers for the supply of DC85. We expect that sanofi-aventis U.S. will obtain DC85 from BASF Corporation through our sales contract with BASF and will enter into a separate supply agreement for famotidine with another third-party supplier. In order to allow sanofi-aventis U.S. to perform its obligations under the agreement, we granted sanofi-aventis U.S. a non-exclusive license to our related intellectual property. In November 2011, the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. In December 2011, Valeant acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. The price for DUEXIS under the agreement varies depending on the configuration and volume of DUEXIS we purchase and is subject to annual adjustments to reflect changes in costs as measured by the Producer Price Index published by the U.S. Department of Labor, Bureau of Labor Statistics and certain other changes and events set forth in the agreement. We have paid for the purchase and installation of equipment necessary to manufacture DUEXIS tablets, and sanofi-aventis U.S. is obligated to pay the costs of routine maintenance of the equipment. Upon expiration or termination of the agreement we may also be obligated to reimburse sanofi-aventis U.S. for the depreciated net book value of any other equipment purchased by sanofi-aventis U.S. in order to fulfill its obligations under the agreement.

The agreement term extends until the eighth anniversary of the first commercial sale of DUEXIS in any country in the territory and automatically extends for successive two year terms unless terminated by either party upon two years prior written notice. Either party may terminate the agreement upon 30 days prior written notice to the other party in the event of breach by the other party that is not cured within 30 days of notice (which notice period may be longer in certain, limited situations) or in the event we lose regulatory approval to market DUEXIS in all countries within the territory, and either party may terminate the agreement without cause upon two years prior written notice to the other party at any time after the third anniversary of the first commercial sale of DUEXIS in any country in the territory.

Pharmaceutics International Master Services Agreement

In September 2008, we entered into a master services agreement with Pharmaceutics International, Inc., or PII. Pursuant to the agreement and several project contracts under the agreement, PII is obligated to perform product development services and prepare regulatory batches in preparation for the manufacturing of commercial products. Services performed by PII include tablet manufacturing, testing, packaging and study design for DUEXIS. Under the agreement, we are obligated to make payment to PII for services according to project budgets specified in advance of each service contract.

The agreement will continue until terminated. We may terminate the agreement or any service contract at any time by giving prior written notice. Either party may terminate the agreement in the event of uncured breach by the other party.

As a result of the FDA approval of the sanofi-aventis Canada, Inc. manufacturing site in Laval, Quebec, sanofi-aventis U.S. is the exclusive manufacturer and supplier of DUEXIS.

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Temmler Supply Agreement

We have entered into an agreement with Temmler Werke GmbH, or Temmler, for the packaging and assembling of LODOTRA. Pursuant to the agreement, we may order LODOTRA according to specified rolling forecasts. Subject to early termination, the agreement will remain in effect until December 21, 2015. Thereafter, the agreement automatically renews for additional one year periods unless either party provides notice to the other party at least twelve months prior to the expiration of the then-current period. Either party may also terminate the agreement at any time for an uncured material breach. There are no minimum purchase requirements under the agreement and we may enter into agreements with other third-party packagers for LODOTRA.

BASF Sales Contract

In July 2010, we entered into a sales contract with BASF Corporation for the purchase of DC85, the active ingredient in DUEXIS. The agreement provides for an initial pre-purchase credit in the hundreds of thousands of dollars to be used as payment for DC85. Pursuant to the agreement, we are obligated to purchase a significant majority of our commercial demand for DC85 from BASF.

The sales contract expires in December 2017. Thereafter, the agreement automatically renews until terminated by either party giving specified prior written notice to the other party. Either party may also terminate the agreement in the event of uncured breach by the other party. If the agreement terminates for any reason before a specified date and we have not purchased requisite amounts of DC85, BASF has the right to withhold from the pre-purchase credit an amount based upon the total amount of DC85 purchased throughout the life of the agreement.

Sales and Marketing

In conjunction with the April 2011 FDA approval of DUEXIS and the potential FDA approval of RAYOS, we began building our commercial organization, including a sales force comprised initially of approximately 80 sales representatives, to target top prescribing primary care physicians, rheumatologists, orthopedic surgeons and pain specialists. We plan to expand our sales force up to a total of approximately 160 sales representatives and explore other additional opportunities to expand the reach and frequency of our sales efforts such as co-promotion partnerships with companies that have commercial activity with similar physician targets and/or add sales representatives through a CSO. We believe that a focused sales force can be effective in the current NSAID market due to a decrease in branded product promotional activity. We intend to enter into licensing or additional distribution agreements for commercialization of our products outside the U.S., such as our relationship with Mundipharma for commercialization of LODOTRA in Europe and certain Asian, Latin American and other countries.

Intellectual Property

Our policy is to patent the technology, inventions and improvements that we consider important to the development of our business. We have a portfolio of patents and applications based on clinical and pharmacokinetic/pharmacodynamic modeling discoveries, and our novel formulations. In addition, we have an exclusive license to pending U.S. and foreign patent applications from SkyePharma. We intend to continue filing patent applications seeking intellectual property protection as we generate anticipated formulation refinements, new methods of manufacturing and clinical trial results.

With respect to LODOTRA/RAYOS, we have filed our own patent applications covering site- and time-controlled GI release of corticosteroids, delayed release corticosteroid treatment of RA and diseases with a suppression of the HPA axis, and delayed release treatment of asthma. We have filed patent applications with the World Intellectual Property Organization covering site- and time-controlled GI release of corticosteroids and

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delayed release treatments for asthma, and have filed patent applications in the U.S. covering site- and time-controlled GI release of corticosteroids and delayed release corticosteroid treatment of RA and diseases with a suppression of the HPA axis. Related patent applications have been filed in the following jurisdictions: Algeria, Argentina, Australia, Brazil, Canada, China, Egypt, Eurasian Patent Organization, European Patent Office, Gulf Cooperation Council, Hong Kong, India, Indonesia, Israel, Japan, Libya, Malaysia, Mexico, Monaco, Norway, Singapore, South Africa, South Korea, Syria, Taiwan, Tunisia, Ukraine and United Arab Emirates. If granted, and not otherwise invalidated, the patents are anticipated to protect the related subject matters until between 2027 and 2030. We have also in-licensed patent applications pending at the World Intellectual Property Organization from SkyePharma for its proprietary drug delivery technology, GeoClock , which cover tablet geometry and design. If granted, and not otherwise invalidated, the in-licensed patent applications are anticipated to expire between 2024 and 2025. In addition, we purchased from a third-party two issued U.S. patents related to 1 mg and 2 mg delayed release dosage forms of prednisone and two methods of treating RA with such dosage forms which are anticipated to expire in 2020 (U.S. Patent No. 6,488,960 and U.S. Patent No. 6,667,326). We are prosecuting our own pending patent applications in the U.S. and those in-licensed from SkyePharma to obtain broader patent coverage on RAYOS.

We are also seeking to expand the patent position of DUEXIS. We have filed multiple patent applications claiming the product and methods for its use in the U.S., as well as related applications in Australia, Canada, China, Europe and Japan. If granted, and not otherwise invalidated, the patents are anticipated to expire between 2026 and 2028. Our patent strategy for DUEXIS aims at providing protection specific to DUEXIS for three times daily administration and is intended to prevent direct product copying as well as the use of any other ibuprofen-famotidine single dose products for three times daily use to treat patients.

On November 29, 2011 two patents covering DUEXIS were issued, U.S. patents 8,067,033 and 8,067,451. These two U.S. patents were listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. On January 4, 2012, EP 2043637 patent was granted in Europe covering DUEXIS.

In the U.S., in addition to any patent protection, DUEXIS has been granted three years of marketing exclusivity under a Section 505(b)(2) NDA. We anticipate that RAYOS will also receive three years of marketing exclusivity upon FDA approval. This marketing exclusivity begins upon marketing approval and runs in parallel with any patents that have issued or we expect to be issued protecting RAYOS and DUEXIS to provide an additional layer of market protection. In the European Union, LODOTRA has received 10 years of marketing exclusivity protection, beginning with its March 2009 marketing authorization in Germany. We anticipate that DUEXIS will also receive 10 years of marketing exclusivity upon European approval.

We will only be able to protect our technologies and products from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. As such, our commercial success will depend in part on receiving and maintaining patent protection and trade secret protection of our technologies and products as well as successfully defending these patents against third-party challenges. On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc., or Par, advising that Par has filed an Abbreviated New Drug Application with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par has not advised us as to the timing or status of the FDA s review of its filing, or whether it has complied with FDA requirements for proving bioequivalence. We are evaluating the Paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to DUEXIS, but we cannot predict the outcome of this matter.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies patents has emerged to date in the U.S. The patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. or other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example:

- we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;

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we or our licensors 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 or the pending patent applications of our licensors will result in issued patents (including our core patent application for DUEXIS, which is currently on appeal with the U.S. PTO);

our issued patents and the issued patents of our licensors may not provide a basis for commercially viable drugs, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;

we may not develop additional proprietary technologies or product candidates that are patentable; or

the patents of others may have an adverse effect on our business.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies and generic drug companies, although we are not currently aware of any other delayed release prednisone drug or ibuprofen/famotidine combination drug in development. We believe that the key competitive factors that will affect the development and commercial success of DUEXIS and LODOTRA/RAYOS, as well as future drug candidates that we may develop, are efficacy, safety and tolerability profile, convenience in dosing, price and reimbursement.

DUEXIS

DUEXIS competes with other branded NSAIDs, including Celebrex, marketed by Pfizer Inc., Vimovo, developed by Pozen Inc. and marketed by AstraZeneca AB, and Arthrotec, marketed by Pfizer.

Celebrex is an NSAID that selectively inhibits the COX-2 enzyme and is an effective anti-arthritic agent that reduces the risk of ulceration compared to traditional NSAIDs such as ibuprofen. However, two other COX-2 inhibitors, Vioxx and Bextra, have been withdrawn from the market due to safety concerns.

Vimovo is a fixed-dose combination of enteric-coated naproxen plus esomeprazole, a PPI. Enteric-coated naproxen is an NSAID indicated for the treatment of OA and esomeprazole is approved to reduce the risk of NSAID-induced gastric ulcers. We believe DUEXIS may offer competitive advantages over Vimovo due to its delayed onset of pain relief related to the enteric-coated naproxen as well as several recent publications highlighting safety concerns with long-term PPI use.

Arthrotec is a fixed-dose combination of diclofenac sodium and misoprostol, a GI mucosal protective prostaglandin E1 analog. Diclofenac sodium is an NSAID prescribed for pain relief and misoprostol is used to reduce the risk of NSAID-induced upper GI ulcers. We believe DUEXIS may offer competitive advantages over Arthrotec based on a significant increase in GI side effects, including abdominal pain and diarrhea, associated with Arthrotec. Rare instances of profound diarrhea leading to severe dehydration have been reported in patients receiving misoprostol. Arthrotec has additional safety issues associated with its components such as cases of hepatic-related adverse events, none of which have been observed in our clinical trials of DUEXIS. In addition, misoprostol has been associated with miscarriage in pregnant women and is contraindicated in those women who are pregnant or likely to become pregnant.

In general, DUEXIS will also face competition from the separate use of NSAIDs for pain relief and ulcer medications to address the risk of NSAID-induced ulcers. Use of these therapies separately in generic form may be cheaper than we expect to offer DUEXIS. In addition, physicians could begin to prescribe both an NSAID and

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a GI protectant to be taken together but in separate pills. We expect to compete with the separate use of NSAIDs and ulcer medications primarily through DUEXIS advantages in dosing convenience and patient compliance, and by educating physicians about such advantages, including through funding we have provided for the American Gastroenterology Association, or AGA, to help physicians and patients better understand and manage NSAID risks. We expect DUEXIS will be the only product containing a histamine-2 receptor antagonist with an indication to reduce the risk of NSAID-induced upper GI ulcers.

LODOTRA/RAYOS

LODOTRA/RAYOS competes in Europe and will compete in the U.S., if approved, with a number of products on the market to treat RA, including corticosteroids, such as prednisone, traditional DMARDs, such as methotrexate and biologic agents, such as HUMIRA and Enbrel. The majority of RA patients, however, are treated with DMARDs. DMARDs, such as methotrexate, are typically used as initial therapy in patients with RA whereas biologic agents are typically added to DMARDs as combination therapy. It is common for an RA patient to take a combination of a DMARD, an oral glucocorticoid, an NSAID and/or a biologic agent.

Manufacturing and Distribution

DUEXIS

The DUEXIS manufacturing process is well-established and we validated the process in accordance with regulatory requirements prior to commercialization in the U.S. We have contracted with internationally recognized pharmaceutical companies with operations in North America and Europe for contract manufacturing and packaging. In May 2011, we entered into a long-term supply and manufacturing agreement with sanofi-aventis U.S. for the manufacture of DUEXIS. In November 2011, the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. In December 2011, Valeant acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. All of the facilities contracted by us are registered with the FDA, EMA and other internationally recognized regulatory authorities. In addition, these facilities have been audited by these agencies within the past two years to confirm compliance. We do not plan to build manufacturing facilities and will scale our operations using our contract manufacturers.

The first active pharmaceutical ingredient, or API, in DUEXIS is ibuprofen in a direct compression blend called DC85, which is manufactured by BASF in Bishop, Texas. DC85 is a proprietary blend of ibuprofen and manufacturing capacity and batch quantities are currently sufficient to meet our forecasted commercial requirements. DC85 is manufactured in compliance with the FDA s current good manufacturing practices regulations for pharmaceuticals, or cGMPs. The second API in DUEXIS is famotidine, which is readily available from a number of international suppliers. We purchase famotidine manufactured by Dr. Reddy s in India. Dr. Reddy s has been audited by the FDA and found to be compliant in all aspects of the product. Our personnel have also completed audits of each supplier location and did not identify any cGMP deficiencies. We currently receive both APIs in powder form and each is blended with a number of United States Pharmacopeia inactive ingredients. We purchase DUEXIS in final, packaged form exclusively from sanofi-aventis U.S. for our commercial requirements for DUEXIS in North America and certain countries and territories in Europe, including the European Union member states and Scandinavia, and South America.

Finished tablets are shipped to a central third-party logistics FDA-compliant warehouse for storage and distribution into the supply chain. Our third-party logistics providers specialize in integrated operations that include warehousing and transportation services that can be scaled and customized to our needs based on market conditions and the demands and delivery service requirements for our products and materials. Their services eliminate the need to build dedicated internal infrastructures that would be difficult to scale without significant

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capital investment. Our third-party logistics provider warehouses all finished product in controlled FDA-registered facilities. Incoming orders are prepared and shipped through an order entry system to ensure just in time delivery of the products throughout the U.S. and Europe.

LODOTRA/RAYOS

We do not intend to manufacture LODOTRA/RAYOS ourselves and rely instead on well-established and highly regarded third-party manufacturers. In Europe, we retain quality responsibilities for LODOTRA/RAYOS by controlling the final release of products. We purchase the primary active ingredients for LODOTRA/RAYOS from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and from Sanofi-Aventis SA in France.

We have contracted with Jagotec for the production of LODOTRA/RAYOS tablets. Jagotec produces LODOTRA/RAYOS operating through its affiliate SkyePharma SAS. The SkyePharma SAS production site in Lyon, France, complies with cGMP requirements and has been audited by the FDA for the production of several sustained release tablets employing SkyePharma s GeoMatrix technology. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to Aenova. As such, Aenova is now a subcontractor for Jagotec for the manufacture of LODOTRA/RAYOS, with our consent. We consider Aenova an experienced and reliable contract manufacturer dedicated largely to advanced oral dosage forms. The commercial scale production of LODOTRA/RAYOS tablets was implemented prior to the launch of LODOTRA in Europe in 2009. Jagotec is the exclusive manufacturer of LODOTRA/RAYOS under our manufacturing and supply agreement, but we retain the right to source a second manufacturer under certain conditions, including if Jagotec cannot meet our commercial demand. Bayer Schering Pharma AG in Germany has been qualified as a backup manufacturer.

Analytical testing of LODOTRA/RAYOS is conducted by PHAST GmbH. PHAST is a German provider of contract analytical services. The packaging of LODOTRA/RAYOS tablets is conducted by Temmler in Munich, Germany. Catalent Pharma Solutions in Schorndorf, Germany is registered as a second site for Europe supplies.

All sites involved in the manufacturing and control of LODOTRA/RAYOS have been inspected by us and audited by national and international authorities in Europe. In addition, all sites except for Temmler s packaging site in Munich have been audited by authorities in the U.S., including the FDA.

Third-Party Reimbursement and Pricing

In both U.S. and foreign markets, our ability to commercialize our products successfully depends in significant part on the availability of adequate coverage and reimbursement from third-party payers, including, in the U.S., government payers such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third-party payers are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. This is especially true in markets where over the counter and generic options exist. Third-party payers may use tiered reimbursement and may adversely affect demand for our products by placing them in a more expensive tier. We cannot be certain that our products will successfully be placed on the list of drugs covered by particular health plan formularies. 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 our products are not included on these preferred drug lists, physicians may not be inclined to prescribe them to their Medicaid patients, thereby diminishing the potential market for our products. We may need to conduct pharmacoeconomic studies to demonstrate the cost effectiveness of our products for formulary coverage and reimbursement. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payers may not provide coverage and reimbursement for our product candidates, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our future business. For

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example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, enacted in March 2010, substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, PPACA establishes:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- a new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period (the donut hole); and
- a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products, and could limit the acceptance and availability of our products. Approval of our products may be delayed or rejected based upon changes in regulatory policy for product approval during the period of product development and regulatory agency review. Changes in regulatory approval policy, regulations or statutes or the process for regulatory review during products development or approval periods may cause delays in the approval or rejection of an application. The adoption of some or all of these proposals could materially impact numerous aspects of our business.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose extensive requirements upon the clinical development, pre-market approval, manufacture, labeling, marketing, promotion, pricing, storage and distribution of pharmaceutical products. These agencies and other regulatory agencies regulate research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, advertising and promotion of drugs. Failure to comply with applicable FDA or foreign regulatory agency requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

In the U.S., the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations. The process required by the FDA before product candidates may be marketed in the U.S. generally involves the following:

- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA s Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;

satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the API and finished drug product are produced and tested to assess compliance with cGMP regulations; and

FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the U.S.

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The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the U.S. IND are required in the EEA and other jurisdictions in which we may conduct clinical trials. Investigator-sponsored or investigator-initiated clinical trials, such as the Phase 2 PMR study of LODOTRA presently being conducted, are studies for which the investigator holds the IND, or equivalent regulatory filing in foreign jurisdictions, and is responsible for compliance with both the investigator and sponsor requirements under applicable law.

Clinical Trials. For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

Phase 1 Clinical Trials. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism, and excretion, typically in healthy humans, but in some cases in patients.

Phase 2 Clinical Trials. Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

Phase 3 Clinical Trials. These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.

Phase 4 Clinical Trials. The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

New Drug Applications. The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which is waived for the first NDA submitted by a qualifying small business. Once the submission has been accepted for filing, the FDA s goal is to review applications within 10 months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an

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advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. The FDA may deny approval of an NDA by issuing a Complete Response Letter if the applicable regulatory criteria are not satisfied. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may occur with Risk Evaluation and Mitigation Strategies, or REMS, which limit the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

The DUEXIS and RAYOS NDAs were submitted under Section 505(b)(2) of the FFDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval 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. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA s findings of safety and effectiveness for previously approved products, such as ibuprofen, famotidine and prednisone.

DUEXIS has obtained, and any other products of ours approved by the FDA could obtain, three years of Hatch-Waxman marketing exclusivity, based upon our conducting or sponsoring new clinical investigations that are essential to approval of the respective NDA. Under this form of exclusivity, the FDA would be precluded from approving a generic drug application or, in some cases, another 505(b)(2) application for a drug product for the protected conditions of approval (for example, a product that incorporates the change or innovation represented by our product) for a period of three years, although the FDA may accept and commence review of such applications at any time. However, this form of exclusivity would not prevent the FDA from approving an NDA that relies on its own clinical data to support the change or innovation. Further, if another company obtains approval for either product candidate for the same indication we are studying before we do, our approval could be blocked until the other company s Hatch-Waxman marketing exclusivity expires.

Other Regulatory Requirements. Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Our product candidates, if approved by the FDA, may be subject to REMS requirements that affect labeling, distribution or post market reporting. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA requires us to recall a drug from distribution or withdraw approval of the NDA for that drug.

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The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available drugs for uses that are not described in the product s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers communications regarding off-label use. If our promotional activities, including any promotional activities that a contracted sales force may perform on our behalf, fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue Warning Letters or Untitled Letters, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business. Thus, we may only market DUEXIS and RAYOS, if approved by the FDA, for their approved indications and we could otherwise be subject to enforcement action for off-label marketing.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution, including a drug pedigree which tracks the distribution of prescription drugs.

Outside the U.S., our partners ability to market a product is contingent upon obtaining marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country.

In the EEA (which is comprised of the 27 Member States of the European Union, plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are three types of marketing authorizations:

the Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

Decentralized Procedure (DCP) MA are available for products not falling within the mandatory scope of the Centralized Procedure. An identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product

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characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States, or CMS, for their approval. If the CMS raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all of the selected Member States (i.e. in the RMS and the selected CMS). Where a product has already been authorized for marketing in a Member State of the EEA, this DCP approval can be recognized in other Member States through the Mutual Recognition Procedure, or MRP.

National Procedure MAs, which are issued by a single competent authority of the Member States of the EEA and only covers their respective territory, are also available for products not falling within the mandatory scope of the Centralized Procedure. Once a product has been authorized for marketing in a Member State of the EEA through the National Procedure, this National MA can also be recognized in other Member States through the MRP.

Under the procedures described above, before granting the MA, the EMA or the competent authority(ies) of the Member State(s) of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Under Regulation (EC) No 726/2004/EC and Directive 2001/83/EC (each as amended), the European Union has adopted a harmonized approach to data and marketing exclusivity (known as the 8 + 2 + 1 formula). The approach permits eight years of data exclusivity and 10 years of marketing exclusivity. An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

The data exclusivity period begins on the date of the product s first MA in the European Union and prevents generics from relying on the marketing authorization holder s pharmacological, toxicological, and clinical data for a period of eight years. After eight years, a generic product application may be submitted and generic companies may rely on the marketing authorization holder s data. However, a generic cannot launch until two years later (or a total of 10 years after the first marketing authorization in the European Union of the innovator product), or three years later (or a total of 11 years after the first MA in the European Union of the innovator product) if the MA holder obtains marketing authorization for a new indication with significant clinical benefit within the eight-year data exclusivity period.

The 8 + 2 + 1 exclusivity scheme applies to products that have been authorized in the European Union by either the EMA through the Centralized Procedure or the competent authorities of the Member States of the EEA (under the Decentralized, or Mutual Recognition procedures).

The holder of a Community MA or National MA is subject to various obligations under applicable EEA regulations, such as pharmacovigilance obligations, requiring it to, among other things, report and maintain detailed records of adverse reactions, and to submit periodic safety update reports to the competent authorities. The holder must also ensure that the manufacturing and batch release of its product is in compliance with the applicable requirements. The MA holder is further obligated to ensure that the advertising and promotion of its products complies with applicable laws, which can differ from Member State to Member State of the EEA.

Healthcare Fraud and Abuse Laws. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our business. We may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. Violations of

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these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the FDA, such as us, and hospitals, physicians and other potential purchasers of such products.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term remuneration is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The reach of the Anti-Kickback Statute was also broadened by PPACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b, effective March 23, 2010. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The federal Anti-Kickback Statute is broad, and despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities, including our activities pursuant to partnerships with other companies and pursuant to contracts with contract research organizations, could be subject to challenge under one or more of such laws. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws, as might violations of the federal physician self-referral laws, such as the Stark laws, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician s family member has a financial interest and prohibit submission of a claim for reimbursement pursuant to a prohibited referral. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of $5,500 to $11,000 for each separate false claim.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

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Healthcare Privacy and Security Laws. We may be subject to, or our marketing activities may be limited by, HIPAA, and its implementing regulations, which established uniform standards for certain covered entities (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA s privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, the new law makes HIPAA s privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney s fees and costs associated with pursuing federal civil actions.

If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Employees

As of December 31, 2011, we had 164 full-time employees, 11 of whom held advanced clinical or scientific degrees. Of our employees as of December 31, 2011, 26 were engaged in development, regulatory and manufacturing activities, 118 were engaged in sales and marketing and 20 were engaged in administration, including business development, finance, information systems, facilities and human resources. None of our employees are subject to a collective bargaining agreement. We consider our employee relations to be satisfactory.

Available Information

We make available free of charge on or through our internet website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. Our internet address is *www.horizonpharma.com.* Information is also available through the Securities and Exchange Commission s website at *www.sec.gov* or is available at the Securities and Exchange Commission s Public Reference Room located at 100 F Street, NE, Washington DC, 20549. Information on the operation of the Public Reference Room is available by calling the Securities and Exchange Commission at 800-SEC-0330.

Item 1A. Risk Factors

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission.

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Risks Related to Our Business and Industry

Our ability to generate revenues from any approved products will be subject to attaining significant market acceptance among physicians, patients and healthcare payers.

DUEXIS, LODOTRA, known as RAYOS in the U.S., and our other product candidates, if approved, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. In December 2011, we began selling DUEXIS in the U.S. market and LODOTRA has only been sold in a limited number of European countries. Sales of DUEXIS and LODOTRA in these markets have been limited to date and sales may not grow to expected levels, in part because we depend on our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for the commercialization of LODOTRA in these markets. We believe that the degree of market acceptance and our ability to generate revenues from any products for which we obtain marketing approval will depend on a number of factors, including:

- timing of market introduction of our products as well as competitive drugs;
- efficacy and safety of our products;
- continued projected growth of the arthritis, pain and inflammation markets;
- prevalence and severity of any side effects;
- acceptance by patients, primary care specialists and key specialists, including rheumatologists, orthopedic surgeons and pain specialists;
- potential or perceived advantages or disadvantages of our products over alternative treatments, including cost of treatment and relative convenience and ease of administration;
- strength of sales, marketing and distribution support;
- the price of our products, both in absolute terms and relative to alternative treatments;
- the effect of current and future healthcare laws;
- availability of coverage and adequate reimbursement and pricing from government and other third-party payers; and
- product labeling or product insert requirements of the Food and Drug Administration, or FDA, or other regulatory authorities.

With respect to DUEXIS, studies indicate that physicians do not commonly co-prescribe GI protective agents to high-risk patients taking NSAIDs. We believe this is due in part to a lack of awareness among physicians prescribing NSAIDs of the risk of NSAID-induced upper GI ulcers, in addition to the inconvenience of prescribing two separate medications and patient compliance issues associated with multiple prescriptions. If physicians remain unaware of, or do not otherwise believe in, the benefits of combining GI protective agents with NSAIDs, our market opportunity for DUEXIS will be limited. Some physicians may also be reluctant to prescribe DUEXIS due to the inability to vary the

dose of ibuprofen or if they believe treatment with NSAIDs or GI protectants other than ibuprofen and famotidine, including those of our competitors, would be more effective for their patients. With respect to both DUEXIS and LODOTRA/RAYOS, their higher cost compared to the generic forms of their active ingredients alone may limit adoption by physicians, patients and healthcare payers. If DUEXIS, LODOTRA/RAYOS or our other product candidates that are approved fail to attain market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

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Our current business plan is highly dependent upon our ability to successfully execute on our sales and marketing strategy for the commercialization of DUEXIS and LODOTRA/RAYOS. If we are unable to successfully execute on our sales and marketing strategy, we may not be able to generate significant product revenues or execute on our business plan.

Our strategy is to build a fully-integrated U.S.-focused biopharmaceutical company to successfully execute the commercial launches of DUEXIS and, if approved by the FDA, RAYOS in the U.S. market. We may not be able to successfully commercialize either DUEXIS or, if approved, RAYOS in the U.S. Prior to initial detailing in December 2011 and our commercial launch of DUEXIS in the U.S. in December 2011, we did not have any experience commercializing pharmaceutical products on our own. LODOTRA was commercially launched in Europe by our exclusive distribution partners Merck Serono and Mundipharma. In order to commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. We currently have limited resources and the continued development of our own commercial organization to market these products and any additional products we may develop will be expensive and time-consuming and could delay any product launch, and we cannot be certain that we will be able to successfully develop this capability. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. We also face competition in our search for potential co-promoters of our products. To the extent we rely on additional third parties to commercialize any approved products, we may receive less revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of any third parties involved in our commercialization efforts. In the event we are unable to successfully develop our own commercial organization or collaborate with a third-party sales and marketing organization or enter into co-promotion agreements, we would not be able to commercialize our product candidates and execute on our business plan. If we are unable to successfully implement our commercial plans and drive adoption by patients and physicians of any approved products through our sales, marketing and commercialization efforts, or if our partners fail to successfully commercialize our products, then we will not be able to generate sustainable revenues from product sales which will have a material adverse effect on our business and prospects.

We are highly dependent on the success of DUEXIS and LODOTRA, and we may not be able to successfully commercialize these products or successfully obtain additional marketing approvals for DUEXIS in Europe or LODOTRA in the U.S.

To date, we have expended significant time, resources and effort on the development of DUEXIS and RAYOS, and a substantial majority of our resources are now focused on the commercialization of DUEXIS in the U.S. and seeking additional marketing approvals for DUEXIS and RAYOS. Our ability to generate significant product revenues in the near term will depend almost entirely on our ability to successfully commercialize DUEXIS and RAYOS in the U.S., obtain European marketing approval for DUEXIS and obtain U.S. marketing approval for RAYOS. DUEXIS is not approved for marketing in any jurisdiction outside of the U.S. and therefore, unless it obtains regulatory approval in other countries it may never be commercialized outside of the U.S. Although LODOTRA is approved for marketing in 16 European countries, to date it has only been marketed in a limited number of European countries. While we anticipate that LODOTRA will be marketed in additional European countries as our distribution partner, Mundipharma, formulates its reimbursement strategy, the ability to market LODOTRA in additional European countries will depend on Mundipharma s ability to obtain regulatory and reimbursement approvals in these countries. Even if we obtain additional marketing and reimbursement approvals, our product revenues in Europe are entirely dependent upon the marketing efforts of our exclusive distribution partner, over which we have no control. RAYOS is not approved for marketing in the U.S., which we believe represents its largest commercial opportunity. Before we can market and sell these products in a particular jurisdiction, we will need to obtain necessary regulatory approvals (from the FDA in the U.S. and from similar foreign regulatory agencies in other jurisdictions) and in some jurisdictions, reimbursement authorization. There are no guarantees that we will obtain any additional regulatory approvals for our products. Even if we obtain additional regulatory approvals, we may never generate significant revenues from any commercial sales of our products. If we fail to successfully commercialize DUEXIS or RAYOS, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial

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condition and results of operations will be adversely affected. We recently entered into a senior secured loan facility that includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end. Should we not meet these quarterly minimum revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. While we believe, based on our current estimates that we will meet the minimum quarterly revenue covenants under the loan facility, there can be no assurance that we will. We also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if we were unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations.

Our products and product candidates are subject to extensive regulation, and we may not obtain additional regulatory approvals for DUEXIS or LODOTRA/RAYOS.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution and other possible activities relating to our product candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions.

We are not permitted to market RAYOS or any of our other product candidates in the U.S. until we obtain regulatory approval from the FDA. To market a new drug in the U.S., we must submit to the FDA and obtain FDA approval of a new drug application, or NDA. To market a new drug in Europe, we must submit to the applicable regulatory authority in the designated Reference Member State and obtain approval of, a Marketing Authorization Application, or MAA. An NDA or MAA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate.

Regulatory approval of an NDA or an MAA is not guaranteed. The number and types of preclinical studies and clinical trials that will be required for NDA or MAA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem a product candidate to be adequately safe and effective;
- may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we do;
- may not approve the manufacturing processes or facilities associated with our product candidates;
- may conclude that we have not sufficiently demonstrated long-term stability of the formulation for which we are seeking marketing approval;
- may change approval policies (including with respect to our product candidates class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is 10 months for a standard application and six

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months for a priority review application. The FDA s review goals are subject to change, and it is unknown whether the review of an NDA filing for any of our product candidates will be completed within the FDA s review goals or will be delayed. Moreover, the duration of the FDA s review may depend on the number and types of other NDAs that are submitted to the FDA around the same time period. Generally, public concern regarding the safety of drug products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In October 2010, we submitted an MAA for DUEXIS in the United Kingdom, or UK, the Reference Member State, through the Decentralized Procedure. In February 2012, we modified the DUEXIS MAA submission to include the recently approved manufacturing site in Laval, Quebec (previously owned and operated by sanofi-aventis U.S.) through the National Procedure in the UK, which is used as the primary site to manufacture DUEXIS for the U.S. market. In connection with our MAA for DUEXIS, and consistent with an identical request we made in our NDA for DUEXIS, we are requesting the Medicines and Healthcare products Regulatory Agency in the UK to approve a formulation that is different from the formulation used in our Phase 3 clinical trials, which we determined had inadequate stability characteristics to be suitable for commercialization. As a result, we were required to demonstrate the bioequivalence of famotidine between the new and old formulations in addition to the other NDA and MAA requirements. We successfully completed this bioequivalence study prior to submitting the NDA and MAA for DUEXIS. We also demonstrated the bioequivalence of ibuprofen between the two formulations of DUEXIS and the reference labeled drug ibuprofen as part of the NDA and MAA submissions. We continue to complete CMC studies with the new formulation, and we cannot be sure that we will not have additional formulation issues related to DUEXIS or any of our other product candidates. The statutory review period for an MAA is 210 days from the date of submission, excluding any periods when the review period is stopped, but there are no guarantees that a decision on our MAA filing will take place on our anticipated timeline, if at all.

We submitted the NDA for RAYOS to the FDA on September 26, 2011, but with the exception of our approved DUEXIS NDA, we have never obtained FDA approval for any drug. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for RAYOS or our other product candidates. Even if we believe that data collected from our preclinical studies, CMC studies and clinical trials of our product candidates are promising and that our information and procedures regarding CMC are sufficient, our data may not be sufficient to support marketing approval by the FDA or any other U.S. or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. In addition, the FDA s regulatory review of NDAs for product candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. Even if approved, product candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed, restricted distribution methods or other limitations. Our business and reputation may be harmed by any failure or significant delay in obtaining regulatory approval for the sale of any of our product candidates. We cannot predict when or whether regulatory approval will be obtained for any product candidate we develop.

To market any drugs outside of the U.S., we and current or future collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed. While we anticipate that LODOTRA will be marketed in additional European Union countries as Mundipharma formulates its reimbursement strategy, the ability to market LODOTRA in additional European Union countries will depend on Mundipharma s ability to obtain regulatory and reimbursement approvals in these countries.

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Our limited operating history makes evaluating our business and future prospects difficult, and may increase the risk of any investment in our common stock.

We were incorporated as Horizon Pharma, Inc. on March 23, 2010. On April 1, 2010, we effected a recapitalization and acquisition pursuant to which we became a holding company that operates through our two wholly-owned subsidiaries, Horizon Pharma USA, Inc. (formerly known as Horizon Therapeutics, Inc.) and Horizon Pharma AG (formerly known as Nitec Pharma AG, or Nitec). Horizon Pharma USA began its operations in 2005 and Nitec began its operations in 2004. We face considerable risks and difficulties as a holding company with limited operating history, particularly as a consolidated entity with operating subsidiaries that also have limited operating histories. If we do not successfully address these risks, our business, prospects, operating results and financial condition will be materially and adversely harmed. Our limited operating history makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. For example, we recently entered into a senior secured loan facility that includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end. Should we not meet these quarterly minimum revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. While we believe, based on our current estimates that we will meet the minimum quarterly revenue covenants under the loan facility, there can be no assurance that we will. We also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if we were unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations. Moreover, we have only two products approved for commercial sale. LODOTRA has only been approved in select countries within Europe, and we have a limited history of marketing LODOTRA through our distribution partners. DUEXIS was approved in the U.S. on April 23, 2011 and we have only recently increased our commercialization activities to enable us to market DUEXIS, and we have generated limited revenues for DUEXIS to date. This limited history of commercial sales also makes evaluating our business and future prospects difficult, and may increase the risk of any investment in our common stock. We have limited experience as a consolidated operating entity, particularly with commercialization activities, and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical or biotechnology areas.

We may not realize the benefits we expected from our recapitalization and acquisition of Nitec.

In April 2010, we completed our recapitalization and acquisition of Nitec pursuant to which Horizon Pharma USA and Horizon Pharma AG became our wholly-owned subsidiaries. The integration of the businesses of our subsidiaries continues to be complex, time-consuming and expensive and may cause disruptions in the combined business. We will need to overcome significant challenges in order to realize any benefits or synergies from the acquisition of Nitec. These challenges include the timely, efficient and successful execution of a number of tasks, including the following:

- managing the regulatory and reimbursement approval processes, intellectual property protection strategies and commercialization activities of the companies, including compliance with the laws of a number of different jurisdictions;
- retaining strategic partners of each company and attracting new strategic partners;
- creating uniform standards, controls, procedures, policies and information systems, including with respect to disclosure controls and procedures and internal control over financial reporting;
- managing international operations; and
- meeting the challenges inherent in efficiently managing an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits and compliance programs.

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Many of these challenges are exacerbated by the fact that Horizon Pharma USA is a U.S.-based company and Horizon Pharma AG is a company based in Switzerland, with most of its European operations occurring through its subsidiary, Horizon Pharma GmbH, in Germany.

We may encounter difficulties successfully managing a substantially larger and internationally diverse organization and may encounter significant delays in achieving successful management of our organization. Integration of our subsidiaries operations has involved considerable risks and may not be successful. These risks include the following:

- the potential disruption of ongoing business and distraction of our management;
- the potential strain on our financial and managerial controls and reporting systems and procedures;
- our inability to manage the research and development, regulatory and reimbursement approval, both in the U.S. and in Europe, and commercialization activities of our subsidiaries; and
- the impairment of relationships with employees and suppliers as a result of any integration of new management personnel or other activities.

We may not succeed in addressing these risks or any other problems encountered in connection with the integration of our subsidiaries businesses. The inability to integrate successfully the operations, technology and personnel of our businesses, or any significant delay in achieving integration, could have a material adverse effect on our business, results of operations and prospects, and on the market price of our common stock.

We have experienced recent growth and expect to continue to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2010, we employed 41 full-time employees as a consolidated entity. In anticipation of the commercial launch of DUEXIS, we hired 80 sales representatives during the period from September 2011 through October 2011. Our management, personnel, systems and facilities currently in place may not be adequate to support this recent growth, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses. As of December 31, 2011, we employed 164 full-time employees as a consolidated entity.

We expect this growth to continue in the near term. As our commercialization plans and strategies develop, and as we continue our transition into operating as a public company, we will need to continue recruiting and training sales and marketing personnel and expect to need to expand the size of our employee base for managerial, operational, financial and other resources. Our ability to manage our planned growth effectively will require us to do, among other things, the following:

- manage the NDA review process for RAYOS and the MAA review process for DUEXIS;
- build an appropriate commercial organization and manage the sales and marketing efforts for DUEXIS and RAYOS, subject to receipt of applicable regulatory approvals;
- enhance our operational, financial and management controls, reporting systems and procedures;
- expand our international resources;

successfully identify, recruit, hire, train, maintain, motivate and integrate additional employees;

establish and increase our access to commercial supplies of our products and product candidates;

expand our facilities and equipment; and

manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators, distributors and other third parties.

Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities and towards managing these growth activities. Our future financial performance and our ability to

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execute on our business plan will depend, in part, on our ability to effectively manage any future growth and our failure to effectively manage growth could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize DUEXIS in the U.S. will be harmed.

As DUEXIS is a newly approved drug, none of the members of our sales force has ever promoted DUEXIS. As a result, we are required to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense DUEXIS. In addition, we must train our sales force to ensure that a consistent and appropriate message about DUEXIS is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of DUEXIS and its proper administration, our efforts to successfully commercialize DUEXIS could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.

We face significant competition from other biotechnology and pharmaceutical companies, including those marketing generic products, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the U.S. and international markets, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or in-licensing on an exclusive basis products that are more effective and/or less costly than DUEXIS and LODOTRA/RAYOS or any product candidates that we are currently developing or that we may develop.

DUEXIS faces competition from Celebrex®, marketed by Pfizer Inc., Vimovo®, marketed by AstraZeneca AB and Arthrotec®, marketed by Pfizer. In addition, DUEXIS faces significant competition from the separate use of NSAIDs for pain relief and GI protective medications to reduce the risk of NSAID-induced upper GI ulcers. Both NSAIDs and GI protective medications are available in generic form and may be less expensive to use separately than DUEXIS. In addition, other product candidates that contain ibuprofen and famotidine in combination, while not currently known to us, may be developed and compete with DUEXIS in the future.

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc., or Par, advising that Par has filed an Abbreviated New Drug Application, or ANDA, with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par has not advised us as to the timing or status of the FDA s review of its filing, or whether it has complied with FDA requirements for proving bioequivalence. We are evaluating the Paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to DUEXIS, but we cannot predict the outcome of this matter.

We expect LODOTRA/RAYOS will compete with a number of pharmaceuticals on the market to treat rheumatoid arthritis, or RA, including corticosteriods, such as prednisone, disease modifying antirheumatic drugs, or DMARDs, such as methotrexate, and biologic agents such as HUMIRA®, marketed by Abbott, and Enbrel®, marketed by Amgen Inc. and Pfizer. It is typical for an RA patient to take a combination of a DMARD, an oral glucocorticoid, an NSAID and/or a biologic agent. Therefore, we expect that LODOTRA/RAYOS s principal competition will be prednisone, the active pharmaceutical ingredient in LODOTRA/RAYOS, or other oral corticosteriods, which, while they may be suboptimal, are or are expected to be less expensive than

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LODOTRA/RAYOS. In addition, other product candidates that contain prednisone or other oral corticosteriods in alternative delayed release forms, while not currently known to us, may be developed and compete with LODOTRA in the future.

The availability and price of our competitors products could limit the demand, and the price we are able to charge, for DUEXIS and LODOTRA/RAYOS. We will not successfully execute on our business objectives if the market acceptance of DUEXIS or LODOTRA is inhibited by price competition, if physicians are reluctant to switch from existing products to DUEXIS or LODOTRA/RAYOS, or if physicians switch to other new products or choose to reserve DUEXIS or LODOTRA/RAYOS for use in limited patient populations.

In addition, established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license and develop novel compounds that could make our products obsolete. Our ability to compete successfully with these companies and other potential competitors will depend largely on our ability to leverage our experience in drug discovery and development to:

- discover and develop medicines that are superior to other products in the market;
- attract qualified scientific, product development and sales and marketing 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 discovery, development and commercialization of new product candidates.

In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to be approved and overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, obtaining FDA approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business. The inability to compete with existing products or subsequently introduced products would have a material adverse impact on our business, financial condition and prospects.

A variety of risks associated with operating our business and marketing our products internationally could materially adversely affect our business.

In addition to our U.S. operations, we have operations in Switzerland and Germany. Moreover, LODOTRA is currently being marketed in a limited number of European countries, and Mundipharma is in the process of obtaining pricing and reimbursement approval for, and preparing to market, LODOTRA in other European countries. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for our products;
- compliance with Swiss laws with respect to our Horizon Pharma AG subsidiary, including laws requiring maintenance of cash in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities;
- difficulties in staffing and managing foreign operations;

in certain circumstances, including with respect to the commercialization of LODOTRA in Europe, increased dependence on the commercialization efforts of our distributors or strategic partners;

compliance with German laws with respect to our Horizon Pharma GmbH subsidiary through which Horizon Pharma AG conducts most of its European operations;

foreign government taxes, regulations and permit requirements;

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- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.

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

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, sales and marketing and scientific and medical personnel, including our Chairman, President and Chief Executive Officer, Timothy P. Walbert, our Executive Vice President and Chief Financial Officer, Robert J. De Vaere, our Executive Vice President, Development, Regulatory Affairs, Manufacturing and Chief Medical Officer, Jeffrey W. Sherman, M.D., our Senior Vice President, Sales, Marketing and Business Development, Todd Smith and our Senior Vice President, Managed Care and Commercial Development, Michael Adatto. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide incentive stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Our scientific team in particular has expertise in many different aspects of drug discovery, development and commercialization, and may be difficult to retain or replace. We conduct our operations at our facilities in Deerfield, Illinois, Reinach, Switzerland and Mannheim, Germany and may face challenges recruiting personnel to these geographic locales. Moreover, these regions are headquarters to many other biopharmaceutical companies and many academic and research institutions and therefore we face increased competition for personnel in those geographies. Competition for skilled personnel in our markets is very intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms.

Despite our efforts to retain valuable employees, members of our management, sales and marketing and scientific and development teams may terminate their employment with us on short notice. Although we have written employment arrangements with all of our employees, these employment arrangements generally provide for at-will employment, which means that our employees can leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. We do not maintain key man insurance policies on the lives of these individuals or the lives of any of our other employees. Our

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success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior sales and marketing and scientific and medical personnel.

Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize products and product candidates will be limited.

If we fail to obtain and maintain approval from regulatory authorities in international markets for DUEXIS and LODOTRA and any future product candidates for which we have rights in international markets, our market opportunities will be limited and our business will be adversely impacted.

Sales of our products and product candidates outside of the U.S. will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries must also approve the manufacturing and marketing of our product candidates in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials. In many countries outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others.

We are, with respect to DUEXIS, and will be, with respect to any other product candidate for which we obtain FDA approval, subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense. Additionally, RAYOS and any other product candidate, if approved by the FDA, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we obtain for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMPs, good clinical practices, or GCPs, international conference on harmonization regulations, or ICH, and good laboratory practices, which are regulations and guidelines enforced by the FDA for all of our products in clinical development, for any clinical trials that we conduct post-approval. For example, as post-marketing requirements for DUEXIS, we are required by the FDA to develop a pediatric suspension formulation for DUEXIS and conduct three pharmacokinetic studies of the drug product in pediatric populations. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

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fines, Warning Letters or holds on clinical trials;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;

product seizure or detention, or refusal to permit the import or export of products; and

injunctions or the imposition of civil or criminal penalties.

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

Reimbursement may not be available, or may be available at only limited levels, for DUEXIS, LODOTRA/RAYOS or any other product candidates that we develop, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of DUEXIS, LODOTRA/RAYOS or any other product candidates that we may develop will depend in large part on global reimbursement policies and may be affected by future healthcare reform measures, both in the U.S. and other key international markets. Successful commercialization of our products will depend in part on the availability of governmental and third-party payer reimbursement for the cost of our products. Government health administration authorities, private health insurers and other organizations generally provide reimbursement. In particular, in the U.S., private health insurers and other third-party payers often provide reimbursement for treatments based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the U.S., the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the U.S. and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

In Europe, the success of our products, including LODOTRA and, if approved, DUEXIS, will depend largely on obtaining and maintaining government reimbursement, because in many European countries patients are unlikely to use prescription drugs that are not reimbursed by their governments. To date, LODOTRA is approved in 16 European countries and Israel and reimbursement for LODOTRA has been obtained in Germany and Italy. Mundipharma is seeking reimbursement in a number of countries in Europe and Israel and currently sells LODOTRA without reimbursed pricing in a limited number of European countries. Negotiating prices with governmental authorities can delay commercialization by 12 months or more. Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceutical products, which we believe has impacted the reimbursement rates and timing to launch for LODOTRA to date, and we expect these discounts to continue as countries attempt to manage healthcare expenditures, especially in light of current economic conditions. For example, legislation was recently enacted in Germany that will increase the rebate on prescription pharmaceuticals and likely lower the revenues from the sale of LODOTRA in Germany that we would otherwise receive. As a result of these pricing practices, it may become difficult to achieve profitability or expected rates of growth in revenue or results of operations. Any shortfalls in revenue could adversely affect our business, financial condition and results of operations.

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In light of such policies and the uncertainty surrounding proposed regulations and changes in the reimbursement policies of governments and third-party payers, we cannot be sure that reimbursement will be available for DUEXIS, for LODOTRA in any additional markets or for any other product candidates that we may develop. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize DUEXIS, LODOTRA/RAYOS or any other product candidates that we may develop.

The U.S. 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 payers in the U.S. 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 U.S., 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 U.S. 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;

- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program 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 to 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, and teaching hospitals, as defined in the PPACA and its implementing regulations, including reporting any payment or 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;

expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

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.

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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, 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 in additional downward pressure on the price that we receive for DUEXIS and any other approved product in the U.S. 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 payers.

We expect to experience pricing pressures in connection with the sale of DUEXIS, LODOTRA/RAYOS and any other products that we may develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. There may be additional pressure by payers and healthcare providers to use generic drugs that contain the active ingredients found in DUEXIS and LODOTRA/RAYOS or any other product candidates that we may develop. If we fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and expected revenue and profitability which would have a material adverse effect on our business, results of operations, financial condition and prospects. We may also experience pressure by payers to certain promotional approaches that we may implement such as co-pay programs whereby we assist patients to achieve an acceptable co-pay for our product, which may be contrary to payers financial interests.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

DUEXIS and any of our other products or product candidates that are approved by the FDA and commercialized in the U.S. may subject us directly, or indirectly through our customers, to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Federal physician self-referral laws, such as the Stark laws and state equivalents, prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician s family member has a financial interest and prohibit submission of a claim for reimbursement pursuant to a prohibited referral. Penalties for violations of the Stark laws include denial of payment, refund of payment, imposition of up to $15,000 in civil monetary penalties for each claim submitted in violation of the laws, up to $100,000 in civil monetary penalties for each arrangement or scheme that violates the laws, a civil monetary penalty of three times the amount claimed, and exclusion from participation in the Medicare program and/or other government health programs.

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The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as qui tam actions, can be brought by any individual on behalf of the government and such individuals, commonly known as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of pharmaceutical, medical device and other healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and report gifts to individual physicians in the states. Other states prohibit pharmaceutical companies from providing gifts or meals to healthcare providers or require companies to post 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. Currently, several additional states are considering similar proposals. Compliance with these laws, including the development of a comprehensive compliance program, is difficult, costly 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 applicable safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

We rely on third parties to manufacture commercial supplies of DUEXIS and LODOTRA/RAYOS, and we intend to rely on third parties to manufacture commercial supplies of any other approved products. The commercialization of any of our products could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.

The facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities. We do not control the manufacturing processes of third-party manufacturers and are currently completely dependent on our third-party manufacturing partners Pharmaceutics International, Inc., located in Hunt Valley, Maryland, and sanofi-aventis U.S. LLC, or sanofi-aventis U.S., and operating through its affiliate sanofi-aventis Canada Inc., located in Laval, Canada for production of DUEXIS, and Jagotec AG, a wholly-owned subsidiary of SkyePharma PLC and operating through its affiliate SkyePharma SAS, located in Lyon, France, for production of LODOTRA. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to the Aenova France SAS, or Aenova. As such, Aenova is now a subcontractor for Jagotec for the manufacture of LODOTRA, with our consent. Bayer Schering Pharma AG in Germany has been qualified as a backup manufacturer. In December 2011, Valeant Pharmaceuticals International, Inc., or Valeant, acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. We purchase the primary active ingredients for DUEXIS from BASF Corporation in Bishop, Texas and Dr. Reddy s Laboratories in India, and the primary active ingredient for LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and Sanofi-Aventis SA in France. If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing

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facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to supply our primary active ingredients or manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products.

Pharmaceutics International performs manufacturing services related to DUEXIS for us pursuant to a master services agreement under which we submit work orders for specific services. Pharmaceutics International is not obligated to accept any work orders that we submit in the future and we cannot be certain that Pharmaceutics International will continue to be willing to perform manufacturing services related to DUEXIS on acceptable terms to us or at all. In May 2011, we entered into a long-term supply and manufacturing agreement with sanofi-aventis U.S. for the manufacture of DUEXIS. In December 2011, Valeant acquired the Dermik dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S.

Although we have entered into supply agreements for the manufacture of our products, our manufacturers may not perform as agreed or may terminate their agreements with us. Under our manufacturing and supply agreement with sanofi-aventis U.S., either we or sanofi-aventis U.S. may terminate the agreement upon an uncured breach by the other party or without cause upon two years prior written notice, so long as such notice is given after the third anniversary of the first commercial sale of DUEXIS. Under our manufacturing and supply agreement with Jagotec, either we or Jagotec may terminate the agreement in the event of an insolvency, liquidation or bankruptcy of the other party or upon an uncured breach by the other party. While we have the right to receive a continuing supply of LODOTRA from Jagotec for a period of 24 months after termination, we cannot assure you that we would be able to establish another commercial supply of LODOTRA in that time-frame, or qualify any new supplier with the applicable regulatory authorities on a timely basis or at all.

In addition, we do not have the capability to package DUEXIS, LODOTRA/RAYOS or any other product candidates for distribution. Consequently, we have entered into an agreement with Temmler Werke GmbH for packaging of LODOTRA in 16 European countries, Israel and in the U.S. if RAYOS is approved by the FDA, as well as any additional countries as may be agreed to by the parties. If we obtain marketing approval from the applicable regulatory authorities including the FDA, we intend to sell drug product finished and packaged by either Temmler Werke GmbH or an alternate packager. Sanofi-aventis Canada Inc. will manufacture and supply DUEXIS to us in final, packaged form in North America and certain countries and territories in Europe, including the European Union member states and Scandinavia, and South America.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Though we believe we have resolved any stability issues with respect to the commercial formulation of DUEXIS, we cannot assure you that any other stability or other issues relating to the manufacture of any of our products will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to launch DUEXIS and LODOTRA in the U.S. or provide any product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in our ability to meet commercial demand for DUEXIS or LODOTRA/RAYOS will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

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Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

We are dependent on Mundipharma to commercialize LODOTRA in Europe and certain Asian, Latin American and other countries. Failure of Mundipharma or any other third parties to successfully commercialize our products and product candidates in the applicable jurisdictions could have a material adverse effect on our business.

We rely on Mundipharma for commercialization of LODOTRA in various European countries and certain Asian, Latin American and other countries. We have limited contractual rights to force Mundipharma to invest significantly in commercialization of LODOTRA in its markets. In the event that Mundipharma or any other third party with any future commercialization rights to any of our products or product candidates fails to adequately commercialize those products or product candidates because it lacks adequate financial or other resources, decides to focus on other initiatives or otherwise, our ability to successfully commercialize our products or product candidates in the applicable jurisdictions would be limited, which would adversely affect our business, financial condition, results of operations and prospects. We also rely on Mundipharma s ability to obtain regulatory approval for LODOTRA in certain Asian, Latin American and other countries. In addition, our agreements with Mundipharma may be terminated by either party in the event of a bankruptcy of the other party or upon an uncured material breach by the other party. If Mundipharma terminated its agreements with us, we may not be able to secure an alternative distributor in the applicable territory on a timely basis or at all, in which case our ability to generate revenues from the sale of LODOTRA would be materially harmed.

DUEXIS, LODOTRA/RAYOS or any other product candidate that we develop may cause undesirable side effects or have other properties that could delay or prevent regulatory approval or commercialization or have a significant impact on customer demand.

Undesirable side effects caused by any product candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, or cause us to evaluate the future of our development programs. In our two Phase 3 trials with DUEXIS, the most commonly reported treatment-emergent adverse events were nausea, dyspepsia, diarrhea, constipation and upper respiratory tract infection. The most commonly reported treatment-emergent adverse events in the Phase 3 clinical trials with LODOTRA/RAYOS included flare in RA-related symptoms, abdominal pain, nasopharyngitis, headache, flushing, upper respiratory tract infection, back pain and weight gain. In addition, the FDA or other regulatory authorities may require, or we may undertake, additional clinical trials to support the safety profile of our product candidates.

In addition, if DUEXIS, LODOTRA/RAYOS or any other product candidate that we may develop that receives marketing approval and we or others later identify undesirable side effects caused by the product, or there is a perception that the product is associated with undesirable side effects:

- regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;
- regulatory authorities may withdraw their approval of the product or place restrictions on the way it is prescribed; and
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product or implement a risk evaluation and mitigation strategy.

If any of these events occurred with respect to DUEXIS or LODOTRA/RAYOS, our ability to generate significant revenues from the sale of these products would be significantly harmed.

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We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or if they experience regulatory compliance issues, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have agreements with third-party contract research organizations, or CROs, to conduct our clinical programs and anticipate that we may enter into other such agreements in the future regarding our other product candidates. We rely heavily on these parties for the execution of our clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol. We and our CROs are required to comply with current GCP or ICH regulations. The FDA enforces these GCP or ICH regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP or ICH regulations, the data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCP or ICH regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our products and product candidates. As a result, our results of operations and the commercial prospects for our products and product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition or prospects.

In addition, pursuant to a March 2011 letter agreement and in connection with our waiver of certain milestone payments, Mundipharma has agreed to conduct a separate clinical trial for LODOTRA for the potential treatment of polymyalgia rheumatica, or PMR, which we expect will be a Phase 3 clinical trial. We have limited control over the timing and implementation of the planned clinical trial and Mundipharma may carry the clinical trial out in a manner that does not maximize the trial s chances of success or could lead to trial results that harm our and Mundipharma s ability to market LODOTRA as a treatment for RA. If Mundipharma does not begin or complete the trial on the timelines that we anticipate, or at all, our ability to obtain marketing approval for LODOTRA/RAYOS for the treatment of PMR will be delayed, and our business prospects would be harmed. While we have the right to use any data resulting from the planned clinical trial, we may not own the results from the trial, which could make it more difficult to pursue the development of LODOTRA/RAYOS as a treatment for PMR on our own.

We also, as part of the April 23, 2011 FDA approval of DUEXIS, have a commitment under the Pediatric Research Equity Act, or PREA, to conduct an assessment of the safety and effectiveness of the product for the

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claimed indication in pediatric patients. Although we are committed to carrying out these commitments, there are challenges in conducting studies in pediatric patients including availability of patients and obtaining parental informed consent.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical testing.

To the extent that we are required to conduct additional clinical development of DUEXIS or LODOTRA/RAYOS or we conduct clinical development of our earlier stage product candidates or additional indications for LODOTRA/RAYOS, we may experience delays in these clinical trials. We are in the process of investigating LODOTRA through an investigator-initiated Phase 2 study as a potential treatment for PMR and pursuant to a March 2011 letter agreement, Mundipharma has agreed to conduct a separate clinical trial for LODOTRA/RAYOS in this indication, which we expect will be a Phase 3 clinical trial. Additionally, we have several earlier stage product candidates to treat pain-related diseases including TRUNOC (tarenflurbil) for the treatment of pain-related diseases and HZN-602, a single pill combination of naproxen and famotidine, for reducing the risk of NSAID-induced upper GI ulcers in patients with mild to moderate pain and arthritis who require the use of naproxen. While we are currently not focusing any resources on these potential product candidates, we do not know whether any additional clinical trials will be initiated in the future, begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement with the FDA on any SPAs we submit;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board or ethics committee approval at each site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial;
- adding new sites; or
- manufacturing sufficient quantities of product candidates for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians and patients perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we expect to rely on CROs and

clinical trial sites to ensure the proper and timely conduct of our future clinical trials and while we intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

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We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our collaborators, the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or if we terminate, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

If we fail to develop and commercialize other product candidates or products, our business and prospects would be limited.

A key element of our strategy is to develop or in-license and commercialize a portfolio of other product candidates in addition to DUEXIS and LODOTRA/RAYOS. Since we do not have proprietary drug discovery technology, the success of this strategy depends in large part upon the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license clinically enabled product candidates for the treatment of pain-related diseases or that otherwise fit into our development plans on terms that are acceptable to us. Identifying, selecting and acquiring or licensing promising product candidates requires substantial technical, financial and human resources and technical expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management s time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects will be limited.

Moreover, any product candidate we identify, select and acquire or license will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risk of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

In addition, if we fail to successfully commercialize and further develop DUEXIS and LODOTRA/RAYOS, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates to follow these lead product candidates, and our business and prospects would therefore be harmed.

We may seek to engage in strategic transactions that could have a variety of negative consequences, and we may not realize the benefits of such transactions or attempts to engage in such transactions.

From time to time, we may seek to engage in strategic transactions with third parties, such as acquisitions of companies or divisions of companies, asset purchases, or in-licensing of product candidates or technologies that we believe will complement or augment our existing business. We may also consider a variety of other business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business

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combinations and other investments. Any such transaction may require us to incur non-recurring and other charges, increase our near and long-term expenditures, pose significant integration challenges, require additional expertise, result in dilution to our existing stockholders and disrupt our management and business, which could harm our operations and financial results. Moreover, we face significant competition in seeking appropriate strategic partners and transactions, and the negotiation process for any strategic transaction can be time-consuming and complex. In addition, we may not be successful in our efforts to engage in certain strategic transactions because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential. There is no assurance that, following the consummation of a strategic transaction, we will achieve the anticipated revenues or net income that justifies such transaction. Any failures or delays in entering into strategic transactions could also delay or negatively impact the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. In addition, any failures or delays in entering into strategic transactions anticipated by analysts or the investment community could result in a decline in our stock price.

Business interruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. While we carry insurance for certain of these events, the occurrence of any of these business interruptions could seriously harm our business and financial condition and increase our costs and expenses. A majority of our management operates in our principal executive offices located in Deerfield, Illinois. If our Deerfield offices were affected by a natural or man-made disaster or other business interruption, our ability to manage our domestic and foreign operations could be impaired, which could materially and adversely affect our results of operations and financial condition. We currently rely, and intend to rely in the future, on third-party manufacturers, located in Hunt Valley, Maryland, Laval, Quebec, Canada, St. Louis, Missouri and Lyon, France, to produce our products. Our ability to obtain commercial supplies of our products could be disrupted, and our results of operations and financial condition could be materially and adversely affected if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The ultimate impact of such events on us, our significant suppliers and our general infrastructure is unknown.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the commercial sales of DUEXIS and LODOTRA/RAYOS and the clinical testing of our product candidates. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products or product candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;

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a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenue;

exhaustion of any available insurance and our capital resources;

an event of default under our $60.0 million senior secured loan;

the inability to commercialize our products or product candidates; and

a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies and commercial product sales in the amount of $10 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of DUEXIS and/or the commercial launch of LODOTRA/RAYOS in additional markets, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our business involves the use of hazardous materials, and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers are subject to federal, state and local as well as foreign laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state, federal or foreign authorities may curtail the use of these materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage. If we are subject to any liability as a result of our third-party manufacturers activities involving hazardous materials, our business and financial condition may be adversely affected. In the future we may seek to establish longer term third-party manufacturing arrangements, pursuant to which we would seek to obtain contractual indemnification protection from such third-party manufacturers potentially limiting this liability exposure.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range

of pricing, discounting, marketing and promotion,

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sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to Our Financial Position and Capital Requirements

We have incurred significant operating losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

We have a limited operating history. We have financed our operations primarily through equity and debt financings and have incurred significant operating losses since our inception. We had a net loss of $113.3 million, $27.1 million and $20.5 million for the years ended December 31, 2011, 2010 and 2009, respectively. As of December 31, 2011, we had an accumulated deficit of $220.3 million. We do not know whether or when we will become profitable. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders deficit and working capital. Our losses have resulted principally from costs incurred in our development activities for our products and product candidates. We anticipate that our operating losses will substantially increase over the next several years as we execute our plan to expand our development and commercialization activities of DUEXIS and LODOTRA/RAYOS.

We have limited product revenues and other sources of revenues. We may never achieve or sustain profitability, which would depress the market price of our common stock, and could cause our investors to lose all or a part of their investment.

Our ability to become profitable depends upon our ability to generate revenues from sales of our products. DUEXIS was approved by the FDA on April 23, 2011, and we began generating limited revenues from sales of DUEXIS in late 2011 following the commercial launch in the U.S. LODOTRA is approved for marketing in Europe, and to date we have generated only limited revenues from sales of LODOTRA. We may never be able to successfully commercialize DUEXIS or develop or commercialize other products or sell RAYOS in the U.S., which we believe represents its most significant commercial opportunity, or sell DUEXIS in Europe. Our ability to generate future revenues depends heavily on our success in:

- commercializing DUEXIS, RAYOS and any other product candidates for which we obtain approval;
- securing U.S. and additional foreign regulatory approvals for LODOTRA/RAYOS and foreign regulatory approvals for DUEXIS; and
- developing and commercializing a portfolio of other product candidates in addition to DUEXIS and LODOTRA/RAYOS.

Even if we do generate additional product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

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The terms of our senior debt facility require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In February 2012, we entered into a $60.0 million senior secured loan with a group of institutional lenders, which we refer to as the Senior Secured Loan. The Senior Secured Loan is secured by a lien covering substantially all of our U.S. based assets including intellectual property and we also pledged as collateral all of our equity interests in Horizon Pharma USA, Inc. and 65% of our equity interests in Horizon Pharma AG.

The loan agreements governing the Senior Secured Loan contain customary affirmative and negative covenants and events of default. Among the affirmative covenants are covenants requiring us to maintain a minimum level of at least $10.0 million in liquidity at all times during the term of the loan unless our quarterly consolidated EBITDA is at least $6.0 million, and to achieve minimum net revenues during specified trailing 12 month periods beginning with the 12 month period ended June 30, 2012. Should we not meet these quarterly minimum revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. While we believe, based on our current estimates that we will meet the minimum quarterly revenue covenants under the loan facility, there can be no assurance that we will. We also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if we were unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations. The negative covenants include, among other things, restrictions on transferring or licensing our assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on our assets, in each case subject to customary exceptions. Further, our lenders may require us to make prepayments of loan principal if we receive net cash proceeds from certain transfers or licenses of our assets or as a result of the loss or destruction of our assets, or if we undergo a change in control. Beginning with our second fiscal quarter of 2013 and in any fiscal quarter thereafter, our lenders may require that we prepay up to an aggregate of approximately $4.0 million for each quarter for which we receive a prepayment request. In addition, if we default under our Senior Secured Loan, our lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, our lenders right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Our lenders could declare a default under our Senior Secured Loan upon the occurrence of any event that the lenders interpret as having a material adverse effect upon us as defined under the loan agreements, thereby requiring us to repay the loans immediately or to attempt to reverse the lenders declaration through negotiation or litigation. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We may need to obtain additional financing even after the recently completed debt and equity financings to successfully commercialize or further develop DUEXIS and LODOTRA/RAYOS, develop other product candidates or continue our other research and development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- launch and commercialize DUEXIS and, if approved, RAYOS in the U.S., including expanding our own sales force in the U.S.;
- complete the regulatory approval process, and any future required clinical development related thereto, for DUEXIS and RAYOS;
- launch and commercialize any other product candidates for which we obtain regulatory approval; and

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- continue our research and development programs to advance our product pipeline in the future, including future clinical trials with respect to LODOTRA/RAYOS for additional indications.

We believe that our existing cash and cash equivalents, including net proceeds from our recently completed debt and equity financings, together with interest thereon, will be sufficient to fund our operations into the second half of 2013. We may need to raise additional funds sooner if we choose to expand our commercialization or development efforts more rapidly than we presently anticipate or our revenues do not meet expectations. We will also require additional capital if the FDA requires us to conduct additional clinical trials with respect to RAYOS.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives. We also could be required to:

- seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or

- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Even if we obtain additional financing, our Horizon Pharma AG subsidiary is subject to Swiss laws regarding overindebtedness that require Horizon Pharma AG to maintain assets in excess of its liabilities. Our Swiss subsidiary was overindebted as of December 31, 2011 and we continue to monitor and review steps to address the overindebtedness. In order to comply with these laws, we may be required to have cash at our Swiss subsidiary in excess of its near term operating needs and could limit the amount of cash available to our U.S. subsidiary. If we are unable to allocate sufficient cash to our U.S. subsidiary, even if we have sufficient cash on a consolidated basis, our ability to execute our U.S. business plan may be harmed.

Any of the above events could significantly harm our business, financial condition and prospects and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish intellectual property rights to our product candidates.

We may seek additional capital through a combination of private and public equity offerings, debt financings, receivables or royalty financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing stockholders ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

While we have restrictions on the usage of the funds from our debt facility through debt covenants, we have broad discretion in the use of our cash from the recent equity financing and may not use it effectively.

Our management has broad discretion in the application of our cash, and investors will be relying on the judgment of our management regarding the use of our cash. Our management may not apply our cash in ways

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that ultimately increase the value of any investment in our securities. We expect to use our existing cash to fund U.S. commercialization activities for DUEXIS and pre-commercialization activities for RAYOS, to fund additional regulatory approvals of DUEXIS and RAYOS, to fund development of LODOTRA/RAYOS for other indications and our other product candidates and for working capital, capital expenditures and general corporate purposes. We may also invest our cash in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause the price of our common stock to decline.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have concluded that as a result of our acquisition of Nitec and related transactions occurring on April 1, 2010, we have triggered an ownership change limitation and that we will be subject to annual limits on our ability to utilize net operating loss carryforwards. We estimate that these annual limits will be $49.9 million, $18.1 million and $16.9 million for 2012, 2013 and 2014, respectively, and will be cumulative such that any use of the carryforwards below the limitation in one year will result in a corresponding increase in the limitation for the subsequent tax year. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including potentially as a result of our recent debt and equity financings. Any limitation on our ability to use our net operating loss carryforwards will likely increase the taxes we would otherwise pay in future years if we were not subject to such limitations.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon commercialization or development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At December 31, 2011, we had $18.0 million of cash and cash equivalents consisting of cash and money market funds. Subsequent to December 31, 2011, we received net proceeds of $34.0 million from the Senior Secured Loan, which was completed on February 22, 2012, and net proceeds of $47.7 million from an equity financing, which was completed on March 2, 2012. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, 2011, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities owned by us.

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Changes in accounting rules or policies may affect our financial position and results of operations.

U.S. generally accepted accounting principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations. In addition, the consolidation of Horizon Pharma AG and Horizon Pharma USA adds additional complexity to the application of U.S. generally accepted accounting principles. Changes in the application of existing rules or guidance applicable to us or our wholly-owned subsidiaries could significantly affect our consolidated financial position and results of operations.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the U.S. or in other foreign countries. If this were to occur, early generic competition could be expected against DUEXIS, LODOTRA/RAYOS and other product candidates in development. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in DUEXIS and LODOTRA/RAYOS have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. On February 15, 2012, we received a Paragraph IV Patent Certification from Par, advising that Par has filed an ANDA with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par has not advised us as to the timing or status of the FDA s review of its filing, or whether it has complied with FDA requirements for proving bioequivalence. We are evaluating the Paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to DUEXIS, but we cannot predict the outcome of this matter. Any adverse outcome in this matter could result in one or more generic versions of DUEXIS being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of DUEXIS and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to DUEXIS and LODOTRA/RAYOS fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them, and threaten our ability to commercialize, our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market DUEXIS and LODOTRA/RAYOS under patent protection could be reduced. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to DUEXIS and LODOTRA/RAYOS or our other product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the U.S. can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to

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enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

The Leahy-Smith America Invents Act, or the Leahy-Smith Act, was recently signed into law and includes a number of significant changes to U.S. patent law. These include changes in the way patent applications will be prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office is currently developing regulations and procedures to administer 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 not clear what, if any, impact the Leahy-Smith Act will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our patent applications and our ability to enforce or defend our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. and Canada. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the U.S. PTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of DUEXIS and LODOTRA/RAYOS and/or our other product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

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Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, we could lose license rights that are important to our business.

We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. For example, we hold an exclusive license to SkyePharma AG s proprietary technology and know-how covering the delayed release of corticosteroids relating to LODOTRA/RAYOS. If we fail to comply with our obligations under our agreement with SkyePharma or our other license agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license, including LODOTRA/RAYOS.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to Ownership of our Common Stock

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

Prior to our initial public offering there was no market for shares of our common stock. Although our common stock is listed on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained. Further, an inactive market may impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The price of our stock is likely to be highly volatile, and you could lose all or part of your investment.

The trading price of our common stock following the completion of our initial public offering has been highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this Risk Factors section and elsewhere in this prospectus, these factors include:

- our failure to successfully execute our commercialization strategy with respect to our approved products, particularly our commercial launch of DUEXIS in the U.S.;

- any adverse development or perceived adverse development with respect to the FDA s review of our RAYOS NDA or the Medicines and Healthcare products Regulatory Agency s review of our MAA for

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DUEXIS filed in the European Union through the Decentralized Procedure, and amended in February 2012 through the National Procedure in the UK;

disputes or other developments relating to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products and product candidates;

unanticipated serious safety concerns related to the use of DUEXIS, LODOTRA/RAYOS or any of our other product candidates;

adverse regulatory decisions;

changes in laws or regulations applicable to our products or product candidates, including but not limited to clinical trial requirements for approvals;

inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;

developments concerning our commercial partners, including but not limited to those with our sources of manufacturing supply;

our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

adverse results or delays in clinical trials;

our failure to successfully develop additional product candidates;

introduction of new products or services offered by us or our competitors;

our inability to effectively manage our growth;

overall performance of the equity markets and general political and economic conditions;

failure to meet or exceed revenue and financial projections we may provide to the public;

actual or anticipated variations in quarterly operating results;

failure to meet or exceed the estimates and projections of the investment community;

publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

our inability to successfully enter new markets;

the termination of a collaboration or the inability to establish additional collaborations;

announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

our inability to maintain an adequate rate of growth;

ineffectiveness of our internal controls;

additions or departures of key scientific or management personnel;

issuances of debt or equity securities;

significant lawsuits, including patent or stockholder litigation;

changes in the market valuations of similar companies;

sales of our common stock by us or our stockholders in the future;

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trading volume of our common stock;

effects of natural or man-made catastrophic events or other business interruptions; and

other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The NASDAQ Global Market and the stocks of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of our Senior Secured Loan, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the increase, if any, of our stock price.

Our directors and principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our directors, five percent or greater stockholders and their respective affiliates held in the aggregate approximately 67% of our outstanding voting stock as of December 31, 2011. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission, or the SEC, and the NASDAQ Stock Market, Inc., or NASDAQ, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations will make it more difficult and more expensive for us to obtain and maintain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. If we fail to comply with the continued listing requirements of NASDAQ, our common stock could be delisted from The NASDAQ Global Market, which would adversely affect the liquidity of our common stock and our ability to obtain future financing.

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The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we will be required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report, commencing in our annual report on Form 10-K for the year ending December 31, 2012, on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Unless we qualify for an exemption as a non-accelerated filer under the Dodd-Frank Wall Street Reform and Consumer Protection Act, our independent registered public accounting firm will also be required to deliver an attestation report on the effectiveness of our internal control over financial reporting. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts, particularly because of our holding company structure and international operations. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we or our independent registered public accounting firm identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our common stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act and rules adopted by the SEC and by NASDAQ, would likely result in increased costs to us as we respond to their requirements.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The lock-up agreements pertaining to our initial public offering expired on January 29, 2012. Upon the expiration of the lock-up agreements, a substantial number of shares of common stock became eligible for sale in the public market, subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, with respect to any of these shares held by directors, executive officers and other affiliates. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans are or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain holders of shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to decline.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions

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at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in subsequent transactions, our existing stockholders may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our 2011 equity incentive plan, or 2011 EIP, our board of directors is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under our 2011 EIP will automatically increase on January 1 of each year starting January 1, 2012 by an amount equal to the lesser of 5% of our capital stock outstanding as of December 31 of the preceding calendar year or 1,474,304 shares, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. In addition, our board of directors may grant or provide for the grant of rights to purchase shares of our common stock pursuant to the terms of the 2011 employee stock purchase plan, or 2011 ESPP. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each year starting January 1, 2012 by an amount equal to the lesser of 4% of our capital stock outstanding as of December 31 of the preceding calendar year or 1,053,074, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year.

On December 15, 2011, pursuant to the terms of our 2011 EIP and 2011 ESPP, our board of directors approved increases in the number of shares available for issuance under the 2011 EIP and the 2011 ESPP of 672,500 shares and 100,000 shares, respectively, effective as of January 1, 2012. Shares available for issuance under the 2011 EIP and 2011 ESPP were initially registered on a registration statement on Form S-8 filed with the Securities and Exchange Commission on July 28, 2011.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management. These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. We are also subject to certain anti-takeover provisions under Delaware law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of

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delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We may become involved in securities class action litigation that could divert management s attention and harm our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Even if we are successful in defending against any such claims, litigation could result in substantial costs and be a distraction to management, and may result in unfavorable results that could adversely impact our financial condition and prospects.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We occupy approximately 21,200 square feet of space in our headquarters in Deerfield, Illinois under a lease that expires on June 30, 2018. We also occupy approximately 7,400 square feet of office space in Mannheim, Germany under a lease that expires on December 31, 2012 and approximately 3,200 square feet of office space in Reinach, Switzerland under a lease that expires on May 31, 2015. We have no laboratory, research or manufacturing facilities. We believe that our current facilities are adequate for our needs and that, should it be needed, suitable additional space or renewal of our existing leases will be available to accommodate expansion of our operations on commercially reasonable terms.

Item 3. Legal Proceedings

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc., or Par, advising that Par has filed an Abbreviated New Drug Application, or ANDA, with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par has not advised us as to the timing or status of the FDA s review of its filing, or whether it has complied with FDA requirements for proving bioequivalence. We are evaluating the Paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to DUEXIS. All of our issued U.S. patents covering DUEXIS are listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange

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Book. Under the FDA s rules and regulations, if we initiate a patent infringement suit to defend the patents identified in the Paragraph IV notice within 45 days after the FDA s receipt of the notice, the FDA would be prevented from approving the ANDA until the earlier of 30 months or a decision in the infringement case that each of the patents are not infringed or invalid.

Item 4. Mine Safety Disclosures

None.

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PART II

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

Market Information

Our common stock began trading on The NASDAQ Global Market on July 28, 2011 under the symbol HZNP. Prior to such time, there was no public market for our common stock. The following table sets forth the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market for the period indicated.

	Price Range	
	High	**Low**
Year Ended December 31, 2011		
Third Quarter (commencing July 28, 2011)	$ 9.34	$ 6.85
Fourth Quarter	$ 8.99	$ 3.86

Holders of Record

The closing price for our common stock as of March 15, 2012 was $3.62. As of March 15, 2012, there were approximately 130 holders of record of our common stock.

Performance Graph

The following graph shows a comparison from July 28, 2011 (the date our common stock commenced trading on The NASDAQ Global Market) through December 30, 2011 of the cumulative total return for our common stock, the NASDAQ US Index and the NASDAQ Pharmaceutical Index. The graph assumes an initial investment of $100 on July 28, 2011. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.

The foregoing graph and table are furnished solely with this report, and are not filed with this report, and shall not be deemed incorporated by reference into any other filing under the Securities Act or the Exchange Act, whether made by us before or after the date hereof, regardless of any general incorporation language in any such filing, except to the extent we specifically incorporate this material by reference into any such filing.

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Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K regarding information about securities authorized for issuance under our equity compensation plans.

Recent Sales of Unregistered Securities

Since January 1, 2011, we have issued and sold the following unregistered securities (excluding those previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K):

1. During 2011, prior to the effectiveness of our Registration Statement on Form S-8, we issued and sold an aggregate of 6,400 shares of our common stock to our employees and consultants at prices ranging from $5.20 per share to $12.94 per share for an aggregate of $0.1 million pursuant to exercises of options granted under our 2005 Stock Plan.

2. In January 2011, pursuant to an amendment to the Series B Preferred Stock and Subordinated Convertible Note Purchase Agreement we issued $5.0 million in aggregate principal amount of convertible promissory notes, or the January 2011 notes, to accredited investors. The January 2011 notes accrued interest at 10% per year. The January 2011 notes were converted into 590,606 shares of common stock upon the completion of our initial public offering.

3. In November 2011, 81,663 warrants were exercised using the net settlement election resulting in the purchase of 81,348 shares of common stock.

4. In February 2012, in connection with our $60.0 million senior secured loan, we issued warrants to purchase an aggregate of 3,277,191 shares of our common stock at an exercise price of $0.01 per share. The warrants expire on January 22, 2017.

5. In March 2012, we received gross proceeds of $50.8 million from the sale of 14,033,829 shares of our common stock and warrants to purchase an aggregate of 3,508,448 shares of our common stock with an exercise price of $4.308 per share to certain institutional and accredited investors in a private placement. For each share of common stock purchased, the investors received a warrant to purchase 0.25 of a share of common stock. The warrants will expire on March 2, 2017 and may be exercised for cash or, if the current market price of our common stock is greater than the per share exercise price, by surrender of a portion of the warrant in a cashless exercise.

6. In March 2012, 42,122 warrants were exercised using the net settlement election resulting in the purchase of 41,797 shares of common stock.

The offers, sales and issuances of the securities described in paragraph (1) were deemed to be exempt from registration under the Securities Act of 1933, as amended, or the Securities Act, in reliance upon Rule 701 promulgated under the Securities Act, as transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701, or Section 4(2) of the Securities Act.

The offers, sales and issuances of the securities described in paragraphs (2), (3), (4), (5) and (6) were deemed to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection

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with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D.

No underwriters were involved in the foregoing sales of securities.

Issuer Repurchases of Equity Securities

None.

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-168504) that was declared effective by the Securities and Exchange Commission on July 28, 2011, which registered $75.9 million worth of shares of our common stock. On August 2, 2011, we sold 5,500,000 shares of common stock at an initial public offering price of $9.00 per share, for aggregate gross proceeds of $49.5 million. Of the net proceeds, as of December 31, 2011, we had used $25.1 million for working capital and general corporate expenses. The remainder of net proceeds has been invested in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government in accordance with our investment policy. We expect our use of the net proceeds from the initial public offering will conform to the intended use of proceeds as described in the final prospectus for the offering filed with the SEC pursuant to Rule 424(b).

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Item 6. Selected Financial Data

The selected statement of operations data for the years ended December 31, 2011, 2010 and 2009, and the balance sheet data as of December 31, 2011 and 2010 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statement of operations data for the years ended December 31, 2008 and 2007, and the balance sheet data as of December 31, 2009, 2008 and 2007 have been derived from audited financial statements which are not included in this Annual Report on Form 10-K.

The following selected financial data also reflects the 1-for-2.374 reverse stock split of our outstanding common stock effected in July 2011.

Our historical results are not necessarily indicative of future results. The selected financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K (amounts in thousands, except per share data).

	Year Ended December 31,				
	2011	2010	2009	2008	2007
Statement of Operations Data:					
Sales of goods	$ 6,773	$ 2,376	$	$	$
Contract revenue	166				
Gross revenues	6,939	2,376			
Sales discounts and allowances	(12)				
Net revenues	6,927	2,376			
Cost of goods sold	(7,267)	4,263			
Gross loss	(340)	(1,887)			
Operating expenses:					
Research and development	15,358	17,697	10,894	22,295	24,483
Sales and marketing	20,314	5,558	2,072	1,337	617
General and administrative	15,008	18,612	5,823	3,235	1,640
Intangible impairment charge	69,621				
Total operating expenses	120,301	41,867	18,789	26,867	26,740
Loss from operations	(120,641)	(43,754)	(18,789)	(26,867)	(26,740)
Interest (expense) income, net	(6,284)	(3,024)	(2,189)	(529)	928
Bargain purchase gain		19,326			
Other income (expense), net			478	(503)	(35)
Foreign exchange loss, net	(1,023)	(273)			
Loss before income tax	(127,948)	(27,725)	(20,500)	(27,899)	(25,847)
Income tax benefit	(14,683)	(660)			
Net loss	$ (113,265)	$ (27,065)	$ (20,500)	$ (27,899)	$ (25,847)
Capital contribution			3,489		
Net loss attributable to common stockholders	(113,265)	$ (27,065)	$ (17,011)	$ (27,899)	$ (25,847)
Net loss per share, basic and diluted	$ (12.56)	$ (21.16)	$ (40.65)	$ (68.01)	$ (66.29)
Weighted average number of shares outstanding	9,014,968	1,279,133	418,520	410,206	389,926

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	As of December 31,				
	2011	2010	2009	2008	2007
Balance Sheet Data:					
Cash and cash equivalents	$ 17,966	$ 5,384	$ 7,160	$ 14,067	$ 20,824
Working capital (deficit)	1,065	(17,944)	(905)	(628)	21,044
Total assets	101,078	161,685	8,213	14,955	23,404
Long-term debt, net of current portion	15,834	10,395	3,133	7,749	1,604
Convertible preferred stock warrant liabilities				657	181
Accumulated deficit	(220,317)	(107,052)	(79,987)	(59,487)	(31,588)
Total stockholders equity (deficit)	45,912	97,056	(3,177)	(8,454)	19,275

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the Risk Factors section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

The discussion below contains forward-looking statements, as defined in Section 21E of the Exchange Act, that reflect our current expectations regarding our future growth, results of operations, cash flows, performance and business prospects and opportunities, as well as assumptions made by, and information currently available to, our management. We have tried to identify forward-looking statements by using words such as anticipate, believe, plan, expect, intend, will, and similar expressions, but these words are not the exclusive means of identifying forward-looking statements. These statements are based on information currently available to us and are subject to various risks, uncertainties, and other factors, including, but not limited to, those matters discussed in Item 1A Risk Factors in Part I of this Annual Report on Form 10-K, that could cause our actual growth, results of operations, cash flows, performance and business prospects and opportunities to differ materially from those expressed in, or implied by, these statements. Except as expressly required by the federal securities laws, we undertake no obligation to update such factors or to publicly announce the results of any of the forward-looking statements contained herein to reflect future events, developments, or changed circumstances, or for any other reason.

As used in this Annual Report on Form 10-K, the terms we, us, our, Horizon Pharma, and the Company refer to Horizon Pharma, Inc. and its wholly-owned subsidiaries. Dollars are presented in millions unless otherwise stated.

Overview

We are a biopharmaceutical company that is developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases. On April 23, 2011, the U.S. Food and Drug Administration, or FDA, approved DUEXIS® (formerly HZT-501), a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis, or RA, and osteoarthritis, or OA, and to decrease the risk of developing upper gastrointestinal, or GI, ulcers in patients who are taking ibuprofen for these indications. On November 14, 2011, we and sanofi-aventis U.S. LLC, or sanofi-aventis U.S., announced the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. In December 2011, Valeant Pharmaceuticals International, Inc., or Valeant, acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. We have hired our initial commercial organization and completed sales force training, and we began detailing DUEXIS to physicians in December 2011 and held our launch meeting for DUEXIS in the U.S. in January 2012. In October 2010, we submitted a Marketing Authorization Application, or MAA, for DUEXIS in the United Kingdom, or UK, the Reference Member State, through the Decentralized Procedure. In February 2012, we modified the DUEXIS MAA submission to include the recently approved manufacturing site in Laval, Quebec through the National Procedure in UK. We anticipate a decision on the MAA in the second half of 2012. Our other lead product, LODOTRA®, known as RAYOS® in the U.S., is a proprietary programmed release formulation of low-dose prednisone that is currently marketed in Europe by our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for the treatment of moderate to severe, active RA in adults when accompanied by morning stiffness. We have successfully completed two Phase 3 clinical trials of LODOTRA/RAYOS and we submitted a new drug application, or NDA, for RAYOS to the FDA on September 26, 2011. As

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a result, we have a Prescription Drug User Fee Act, or PDUFA, goal date for RAYOS of July 26, 2012. We have worldwide marketing rights for DUEXIS and have retained exclusive marketing rights in the U.S. for all of our products. Our strategy is to commercialize our products in the U.S., to explore co-promotion opportunities for DUEXIS in the U.S. and to enter into licensing or additional distribution agreements for commercialization of our products outside the U.S.

On April 1, 2010, we effected a recapitalization and acquisition pursuant to which Horizon Pharma, Inc. became a holding company that operates through its wholly-owned subsidiaries Horizon Pharma USA, Inc. (formerly Horizon Therapeutics, Inc.) and Horizon Pharma AG (formerly Nitec Pharma AG, or Nitec). Our LODOTRA/RAYOS product was developed and is owned by Horizon Pharma AG and our historical financial statements and results of operations do not reflect the results of operations of Nitec for any period prior to the recapitalization and acquisition in April 2010. As a result of the acquisition of Nitec and organic growth, our organization has grown from 12 full-time employees as of March 31, 2010 to 164 full-time employees as of December 31, 2011. Our development efforts have also expanded significantly through the acquisition of Nitec. Consequently, we expect our expenses to increase from prior periods. As a result of the recapitalization and acquisition, our future operations will be impacted by both the operations of our U.S. subsidiary Horizon Pharma USA and our Swiss subsidiary Horizon Pharma AG.

We market LODOTRA in Europe through three separate agreements. Pursuant to two separate agreements, we granted Merck Serono GmbH, or Merck Serono, and Merck GesmbH, an affiliate of Merck Serono, exclusive rights to distribute and market LODOTRA in each of Germany and Austria, respectively, and pursuant to the third agreement, we granted Mundipharma exclusive rights to distribute and market LODOTRA in the rest of Europe. In April 2011 and September 2011, we consented to assignment of the agreements with respect to Germany and Austria to Mundipharma. Pursuant to another agreement, we granted Mundipharma exclusive rights to distribute and market LODOTRA in certain Asian, Latin American and other countries. We also have a manufacturing and supply agreement with Jagotec AG, or Jagotec, under which Jagotec or its affiliates manufacture and supply LODOTRA exclusively to us as bulk tablets. We have committed to certain minimum orders under the agreement, and we also supply the active ingredient to Jagotec for use in the manufacture of LODOTRA.

We are also focusing our efforts and capital resources on obtaining additional approvals for DUEXIS and LODOTRA/RAYOS and commercializing these products in the U.S. In addition to DUEXIS and LODOTRA/RAYOS, we have a pipeline of earlier stage product candidates to treat pain-related diseases and chronic inflammation. However, we do not intend to develop them further at this time.

We are subject to risks common to biopharmaceutical companies in the development stage, including, but not limited to, dependence upon market acceptance of our products, obtaining regulatory approval for our product candidates, risks associated with intellectual property, pricing and reimbursement, intense competition, development of markets and distribution channels and dependence on key personnel. We have a limited operating history and have yet to generate significant revenues. To date, we have been funded predominantly by equity and debt financings. Our ultimate success is dependent upon our ability to successfully develop, obtain approval for and market our products. We anticipate we will continue to incur net losses for at least the next few years as we:

- establish and expand our sales and marketing capabilities for the U.S. commercial launch of DUEXIS and RAYOS;
- expand our corporate infrastructure to support our growth and our commercialization activities;
- evaluate the potential use of LODOTRA/RAYOS for the treatment of other diseases and conduct additional clinical trials with respect to the same;
- incur expenses as we seek regulatory approval of RAYOS in the U.S. and DUEXIS in Europe;

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advance the clinical development of other product candidates either currently in our pipeline or that we may in-license or acquire in the future; and

incur expenses to defend DUEXIS IP-related challenges.

On July 7, 2011, we effected a 1-for-2.374 reverse stock split of our common stock and a proportional adjustment to the existing conversion ratios for each series of preferred stock. Accordingly, all share and per share amounts, except as noted, have been retroactively adjusted to give effect to the reverse stock split.

On August 2, 2011, we completed our initial public offering, and we sold 5,500,000 shares of common stock at an offering price of $9.00 per share, resulting in net proceeds of approximately $41.9 million, after deducting underwriting discounts of $3.5 million and offering costs of $4.1 million. Upon the consummation of our initial public offering, all outstanding shares of preferred stock were automatically converted into common stock, and all outstanding preferred stock warrants were automatically converted into warrants to purchase an aggregate of 459,003 shares of common stock. In addition, the convertible promissory notes in the aggregate principal amount $10.0 million issued in July 2010, or 2010 notes, the convertible promissory notes in the aggregate principal amount $5.0 million issued in January 2011, or January 2011 notes, and the convertible promissory notes in the aggregate principal amount of $1.7 million issued in April 2011, or April 2011 notes, and interest accrued thereon, were converted into an aggregate of 2,017,242 shares of common stock, based on a conversion price of $9.00 per share.

As of December 31, 2011 we had cash and cash equivalents of $18.0 million. In February 2012, we received $60.0 million under a senior secured loan entered into with a group of institutional lenders, which we refer to as the Senior Secured Loan. We used $22.4 million of the loan proceeds to repay the remaining obligations under our debt facilities with Kreos Capital III (UK), or the Kreos facility, and Oxford Finance LLC, or the Oxford facility. Also, in March 2012, we received gross proceeds of $50.8 million from the sale of 14,033,829 shares of our common stock and warrants to purchase an aggregate of 3,508,448 shares of our common stock with an exercise price of $4.308 per share to certain institutional and accredited investors in a private placement, or PIPE financing. For each share of common stock purchased, the investors received a warrant to purchase 0.25 of a share of common stock. The warrants will expire on March 2, 2017 and may be exercised for cash or, if the current market price of our common stock is greater than the per share exercise price, by surrender of a portion of the warrant in a cashless exercise.

We believe that our existing cash and cash equivalents (including net proceeds from our recently completed debt and equity financings), together with interest thereon, will be sufficient to fund our operations into the second half of 2013. In addition to the near-term funding we will need to support the continued commercialization of DUEXIS in the U.S., we will need additional future financing in the event that we do not obtain additional regulatory approvals for DUEXIS in Europe and RAYOS in the U.S. when expected or if the future sales of DUEXIS, LODOTRA/RAYOS and any additional products we may develop or acquire do not generate sufficient revenues to fund our operations. Our failure to raise capital if and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies.

Unless otherwise indicated, historical amounts presented with respect to Nitec are presented in accordance with accounting principles generally accepted in the U.S., or U.S. GAAP.

Financial Overview

Prior to our acquisition of Nitec we had no revenues and incurred significant operating losses since inception. Before our acquisition of Nitec, as of March 31, 2010, we had an accumulated deficit of $87.9 million. As of December 31, 2011, we had an accumulated deficit of $220.3 million.

Revenue and Cost of Goods Sold

As a result of our acquisition of Nitec in April 2010, we began recognizing revenues from the sale of LODOTRA. In December 2011, we began recognizing revenue from the sale of DUEXIS following its commercial launch. We recognize revenues from out-licensing marketing and distribution rights to third parties

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in Europe and certain Asian, Latin American and other countries, including upfront fees, milestone payments and product sales. Upfront fees and payments for non-substantive milestones are recorded as deferred revenue when paid and recognized over the remaining life of the marketing and distribution agreement or manufacturing and supply agreement, as applicable. Milestone payments are considered non-substantive if any portion of the associated milestone payment is determined to not relate solely to past performance or if a portion of the consideration earned from achieving the milestone may be refunded. Cost of goods sold consists of raw materials, manufacturing and other supply chain costs for the manufacture of LODOTRA, and royalty amounts payable to SkyePharma AG on LODOTRA sales and upon receipt of certain milestone payments. In addition, cost of goods sold includes amortization of developed technology relating to our acquisition of Nitec. We expect to record approximately $3.0 million annually related to amortization of developed technology, subject to currency fluctuations. We will adjust the rate of amortization if there are changes in our expected LODOTRA sales in Europe that indicate impairment of the developed technology or change in the expected useful life of the developed technology. The use of material is charged applying the first-in first-out , or FIFO, method on capitalized inventory stock. We expect the per unit cost of goods sold for LODOTRA to decrease as sales volumes increase, due to lower per-unit manufacturing costs at higher volumes.

The process of commercializing products is costly and time consuming. The probability of success may be affected by a variety of factors, including, among others, competition, pricing and reimbursement, manufacturing capabilities and commercial viability. As a result of these uncertainties, we are unable to determine when, or to what extent, we will generate significant revenues from the commercialization and sale of any of our products. We are also currently focused on obtaining U.S. regulatory approval of RAYOS. We would also need to raise substantial additional capital to the extent that we decide to pursue further development and commercialization of other product candidates.

Research and Development Expenses

Research and development expenses consist of: (1) expenses incurred under agreements with contract research organizations, or CROs, and investigative sites, which conduct our clinical trials and our preclinical studies; (2) the cost of manufacturing clinical trial materials; (3) payments to consultants; (4) employee-related expenses, which include salaries and benefits and (5) stock-based compensation expense. All research and development costs are expensed as incurred. Conducting a significant amount of research and development has been central to our business model, which in the past had focused primarily on clinical research and trials and more recently has focused on development work, including regulatory approval and manufacturing activities. We expect that this trend will continue through 2012 as we focus on obtaining additional regulatory approvals for DUEXIS and LODOTRA/RAYOS. Through December 31, 2011, we had incurred approximately $95.2 million in research and development expenses since our inception in 2005. The following table summarizes our research and development expenses for the years ended December 31, 2011, 2010 and 2009:

	Years Ended December 31,		
	2011	**2010**	**2009**
External Research and Development Expenses			
LODOTRA/RAYOS-Rheumatoid Arthritis	$ 5,389	$ 5,814	$
LODOTRA/RAYOS-Severe Asthma	10	36	
TRUNOC*	31	(91)	
DUEXIS	3,811	8,850	9,581
HZN-602*			116
Total External Research and Development Expenses	9,241	14,609	9,697
Total Internal Research and Development Expenses	6,117	3,088	1,197
Total Research and Development Expenses	$ 15,358	$ 17,697	$ 10,894

* At the present time, we have no plans to further develop these assets.

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Substantially all of our research and development expenses prior to our acquisition of Nitec were attributable to development of DUEXIS. A portion of our internal costs, including indirect costs relating to our product candidates, are not tracked on a project basis and are allocated based on management estimates of where the benefit accrues, or as a percentage of direct project costs. Our research and development expenses increased in 2010 as a result of our acquisition of Nitec and continued into 2011 primarily attributable to the development of LODOTRA/RAYOS, including expenses related to obtaining additional regulatory approvals for RAYOS and post-marketing studies of DUEXIS.

We generally consider our development of a product to be complete when we receive approval from regulatory authorities to market the product in the applicable jurisdiction. As a result, we are unable to reasonably estimate our additional research and development costs to complete our development work with respect to RAYOS in the U.S. and DUEXIS in Europe, including our regulatory approval and manufacturing activities. Such estimates depend on numerous factors that are outside of our control, such as whether regulatory authorities will change their approval criteria for products in the same class as DUEXIS or LODOTRA/RAYOS, whether our applications for marketing approval will be accepted for review by regulatory authorities, whether regulatory authorities will require that we complete additional studies before or after granting marketing approval, and when, if ever, regulatory authorities will approve any applications for marketing approval that we submit. For similar reasons, we are unable to reasonably estimate when, if ever, our development work with respect to DUEXIS and LODOTRA/RAYOS will be complete or when we may receive material net cash inflows related to our on-going development work with respect to DUEXIS and LODOTRA/RAYOS. We submitted an MAA in selected European countries in October 2010 to market DUEXIS, and in February 2012, we modified the DUEXIS MAA submission to include the recently approved manufacturing site in Laval, Quebec through the National Procedure in the UK. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. We submitted an NDA for RAYOS in the U.S. on September 26, 2011. However, we cannot estimate when, if ever, the applicable regulatory authorities will grant marketing approvals based on these submissions.

If we experience delays in submitting or receiving approval of our marketing applications for DUEXIS or LODOTRA/RAYOS, our ability to generate significant revenues from these product candidates will also be delayed, which will negatively affect our financial position and liquidity. If the FDA or other regulatory authorities require that we complete additional studies prior to approving our marketing applications, the costs of such studies could have a further material adverse effect on our capital resources and financial position. We believe that if we experience delays in receiving marketing approval for our product candidates, our ability to raise additional funds to continue our operations would also be adversely affected.

Sales and Marketing Expenses

Sales and marketing expenses of Horizon Pharma USA and Horizon Pharma AG historically have consisted principally of business development expenses, trade show expenses and pre-launch marketing activities, including market research and pricing reimbursement studies in anticipation of our market launch for DUEXIS and RAYOS in the U.S. Sales and marketing expenses also consist of stock-based compensation expense. As of December 31, 2011, our sales and marketing headcount was 118 full-time equivalents, primarily as a result of recruiting and hiring our sales organization. We expect sales and marketing expenses to increase significantly as we continue to establish sales and marketing capabilities to commercialize DUEXIS and RAYOS in the U.S.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, accounting, information technology and human resources functions. Other general and administrative expenses include facility costs, professional fees for legal, consulting and auditing and tax services. General and administrative expenses also consist of stock-based compensation expense. As of December 31, 2011, our general and administrative headcount was 20 full-time equivalents. We expect general

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and administrative expenses to increase as we continue to build our corporate infrastructure in support of our activities relating to commercializing DUEXIS and obtaining regulatory approval of and commercializing RAYOS in the U.S., and as a result of operating a public company. These increases likely will include salaries and related expenses, legal and consultant fees, accounting fees, director fees, increased directors and officers insurance premiums, fees for investor relations services and costs of enhanced business and accounting systems.

Interest Expense

Interest expense, both historically and prospectively, is related to interest and fees on certain debt facilities. Through August 2, 2011, we were incurring interest expense on the 2010 convertible promissory notes, the January 2011 convertible promissory notes, and the April 2011 convertible promissory notes. Upon the closing of our initial public offering on August 2, 2011, all of the outstanding convertible promissory notes were converted into common stock and therefore, we are no longer incurring interest on these notes. In June 2011, we entered into the Oxford facility, which incrementally increased interest expense in 2011 by approximately $1.0 million. The Oxford facility was repaid in its entirety in connection with the Senior Secured Loan we entered into in February 2012. As of February 2012, we expect to incur interest expense related to the Senior Secured Loan of approximately $8.7 million in 2012, $10.2 million for each of the years in 2013 to 2016, and $1.5 million in 2017. The Senior Secured Loan allows us, at our option each fiscal quarter, to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reported period. We evaluate our estimates and judgments on an ongoing basis. Actual results could differ materially from those estimates.

We believe the following critical accounting policies involve significant areas where management applies judgments and estimates in the preparation of our financial statements.

Revenue Recognition

Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured. Some of our agreements contain multiple elements and in accordance with these agreements, we may be eligible for upfront license fees, marketing or commercial milestones and payment for product deliveries.

Revenue from up-front license fees.

We recognize revenues from the receipt of non-refundable, up-front license fees. In situations where the licensee is able to obtain stand-alone value from the license and no further performance obligations exist on our part, revenues are recognized on the earlier of when payments are received or collection is assured. Where continuing involvement by us is required in the form of technology transfer, product manufacturing or technical support, revenues are deferred and recognized over the term of the agreement.

Revenue from milestone receipts.

Milestone payments are recognized as revenue based on achievement of the associated milestones, as defined in the relevant agreements. Revenue from a milestone achievement is recognized when earned, as evidenced by acknowledgment from our partner, provided that (1) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (2) the milestone represents the

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culmination of an earnings process and (3) the milestone payment is non-refundable. If all of these criteria are not met, revenue from the milestone achievement is recognized over the remaining minimum period of our performance obligations under the agreement.

Revenue from product deliveries.

We recognize revenue from the delivery of our products when delivery has occurred, title has transferred to the partner, the selling price is fixed or determinable, collectability is reasonably assured and we have no further performance obligations. Products sold to our wholesale distributors and retail chains are recognized based on the amount of product sold through to the end user consumer until such time as a reasonable estimate of allowances for product returns, rebates and discounts can be made.

As a result of the acquisition of Nitec in April 2010, we began recognizing revenues from the sale of LODOTRA. We recognize LODOTRA revenues from marketing and distribution agreements with third parties in Europe and certain Asian, Latin American and other countries, including up-front license fees, milestone payments and product deliveries.

Prior to 2011, revenues from the sale of LODOTRA made to our distribution partner, Mundipharma, were accounted for using the sell-through method. Under the sell-through method, we recognized revenue based on an estimate of the amount of product sold through to the customers of our distribution partners and end users.

Under a manufacturing and supply agreement with Mundipharma Medical Company, or Mundipharma Medical, Mundipharma Medical agreed to purchase LODOTRA exclusively from us at the price which is a specified percentage of the average net selling price, or ANSP, for sales in a given country, subject to a minimum price. Mundipharma Medical has a nine-month period from purchase date to request for an ANSP adjustment. If the ANSP is lower than the actual purchase price, then Mundipharma Medical would receive a price adjustment. Beginning in 2011, products sold to Mundipharma Medical were recognized upon delivery at the minimum price, as no contractual right of return exists. The difference between the actual selling price and the minimum price is recorded as deferred revenue until such time as adjustments for product returns, rebates and discounts can be reliably estimated or the nine-month period ANSP adjustment passes at which time any previously deferred revenue would be recognized as revenue.

In December 2011, we began recognizing revenue from the sale of DUEXIS following its commercial launch in the U.S. DUEXIS is currently sold to wholesale pharmaceutical distributors and to several national and regional retail pharmacy chains. Until we can reliably estimate returns, we have determined that shipment of product to wholesale distributors and retail chains do not meet the criteria for revenue recognition at the time of shipment. We currently defer DUEXIS revenue recognition until the right of return no longer exists, which is the earlier of DUEXIS being dispensed through patient prescriptions or the expiration of the right of return (twelve months after the expiration date of the product). We also defer the related cost of product sales and record such amounts as finished goods inventory held by others until revenue is recognized.

Product Sales Discounts and Allowances

We record DUEXIS sales to wholesale pharmaceutical distributors and national and regional retail chains net of allowances for product returns, rebates and discounts. We are required to make significant judgments and estimates in determining some of these allowances. If actual results differ from our estimates, we will be required to make adjustments to these allowances in the future. Our product sales discounts and allowances and the specific considerations we use in estimating these amounts include:

Prompt Pay Discounts. As an incentive for prompt payment, we offer a 2% cash discount to customers. We expect that all customers will comply with the contractual terms to earn the discount. We recorded the discount as an allowance against accounts receivable and a reduction of deferred revenue.

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Product Launch Discounts. We offer additional discounts to wholesale distributors for initial product purchases. We recorded the discount as an allowance against accounts receivable and a reduction of deferred revenue based on orders placed.

Patient Discount Programs. We offer discount card programs under which the patient receives a discount on his or her prescription. We reimburse pharmacies for this discount through third-party vendors. We record the total amount of discounts issued in the period as a reduction of deferred revenue.

Distribution Service Fees. We pay distribution services fees to each wholesaler for distribution and inventory management services. We accrue for the fees based on contractually defined terms with each wholesaler and record the expense as deferred cost of goods sold for distribution fees earned.

Chargebacks. We provide discounts to federal government qualified entities with whom we have contracted. These federal entities purchase products from the wholesalers at a discounted price, and the wholesalers then charge back to us the difference between the current retail price and the contracted price the federal entity paid for the product. We accrue estimated chargebacks based on contract prices and sell-through sales data obtained from third party information.

Rebates. We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program. We accrue rebates based on contract prices, estimated percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel.

At December 31, 2011 the total sales discount and allowances recognized related to the sale of DUEXIS following its commercial launch in the U.S. was not material.

Cost of Goods Sold

As a result of our acquisition of Nitec in April 2010, we began to recognize cost of goods sold in connection with the sale of LODOTRA. Cost of sales of LODOTRA includes all costs directly related to the manufacture and delivery of product and out-licensing of distribution and marketing rights to third parties. The costs in connection with product delivery to our distribution partners consist of raw material costs, costs associated with third parties who manufacture LODOTRA for us, supply chain costs, royalty payments to third parties for the use of certain licensed patents and applicable taxes. Cost of goods sold also includes amortization of developed technology related to the acquisition of Nitec.

As a result of the commercial launch of DUEXIS in the U.S. in December 2011, we began to recognize cost of goods sold in connection with the sale of DUEXIS. Cost of sales of DUEXIS includes all costs directly related to the acquisition of product from our manufacturer, including freight charges. We defer the DUEXIS related cost of goods sold and record such amounts as other current assets until revenue is recognized.

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market value. Inventories consist of raw materials, work-in-process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. Inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs.

Inventories exclude product sample inventory, which are included in other current assets and are expensed as a component of sales and marketing expense when provided to physicians or healthcare providers.

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Acquisitions and Other Intangible Assets

We account for acquired businesses using the acquisition method of accounting in accordance with U.S. GAAP accounting rules for business combinations which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of net assets acquired is recorded as goodwill. Any excess of the fair value of assets acquired and liabilities assumed over the purchase price is recorded as a bargain purchase gain. The fair value of intangible assets, including developed product and in-process research and development, or IPR&D, is based on significant judgments made by management. The valuations and useful life assumptions are based on information available near the acquisition date and are based on expectations and assumptions that are considered reasonable by management. In our assessment of the fair value of identifiable intangible assets acquired in the Nitec acquisition, management used valuation techniques and made various assumptions. Our analysis and financial projections were based on management s prospective operating plans and the historical performance of the acquired business. In connection with our acquisition of Nitec on April 1, 2010, we engaged consultants to assist management in the following:

- developing an understanding of the economic and competitive environment for the industry in which we and the acquired company participate;
- identifying the intangible assets acquired;
- reviewing the acquisition agreements and other relevant documents made available;
- interviewing our employees, including the employees of the acquired company, regarding the history and nature of the acquisition, historical and expected financial performance, product lifecycles and roadmap, and other factors deemed relevant to our valuation analysis;
- performing additional market research and analysis deemed relevant to our valuation analysis;
- estimating the fair values and recommending useful lives of the acquired intangible assets; and
- preparing a narrative report detailing methods and assumptions used in the valuation of the intangible assets.

All work performed by consultants was discussed and reviewed in detail by management to determine the estimated fair values of the intangible assets. The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed, as well as asset lives, can materially impact our results of operations.

In the fourth quarter of 2010, we revised the value of our deferred tax liabilities to reflect the appropriate effective tax rate in Switzerland, which resulted in the reduction in the original amount of deferred tax liabilities recorded in connection with the acquired intangible assets. This correction to our expected effective tax rate in Switzerland resulted in a net decrease in the initial amount of deferred tax liabilities of $4.6 million to a revised amount of $26.0 million, and a net increase of $4.6 million to the bargain purchase gain we had originally recorded, to $19.3 million.

Impairment of Intangible Assets

We review our indefinite-lived intangible assets for impairment at least annually, in the fourth fiscal quarter, or more frequently if an event occurs indicating the potential for impairment, until such time as the related research and development efforts are completed or abandoned. If the research and development efforts are completed successfully, we will reclassify the in-process research and development, or IPR&D, to finite lived intangible assets and begin amortization of the assets. If the IPR&D project is abandoned, the indefinite-lived asset is charged to expense. We review our intangible assets that have finite useful lives when an event occurs indicating the potential for impairment. We review for

impairment by analyzing any facts or circumstances, either external or internal, indicating that it may not recover the carrying value of the asset. We measure impairment losses related to long-lived assets based on the amount by which the carrying amounts of these assets exceed their fair values. We measure fair value generally based on the estimated discounted future cash flows.

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Our analysis is based on available information and on assumptions and projections that we consider to be reasonable and supportable. If necessary, we perform subsequent calculations to measure the amount of the impairment loss based on the excess of the carrying value over the fair value of the impaired assets.

In the fourth quarter of 2011, our stock price declined significantly. This decline triggered an impairment of the IPR&D as part of our annual test. To determine the fair value of the IPR&D, we calculated a business enterprise value, which equated to our market value attributed to it in the public markets as of December 31, 2011, along with an appropriate control premium. The business enterprise value, which included the IPR&D, was determined using a discounted cash flow approach. The fair value of the IPR&D utilizing this method was estimated to be $36.6 million as of December 31, 2011. Accordingly, we recorded an intangible impairment charge related to our IPR&D asset of $69.6 million during the fourth quarter. This impairment charge was recorded within operating expenses in our consolidated statement of operations for the year ended December 31, 2011.

We will continue to monitor the fair value of IPR&D in our annual reporting periods. Given the uncertainty surrounding the FDA approval of any drug, including RAYOS, there can be no assurance that the estimates and assumptions made for purposes of the 2011 impairment testing will prove to be accurate predictions of the future. If our estimated cash flows related to IPR&D decrease, we may have to record further impairment charges in the future. Additionally, changes in the broader economic environment could cause changes to our market value or estimated discount rates, which will impact our estimated fair values and may require us to record further impairment charges in the future.

Provision for Income Taxes

We account for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are recognized for deductible temporary differences, and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the year that the change is enacted. We also account for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return.

We are subject to both state and federal income taxes, and commencing on April 1, 2010, we became subject to taxation in foreign jurisdictions as a result of our acquisition of Nitec. As of December 31, 2011, we had net operating loss carryforwards of approximately $299.6 million available to reduce future taxable income, if any, for federal, state, and foreign income tax purposes. Net operating loss carryforwards for state and federal income tax purposes will begin to expire in 2015 and 2025, respectively. Additionally, utilization of the net operating loss carryforwards may be subject to annual limitations as prescribed by federal and state statutory provisions. The annual limitation may result in the expiration of net operating loss carryforwards prior to its utilization.

Stock-Based Compensation

We account for employee stock-based compensation by measuring and recognizing compensation expense for all stock-based payments based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee s requisite service period, which is generally the vesting period. Under ASC Topic 718 *Compensation-Stock Compensation*, we estimate the fair value of our share-based awards to employees using the Black-Scholes option pricing model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price, volatility, risk-free interest rate, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs.

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The following table summarizes our weighted average assumptions used in the Black-Scholes option pricing model:

	For the Years Ended December 31,		
	2011	2010	2009
Expected volatility	89%	79%	98%
Risk-free interest rate	1.2%	2.3%	2.7%
Expected term (in years)	6.03	5.06	6.25
Expected dividends	0%	0%	0%

The replacement stock options granted on April 1, 2010 were granted in substitution for Nitec options which were cancelled. The substituted options were issued with the same vesting schedule and terms as the cancelled Nitec options, with continuous service with Nitec credited towards the original vesting period and share amounts adjusted in a manner consistent with the share exchange agreement. We estimated the fair value of the stock options using the Black-Scholes option pricing model with the following assumptions as of April 1, 2010: expected volatility of 75%, risk-free interest rate of 1.03%, expected term of 2.3 years and expected dividend yield of 0%.

We recorded employee stock-based compensation expense of $2.3 million, $2.4 million and $0.4 million during the years ended December 31, 2011, 2010, and 2009, respectively. As of December 31, 2011, we had $10.2 million of unrecognized stock-based compensation expense, net of estimated forfeitures, that is expected to be recognized over a weighted-average period of 3.4 years. In future periods, our stock-based compensation expense is expected to increase materially as a result of our existing unrecognized stock-based compensation expense and as we issue additional stock-based awards to continue to attract and retain employees and non-employee directors.

We also account for stock options issued to non-employees based on the stock options estimated fair value determined using the Black-Scholes option pricing model. However, the fair value of the equity awards granted to non-employees is re-measured at each reporting date, and the resulting increase (decrease) in value, if any, is recognized as expense (income) during the period the related services are rendered.

RESULTS OF OPERATIONS

Year Ended December 31, 2011 Compared to Year Ended December 31, 2010

	Years Ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2011	2010		
	(in thousands, except percentages)			
Net revenues	$ 6,927	$ 2,376	$ 4,551	192%
Cost of goods sold	7,267	4,263	3,004	70%
Gross loss	(340)	(1,887)	(1,547)	(82%)
Research and development expenses	15,358	17,697	(2,339)	(13%)
Sales and marketing expenses	20,314	5,558	14,756	265%
General and administrative expenses	15,008	18,612	(3,604)	(19%)
Intangible impairment charge	69,621		69,621	*
Interest expense, net	(6,284)	(3,024)	3,260	108%
Bargain purchase gain		19,326	(19,326)	*
Foreign exchange loss	(1,023)	(273)	750	275%
Income tax benefit	(14,683)	(660)	14,023	2,125%

* Percentage change is not meaningful.

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Net Revenues. Revenues increased $4.6 million, from $2.4 million during the year ended December 31, 2010, to $6.9 million during the year ended December 31, 2011. The increase in revenues was primarily attributable to higher product sales and the recognition of revenues from milestone receipts for LODOTRA during the fourth quarter of 2011. Additionally, revenues were higher during 2011 due to the inclusion of full year revenues associated with LODOTRA compared to the prior year, which only included LODOTRA revenues since April 2010, the time we acquired Nitec.

Cost of Goods Sold. Cost of goods sold increased $3.0 million, from $4.3 million during the year ended December 31, 2010, to $7.3 million during the year ended December 31, 2011. The increase in cost of goods sold was attributable to higher production costs as a result of an increase in our LODOTRA product sales and primarily, higher amortization expense associated with our developed technology. During the year ended December 31, 2011, our amortization expense of developed technology increased by approximately $1.1 million, to $3.8 million, as a result of the inclusion of full year operating results compared to the prior year.

Research and Development Expenses. Research and development expenses decreased 13% or $2.3 million, from $17.7 million during the year ended December 31, 2010, to $15.4 million during the year ended December 31, 2011. The decrease in research and development expenses was primarily associated with a $2.1 million reduction in contract manufacturing related to clinical research for DUEXIS and a decrease of $2.1 million in expenses related to regulatory activities related to RAYOS. The decrease was partially offset by an increase of $1.7 million in personnel-related costs to support DUEXIS development and regulatory activities.

Sales and Marketing Expenses. Sales and marketing expenses increased $14.8 million, from $5.6 million during the year ended December 31, 2010, to $20.3 million during the year ended December 31, 2011. The increase in sales and marketing expenses was primarily attributable to staffing our sales and marketing functions during the fourth quarter of 2011 and as a result of higher consulting, outside service costs and marketing related expenses to launch and commercialize product sales of DUEXIS in the U.S. During the year ended December 31, 2011, personnel related costs increased approximately $9.2 million as we hired 80 sales representatives and staffed our sales and marketing support functions in anticipation of our product launch of DUEXIS in December 2011. Additionally, we incurred approximately $3.2 million in commercialization expense related to the launch of DUEXIS and approximately $2.4 million in consulting and outside service costs associated with pre-commercialization activities for DUEXIS.

General and Administrative Expenses. General and administrative expenses decreased $3.6 million, from $18.6 million during the year ended December 31, 2010, to $15.0 million during the year ended December 31, 2011. The decrease in general and administrative expenses was primarily due to the absence of Nitec acquisition related costs, which included investment banking fees and legal and accounting fees. During the year ended December 31, 2010, we incurred approximately $2.3 million in legal and consulting fees in connection with our April 2010 acquisition of Nitec. In addition, we also incurred approximately $1.6 million during 2010 for legal, consulting and audit related services in preparation for our initial public offering.

Intangible Impairment Charge. The intangible impairment charge of $69.6 million was related to an impairment of IPR&D as of December 31, 2011. Our impairment analysis concluded that as a result of the significant decline in our stock price in the fourth quarter of 2011, and the market value attributed to us in the public markets, along with an appropriate control premium, that the IPR&D s fair value calculated under the business enterprise value was estimated to be $36.6 million as of December 31, 2011,which resulted in an impairment charge of $69.6 million.

Interest Expense, Net. Interest expense, net increased $3.3 million, from $3.0 million during the year ended December 31, 2010, to $6.3 million during the year ended December 31, 2011. The increase in interest expense was attributable to a $2.0 million write-off of deferred financing fees as a result of the debt extinguishment under the $12.0 million debt facility with Kreos Capital III (UK) and Silicon Valley Bank, or the Kreos-SVB facility, and the 7.5 million Euro Kreos facility in addition to a higher borrowing base of debt as a result of the $17.0 million Oxford facility.

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Foreign Exchange (Loss) Gain, Net. Foreign exchange loss increased $0.7 million, from $0.3 million during the year ended December 31, 2010, to $1.0 million during the year ended December 31, 2011. The increase in the current year foreign exchange loss was primarily due to an increase in non-Euro denominated transactions for our Horizon Pharma AG subsidiary in addition to a strengthening of the U.S. dollar during the second half of the current year.

Income Tax Benefit. The increase in income tax benefit was primarily a result of a reduction in deferred tax assets associated with the IPR&D intangible impairment charge of $69.6 million.

Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

	Years Ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2010	2009		
	(in thousands, except percentages)			
Net revenues	$ 2,376	$	$ 2,376	*
Cost of goods sold	4,263		4,263	*
Gross loss	(1,887)		(1,887)	*
Research and development expenses	17,697	10,894	6,803	62%
Sales and marketing expenses	5,558	2,072	3,486	168%
General and administrative expenses	18,612	5,823	12,789	220%
Interest expense, net	(3,024)	(2,189)	(835)	38%
Bargain purchase gain	19,326		19,326	*
Other income, net		478	(478)	*
Foreign exchange loss	(273)		(273)	*

* Percentage change is not meaningful.

Net Revenues and Gross Loss. During the year ended December 31, 2010, we recognized revenue of $2.4 million from the sale of LODOTRA in Europe. We had no revenue prior to our acquisition of Nitec on April 1, 2010. Our cost of goods sold during the year ended December 31, 2010 was $4.3 million, including $2.6 million of amortization of developed technology. As a result, we had a gross loss of $1.9 million during this period.

Research and Development Expenses. The increase in research and development expenses during the year ended December 31, 2010, compared to the same period in 2009, was primarily due to a $2.8 million increase in personnel-related costs due to the acquisition of Nitec and increase in headcount to support DUEXIS development activities, an increase of $1.4 million for manufacturing expenses, including payments made to sanofi-aventis U.S. under the Technical Transfer Agreement dated November 9, 2009, between us and sanofi-aventis U.S. and an increase of $2.7 million for expenses associated with regulatory activities.

Sales and Marketing Expenses. The increase in sales and marketing expenses during the year ended December 31, 2010 compared to the same period in 2009 was due to an increase of $1.2 million in personnel-related costs and $2.2 million of increased spending associated with commercialization activities for LODOTRA in Europe and market research and pre-commercialization activities for DUEXIS and for LODOTRA in the U.S. Sales and marketing expenses as a whole increased during 2010 due to our acquisition of Nitec in April 2010.

General and Administrative Expenses. The increase in general and administrative expenses during the year ended December 31, 2010, compared to the same period in 2009, was primarily due to an increase of $3.0 million for acquisition-related expenses, which consisted of $1.1 million for investment banking fees and $1.9 million for legal and consulting fees, an increase of $4.0 million related to the preparation of our initial public offering for legal, audit and consulting fees, an increase of $2.5 million related to personnel costs resulting from higher headcount attributable to the acquisition of Nitec, and an increase of $2.9 million for other consulting fees and travel and office expenses related to the building of our corporate infrastructure.

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Interest Expense, Net. The net increase of $0.8 million in interest expense during the year ended December 31, 2010, compared to the same period in 2009, was due to $2.2 million of incremental interest expense under the Kreos facility and the Kreos-SVB facility, and an increase of $0.5 million for interest expense related to the 2010 notes. The increase was offset by a reduction of $1.4 million in interest expense associated with the convertible promissory notes that were converted to convertible preferred stock in December 2009, and a $0.5 million decrease in interest expense associated with the Hercules facility which was subsequently retired.

Bargain Purchase Gain. The bargain purchase gain of $19.3 million was recognized in connection with the Nitec acquisition as a result of the fair market value of the acquired tangible and intangible assets exceeding the purchase price.

Other Income (Expense), Net. The $0.5 million in other income, net for the year ended December 31, 2009 was primarily related to the change in the fair value of convertible preferred stock warrants. At December 31, 2009, in connection with the issuance of our Series D convertible preferred stock (upon which the bridge warrants became exercisable for shares of Series D convertible preferred stock at a known exercise price), the aggregate fair value of the bridge warrants was reclassified from liabilities to equity and the periodic fair value adjustments were discontinued.

Foreign Exchange Loss. The $0.3 million foreign exchange loss for the year ended December 31, 2010 was primarily a result of the increase in value of the U.S. dollar against the Euro in connection with translating foreign currency transactions during the year ended December 31, 2010.

Liquidity and Capital Resources

We have incurred losses since our inception in June 2005 and, as of December 31, 2011, we had an accumulated deficit of $220.3 million. We anticipate that we will continue to incur net losses for at least the next few years. We expect that our development, sales and marketing, and general and administrative expenses will continue to increase as a result of our development and commercialization of DUEXIS and LODOTRA/RAYOS. As a result, we will need to generate significant net product sales, and royalty and other revenues to achieve profitability.

We have financed our operations to date through equity financings, debt financings and the issuance of convertible notes. As of December 31, 2011, we had $18.0 million in cash and cash equivalents. Subsequent to December 31, 2011, we received net proceeds of $34.0 million, consisting of $60.0 million of gross proceeds less $22.4 million used to repay the remaining obligations under the Oxford facility and the Kreos facility and $3.6 million in fees, in connection with the Senior Secured Loan, which was completed on February 22, 2012, and net proceeds of $47.7 million, consisting of $50.8 million gross proceeds less $3.1 million of fees, from the equity financing, which was completed on March 2, 2012.

On August 2, 2011, we completed our initial public offering and we sold 5,500,000 shares of common stock at a price of $9.00 per share. We received net proceeds of approximately $41.9 million from the initial public offering, net of underwriting discounts, commissions, and offering costs.

Through December 31, 2011, we have received net proceeds of $96.4 million from the issuance of convertible preferred stock as follows: in October 2005, we issued an aggregate of 1,192,118 shares of Series A convertible preferred stock at a purchase price of $5.075 per share, for net proceeds of approximately $6.0 million; in November 2006, we issued an aggregate of 1,482,213 shares of Series B convertible preferred stock at a purchase price of $10.12 per share, for net proceeds of approximately $14.9 million; in July 2007, we issued an aggregate of 2,109,706 shares of Series C convertible preferred stock at a purchase price of $14.22 per share, for net proceeds of approximately $29.9 million and in December 2009 and January 2010, we issued an aggregate of 4,978,674 shares of Series D convertible preferred stock at a purchase price of $5.201 per share, for net proceeds of approximately $25.8 million.

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As of April 1, 2010, we recapitalized all of our outstanding shares of Series A, B, C and D convertible preferred stock, and converted those shares into a new Series A convertible preferred stock in connection with our recapitalization and acquisition of Nitec. We also concurrently completed a Series B convertible preferred stock financing in which we issued an aggregate of 2,510,040 shares of Series B convertible preferred stock at a purchase price of $7.968 per share, raising net proceeds of $19.8 million.

In July 2010, January 2011 and April 2011, we issued the 2010 notes, the January 2011 notes and the April 2011 notes, respectively, to holders of our Series B convertible preferred stock in accordance with our Series B Preferred Stock and Convertible Note Purchase Agreement dated April 1, 2010. The 2010 notes, the January 2011 notes and the April 2011 notes converted into an aggregate of 2,017,242 shares of our common stock upon the closing of our initial public offering. Upon the closing of our initial public offering, all of the outstanding shares of our Series A and Series B convertible preferred stock converted into common stock and all of our outstanding warrants were adjusted and became exercisable for shares of our common stock.

In connection with our acquisition of Nitec, we renegotiated the payment terms of Nitec s outstanding Kreos facility. The Kreos facility was secured by a lien on all of Horizon Pharma AG s trade receivables and intellectual property. The loan bore interest at 11.9% per annum. We were required to pay only interest on the Kreos facility through December 31, 2010 and were required to pay equal monthly installments of principal and interest through November 2013. In June 2011, in connection with the Oxford facility described below, we paid Kreos $1.4 million (1.0 million Euros) in exchange for Kreos consent to a partial assignment of the Kreos facility to Horizon Pharma, Inc. As a result, Horizon Pharma, Inc. became a co-lender with Kreos to Horizon Pharma AG. In February 2012, in connection with the Senior Secured Loan described below, we repaid the entire outstanding balance due under the Kreos facility.

In June 2011, we entered into the Oxford facility and borrowed the full $17.0 million available under this facility. The debt under the Oxford facility accrued interest at a fixed rate of 11.5% per annum, with interest only payments through June 1, 2012, followed by 36 equal monthly installments of principal and interest. The Oxford facility was secured by a lien on substantially all of our assets and those of Horizon Pharma USA, including intellectual property, but excluding the shares of Horizon Pharma AG. With the loan proceeds, we repaid all $8.5 million due under the Kreos-SVB facility. We also paid Kreos $1.4 million (1.0 million Euros) and Horizon Pharma, Inc. assumed from Kreos a like amount of debt under the Kreos facility (and became a co-lender with Kreos to Horizon Pharma AG), as partial consideration for Kreos consent to enter into the Oxford facility. In February 2012, in connection with the Senior Secured Loan described below, we repaid the entire outstanding balance due under the Oxford facility.

In February 2012, we entered into the $60.0 million Senior Secured Loan with a group of institutional lenders. We used $22.4 million of the loan proceeds to repay the remaining obligations under the Oxford facility and the Kreos facility. Under the terms of the Senior Secured Loan, the outstanding principal accrues interest until maturity in January 2017 at a rate of 17% per annum, payable quarterly unless repaid earlier. The Senior Secured Loan allows us to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt. Beginning in April 2013, and for each quarter thereafter, the lenders may require us to repay $4.0 million of the loan principal. We may prepay the loan at any time, subject to certain prepayment premiums. In connection with the Senior Secured Loan, we also issued warrants to the lenders to purchase up to an aggregate of approximately 3.3 million shares of our common stock at an exercise price of $0.01 per share. The warrants will become exercisable 180 days after issuance and will remain exercisable until the maturity date of the Loan on January 22, 2017, subject to limited exceptions. The Senior Secured Loan is secured by a lien covering substantially all of our assets including intellectual property in addition to pledging all of our equity interests in Horizon Pharma USA, Inc. and 65% of our equity interests in Horizon Pharma AG.

The Senior Secured Loan restricts our ability to incur additional indebtedness, incur liens, pay dividends and engage in significant business transactions, such as a change of control, so long as we owe any amounts to the lenders under the related loan agreements. If we default under our Senior Secured Loan, our lenders may

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accelerate all of our repayment obligations and take control of our pledged assets. Our lenders could declare us in default under our debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect upon us as defined under the loan agreements, thereby requiring us to repay the loans immediately or to attempt to reverse the lenders declaration through negotiation or litigation. Among other loan covenant requirements, the Senior Secured Loan also requires us to maintain a minimum level of liquidity in the near-term of at least $10.0 million at all times during the term of the loan unless our quarterly consolidated EBITDA is at least $6.0 million and to meet specified minimum net revenues during a trailing twelve-month period commencing on June 30, 2012. The negative covenants include, among other things, restrictions on transferring or licensing our assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions and creating other liens on our assets, in each case subject to customary exceptions.

While we currently expect to comply with our Senior Secured Loan operating and financial covenants, our ability to do so will be dependent on several factors including; the continued growth of the arthritis, pain and inflammation markets; whether we are able to obtain marketing approvals for RAYOS in the U.S. and DUEXIS in Europe; acceptance of our products by patients, primary care specialists and key specialists, including rheumatologists, orthopedic surgeons and pain specialists; and potential or perceived advantages or disadvantages of our products over alternative treatments, including cost of treatment and relative convenience and ease of administration. Changes in key markets or our inability to execute our operating plan could result in non-compliance with our operating and financial covenants which may adversely affect our cost of financing or cause an acceleration of our debt obligations.

Also, in March 2012, we sold 14,033,829 shares of our common stock and warrants to purchase an aggregate of 3,508,448 shares of our common stock with an exercise price of $4.308 per share to certain institutional and accredited investors in a private placement. For each share of common stock purchased, the investors received a warrant to purchase 0.25 of a share of common stock. The warrants will expire on March 2, 2017 and may be exercised for cash or, if the current market price of our common stock is greater than the per share exercise price, by surrender of a portion of the warrant in a cashless exercise.

In addition, we are required to maintain compliance with applicable Swiss laws with respect to our Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. We review on a regular basis whether our Swiss subsidiary is overindebted. In June 2010, we took steps to address overindebtedness through a subordinated loan to our Swiss subsidiary. As of December 31, 2011 and December 31, 2010, our Swiss subsidiary continued to be overindebted and we continue to monitor and review steps to address the overindebtedness, until such time as our Swiss subsidiary generates positive income at a statutory level, which could require us to have cash at our Swiss subsidiary in excess of its near term operating needs, including a portion of our net proceeds from our initial public offering, and could affect our ability to have sufficient cash at our U.S. subsidiary to meet its near term operating needs.

The following table provides a summary of our cash flows for the periods indicated (in thousands):

	Years Ended December 31,		
	2011	2010	2009
Cash and cash equivalents	$ 17,966	$ 5,384	$ 7,160
Cash provided by (used in):			
Operating activities	(41,540)	(37,532)	(18,392)
Investing activities	(2,154)	5,575	(357)
Financing activities	55,152	29,760	11,842

Net Cash Used in Operating Activities

During 2011, 2010 and 2009, our operating activities used cash of $41.5 million, $37.5 million $18.4 million, respectively. The use of cash in all periods primarily resulted from our net losses and changes in our working capital accounts.

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The decrease in cash used in operations during 2011, as compared to 2010, was primarily due to decreases in general and administrative expenses related to investment banking fees and professional fees associated with the acquisition of Nitec, and legal, audit and consulting fees, offset by increases in sales and marketing expenses resulting from increased headcount to establish sales and marketing capabilities to commercialize DUEXIS in the U.S. and in consulting and promotional activities expenditures associated with pre-commercialization activities for DUEXIS in the U.S.

The increase in cash used in operations 2010 as compared to 2009 was primarily due to incremental operating costs of our subsidiary, Horizon Pharma AG, related to regulatory activities for LODOTRA/RAYOS, increases in general and administrative expenses related to investment banking fees and professional fees associated with the acquisition of Nitec, increased expenses indirectly related to the preparation of our initial public offering, and increased regulatory and manufacturing expenses in preparation for the submission for our NDA for DUEXIS, offset by decreased clinical trial expenses in 2010. The changes in operating assets and liabilities were primarily a result of clinical trial costs, regulatory consulting, personnel-related costs and professional fees associated with the acquisition of Nitec.

We believe that our existing cash and cash equivalents (including net proceeds from our recently completed debt and equity financings) will be sufficient to fund our operations into the second half of 2013. In addition to the near-term funding we will need to support the continued commercialization of DUEXIS in the U.S., we will need additional future financing in the event that we do not obtain additional regulatory approvals for DUEXIS in Europe and RAYOS in the U.S. when expected or if the future sales of DUEXIS, LODOTRA/RAYOS and any additional products we may develop or acquire do not generate sufficient revenues to fund our operations. Our failure to raise capital if and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies.

We are highly dependent in the near term on the commercial success of DUEXIS in the U.S. market, where we only recently launched, and we have insufficient commercial operating history to accurately predict its future performance. We recently entered into a senior secured loan facility that includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end. Should we not meet these quarterly minimum revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. While we believe, based on our current estimates that we will meet the minimum quarterly revenue covenants under our loan facility, there can be no assurance that we will. We also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if we were unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations. These uncertainties and lack of commercial operating history raise substantial doubt about our ability to continue as a going concern. Due to the circumstances described above, the report of our independent registered public accounting firm on our consolidated financial statements for the year ended December 31, 2011, includes an explanatory paragraph regarding our ability to continue as a going concern.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities during 2011, 2010 and 2009 was primarily related to the purchase of property and equipment, partially offset by the proceeds from the sale of manufacturing equipment. The increase in cash provided by investing activities in the 2010 compared to 2011 and 2009 was primarily due to $6.5 million of cash acquired in the Nitec acquisition.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in 2011 was primarily attributable to the receipt of proceeds of $44.7 million from our initial public offering, net of underwriting and deferred offering costs of $4.9 million. Additionally, we received $6.8 million in proceeds from the issuance of the January 2011 notes and April 2011 notes and $16.7 million in net proceeds from the Oxford facility, net of repayments made on outstanding loan amounts of $13.1 million.

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Net cash provided by financing activities in 2010 was primarily attributable to the issuance of Series B convertible preferred stock of $20.7 million, proceeds from a debt financing of $12.0 million and proceeds from the issuance of 2010 notes payable to related parties of $10.0 million, net of repayments made on outstanding loan amounts of $11.0 million and deferred financing expenses related to our initial public offering of $1.9 million.

Net cash provided by financing activities in 2009 was primarily attributable to the issuance of Series D convertible preferred stock of $7.0 million and proceeds from the issuance of notes payable to related parties of $9.0 million, net of repayments made on outstanding loan amounts of $4.2 million.

Contractual Obligations

The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2011 (in thousands including notes):

		Payments Due as of December 31, 2011			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Debt[1]	$ 25,585	$ 6,657	$ 18,928	$	$
Purchase commitments[2][3][4]	7,381	5,271	2,110		
Operating lease obligations[5]	2,928	576	1,336	807	209
Total	$ 35,894	$ 12,504	$ 22,374	$ 807	$ 209

(1) Represents interest and principal repayments under the Oxford and Kreos facilities. In February 2012, in connection with the Senior Secured Loan, all outstanding amounts under the Oxford and Kreos facilities were paid. See Note 17 to our consolidated financial statements for additional information.

(2) Telecommunications services agreement with Global Crossing Telecommunications, Inc. dated July 30, 2010 with $33 due over a 3 year period through September 2013.

(3) Minimum purchase commitment for LODOTRA/RAYOS tablets from Jagotec through March 2014 (the end of the minimum term), which is the firm commitment term under the contract. December 31, 2011 amounts are based on pricing terms in effect as of December 31, 2011, the minimum purchase commitment for 2011 and the subsequent 1-3 years was $1,051 and $2,101, respectively.

(4) Purchase commitment of $4,019 for final packaged DUEXIS tablets from sanofi-aventis U.S. through June 2012.

(5) These amounts reflect payments due under the following operating leases:

lease for our corporate headquarters in Deerfield, Illinois with a lease term from December 1, 2011 to June 30, 2018, at the minimum rent of approximately $30 per month during the first year and will increase each year during the initial term, up to approximately $35 per month after the sixth year. The Company has the option to extend the lease for an additional five-year term, which would commence upon the expiration of the initial term.

leases for our offices in Reinach, Switzerland and in Mannheim, Germany. The Reinach office lease rate is approximately $7 (6 CHF) per month, and in June 2010, the lease term was extended to May 31, 2015. The Mannheim office lease rate is approximately $6 (5 EUR) per month, expiring on December 31, 2012, with the option to renew annually.

vehicle leases at our Reinach, Switzerland and Mannheim, Germany offices. As of December 31, 2011, $64 of payments were due in 2012 and $16 were due over the 1-3 years period. All of these lease contracts expire no later than July 2013.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities, other than the indemnification agreements discussed in Note 7, Commitments and Contingencies in the consolidated financial statements included in this report.

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Recent Accounting Pronouncements

Recent accounting pronouncements, are discussed in Note 2, Summary of Significant Accounting Policies in the consolidated financial statements included in this report.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to various market risks, which include potential losses arising from adverse changes in market rates and prices, such as interest rates and foreign exchange fluctuations. We do not enter into derivatives or other financial instruments for trading or speculative purposes.

Interest Rate Risk. Our exposure to interest rate risk is confined to our cash and cash equivalents with maturities of less than three months. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant risk, we maintain our excess cash and cash equivalents in money market funds. Because of the short-term maturities of our cash equivalents, we do not believe that a decrease in interest rates would have any material negative impact on the fair value of cash equivalents.

Foreign Currency Risk. Our sales contracts relating to LODOTRA are principally denominated in Euros and therefore, until we derive material revenues from sales of DUEXIS and, if approved, RAYOS, in the U.S., our revenues will be subject to significant foreign currency risk. We also incur certain operating expenses in currencies other than the U.S. dollar in relation to Horizon Pharma AG; therefore, we are subject to volatility in cash flows due to fluctuations in foreign currency exchange rates, particularly changes in the Euro. To date, we have not entered into any hedging contracts since exchange rate fluctuations have had minimal impact on our results of operations and cash flows.

Inflation Risk. We do not believe that inflation has had a material impact on our business or results of operations during the periods for which the consolidated financial statements are presented in this report.

Item 8. Financial Statements and Supplementary Data

The financial information required by Item 8 is contained in Part IV, Item 15 of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Annual Report on Form 10-K of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed

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by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded no such changes during the most recent fiscal quarter that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

The following table sets forth information regarding our directors and executive officers as of March 15, 2012:

Name	Age	Position with the Company
Directors		
Timothy P. Walbert	44	President, Chief Executive Officer and Chairman of the Board of Directors
Jeffrey W. Bird, M.D., Ph.D. (3)	51	Director
Louis C. Bock (1)	47	Director
Jean-François Formela, M.D. (2)	55	Director
Michael Grey (1, 2)	59	Director
Jeff Himawan, Ph.D. (2)	47	Director
Ronald Pauli (1, 3)	51	Director
Gino Santini (1, 3)	55	Director
Executive Officers (other than Mr. Walbert)		
Robert J. De Vaere	54	Executive Vice President, Chief Financial Officer
Jeffrey W. Sherman, M.D., FACP	57	Executive Vice President, Development, Regulatory Affairs, Manufacturing and Chief Medical Officer
Michael Adatto	51	Senior Vice President, Managed Care and Commercial Development
Todd N. Smith	42	Senior Vice President, Sales, Marketing and Business Development

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and governance committee.

Directors

Timothy P. Walbert. Mr. Walbert has served as chairman of our board of directors and our president and chief executive officer since our inception in March 2010. Mr. Walbert has also served as the president and chief executive officer of Horizon Pharma USA since June 2008 and on its board of directors since July 2008. From May 2007 to June 2009, Mr. Walbert served as president, chief executive officer and director of IDM Pharma, Inc., or IDM, a biopharmaceutical company which was acquired by Takeda America Holdings, Inc., or Takeda, in June 2009. From January 2006 to May 2007, Mr. Walbert served as executive vice president, commercial operations of NeoPharm, Inc., a biopharmaceutical company. From June 2001 to August 2005, Mr. Walbert served as divisional vice president and general manager, Immunology, where he led the global development and launch of HUMIRA, and divisional vice president, global cardiovascular strategy at Abbott Laboratories, a broad-based healthcare company. From April 1998 to June 2001, Mr. Walbert served as director, Celebrex North America and arthritis team leader, Asia Pacific, Latin America and Canada at G.D. Searle & Company, or G.D. Searle, a pharmaceutical company. From 1991 to 1998, Mr. Walbert also held sales and marketing roles with increasing responsibility at G.D. Searle, Merck & Co., Inc. and Wyeth. Mr. Walbert received his B.A. in business

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from Muhlenberg College, in Allentown, Pennsylvania. Mr. Walbert also serves on the board of directors of XOMA Ltd., Raptor Pharmaceuticals Corp., the Biotechnology Industry Organization (BIO), the Illinois Biotechnology Industry Organization (iBIO) and the Greater Chicago Arthritis Foundation. Our board believes that Mr. Walbert s business expertise, including his prior executive level leadership, give him the operational expertise, breadth of knowledge and valuable understanding of our industry, which qualify him to serve as a director and to lead our board as chairman.

Jeffrey W. Bird, M.D., Ph.D. Dr. Bird has served on our board of directors since our inception in March 2010 and has served on the board of directors of Horizon Pharma USA since July 2007. Dr. Bird has been a managing director of the general partner of Sutter Hill Ventures, a California Limited Partnership, a venture capital firm, since July 2003. Dr. Bird also serves on the boards of directors of Artemis Health, Inc., Drais Pharmaceuticals, Inc., NuGen Technologies, Inc., Portola Pharmaceuticals, Inc., Restoration Robotics, Inc., Threshold Pharmaceuticals, Inc. and ViroBay, Inc. From 1988 to 1990 and from 1992 to 2000, Dr. Bird served as a Senior Vice President, Business Operations at Gilead Sciences, Inc., a biopharmaceutical company, where he oversaw business development and commercial activities. Dr. Bird received his B.S. in biological sciences from Stanford University and his doctorate in cancer biology and M.D. from Stanford Medical School. Our board believes that Dr. Bird s drug development and commercialization expertise and experience as a successful venture capitalist will bring important strategic insight and drug commercialization expertise to our board, as well as provide experience working with the investment community.

Louis C. Bock. Mr. Bock has served on our board of directors since our inception in March 2010 and has served on the board of directors of Horizon Pharma USA since October 2005. Mr. Bock has been a managing director of Scale Venture Partners, a venture capital firm, since September 1997. Mr. Bock also serves on the boards of directors of Ascenta Therapeutics, Inc., diaDexus, Inc., Orexigen Therapeutics, Inc., Sonexa Therapeutics, Inc., Zogenix, Inc., New Century Hospice, Inc. and Arizona Technology Enterprises, LLC, a non-profit organization. Mr. Bock has also served as a member of the boards of directors of Cellective Pharmaceuticals, Inc., Dynavax Technologies, Inc., Somaxon Pharmaceuticals, Inc. and SGX Pharmaceuticals, Inc., which was acquired by Eli Lilly and Company, or Lilly, in 2008. From September 1989 to September 1997, Mr. Bock served as a project manager for Gilead Sciences, or Gilead, where he managed Gilead s approved antiviral drug, Vistide®. From November 1987 to September 1989, Mr. Bock served as a research associate for Genentech, Inc., a biotechnology company. Mr. Bock received his M.B.A. from California State University, San Francisco and his B.S. in biology from California State University, Chico. Our board believes that Mr. Bock s management experience and his service on other boards of directors in the biotechnology and pharmaceutical industries, including his experience in finance, give him a breadth of knowledge and valuable understanding of our industry which qualify him to serve as a director on our board.

Jean-François Formela, M.D. Dr. Formela has served on our board of directors since April 2010. Dr. Formela is a partner at Atlas Venture, a venture capital firm, which he joined in 1993. Dr. Formela also serves on the boards of directors of ARCA Biopharma, Inc., Cellzome, Inc., Egalet Ltd., Resolvyx Pharmaceuticals, Inc. and f-star Biotechnologische Forschungs- and Entwicklungsges.m.b.H. Dr. Formela has also served as a member of the boards of directors of Achillion Pharmaceuticals, Inc., Biochem Pharma, Inc., DeCode Genetics, Exelexis, Inc., Novexel SA, which was acquired by Astrazeneca PLC in 2010, Nuvelo, Inc., NxStage Medical, Inc. and SGX, which was acquired by Lilly in 2008. Prior to joining Atlas Venture, Dr. Formela served as a senior director of medical marketing and scientific affairs at Schering-Plough Corporation, a pharmaceutical company which merged with Merck & Co., Inc., where he was responsible for the marketing of Intron®A and directed U.S. Phase 4 clinical trials. Dr. Formela has also practiced emergency medicine at Necker University Hospital in Paris, France. Dr. Formela received his M.B.A. from Columbia University and his M.D. from Paris University School of Medicine. Our board believes that Dr. Formela s leadership and business experience in the pharmaceutical industry and his success as a venture capitalist will bring valuable insight to our board.

Michael Grey. Mr. Grey has served on our board of directors since September 2011. Mr. Grey currently serves as president and chief executive officer at Lumena Pharmaceuticals, Inc. and is a venture partner at Pappas

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Ventures. Mr. Grey holds over 30 years of experience in the pharmaceutical and biotechnology industries, and has held senior positions at a number of companies, including president and chief executive officer of SGX Pharmaceuticals, Inc. (sold to Eli Lilly in 2008), president and chief executive officer of Trega Biosciences, Inc. (sold to Lion Bioscience in 2001) and president of BioChem Therapeutic Inc. For approximately 20 years, Mr. Grey served in various roles with Glaxo, Inc. and Glaxo Holdings, P.L.C., culminating in his position as vice president, corporate development and director of international licensing. Mr. Grey also serves on the board of directors of BioMarin Pharmaceutical Inc. and Selventa, Inc. Mr. Grey received a B.S. in chemistry from the University of Nottingham in the United Kingdom. Our board believes that Mr. Grey s extensive experience managing pharmaceutical and biophmaceutical companies will bring important strategic insight to our board as we plan Horizon s future growth.

Jeff Himawan, Ph.D. Dr. Himawan has served on our board of directors since our inception in March 2010 and has served on the board of directors of Horizon Pharma USA since July 2007. In 1999, Dr. Himawan joined Essex Woodlands Health Ventures, L.P., a venture capital firm, where he now serves as a managing director. Dr. Himawan also serves on the boards of directors of Catalyst Biosciences, Inc., MediciNova, Inc., Light Sciences Oncology, Inc., and Symphogen, Inc. Dr. Himawan also served on the board of directors of Iomai Corporation from 2001 to 2007, when it was acquired by Intercell AG. Dr. Himawan co-founded Seed-One Ventures, a venture capital firm, where from 1996 to 2001 he served as a managing director. From 1983 to 1996, Dr. Himawan was a scientist in academic and industrial settings. Dr. Himawan has written several patents in the fields of wireless communication, biotechnology and protein chemistry. Dr. Himawan received his B.S. in biology from the Massachusetts Institute of Technology and his doctorate in biological chemistry and molecular pharmacology from Harvard University. Our board believes that, as a successful venture capitalist, Dr. Himawan will bring important strategic insight to our board, as well as experience working with the investment community.

Ronald Pauli. Mr. Pauli has served on our board of directors since September 2011. Mr. Pauli is currently chief business officer at Sagent Pharmaceuticals, Inc., where he was recently promoted from his role as chief financial officer. As chief financial officer, he played a key role in Sagent s recent initial public offering. In addition, Mr. Pauli has held senior positions at a number of biopharmaceutical companies, including chief financial officer at NeoPharm, Inc. and corporate controller and interim chief financial officer at Abraxis BioScience, Inc. (formerly American Pharmaceutical Partners, Inc.). Mr. Pauli previously served as corporate controller for Applied Power, Inc. and R.P. Scherer Corporation and held multiple finance positions at Kmart Corporation. Mr. Pauli received a B.S. in accounting from Michigan State University and a master s degree in finance from Walsh College. Our board believes that Mr. Pauli s financial experience at numerous biotechnology and pharmaceutical companies will add valuable expertise in guiding the strategic direction of the company and working with the investment community.

Gino Santini. Mr. Santini has served on our board of directors since March 2012. Mr. Santini is currently retired from a distinguished career with Eli Lilly and Company that spanned nearly three decades. During his tenure at Lilly, Mr. Santini held various leadership positions of increasing responsibility, including manager of various international regions, president of the women s health franchise and president of U.S. operations. Mr. Santini capped his career at Lilly as a member of the company s executive committee and as the senior vice president of corporate strategy and business development. Mr. Santini, fluent in four languages, holds an undergraduate degree in mechanical engineering from the University of Bologna and a master s in business administration from the University of Rochester. Our board believes that Mr. Santini s extensive international and domestic commercial and business development experience will bring important insight to our board as we plan Horizon s future growth.

Executive Officers (other than Mr. Walbert)

Robert J. De Vaere. Mr. De Vaere has served as our executive vice president and chief financial officer since our inception in March 2010 and as the executive vice president and chief financial officer of Horizon Pharma USA since October 2008. From May 2007 to June 2009, Mr. De Vaere served as senior vice president,

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finance and administration and chief financial officer at IDM, which was acquired by Takeda in 2009. From August 2006 to April 2007, Mr. De Vaere served as chief financial officer at Nexa Orthopedics, Inc., a medical device company, which was acquired by Tornier, Inc. in February 2007. From August 2005 to March 2006, Mr. De Vaere served as vice president, finance and administration and chief financial officer at IDM. From May 2000 to August 2005, Mr. De Vaere served as vice president and chief financial officer at Epimmune Incorporated, a pharmaceutical company focused on the development of vaccines, which was combined with IDM in August 2005. Prior to 2000, Mr. De Vaere served as vice president of finance and administration and chief financial officer at Vista Medical Technologies, Inc., a medical device company. Mr. De Vaere received his B.S. from the University of California, Los Angeles.

Jeffrey W. Sherman, M.D., FACP. Dr. Sherman has served as our executive vice president, development, regulatory affairs, manufacturing and chief medical officer since June 2011, as our executive vice president, development and regulatory affairs and chief medical officer since our inception in March 2010 and as the executive vice president, development and regulatory affairs and chief medical officer of Horizon Pharma USA since June 2009. From June 2009 to June 2010, Dr. Sherman served as president and board member of the Drug Information Association, or DIA, a nonprofit professional association of members who work in government regulatory, academia, patient advocacy, and the pharmaceutical and medical device industry. Dr. Sherman is presently serving as immediate past president and as a member of the board of directors of DIA. Dr. Sherman is an adjunct assistant professor of Medicine at the Northwestern University Feinberg School of Medicine and is a member of a number of professional societies as well as a diplomat of the National Board of Medical Examiners and the American Board of Internal Medicine. From August 2007 to June 2009, Dr. Sherman served as senior vice president of research and development and chief medical officer at IDM which was acquired by Takeda in 2009. From June 2007 to August 2007, Dr. Sherman served as vice president of clinical science at Takeda, a pharmaceutical research and development center. From September 2000 to June 2007, Dr. Sherman served as chief medical officer and executive vice president at NeoPharm, Inc., a biopharmaceutical company. From October 1992 to August 2000, Dr. Sherman served as director, senior director and executive director of clinical research and head of oncology global medical operations at Searle/Pharmacia, or Searle, a pharmaceutical company. Prior to joining Searle, Dr. Sherman worked in clinical pharmacology and clinical research at Bristol-Myers Squibb Company, a biopharmaceutical company. Dr. Sherman received his M.D. from the Rosalind Franklin University/Chicago Medical School. Dr. Sherman completed an internal medicine internship, residency and chief medical residency at Northwestern University as well as fellowship training at the University of California, San Francisco, or UCSF. Dr. Sherman was also a research associate at the Howard Hughes Medical Institute at UCSF.

Todd N. Smith. Mr. Smith has served as the senior vice president, sales, marketing and business development of Horizon Pharma USA since October 1, 2010. From January 2009 to August 2010, Mr. Smith served as vice president, global marketing, strategy and business development at Fenwal, Inc., a global medical device technology company, and managed a team of approximately 100 people located in the U.S. and abroad. Mr. Smith also served as vice president of automated business from May 2008 to January 2009, and amicus category business unit director from November 2007 to May 2008 at Fenwal. From April 2006 to November 2007, Mr. Smith served as director of marketing, virology franchise, at Abbott Laboratories and managed marketing and field teams of approximately 85 people. From March 2004 to April 2006, Mr. Smith served as director of sales, virology franchise, at Abbott Laboratories managing a sales and training team of approximately 200 people. From April 2003 to April 2004, Mr. Smith served as deputy director product management, segment markets and managed care, at Bayer Biological Products, a pharmaceutical company. At Bayer Biological Products, Mr. Smith also served as associate director of coagulation products from April 2002 to April 2003. From April 2001 to April 2002, Mr. Smith served as associate director of business development at Achillion Pharmaceuticals, Inc., a biopharmaceutical company focused on infectious disease. Prior to April 2001, Mr. Smith served as a regional sales manager, product manager and sales specialist at Agouron Pharmaceuticals, Inc., a pharmaceutical company, which was acquired by Pfizer Inc. in February 2000.
Mr. Smith received his B.A. from Norwich University.

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Michael Adatto. Mr. Adatto has served as the senior vice president, managed care and commercial development of Horizon Pharma USA since August 2, 2010. From November 2005 to July 2010, Mr. Adatto served as senior director, managed markets marketing at Takeda Pharmaceuticals North America Inc., a pharmaceutical company, and managed a department of 12 people in the development and execution of a managed markets franchise strategy for multiple products. From December 2003 to October 2005, Mr. Adatto served as vice president, sales and marketing, at Winston Laboratories, Inc., a subsidiary of Winston Pharmaceuticals, Inc., a pharmaceutical company. From November 2001 to December 2003, Mr. Adatto served as practice lead, life science sales and marketing effectiveness, at BearingPoint, Inc., a management consulting firm. Prior to November 2001, Mr. Adatto served as executive director of sales, Midwest business unit, at Searle Pharmaceuticals, Inc., which was acquired by Pfizer Inc. in 2003. Mr. Adatto received his M.B.A. from Northwestern University and his B.B.A from Pace University.

Board Composition

Our board of directors currently consists of eight members. We have divided our board of directors into three classes, as follows:

- Class I, which consists of Mr. Bock, Mr. Grey and Mr. Pauli, and whose term will expire at our 2012 annual meeting of stockholders;
- Class II, which consists of Dr. Formela and Dr. Himawan, and whose term will expire at our 2013 annual meeting of stockholders; and
- Class III, which consists of Dr. Bird, Mr. Santini and Mr. Walbert, and whose term will expire at our 2014 annual meeting of stockholders.

At each annual meeting of stockholders, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% of our voting stock.

Director Independence

Our board of directors has reviewed the materiality of any relationship that each of our directors has with us, either directly or indirectly. Based on this review, our board has determined that, with the exception of Mr. Walbert, all of the directors are independent directors as defined by Rule 5605(a)(2) of the NASDAQ Listing Rules.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. The board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

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Board Committees

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee.

Audit Committee

Our audit committee consists of Mr. Bock, Mr. Pauli, Mr. Grey and Mr. Santini each of whom is a non-employee director of our board of directors. Mr. Pauli serves as the chair of our audit committee. Our board of directors has also determined that each of the directors serving on our audit committee is independent within the meaning of Securities and Exchange Commission, or SEC, regulations and the NASDAQ Listing Rules. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent registered public accounting firm and determining whether to retain our existing independent registered public accounting firm or engage a new independent registered public accounting firm;
- reviewing and approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent registered public accounting firm on our engagement team as required by law;
- reviewing our annual and quarterly financial statements and reports and discussing the statements and reports with our independent registered public accounting firm and management;
- reviewing with our independent registered public accounting firm and management significant issues that arise regarding accounting principles and financial statement presentation, and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our independent registered public accounting firm any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight with respect to any related party transactions and monitoring compliance with our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;

reviewing our investment policy on a periodic basis; and

reviewing and evaluating, at least annually, the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that Mr. Pauli qualifies as an audit committee financial expert within the meaning of SEC regulations and the NASDAQ Listing Rules. In making this determination, our board has considered the formal education and nature and scope of Mr. Pauli s previous experience, coupled with past and present service on various audit committees. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Compensation Committee

Our compensation committee consists of Dr. Formela, Mr. Grey and Dr. Himawan. Dr. Formela serves as the chair of our compensation committee. Each member of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, is an

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outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the IRC, and satisfies the NASDAQ independence requirements. The functions of this committee include, among other things:

- reviewing and recommending to our board of directors the compensation and other terms of employment of our executive officers;
- reviewing and recommending to our board of directors performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- evaluating and approving the equity incentive plans, compensation plans and similar programs advisable for us, as well as modification or termination of existing plans and programs;
- evaluating and recommending to our board of directors the type and amount of compensation to be paid or awarded to non-employee board members;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and recommending to our board of directors the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management our disclosures under the caption Compensation Discussion and Analysis and recommending to the full board its inclusion in our periodic reports to be filed with the SEC;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing the adequacy of our compensation committee charter on a periodic basis;
- reviewing and evaluating, at least annually, the performance of the compensation committee; and
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Dr. Bird, Mr. Pauli and Mr. Santini. Our board of directors has determined that each of the members of this committee satisfies the NASDAQ independence requirements. Dr. Bird serves as the chair of our nominating and corporate governance committee. The functions of this committee include, among other things:

identifying, reviewing and evaluating candidates to serve on our board of directors;

determining the minimum qualifications for service on our board of directors;

evaluating director performance on the board and applicable committees of the board;

considering nominations by stockholders of candidates for election to our board;

considering and assessing the independence of members of our board of directors;

developing, as appropriate, a set of corporate governance principles, and reviewing and recommending to our board of directors any changes to such principles;

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periodically reviewing our policy statements to determine their adherence to our code of business conduct and ethics and considering any request by our directors or executive officers for a waiver from such code;

reviewing the adequacy of its charter on an annual basis; and

evaluating, at least annually, the performance of the nominating and corporate governance committee.

Section 16(a) Beneficial Ownership Reporting Compliance

Under Section 16(a) of the Exchange Act, directors, officers and beneficial owners of 10% or more of our common stock are required to file with the SEC on a timely basis initial reports of beneficial ownership and reports of changes regarding their beneficial ownership of our common stock. Officers, directors and 10% beneficial owners are required by SEC regulations to furnish us with copies of all Section 16(a) forms that they file.

Based solely on our review of the copies of such forms received and the written representations from certain reporting persons, we have determined that no officer, director or 10% beneficial owner known to us was delinquent with respect to their reporting obligations as set forth in Section 16(a) of the Exchange Act during the fiscal year ended December 31, 2011, with the exception of Timothy P. Walbert, Robert J. De Vaere and Jeffrey W. Sherman who each filed one Form 4 reporting a transaction one day late.

Code of Ethics

We have established a Code of Business Conduct and Ethics, or Code, that applies to our officers, directors and employees which is available on our internet website at *www.horizonpharma.com.* The Code contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a code of ethics within the meaning of Section 406 of the Sarbanes-Oxley Act of 2003 and Item 406 of Regulation S-K. If we make any substantive amendments to the Code or grant any waiver from a provision of the Code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

Item 11. Executive Compensation

Compensation Discussion and Analysis

Overview

This Compensation Discussion and Analysis explains our compensation philosophy, policies and practices with respect to our named executive officers. Our board of directors has delegated responsibility for creating and reviewing the compensation of our executive officers to the compensation committee of our board of directors, which is composed of independent directors under SEC regulations and the NASDAQ Listing Rules. The role of the compensation committee is to oversee our compensation and benefit plans and policies, to administer our equity incentive plans and to annually review and make recommendations to our board of directors regarding all compensation decisions relating to our executive officers.

Compensation Objectives

We believe in providing a competitive total compensation package to our executive management team through a combination of base salary, discretionary annual bonuses, grants under our equity incentive compensation plan and severance and change in control benefits. Our executive compensation programs are designed to achieve the following objectives:

attract and retain talented and experienced executives;

motivate and reward executives whose knowledge, skills and performance are critical to our success;

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- align the interests of our executive officers and stockholders by motivating executive officers to increase stockholder value;
- provide a competitive compensation package in which total compensation is primarily determined by company and individual results and the creation of stockholder value;
- reward the achievement of key performance measures; and
- compensate our executives to manage our business to meet our long-term objectives.

Our compensation committee believes that our executive compensation programs should include short- and long-term components, including cash and equity-based compensation, and should reward consistent performance that meets or exceeds expectations by increasing base salary levels, awarding cash bonuses and granting additional equity awards, as appropriate. The compensation committee evaluates both performance and compensation to make sure that the compensation provided to our executives remains competitive relative to compensation paid by companies of similar size, geographic location and stage of development operating in the life sciences industries, taking into account our relative performance and our own strategic objectives.

Setting Executive Compensation

The compensation committee reviews and determines generally on an annual basis the compensation to be paid to our chief executive officer and other executive officers. As part of this process, we conduct an annual review of the aggregate level of our executive compensation, as well as the mix of elements used to compensate our executive officers.

When setting executive compensation, the compensation committee generally considers compensation paid by life sciences and healthcare services companies included in the Radford Global Life Sciences Survey, together with other information available to it. While this information may not always be appropriate as a stand-alone tool for setting compensation due to the aspects of our business and objectives that may be unique to us, the compensation committee generally believes that gathering this information is an important part of our compensation-related decision-making process and typically provides additional context and validation for executive compensation decisions.

Although our compensation committee has used this survey data as a tool in determining executive compensation, it typically has applied its subjective discretion to make compensation decisions and, except as described below, has not benchmarked our executive compensation against any group of companies or used a formula to set our executives compensation in relation to this survey data. In addition, our compensation committee has typically taken into account advice from other non-employee members of our board of directors and publicly available data relating to the compensation practices and policies of other companies within and outside our industry.

The compensation committee has also considered and intends to continue to consider key performance objectives and milestones and the achievement level of these performance objectives and milestones by our executive officers in setting their base compensation and discretionary bonus levels, and awarding bonuses and long term incentives.

Our compensation committee retains the services of third-party executive compensation specialists and consultants from time to time, as it sees fit, in connection with the establishment of cash and equity compensation and related policies. In 2011, we engaged Towers Watson, an executive compensation specialist to allow our compensation committee to more formally guide and compare our executive compensation against a general industry group of fourteen companies that had recently completed initial public offerings and had similar market

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capitalizations as us, and a peer group of twenty-six public pharmaceutical companies with similar market capitalizations as us at the time of their initial public offerings. The following table shows the fourteen companies that made up the general industry group and the twenty-six companies that made up the peer group.

General Industry Group:		**Peer Group:**
Addus HomeCare Corporation	Adolor	NeurogesX
ArcSight	Affymax	Orexigen Therapeutics
Cellu Tissue Holdings	Alexza Pharmaceuticals	Pain Therapeutics
Cumberland Pharmaceuticals	Allos Therapeutics	POZEN
Echo Global Logistics	Arena Pharmaceuticals	Progenics Pharmaceuticals
Global Defense Technology & Systems	Cornerstone Therapeutics	Sangamo Biosciences
IPC The Hospitalist Company	DepoMed	Santarus
Mistras Group	DURECT	Somaxon Pharmaceuticals
NeurogesX	Dyax	Sucampo Pharmaceuticals
NovaBay Pharmaceuticals	GTX	Synta Pharmaceuticals
Oculus Innovative Sciences	Indenix Pharmaceuticals	Transcept Pharmaceuticals
Optimer Pharmaceuticals	Maxgen	Vanda Pharmaceuticals
RHI Entertainment	Neurocrine Biosciences	Xenoport
SoundBite Communications		

Towers Watson was specifically engaged to analyze long term incentive compensation provided by these companies to their employees, including executive management, at or around the time they became public companies. The compensation committee may make adjustments, including upward adjustments, in our executive compensation levels in the future as a result of this more formal compensation benchmarking process.

Role of Chief Executive Officer in Compensation Decisions

The chief executive officer typically evaluates the performance of other executive officers and employees, along with the performance of the company as a whole against previously determined objectives, on an annual basis and makes recommendations to the board of directors or compensation committee with respect to annual salary adjustments, bonuses and annual stock option grants. The board of directors or compensation committee exercises its own independent discretion in recommending salary adjustments and discretionary cash and equity-based awards for all executive officers. The chief executive officer is not present during deliberations or voting with respect to the compensation for himself.

Elements of Executive Compensation

The compensation program for our executive officers consists principally of base salary, annual cash incentive compensation and long-term compensation in the form of stock options and restricted stock units, as well as severance protection for certain of our executive officers through employment agreements with those executive officers. As discussed in more detail below, base salary is based primarily on market factors and annual cash incentive compensation is generally a discretionary cash bonus that is a percentage of base salary. The amount of cash compensation and the amount of equity awards granted to our executives are both considered in determining total compensation for our executive officers.

Base Salary. Base salaries for our executives are established based on the scope of their responsibilities and individual experience. Base salaries are reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. The board of directors or compensation committee does not apply specific formulas to determine increases, although it has generally awarded increases as a percentage of an executive officer s then current base salary.

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The base salaries for each of 2012, 2011, 2010 and 2009 are as follows:

	Base Salary			
Named Executive Officer	**2012**	**2011**	**2010**	**2009**
Timothy P. Walbert	$ 572,000	$ 550,000	$ 450,625	$ 437,750
Robert J. DeVaere	$ 364,000	$ 350,000	$ 324,450	$ 315,000
Jeffrey W. Sherman	$ 384,800	$ 370,000	$ 333,900	$ 315,000
Michael Adatto	$ 300,000	$ 274,275	$ 265,000	$
Todd N. Smith	$ 300,000	$ 274,275	$ 265,000	$

In May 2011, our compensation committee approved an increase to the annual base salary of Mr. Walbert from $450,625 to $550,000, an increase to the annual base salary of Mr. De Vaere from $324,450 to $350,000, an increase to the annual base salary of Dr. Sherman from $333,900 to $370,000 and 3.5% increases to the annual base salaries of Mr. Adatto and Mr. Smith, but deferred payment of the salary increases contingent upon the completion of the initial public offering or another financing, as determined by the compensation committee. As a result, upon completion of the initial public offering in August 2011, the annual base salary was increased retroactively on January 1, 2011.

Annual Cash Incentive Compensation. In addition to base salaries, we believe that performance-based cash bonuses play an important role in providing appropriate incentives to our executives to achieve defined annual corporate goals. Pursuant to their employment agreements, each executive officer has an established target cash bonus represented as a percentage of base salary as follows: 50% for Mr. Walbert, 40% for Mr. De Vaere, 30% for Dr. Sherman, 30% for Mr. Adatto and 30% for Mr. Smith. Bonus target percentages are reviewed annually and may be adjusted by the compensation committee in its discretion, although pursuant to the respective employment agreements with Mr. Walbert, Mr. De Vaere and Dr. Sherman, such percentages may not be reduced without the consent of the executive. In May 2011, our compensation committee approved bonus target percentages for our named executive officers for 2011 as follows: 60% for Mr. Walbert, 40% for Mr. De Vaere, 40% for Dr. Sherman, 35% for Mr. Adatto and 35% for Mr. Smith. At the end of each year, the compensation committee reviews and determines the level of achievement for each corporate goal and milestone. Final determinations as to discretionary bonus levels are based in part on the achievement of these corporate goals or milestones, as well as the compensation committee s assessment as to the overall development of our business and corporate accomplishments. These corporate goals and milestones, and the proportional emphasis placed on each goal and milestone may vary, from time to time, depending on our overall strategic objectives, but relate generally to factors such as achievement of clinical, regulatory, manufacturing, commercialization and sales milestones for product candidates, financial factors such as raising or preserving capital and performance against our operating budget.

During 2011, the key corporate objectives and milestones considered by the compensation committee included the successful completion of our initial public offering, hiring of a third party logistics organization and ensuring adequate supply available to launch DUEXIS, completion of the DUEXIS launch plan, including comprehensive sales operations plans with the hiring and training of the initial sales force and a marketing and reimbursement plan, securing wholesaler and retail contracts and generating an initial order target. Specific performance objectives relating to clinical development and regulatory milestones included the completion of the DUEXIS MAA submission in the United Kingdom, the approval and adherence to post approval commitments for DUEXIS in the U.S., submission and acceptance of the RAYOS NDA in the U.S. and the approval of LODOTRA CAPRA-2 variation data in Europe.

In May 2011, based upon management s recommendations and the compensation committee s own deliberations, the compensation committee approved a discretionary performance incentive bonus amount of $337,969 for Mr. Walbert for 2010. Payment of the discretionary bonus for Mr. Walbert was deferred until the completion of the initial public offering, which occurred in August 2011.

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In December 2011, based on management s recommendations and the compensation committee s own deliberations, the compensation committee approved discretionary performance incentive bonus amounts of $363,000 for Mr. Walbert, $162,800 for Mr. De Vaere, $162,800 for Dr. Sherman, $96,250 for Mr. Adatto and $96,250 for Mr. Smith based upon its assessment of our performance against our corporate goals for 2011, which included the completion of the initial public offering, gaining approval of and launching DUEXIS and submitting the LODOTRA NDA to the FDA for review. Payments of the discretionary bonuses were deferred until the completion of our debt financing, which occurred in February 2012.

Long-term Incentive Program. We believe that by providing our executives the opportunity to increase their ownership of our stock, the best interests of stockholders and executives will be more aligned and will encourage long-term performance. The stock awards enable our executive officers to benefit from the appreciation of stockholder value, while personally participating in the risks of business setbacks. Our equity benefit plans have provided our executive officers the primary means to acquire equity or equity-linked interests in us.

In December 2011, we granted stock options and restricted stock units and in January 2012, we granted performance-based restricted stock units to our named executive officers as part of overall compensation and to reward our executives for the completion of the initial public offering, approval of DUEXIS in the U.S., submission of the RAYOS NDA in the U.S. and significant progress following the acquisition of Nitec. In reaching its decision to provide multiple stock grants to the executive officers as part of total compensation for 2011, the compensation committee considered several factors, including the number of shares included in prior grants to the executive officers, the current and potential value of the underlying shares, the number of shares awarded in stock grants to non-executive employees at the same time and with the same vesting terms, and the expense relative to other options available to it in making its decision to provide multiple stock grants, as well as survey data and equity compensation at comparable companies.

The performance-based restricted stock units granted in January 2012 only vest upon achievement of certain performance objectives, which shall in no event take place later than December 31, 2012. The performance objectives include completion of an equity financing transaction, a specific DUEXIS net sales target, FDA approval of RAYOS, DUEXIS prescriptions and access to reimbursement through healthcare plans.

Severance and Change in Control Benefits. Our named executive officers are entitled to certain severance and change in control benefits, the terms of which are described below under Potential Payments Upon Termination or Change-in-Control. We believe these severance and change in control benefits are an essential element of our overall executive compensation package and assist us in recruiting and retaining talented individuals and aligning the executives interests with the best interests of the stockholders.

Severance Benefit Plan. In July 2010, our board approved a Severance Benefit Plan, which was amended and restated in March 2012, for U.S. officers employed by Horizon Pharma USA and/or Horizon Pharma for at least six months at the level of executive vice president, senior vice president or vice president. Severance benefits include payment of three months base salary and Consolidated Omnibus Budget Reconciliation Act, or COBRA, health insurance premiums for vice presidents and six months base salary and COBRA health insurance premiums for executive vice presidents and senior vice presidents. In addition, stock option and other equity awards are subject to acceleration in the event of a qualifying termination within 90 days prior to or within 18 months following a change in control. Severance benefits are payable if the officer s employment is involuntarily terminated without cause or constructively terminated under certain circumstances and are intended to keep our officers focused on corporate interests while employed and to ease the consequences to an officer of a termination of employment. The advantages to us also include our receipt of a waiver and release of claims, which the separated officer must provide to us as a condition to receiving benefits. Any payments payable under the Severance Benefit Plan are reduced by severance benefits payable by us under any individual employment agreement or any other agreement, policy, plan, program or arrangement.

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Other Compensation. All of our executive officers are eligible to receive benefits offered to our employees generally. Consistent with our compensation philosophy, we intend to continue to maintain the current benefits for our executive officers; however, our compensation committee, in its discretion, may in the future revise, amend or add to the benefits of any executive officer it deems it advisable.

Deductibility of Compensation under Section 162(m). Section 162(m) of the Internal Revenue Code of 1986 as amended, or the IRC, limits our deduction for federal income tax purposes to not more than $1 million of compensation paid to certain executive officers in a calendar year. Compensation above $1 million may be deducted if it is performance-based compensation. To maintain flexibility in compensating our executive officers in a manner designed to promote our objectives, the compensation committee has not adopted a policy that requires all compensation to be deductible. However, the compensation committee intends to evaluate the effects of the compensation limits of Section 162(m) on any compensation it proposes to grant, and the compensation committee intends to provide future compensation in a manner consistent with our best interests and those of our stockholders.

Summary Compensation Table

The following table provides information regarding the compensation earned during the years ended December 31, 2011, 2010 and 2009 by our Chairman, President and Chief Executive Officer; Executive Vice President and Chief Financial Officer; Executive Vice President, Development, Regulatory Affairs, Manufacturing and Chief Medical Officer; Senior Vice President, Managed Care and Commercial Development; and Senior Vice President, Sales, Marketing and Business Development, who we collectively refer to as our named executive officers.

Name and Principal Position	Year	Salary	Bonus	Option Awards[1]	Stock Awards[2]	Non Equity Incentive Plan	All Other Compensation[8]	Total
Timothy P. Walbert	2011	$ 550,000	$	$ 797,744	$ 658,883	$ 363,000[3]	$ 1,218	$ 2,370,845
President and Chief Executive Officer	2010	$ 450,625	$	$ 2,182,343	$	$ 337,969[3]	$ 1,077	$ 2,972,014
	2009	$ 437,750	$	$	$	$ 175,100	$ 991	$ 613,841
Robert J. DeVaere	2011	$ 350,000	$	$ 197,170	$ 162,843	$ 162,800[4]	$ 1,156	$ 873,969
Executive Vice President and Chief Financial	2010	$ 324,450	$	$ 813,744	$	$ 162,225[4]	$ 1,657	$ 1,302,076
Officer	2009	$ 315,000	$	$	$	$ 100,800	$ 1,601	$ 417,401
Jeffrey W. Sherman	2011	$ 370,000	$	$ 197,170	$ 162,843	$ 162,800[5]	$ 1,070	$ 893,883
Executive Vice President, Development, Regulatory	2010	$ 333,900	$	$ 813,744	$	$ 125,213[5]	$ 3,139	$ 1,275,996
Affairs, Manufacturing and Chief Medical Officer[5]	2009	$ 159,886	$	$ 165,517	$	$ 47,250	$ 1,372	$ 374,025
Michael Adatto	2011	$ 274,275	$	$ 80,455	$ 66,448	$ 96,250[6]	$ 1,331	$ 518,759
Senior Vice President, Managed Care, Trade and	2010	$ 110,417	$	$ 173,233	$	$ 36,440[6]	$ 324	$ 320,414
Commercial Development[6]	2009	$	$	$	$	$	$	$
Todd N. Smith	2011	$ 274,275	$	$ 80,455	$ 66,448	$ 96,250[7]	$ 824	$ 518,252
Senior Vice President, Sales, Marketing and	2010	$ 66,250	$	$ 182,835	$	$ 21,863[7]	$ 127	$ 271,075
Business Development[7]	2009	$	$	$	$	$	$	$

(1) Amounts shown in this column do not reflect dollar amounts actually received by our named executive officers. Instead, these amounts reflect the grant date fair value of such awards for financial statement reporting in accordance with the provisions of FASB ASC Topic 718 *Compensation Stock Compensation*. Assumptions used in the calculation of these amounts are included in Note 11, Equity Incentive Plans , of the notes to our consolidated financial statements. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

(2) The grant date fair values of stock awards were based on the closing stock price of our common stock on the date of grant and were determined in accordance with the provisions of ASC Topic 718. For information about the assumptions used in the calculation of grant date fair values, see Note 11 Equity Incentive Plans in Part IV, Item 15 in the notes to our consolidated financial statements.

(3) Mr. Walbert s target bonus amount for 2009 was $218,875. Our board approved payment of 80% of such amount, or $175,100, contingent upon the subsequent completion of our recapitalization and acquisition of Nitec which occurred in April 2010. Our compensation committee approved Mr. Walbert s bonus for 2010 in the amount of $337,969, but deferred payment of the bonus until August 2011, after completion of the initial public offering. In December 2011, our board also approved Mr. Walbert s 2011 bonus in the amount of $363,000, but deferred payment until completion of the debt financing, which occurred in February 2012.

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(4) Mr. De Vaere s target bonus amount for 2009 was $126,000. Our board approved payment of 80% of such amount, or $100,800, contingent upon the subsequent completion of our recapitalization and acquisition of Nitec which occurred in April 2010. Our compensation committee approved Mr. De Vaere s bonus for 2010 in the amount of $162,225, but deferred payment of the bonus until August 2011, upon completion of the initial public offering. In December 2011, our board also approved Mr. De Vaere s 2011 bonus in the amount of $162,800, but deferred payment until the completion of the debt financing, which occurred in February 2012.

(5) Dr. Sherman joined us on June 29, 2009. If he had been employed for the complete fiscal year 2009, Dr. Sherman would have earned an annual base salary of $315,000. His target bonus amount for 2009 was $94,500, which was pro rated to $47,250 since his employment began in mid 2009. Our board approved payment of the full pro rated amount, or $47,250, contingent upon the subsequent completion of our recapitalization and acquisition of Nitec which occurred in April 2010. Our compensation committee approved Dr. Sherman s bonus for 2010 in the amount of $125,213, but deferred payment of the bonus until August 2011, upon completion of the initial public offering. In December 2011, our board also approved Dr. Sherman s 2011 bonus in the amount of $162,800, but deferred payment until the completion of the debt financing, which occurred in February 2012.

(6) Mr. Adatto joined us on August 2, 2010. If he had been employed for the complete fiscal year 2010, Mr. Adatto would have earned an annual base salary of $265,000. His target bonus amount for 2010 was $79,500, which was pro-rated to $36,440 since his employment began in August 2010. Our compensation committee approved payment of the full pro-rated amount, or $36,440, but deferred payment of the bonus until August 2011, upon completion of the initial public offering. In December 2011, our board also approved Mr. Adatto s 2011 bonus in the amount of $96,250, but deferred payment until the completion of the debt financing, which occurred in February 2012.

(7) Mr. Smith joined us on October 1, 2010. If he had been employed for the complete fiscal year 2010, Mr. Smith would have earned an annual base salary of $265,000. His target bonus amount for 2010 was $79,500, which was pro-rated to $21,863 since his employment began in October 2010. Our compensation committee approved payment of the full pro-rated amount, or $21,863, but deferred payment of the bonus until August 2011, upon completion of the initial public offering. In December 2011, our board also approved Mr. Smith s 2011 bonus in the amount of $96,250, but deferred payment until the completion of the debt financing, which occurred in February 2012.

(8) Amounts shown in this column include imputed income on life insurance benefits.

Potential Payments Upon Termination or Change in Control

Payments Made Upon Termination. Regardless of the manner in which a named executive officer s employment terminates, the named executive officer is entitled to receive amounts earned during his term of employment, including salary and unused vacation pay.

Potential Termination-Based Payments under Employment Arrangements. In July 2010, we entered into an amended and restated employment agreement with Mr. Walbert, our president and chief executive officer, that provides if we terminate Mr. Walbert without cause or if Mr. Walbert resigns for good reason, he will be entitled to (1) be compensated at his then annual base salary for 12 months from his date of termination, (2) receive his target bonus for the previous year, and (3) receive COBRA health insurance premiums for up to 12 months from the date of his termination. In addition, if Mr. Walbert is terminated without cause or if Mr. Walbert resigns for good reason within 90 days prior to or within 18 months following a change in control, 100% of the shares subject to options and restricted stock awards granted to Mr. Walbert will fully vest as of the termination date. Cause is defined as gross negligence or willful failure to substantially perform duties and responsibilities to us or willful and deliberate violation of any of our policies; conviction of a felony involving commission of any act of fraud, embezzlement or dishonesty against us or involving moral turpitude; the unauthorized use or disclosure of any of our proprietary information or trade secrets and willful and deliberate breach of the executive s obligations under the employment agreement that cause material injury to us. Resignation for good reason is defined as a material reduction in duties, authority or responsibilities, the relocation of place of employment by more than 50 miles, or a material reduction of salary or annual target bonus opportunity. In the event of termination due to Mr. Walbert s death or complete disability, he and/or his heirs shall be eligible to receive a pro-rated bonus for the year in which such termination occurs, as determined by our board or compensation committee based on actual performance.

In July 2010, we entered into an amended and restated employment agreement with Mr. De Vaere, our executive vice president and chief financial officer, that provides if we terminate Mr. De Vaere without cause or if Mr. De Vaere resigns for good reason, he will be entitled to be compensated at his then annual base salary for 12 months from his date of termination and will also be entitled to receive COBRA health insurance premiums for up to 12 months from the date of his termination. In addition, if Mr. De Vaere is terminated without cause or resigns for good reason within 90 days prior to or within 18 months following a change in control, 100% of the shares subject to options and restricted stock awards granted to Mr. De Vaere will fully vest as of the termination

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date. Cause is defined as gross negligence or willful failure to substantially perform duties and responsibilities to us or willful and deliberate violation of any of our policies; conviction of a felony or the commission of any act of fraud, embezzlement or dishonesty against us or involving moral turpitude; the unauthorized use or disclosure of any of our proprietary information or trade secrets; and willful and deliberate breach of the executive s obligations under the employment agreement that cause material injury to us. Resignation for good reason is defined as a material reduction in duties, authority or responsibilities, the relocation of place of employment by more than 50 miles, or a material reduction of salary or annual target bonus opportunity. In the event of termination due to Mr. De Vaere s death or complete disability, he and/or his heirs shall be eligible to receive a pro-rated bonus for the year in which such termination occurs, as determined by our board or compensation committee based on actual performance.

In July 2010, we entered into an amended and restated employment agreement with Dr. Sherman, our executive vice president of development, regulatory affairs, manufacturing and chief medical officer, that provides if we terminate Dr. Sherman without cause or if Dr. Sherman resigns for good reason, he will be entitled to be compensated at his then annual base salary for 12 months from his date of termination and will also be entitled to receive COBRA health insurance premiums for up to 12 months from the date of his termination. In addition, if Dr. Sherman is terminated without cause or resigns for good reason within 90 days prior to or within 18 months following a change in control, 100% of the shares subject to options and restricted stock awards granted to Dr. Sherman will fully vest as of the termination date. Cause is defined as gross negligence or failure to substantially perform duties and responsibilities to us or willful violation of any of our policies; conviction of a felony or the commission of any act of fraud, embezzlement or dishonesty against us or involving moral turpitude the unauthorized use or disclosure of any of our proprietary information or trade secrets; and breach of the executive s obligations under the employment agreement that causes injury to us. Resignation for good reason is defined as the relocation of place of employment by more than 50 miles, or a material reduction of salary or annual target bonus opportunity. In the event of termination due to Dr. Sherman s death or complete disability, he and/or his heirs shall be eligible to receive a pro-rated bonus for the year in which such termination occurs, as determined by our board or compensation committee based on actual performance.

Our employment agreements with Mr. Adatto and Mr. Smith do not include provisions for potential payments upon termination or change in control. However, because Mr. Adatto and Mr. Smith are both senior vice presidents who have been employed for at least six months they both are eligible for payments under our Severance Benefit Plan.

Change in Control. A change in control under our employment agreements with Mr. Walbert, Mr. De Vaere and Dr. Sherman is defined generally as the sale of all or substantially all of our assets; a merger or consolidation in which we are not the surviving entity and in which the holders of our voting stock immediately prior to such transaction own less than 50% of voting power of the entity surviving the transaction or, where the surviving entity is a wholly-owned subsidiary of another entity, the surviving entity s parent; a reverse merger in which we are the surviving entity but the shares of common stock outstanding prior to the merger are converted into other property and in which the holders of our voting stock immediately prior to such transaction own less than 50% of the voting power of our stock, or where we are a wholly-owned subsidiary of another entity, of our parent; or an acquisition by any person, entity or group of beneficial ownership of at least 75% of the combined voting power entitled to vote in an election of our directors.

Releases. All termination-based payments (other than due to death or complete disability) to Mr. Walbert, Mr. De Vaere and Dr. Sherman pursuant to their employment agreements are contingent upon (1) the executive s execution of a standard release of claims in our favor and (2) the executive s entering into a non-competition agreement to be effective during the period during which the executive receives severance benefits.

Sections 280G and 4999. Any payment or benefit provided under our named executive officers employment agreements or otherwise in connection with a change in control may be subject to an excise tax under Section 4999 of the IRC. These payments also may not be eligible for a company tax deduction pursuant to Section 280G of the IRC. If any of these payments or benefits are subject to the excise tax, they may be reduced

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to provide the individual with the best after-tax result. Specifically, the individual will receive either a reduced amount so that the excise tax is not triggered, or the individual will receive the full amount of the payments and benefits and then be liable for any excise tax.

The following table sets forth potential payments payable to our named executive officers upon a termination of employment without cause or resignation for good reason or termination of employment without cause or resignation for good reason following a change in control. The table below reflects amounts payable to our executive officers assuming their employment was terminated on December 31, 2011 and, if applicable, a change in control also occurred on such date:

	Upon Termination Without Cause or Resignation for Good Reason No Change of Control					Upon Termination Without Cause or Resignation for Good Reason Change of Control(1)				
Name	Salary	Continuation of Medical Benefits	Bonus	Value of Accelerated Vesting(2)	Total	Salary	Continuation of Medical Benefits	Bonus	Value of Accelerated Vesting(2)	Total
Timothy P. Walbert	$ 550,000	$ 26,875	$ 330,000	$	$ 906,875	$ 550,000	$ 26,875	$ 330,000	$ 531,368	$ 1,438,243
Robert J. De Vaere	$ 350,000	$ 29,961	$	$	379,961	$ 350,000	$ 29,961	$	$ 131,328	$ 511,289
Jeffrey W. Sherman	$ 370,000	$ 28,177	$	$	398,177	$ 370,000	$ 28,177	$	$ 131,328	$ 529,505
Michael Adatto	$ 137,138	$ 14,075	$	$	131,213	$ 137,138	$ 14,075	$	$ 53,588	$ 204,801
Todd N. Smith	$ 137,138	$ 14,168	$	$	151,306	$ 137,138	$ 14,168	$	$ 53,588	$ 204,894

(1) Amounts in these columns assume that termination occurs within 90 days immediately preceding or during the 18 months immediately following a change in control.

(2) The value of accelerated vesting is equal to the closing stock price of $4.00 per share on December 31, 2011, multiplied by the number of shares subject to accelerated vesting, less the stock option exercise price, if applicable.

Grants of Plan-Based Awards

The following table sets forth certain information regarding grants of non-equity incentive plan and equity incentive plan-based awards to our named executive officers for 2011.

Name	*Grant Date*	*Estimated Future Payouts Under Non-Equity Incentive Plan Awards* Target	*All Option Awards: Number of Shares of Stock or Units (#)*	*Exercise or Base Price of Option Awards ($/Share)*	*Grant Date Fair Value of Option Awards ($)*(6)
Timothy P. Walbert	12/8/11		132,842(1)	$	$ 658,883
	12/8/11		216,955(2)	$ 4.96	$ 797,744
	N/A	$ 363,000(3)			
Robert J. De Vaere	12/8/11		32,832(1)	$	$ 162,843
	12/8/11		53,621(2)	$ 4.96	$ 197,170
	N/A	$ 162,800(4)			
Jeffrey W. Sherman, M.D., FACP	12/8/11		32,832(1)	$	$ 162,843
	12/8/11		53,621(2)	$ 4.96	$ 197,170
	N/A	$ 162,800(4)			
Michael Adatto	12/8/11		13,397(1)	$	$ 66,448
	12/8/11		21,880(2)	$ 4.96	$ 80,455
	N/A	$ 96,250(5)			
Todd N. Smith	12/8/11		13,397(1)	$	$ 66,448
	12/8/11		21,880(2)	$ 4.96	$ 80,455

	N/A	$	96,250[5]

(1) 1/4th of the shares vest in equal annual installments over the four years following the December 8, 2011 vesting commencement date.

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(2) 1/48th of the shares vest in equal monthly installments over the four years following the December 8, 2011 vesting commencement date.

(3) Mr. Walbert s target bonus for 2011 was 60% of his base salary. Our compensation committee approved Mr. Walbert s bonus for 2011 in the amount of $363,000, which represents 110% of his target bonus amount, but deferred payment of the bonus until completion of the debt financing, which occurred in February 2012.

(4) Mr. De Vaere s and Dr. Sherman s target bonus for 2011 was 40% of their base salary. Our compensation committee approved Mr. De Vaere s and Dr. Sherman s bonus for 2011 in the amount of $162,800 each, which represents 110% of their target bonus amount, but deferred payment of the bonuses until completion of the debt financing, which occurred in February 2012.

(5) Messrs. Adatto s and Smith s target bonus for 2011 was 35% of their base salary. Our compensation committee approved Mr. Adatto s and Mr. Smith s target bonus for 2011 in the amount of $96,250 each, which represents 100% of their target bonus amount, but deferred payment of the bonuses until completion of the debt financing, which occurred in February 2012.

(6) Amounts shown in this column do not reflect dollar amounts actually received by our named executive officers. Instead, this amount reflects the grant date fair value of such award for financial statement reporting in accordance with the provisions of ASC Topic 718, *Compensation Stock Compensation*. Assumptions used in the calculation of this amount are included in Note 11, Equity Incentive Plans , of the notes to our consolidated financial statements.

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Outstanding Equity Awards at December 31, 2011

The following table sets forth certain information regarding outstanding stock options held by our named executive officers on December 31, 2011.

		Option Awards					Stock Awards			
Name	Award Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested[5]	Market Value of Stock that Has Not Vested[6]	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that Have Not Vested(#)	Equity Incenetive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that Have Not Vested ($)
Timothy P. Walbert	7/16/2008	121,701[1][2]			$ 10.43	7/15/2018				
	2/3/2010	61,782[3]	67,155[3]		$ 5.20	2/2/2020				
	6/16/2010	44,644[3]	68,143[3]		$ 12.94	6/15/2020				
	12/8/2011	4,519[4]	212,436[4]		$ 4.96	12/7/2021	132,842	$ 531,368		$
		232,646	347,734				132,842	$ 531,368		$
Robert J. De Vaere	10/6/2008	46,335[1][2]			$ 10.43	10/5/2018				
	2/3/2010	22,833[3]	24,821[3]		$ 5.20	2/2/2020				
	6/16/2010	16,741[3]	25,554[3]		$ 12.94	6/5/2020				
	12/8/2011	1,117[4]	52,504[4]		$ 4.96	12/7/2021	32,832	$ 131,328		$
		87,026	102,879				32,832	$ 131,328		$
Jeffrey W. Sherman	6/23/2009	46,335[1][2]			$ 13.47	6/22/2019				
	2/3/2010	22,833[3]	24,821[3]		$ 5.20	2/2/2020				
	6/16/2010	16,741[3]	25,554[3]		$ 12.94	6/15/2020				
	12/8/2011	1,117[4]	52,504[4]		$ 4.96	12/7/2021	32,832	$ 131,328		$
		87,026	102,879				32,832	$ 131,328		$
Michael Adatto	6/16/2010	5,835[2]	8,908[2]		$ 12.94	6/15/2020				
	12/8/2011	455[4]	21,425[4]		$ 4.96	12/7/2021	13,397	$ 53,588		$
		6,290	30,333				13,397	$ 53,588		$
Todd N. Smith	12/2/2010	5,922[2]	13,033[2]		$ 20.78	12/1/2020				
	12/8/2011	455[4]	21,425[4]		$ 4.96	12/7/2021	13,397	$ 53,588		$
		6,377	34,458				13,397	$ 53,588		$

(1) The initial grant for each officer is early exercisable; as such, 100% of the option is exercisable.
(2) 1/4th of the shares vest one year after the vesting commencement date, 1/48th of the shares vest monthly thereafter over the next three years. The options reflected in the table have the following vesting commencement dates: Mr. Walbert June 30, 2008, Mr. De Vaere October 6, 2008, Dr. Sherman June 29, 2009, Mr. Adatto June 21, 2010 and Mr. Smith October 1, 2010.
(3) 1/4th of the shares vest one year after the vesting commencement date, which is the same date as the grant date, 1/48th of the shares vest monthly thereafter over the next three years.
(4) 1/48th of the shares vest in equal monthly installments over the four years following the vesting commencement date, which is the grant date.
(5) RSUs will vest in equal annual installments, such that the RSUs shall be 100% vested on the fourth anniversary of the vesting commencement date.
(6) The value of the stock awards is based on our closing stock price of $4.00 per share on December 30, 2011.

Option Exercises and Stock Vested

Our named executive officers did not exercise any stock option awards during the fiscal year ended December 31, 2011.

Option Repricings

We did not engage in any repricings or other modifications to any of our named executive officers outstanding equity awards during the year ended December 31, 2011.

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Pension Benefits

None of our named executive officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our compensation committee may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

Nonqualified Deferred Compensation

None of our named executive officers participate in or have account balances in nonqualified deferred contribution plans or other nonqualified deferred compensation plans maintained by us. Our compensation committee may elect to provide our executive officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Other benefits

Our named executive officers are eligible to participate in all of our employee benefit plans, such as medical, dental, vision, group life and disability insurance and our 401(k) plan, in each case on the same basis as our other employees.

Non-Employee Director Compensation

Our board of directors has adopted a compensation policy for our non-employee directors who are not affiliated with any holder of more than 5% of our common stock, which became effective upon the initial public offering. The policy provides for an annual board service retainer, payable in quarterly installments, of $40,000 for a non-executive chairman of the board or lead independent director and $30,000 for all other eligible non-employee directors and committee member service fees ranging from $3,750 to $15,000 per year. In addition, eligible non-employee directors elected to the board after the completion of our initial public offering will receive a stock option for 10,530 shares, vesting in equal installments over 36 month from the date of grant. Thereafter, at each annual meeting of our shareholders, eligible non-employee directors will automatically receive stock option grants of 5,265 shares, vesting in equal installments over 12 months from the date of grant.

None of our non-employee directors received fees or any other compensation for services as a director during the fiscal year ended December 31, 2011, other than stock options. Our non-employee directors were granted options to purchase shares of our common stock in fiscal year 2011 as follows:

Name	Date of Grant	Number of Shares Underlying Unexercised Options	Exercise Price Per Share($)	Vesting Start Date[1]	Grant Date Fair Value of Option Awards[2]
Ronald Pauli	9/29/11	10,530	$ 7.48	9/29/11	$ 37,308
Michael Grey	9/29/11	10,530	$ 7.48	9/29/11	$ 37,308

(1) 1/36th of the shares vest in equal monthly installments over the three years following the vesting commencement date.

(2) Amounts shown in this column do not reflect dollar amounts actually received by our directors. Instead, this amount reflects the grant date fair value of such award for financial statement reporting in accordance with the provisions of ASC Topic 718, *Compensation Stock Compensation*. Assumptions used in the calculation of this amount are included in Note 11, *Stock Option Plan*, of the Notes to our Financial Statements.

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Limitation of Liability and Indemnification

Our amended and restated certificate of incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to the corporation or its stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- transaction from which the directors derived an improper personal benefit.

Our amended and restated certificate of incorporation does not eliminate a director s duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, which remain available under Delaware law. These limitations also do not affect a director s responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Our amended and restated bylaws provide that we will indemnify our directors and officers, and may indemnify employees and other agents, to the extent not prohibited by law. Our amended and restated bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding and also permit us to secure insurance on behalf of any officer, director, employee or other agent required or permitted to be indemnified by our amended and restated bylaws. We have obtained a policy of directors and officers liability insurance.

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder s investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee has ever been an executive officer or employee of ours. None of our officers currently serves, or has served during the last completed year, on the compensation committee or board of directors of any other entity that has one or more officers serving as a member of our board of directors or compensation committee. Prior to establishing the compensation committee, our full board of directors made decisions relating to compensation of our officers.

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Compensation Committee Report

The compensation committee of our board of directors has submitted the following report for inclusion in this Annual Report on Form 10-K:

The compensation committee has reviewed and discussed with management the Compensation Discussion and Analysis set forth above. Based on such review and discussions, the compensation committee has recommended to the board of directors that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K, filed by us with the SEC.

This report of the compensation committee is not soliciting material, shall not be deemed filed with the SEC and shall not be incorporated by reference by any general statement incorporating by reference this Annual Report on Form 10-K into any filing 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, except to the extent that we specifically incorporate this information by reference, and shall not otherwise be deemed filed under such acts.

The foregoing report has been furnished by the compensation committee.

Respectively submitted,

The Compensation Committee of the Board of Directors

Jean-François Formela, M.D., Chairman

Michael Grey

Jeff Himawan, Ph.D.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters
Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2011, with respect to shares of our common stock that may be issued under our existing equity compensation plans:

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 issuances under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders:			
2005 Stock Plan	1,291,503 (1)	$ 13.96	
2011 Equity Incentive Plan	1,545,649 (1)	$ 4.60	528,403
2011 Employee Stock Purchase Plan		$	445,580
Equity compensation plans not approved by stockholders:			
None			

(1) All shares issuable upon exercise of options.

2005 Stock Plan. Our board of directors adopted and our stockholders approved our 2005 stock plan, or the 2005 plan, in October 2005 for eligible employees, directors and consultants. The 2005 plan provided for the grant of up to 1,771,289 shares of our common stock as stock awards. The terms of the stock option agreements, including vesting requirements, were determined by our compensation committee, subject to the provisions of the 2005 plan. Options granted under the 2005 plan generally vest over four years and are exercisable after they have

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been granted and up to ten years from the date of grant. The exercise price of the incentive stock options must equal at least the fair market value of the stock on the date of grant. Following the signing of the underwriting agreement for our initial public offering and stockholder approval of the 2011 equity incentive plan, or 2011 EIP, all future equity awards will be granted under our 2011 plan. However, all stock options granted under the 2005 plan prior to the initial public offering will continue to be governed by the terms of the 2005 plan.

2011 Equity Incentive Plan. The 2011 EIP provides for the grant of grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of equity compensation, or collectively, stock awards. In addition, the 2011 EIP provides for the grant of performance cash awards. Incentive stock options may be granted only to employees, subject to certain limitations. All other awards may be granted to employees, including officers, as well as directors and consultants. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2011 EIP was 3,366,228 shares, which number is the sum of (1) the number of shares reserved for future issuance under the 2005 plan at the time the 2011 plan became effective, (2) an additional number of shares, up to 1,317,534, that are subject to outstanding stock awards granted under the 2005 plan that expire or terminate for any reason prior to their exercise or settlement and would otherwise return to the 2005 Plan reserve and (3) an additional 1,600,673 of new shares. Then, the number of shares of our common stock reserved for issuance under the 2011 plan will automatically increase on January 1 of each year, starting on January 1, 2012 and continuing through January 1, 2021, by the least of (a) 5% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (b) 1,474,304 shares, or (c) such lesser number of shares of common stock as determined by our board of directors. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2011 EIP is 2,106,149 shares plus the number of shares that are added to the 2011 plan share reserve pursuant to annual evergreen increases or pursuant to outstanding 2005 plan awards that expire or terminate prior to exercise or settlement. The exercise price for an incentive or a non-statutory stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted will generally vest over a four-year period and the term can be up to ten years. As of December 31, 2011, there were 528,403 shares available for future grants under the 2011 EIP. On December 15, 2011, pursuant to the terms of our 2011 EIP, our board of directors approved an increase in the number of shares available for issuance under the 2011 EIP of 672,500 shares, effective as of January 1, 2012.

Employee Stock Purchase Plan. Our board of directors adopted our 2011 employee stock purchase plan, or the 2011 purchase plan, in July 2010 and our stockholders approved the 2011 purchase plan in June 2011. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the 2011 purchase plan and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the 2011 purchase plan. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the 2011 purchase plan at a price per share equal to the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering or (b) 85% of the fair market value of a share of our common stock on the date of purchase. Initially, the 2011 purchase plan authorized the issuance of 463,352 shares of our common stock pursuant to purchase rights granted to our employees or to employees of our subsidiaries. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2012 through January 1, 2021, by the least of (a) 4% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year, (b) 1,053,074 shares, or (c) a number determined by our board of directors that is less than (a) or (b). As of December 31, 2011, there were 445,580 shares available for future grants under the 2011 purchase plan. On December 15, 2011, pursuant to the terms of our 2011 purchase plan, our board of directors approved an increase in the number of shares available for issuance under the 2011 purchase plan of 100,000 shares, effective as of January 1, 2012.

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Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding the beneficial ownership of our common stock as of March 15, 2012 for:

- each of our Named Executive Officers as defined in Part III Item 11, Executive Compensation of this report;
- each of our directors;
- each person known by us to beneficially own more than 5% of our common stock; and
- all of our Named Executive Officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting and investment power with respect to the securities. Except as indicated by footnote, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. The number of shares of common stock used to calculate the percentage ownership of each listed person includes the shares of common stock underlying options held by such persons that are exercisable as of May 14, 2012, which is 60 days after March 15, 2012.

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Percentage of beneficial ownership is based on 33,703,370 shares of common stock outstanding as of March 15, 2012. Unless otherwise indicated, the address for the following stockholders is c/o Horizon Pharma, Inc., 520 Lake Cook Road, Suite 520, Deerfield, IL 60015.

Name and Address of Beneficial Owner or Identity of Group	Number and Percentage of Shares Beneficially Owned	
	Shares	Percentage
5% or greater stockholders:		
Essex Woodlands Health Ventures Fund VII, L.P.[1] 335 Bryant St., 3rd Floor Palo Alto, CA 94301	5,815,940	16.9%
Fidelity[2] 82 Devonshire Street, V13H Boston, MA 02109	5,077,822	14.8%
Atlas Venture Fund VI, L.P. and its affiliates[3] 25 First Street, Suite 303 Cambridge, MA 02141	3,895,404	11.5%
Quaker BioVentures Capital II, L.P.[4] 2929 Arch Street, Suite 1650 Philadelphia, PA 19104-2868	3,451,846	10.0%
Scale Venture Partners II, L.P[5] 950 Tower Lane, Suite 700 Foster City, CA 94404	2,266,631	6.7%
Sutter Hill Ventures, L.P. and its affiliates[6] 755 Page Mill Road, Suite A-200 Palo Alto, CA 94304	2,257,695	6.6%
NGN Biomed Opportunity I, L.P. and its affiliates[7] 369 Lexington Avenue, 17th Floor New York, NY 10017	1,940,383	5.7%
Directors and named executive officers:		
Jeff Himawan, Ph.D.[8]	5,815,940	16.9%
Jean-François Formela, M.D.[9]	3,895,404	11.5%
Louis C. Bock[10]	2,266,631	6.7%
Jeffrey W. Bird, M.D., Ph.D.[11]	2,295,282	6.8%
Michael Grey[12]	1,755	*
Ronald Pauli[13]	1,755	*
Timothy P. Walbert[14]	284,793	*
Robert J. De Vaere[15]	119,614	*
Jeffrey W. Sherman, M.D., FACP[16]	119,614	*
Michael Adatto[17]	8,493	*
Todd N. Smith[18]	8,474	*
All executive officers and directors as a group (11 persons)[19]	14,817,755	41.7%

* Represents beneficial ownership of less than one percent.

(1) Includes (a) 5,064,731 shares and (b) 751,209 shares issuable upon exercise of warrants. James L. Currie, Jeff Himawan, Martin Sutter, Immanuel Thangaraj and Petri Vainio share voting and investment power over the shares held by Essex Woodlands Health Ventures Fund VII, L.P. and each disclaim beneficial ownership of such shares except to the extent of any pecuniary interest therein.

(2) Includes (a) 4,394,366 shares and (b) 683,456 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on March 12, 2012 by FMR LLC, which reflects beneficial ownership as of February 29, 2012. FMR LLC reported that it had beneficial ownership of, and sole

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dispositive power with respect to, 4,920,253 shares of our common stock, including 659,610 shares issuable upon exercise of warrants. The Schedule 13G includes shares beneficially owned by Edward C. Johnson, 3d and family members, and Fidelity Management & Research Company, or Fidelity, a wholly owned subsidiary of FMR LLC, in its capacity as investment adviser to various registered investment companies, or Fidelity funds. Mr. Johnson is Chairman of FMR LLC. The Schedule 13G states that Mr. Johnson and various family members, through their ownership of FMR LLC voting common stock and the execution of a stockholders voting agreement, may be deemed a controlling group with respect to FMR LLC. The Schedule 13G also states that neither FMR LLC nor Mr. Johnson has the sole power to vote or direct the voting of the shares owned directly by the Fidelity funds, which power resides with the Fidelity funds boards of trustees pursuant to established guidelines. Additionally, Pyramis Global Advisors Trust Company, or PGATC, an indirect wholly-owned subsidiary of FMR LLC, is the beneficial owner of 157,629 shares of our common stock, including 23,846 shares issuable upon exercise of warrants, as a result of its serving as investment manager of institutional accounts owning such shares. Edward C. Johnson 3d and FMR LLC, through its control of PGATC, each has sole dispositive power over 157,629 shares and sole power to vote or to direct the voting of 157,629 shares of Common Stock owned by the institutional accounts managed by PGATC.

(3) Includes (a) 3,516,377 shares held by Atlas Venture Fund VI, L.P., or Atlas VI, (b) 64,385 shares held by Atlas Venture Fund VI GmbH & Co. KG, or Atlas GmbH, (c) 107,532 shares held by Atlas Venture Entrepreneurs Fund VI, L.P., or Atlas EVC and (d) 197,456, 3,616, and 6,038 shares issuable upon exercise of warrants held by Atlas VI, Atlas GmbH and Atlas EVC, respectively. These shares are held directly by Atlas VI, Atlas EVC and Atlas GmbH. Atlas Venture Associates VI, L.P., or AVA VI L.P., is the sole general partner of the Atlas VI and Atlas EVC and the managing limited partner of Atlas GmbH. Atlas Venture Associates VI, Inc., or AVA VI Inc., is the sole general partner of AVA VI L.P. Jean-Francois Formela, M.D. is the sole director of AVA VI Inc. As a result, Dr. Formela may be deemed to have beneficial ownership with respect to all shares held by AVA VI Inc. Each of the foregoing disclaims beneficial ownership of these shares except to the extent of their pecuniary interest therein.

(4) Includes (a) 2,761,477 shares and (b) 690,369 shares issuable upon exercise of warrants.

(5) Includes (a) 2,204,465 shares and (b) 62,166 shares issuable upon exercise of warrants held by Scale Venture Partners II, L.P., or Scale. Louis Bock, Mark Brooks, Kate Mitchell, Rory O Driscoll and Sharon Wienbar, managing members of Scale Venture Management II, LLC, the ultimate general partner of Scale, share voting and investment authority over the shares held by Scale and disclaim beneficial ownership of such shares except to the extent of any pecuniary interest therein.

(6) Includes (a) 1,609,980 shares held by Sutter Hill Ventures, a California Limited Partnership, or SHV, (b) 367,642 shares held by Sutter Hill Associates, or SHA, (c) 188,163 shares issuable upon exercise of warrants held by SHV and (d) 91,910 shares issuable upon exercise of warrants held by SHA. David L. Anderson, G. Leonard Baker, Jr., Jeffrey W. Bird, Tench Coxe, James C. Gaither, Gregory P. Sands, Andrew T. Sheehan, Michael L. Speiser, David E. Sweet, James N. White and William H. Younger, Jr. share voting and investment authority over the shares held by SHV, and disclaim beneficial ownership of such shares except to the extent of any pecuniary interest therein.

(7) Includes (a) 1,086,129 shares held by NGN Biomed Opportunity I, L.P., or NGN L.P., (b) 785,217 shares held by NGN Biomed Opportunity I GmbH & Co. Beteiligungs KG, or NGN GmbH, (c) 40,069 shares issuable upon exercise of warrants held by NGN L.P. and (d) 28,968 shares issuable upon exercise of warrants held by NGN GmbH. Peter Johann, Ph.D., Kenneth S. Abramowitz, John R. Costantino and Georg Nebgen, Ph.D., managing members of NGN Capital LLC, the general partner and investment manager of NGN L.P. and NGN GmbH, share voting and investment authority over the shares held by NGN L.P. and NGN GmbH and disclaim beneficial ownership of such shares except to the extent of any pecuniary interest therein.

(8) Includes the shares referred to in footnote (1) above. Dr. Himawan disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.

(9) Includes the shares referred to in footnote (3) above. Dr. Formela disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.

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(10) Includes the shares referred to in footnote (5) above. Mr. Bock disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
(11) Includes (a) the shares referred to in footnote (6) above, (b) 36,562 shares held by the Jeffrey W. Bird and Christina R. Bird Trust dated October 31, 2000, or the Bird Trust, of which Dr. Bird is a trustee and (c) 1,025 shares issuable upon exercise of warrants held by the Bird Trust. Dr. Bird disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
(12) Includes 1,755 shares that Mr. Grey has the right to acquire from us within 60 days of March 15, 2012 pursuant to the exercise of stock options.
(13) Includes 1,755 shares that Mr. Pauli has the right to acquire from us within 60 days of March 15, 2012 pursuant to the exercise of stock options.
(14) Includes 284,793 shares that Mr. Walbert has the right to acquire from us within 60 days of March 15, 2012 pursuant to the exercise of stock options.
(15) Includes (a) 2,732 shares and (b) 116,882 shares that Mr. De Vaere has the right to acquire from us within 60 days of March 15, 2012 pursuant to the exercise of stock options.
(16) Includes (a) 2,732 shares and (b) 116,882 shares that Dr. Sherman has the right to acquire from us within 60 days of March 15, 2012 pursuant to the exercise of stock options.
(17) Includes (a) 677 shares and (b) 7,816 shares that Mr. Adatto has the right to acquire from us within 60 days of March 15, 2012 pursuant to the exercise of stock options.
(18) Includes 8,474 shares that Mr. Smith has the right to acquire from us within 60 days of March 15, 2012 pursuant to the exercise of stock options.
(19) Includes the following held by our executive officers and directors, in the aggregate: (a) 6,141 shares, (b) 538,357 shares that can be acquired within 60 days of March 15, 2012 pursuant to the exercise of stock options and (c) 1,301,583 shares issuable upon exercise of warrants.

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

We describe below transactions and series of similar transactions, since the beginning of fiscal year 2011, with respect to which we were a party, will be a party, or otherwise benefited, in which:

- the amounts involved exceeded or will exceed $120,000; and
- a director, executive officer, holder of more than 5% of our common stock or any member of their immediate family had or will have a direct or indirect material interest.

We also describe below certain other transactions with our directors, executive officers and stockholders. We believe that the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm s-length transactions.

2011 Convertible Note Financings

In January 2011, pursuant to an amendment to the Series B Preferred Stock and Subordinated Convertible Note Purchase Agreement, we issued $5.0 million in aggregate principal amount of subordinated convertible promissory notes, or the January 2011 notes, in a private placement to holders of our Series B preferred stock. Additionally, in April 2011, pursuant to an amendment to the Series B Preferred Stock and Subordinated Convertible Note Purchase Agreement, we issued $1.7 million in aggregate principal amount of subordinated promissory notes, or the April 2011 notes, in a private placement to holders of our Series B preferred stock. The January 2011 notes and April 2011 notes were subordinate to the indebtedness under the Oxford facility and other indebtedness we might have incurred to certain lenders and were convertible into equity securities upon the occurrence of certain events. The January 2011 notes and April 2011 notes accrued interest at a rate of 10% per annum. The January 2011 notes and April 2011were converted into common stock in connection with our initial public offering.

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Purchasers of our January 2011 notes and April 2011 notes included the following holders of more than 5% of our capital stock, or entities affiliated with them at the time of the transaction. The following table sets forth the principal amount of the January 2011 notes and April 2011 notes purchased by such holders:

Participants[1]	January 2011 notes Loan Amount	April 2011 notes Loan Amount
5% or Greater Stockholders		
Atlas Venture Fund VI, L.P.[2]	$ 1,100,001	$ 380,000
Essex Woodlands Health Ventures Fund VII, LP	$ 981,885	$ 339,197
Scale Venture Partners II, LP	$ 939,771	$ 324,648
NGN Biomed Opportunity I, L.P.[3]	$ 578,947	$ 200,000
Sutter Hill Ventures, a California Limited Partnership[4]	$ 426,344	$ 147,283
The Global Life Science Ventures Fund II Limited Partnership[5]	$ 384,973	$ 122,668
TVM Life Science Ventures VI, L.P.[6]	$ 329,999	$ 26,036

(1) Additional detail regarding these stockholders and directors affiliated with these stockholders and their equity holdings is provided in Item 12.
(2) Represents convertible notes held by Atlas Venture Fund VI, L.P., Atlas Venture Fund VI GmbH & Co. KG and Atlas Venture Entrepreneurs Fund VI, L.P.
(3) Represents convertible notes held by NGN Biomed Opportunity I, L.P. and NGN Biomed Opportunity I GmbH & Co. Beteiligungs KG.
(4) Represents convertible notes held by Sutter Hill, a California Limited Partnership, and Jeffrey W. Bird and Christina R. Bird Trust dated October 31, 2000, of which Dr. Bird is a trustee.
(5) Represents convertible notes held by The Global Life Science Ventures Fund II Limited Partnership and The Global Life Science Ventures Funds II GmbH & Co. KG.
(6) Represents convertible notes held by TVM Life Science Ventures VI, L.P. and TVM Life Science Ventures VI GmbH & Co. KG.

Participation in the Initial Public Offering

Entities affiliated with Atlas Venture, Essex Woodlands Health Ventures, Scale Venture Partners, NGN Biomed, Sutter Hill Ventures, The Global Life Science Ventures and TVM Life Science Ventures, each of which is a current stockholder, purchased an aggregate of approximately $15.0 million of shares of our common stock in our initial public offering, which was allocated pro rata among them based on each such stockholder s then current beneficial ownership of our outstanding capital stock at the time of our initial public offering, as follows:

Participants[1]	Shares Purchased	Proceeds
5% or Greater Stockholders		
Atlas Venture Fund VI, L.P.[2]	369,814	$ 3,328,326
Essex Woodlands Health Ventures Fund VII, LP	330,104	$ 2,970,936
Scale Venture Partners II, LP	315,946	$ 2,843,514
NGN Biomed Opportunity I, L.P.[3]	194,639	$ 1,751,751
Sutter Hill Ventures, a California Limited Partnership[4]	203,318	$ 1,829,862
The Global Life Science Ventures Fund II Limited Partnership[5]	80,000	$ 720,000
TVM Life Science Ventures VI, L.P.[6]	156,162	$ 1,405,458

(1) Additional detail regarding these stockholders and directors affiliated with these stockholders and their equity holdings is provided in Item 12.

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(2) Represents shares purchased by Atlas Venture Fund VI, L.P., Atlas Venture Fund VI GmbH & Co. KG and Atlas Venture Entrepreneurs Fund VI, L.P.
(3) Represents shares purchased by NGN Biomed Opportunity I, L.P. and NGN Biomed Opportunity I GmbH & Co. Beteiligungs KG.
(4) Represents shares purchased by Sutter Hill, a California Limited Partnership, and Jeffrey W. Bird and Christina R. Bird Trust dated October 31, 2000, of which Dr. Bird is a trustee.
(5) Represents shares purchased by The Global Life Science Ventures Fund II Limited Partnership and The Global Life Science Ventures Funds II GmbH & Co. KG.
(6) Represents shares purchased by TVM Life Science Ventures VI, L.P. and TVM Life Science Ventures VI GmbH & Co. KG.

PIPE Financing

In March 2012, we closed a private placement, or PIPE financing, with a select group of institutional and accredited investors. Upon the closing of the PIPE financing, we received gross proceeds of approximately $50.8 million resulting from the sale of 14,033,829 units at a price of $3.62125 per unit. Each unit consisted of one share of our common stock and a warrant to purchase 0.25 shares of our common stock at an exercise price of $4.308 per share.

Purchasers in the PIPE financing included the following holders of more than 5% of our capital stock, or entities affiliated with them. The following table sets forth the proceeds received, units purchased and warrants issued to such holder in the PIPE financing:

Participants[1]	Proceeds	Common Stock	Warrants
5% or Greater Stockholders			
Quaker BioVentures Capital II, L.P.	$ 9,999,999	2,761,477	690,369
Fidelity	$ 9,899,864	2,733,825	683,456
Atlas Venture Fund VI, L.P.[2]	$ 2,999,999	828,443	207,110
Essex Woodlands Health Ventures Fund VII, LP	$ 9,999,999	2,761,477	690,369
NGN Biomed Opportunity I, L.P.[3]	$ 1,000,001	276,148	69,037
Sutter Hill Ventures, a California Limited Partnership[4]	$ 3,669,999	1,013,462	253,365

(1) Additional detail regarding these stockholders and directors affiliated with these stockholders and their equity holdings is provided in Item 12.
(2) Represents shares purchased by Atlas Venture Fund VI, L.P., Atlas Venture Fund VI GmbH & Co. KG and Atlas Venture Entrepreneurs Fund VI, L.P.
(3) Represents shares purchased by NGN Biomed Opportunity I, L.P. and NGN Biomed Opportunity I GmbH & Co. Beteiligungs KG.
(4) Represents shares purchased by Sutter Hill, a California Limited Partnership, and Jeffrey W. Bird and Christina R. Bird Trust dated October 31, 2000, of which Dr. Bird is a trustee.

Employment Agreements and Change of Control Arrangements

We have entered into employment agreements, which are described in Part III Item 11, Executive Compensation of this Annual Report on Form 10-K, with our executive officers.

Stock Options and Stock Awards Granted to Executive Officers and Directors

We have granted stock options and stock awards to our executive officers and directors, which are described in Part III Item 11, Executive Compensation of this Annual Report on Form 10-K.

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Indemnification of Officers and Directors

Our restated certificate of incorporation and our bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have entered into indemnification agreements with each of our directors and officers, and we have purchased a policy of directors and officers liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances.

Policies and Procedures for Transactions with Related Persons

We have adopted a written Related-Person Transactions Policy that sets forth our policies and procedures regarding the identification, review, consideration, approval and oversight of related-person transactions. For purposes of our policy only, a related-person transaction is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any related person are participants, the amount involved exceeds $120,000 and a related person has a direct or indirect material interest. Transactions involving compensation for services provided to us as an employee, director, consultant or similar capacity by a related person are not covered by this policy. A related person is any executive officer, director or nominee to become director, a holder of more than 5% of our common stock, including any immediate family members of such persons or any entity owned or controlled by such persons. Any related-person transaction may only be consummated if our audit committee has approved or ratified the transaction in accordance with the policy guidelines set forth below.

The policy imposes an affirmative duty upon each director and executive officer to identify, and we will request that significant stockholders identify, any transaction involving them, their affiliates or family members that may be considered a related-party transaction before such person engages in the transaction. Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. In considering related-person transactions, our audit committee takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director s independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval process. Before the recent adoption of our Related-Person Transactions Policy, we did not have a formal policy concerning transactions with related persons.

Director Independence

Our board of directors has reviewed the materiality of any relationship that each of our directors has with us, either directly or indirectly, including any director that served on our board of directors in 2011. Based on this review, our board has determined that, with the exception of Mr. Walbert, all of our current directors and ex-directors that served on our board during 2011 are and were, as applicable, independent directors as defined by Rule 5605(a)(2) of the NASDAQ Listing Rules.

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The following directors and ex-directors are affiliated with our principal stockholders as indicated in the table below:

Director	Principal Stockholder
Jeffrey Bird, M.D., Ph.D.	Sutter Hill Ventures, a California Limited Partnership
Louis C. Bock	Scale Venture Partners II, L.P.
Jean-François Formela, M.D.	Atlas Venture Fund VI, L.P.
Jeff Himawan, Ph.D.	Essex Woodlands Health Ventures Fund VII, L.P.
Peter Johann, Ph.D.	NGN Biomed Opportunity I, L.P.

Item 14. Principal Accounting Fees and Services

Audit and All Other Fees

The following table presents fees for services rendered by PricewaterhouseCoopers LLP, our independent registered public accounting firm, for 2011 and 2010 in the following categories:

	2011	2010
Audit fees [(1)]	$ 847,000	$ 3,040,000
Tax fees [(2)]	36,000	62,000
Total	$ 883,000	$ 3,102,000

(1) Audit fees consist of fees for professional services performed by PricewaterhouseCoopers LLP for the audit of our annual financial statements, review of our quarterly financial statements, review of our registration statements, including our registration statement on Form S-1 for our initial public offering, and related services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) Tax fees consist of fees for professional services performed by PricewaterhouseCoopers LLP with respect to tax compliance, tax advice and tax planning.

The audit committee has considered whether the provision of non-audit services is compatible with maintaining the independence of PricewaterhouseCoopers LLP, and has concluded that the provision of such services is compatible with maintaining the independence of our registered public accounting firm.

Audit Committee Policy Regarding Pre-Approval of Audit and Permissible Non-Audit Services of Our Independent Registered Public Accounting Firm

The audit committee has established a policy that all audit and permissible non-audit services provided by our independent registered public accounting firm will be pre-approved by the audit committee, and all such services were pre-approved in accordance with this policy during the fiscal years ended December 31, 2011 and 2010. These services may include audit services, audit-related services, tax services and other services. The audit committee considers whether the provision of each non-audit service is compatible with maintaining the independence of our independent registered public accounting firm. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. Our independent registered public accounting firm and management are required to periodically report to the audit committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report.

1. Financial Statements

The financial statements listed on the Index to Financial Statements F-3 to F-41 are filed as part of this Annual Report on Form 10-K.

2. Financial Statement Schedules

These schedules have been omitted because the required information is included in the consolidated financial statements or notes thereto or because they are not applicable or not required.

3. Exhibits

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SIGNATURES

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

HORIZON PHARMA, INC.

Dated: March 23, 2012

By: /s/ Timothy P. Walbert
Timothy P. Walbert
President, Chief Executive Officer and Chairman of the Board

Know All Persons By These Presents, that each person whose signature appears below constitutes and appoints Timothy P. Walbert and Robert J. De Vaere, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all 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 in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, 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.

Signature	Title	Date
/s/ Timothy P. Walbert **Timothy P. Walbert**	President, Chief Executive Officer and Chairman of the Board	March 23, 2012
/s/ Robert J. De Vaere **Robert J. De Vaere**	Executive Vice President and Chief Financial Officer	March 23, 2012
/s/ Jeffrey Bird **Jeffrey Bird, M.D., Ph.D.**	Director	March 23, 2012
/s/ Louis C. Bock **Louis C. Bock**	Director	March 23, 2012
/s/ Jean-Francois Formela **Jean-Francois Formela, M.D.**	Director	March 23, 2012
/s/ Michael Grey **Michael Grey**	Director	March 23, 2012
/s/ Jeff Himawan	Director	March 23, 2012

	Jeff Himawan, Ph.D.		
/s/ Ronald Pauli		Director	March 23, 2012
	Ronald Pauli		
/s/ Gino Santini		Director	March 23, 2012
	Gino Santini		

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HORIZON PHARMA, INC.

Index to Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Horizon Pharma, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of stockholders equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Horizon Pharma, Inc. and its subsidiaries at December 31, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. 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 of these statements 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has a limited commercial operating history and may not be able to comply with certain debt covenants, which raises substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP

Chicago, Illinois

March 23, 2012

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HORIZON PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	As of December 31, 2011	2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 17,966	$ 5,384
Restricted cash	750	200
Accounts receivable, net	2,372	575
Inventories, net	1,195	306
Prepaid expenses and other current assets	2,763	903
Total current assets	25,046	7,368
Property and equipment, net	3,245	2,107
Developed technology, net	35,602	39,990
In-process research and development	36,638	108,746
Other assets	547	3,474
TOTAL ASSETS	$ 101,078	$ 161,685
LIABILITIES AND STOCKHOLDER S EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 8,170	$ 2,514
Accrued expenses	8,926	6,733
Deferred revenues current portion	3,281	1,845
Notes payable current portion	3,604	4,220
Bridge notes payable to related parties		10,000
Total current liabilities	23,981	25,312
LONG-TERM LIABILITIES:		
Notes payable, net of current	15,834	10,395
Deferred revenue, net of current	5,666	4,123
Deferred tax liabilities, net	9,561	24,798
Other long term liabilities	124	1
Total long-term liabilities	31,185	39,317
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY:		
Convertible preferred stock, $0.0001 par value; 0 and 27,400,000 shares authorized at December 31, 2011 and 2010, respectively; 0 and 24,961,340 shares issued and outstanding at December 31, 2011 and 2010, respectively; (Liquidation preference: $0 and $177,002 at December 31, 2011 and 2010, respectively)		2
Common stock, $0.0001 par value; 200,000,000 and 35,400,000 shares authorized at December 31, 2011 and 2010, respectively; 19,627,744 and 1,490,551 shares issued and outstanding at December 31, 2011 and 2010, respectively	2	
Additional paid-in capital	270,015	206,336
Accumulated other comprehensive loss	(3,788)	(2,230)
Accumulated deficit	(220,317)	(107,052)

Total stockholders equity	45,912	97,056
TOTAL LIABILITIES AND STOCKHOLDER S EQUITY	$ 101,078	$ 161,685

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

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HORIZON PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share data)

	For the Years Ended December 31,		
	2011	**2010**	**2009**
REVENUES:			
Sale of goods	$ 6,773	$ 2,376	$
Contract revenue	166		
Gross revenues	6,939	2,376	
Sales discounts and allowances	(12)		
Net sales	6,927	2,376	
Cost of goods	7,267	4,263	
Gross loss	(340)	(1,887)	
OPERATING EXPENSES:			
Research and development	15,358	17,697	10,894
Sales and marketing	20,314	5,558	2,072
General and administrative	15,008	18,612	5,823
Intangible impairment charge	69,621		
Total operating expenses	120,301	41,867	18,789
Operating loss	(120,641)	(43,754)	(18,789)
OTHER (EXPENSE) INCOME, net:			
Interest expense, net	(6,284)	(3,024)	(2,189)
Bargain purchase gain		19,326	
Foreign exchange loss	(1,023)	(273)	
Other, net			478
Total other (expense) income, net	(7,307)	16,029	(1,711)
Loss before benefit for income taxes	(127,948)	(27,725)	(20,500)
BENEFIT FOR INCOME TAXES	(14,683)	(660)	
NET LOSS	(113,265)	(27,065)	(20,500)
Plus: capital contribution			3,489
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (113,265)	$ (27,065)	$ (17,011)
NET LOSS PER COMMON SHARE Basic and diluted	$ (12.56)	$ (21.16)	$ (40.65)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING Basic and diluted	9,014,968	1,279,133	418,520

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

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HORIZON PHARMA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

(In thousands, except share data)

	Total Comprehensive Loss	Convertible Preferred Stock		Special Preferred Stock		Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders Equity (Deficit)
		Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2008		4,784,037	$		$	1,010,950	$	168,492	$	$ 51,033	$	$ (59,487)	$ (8,454)
Issuance of Series D convertible preferred stock in December 2009 at $5.201 per share for cash, net of issuance costs of $124		1,373,936								7,022			7,022
Issuance of Series D convertible preferred stock in December 2009 at $5.201 per share upon conversion of bridge loan and accrued interest of $894		3,440,463	1							17,893			17,894
Conversion of Series A convertible preferred stock to special preferred stock in December 2009		(246,305)								(1,250)			(1,250)
Conversion of Series B convertible preferred stock to special preferred stock in December 2009		(247,035)								(2,500)			(2,550)
Conversion of Series C convertible preferred stock to special preferred stock in December 2009		(17,580)								(250)			(250)
Conversion of Series A, B & C convertible preferred stock to special preferred stock in December 2009				510,920						4,000			4,000
Stock-based compensation										402			402
Reclassification of convertible preferred stock warrant liabilities										459			459
Net loss	$ (20,500)											(20,500)	(20,500)
Comprehensive loss	$ (20,500)												

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HORIZON PHARMA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands, except share data)

	Total Comprehensive Loss	Convertible Preferred Stock		Special Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders Equity (Deficit)
		Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2009		9,087,516	$ 1	510,920	$	1,010,950	$	168,492	$	$ 76,809	$	$ (79,987)	$ (3,177)
Issuance of Series D convertible preferred stock in January 2010 at $5.201 per share for cash, net of issuance costs of $15		164,275								839			839
Conversion of Series A, B, C, D convertible preferred stock in April 1, 2010 to Series A convertible preferred stock		(9,251,791)	(1)										(1)
Conversion of Series A, B, C, D convertible preferred stock in April 1, 2010 to Series A convertible preferred stock		10,232,057	1										1
Issuance of Series A convertible preferred stock and common stock, including option to purchase up to 328,074 shares of common stock in April 2010 in connection with acquisition of Nilec under share exchange agreement		11,211,413	1			857,400				104,134			104,135
Issuance of Series B convertible preferred stock in April 1, 2010 at $7.968 per share for cash, net of issuance costs of $156		2,510,040								19,844			19,844
		1,007,830				(424,527)							

Conversion of common stock to preferred stock on April 1, 2010							
Conversion of special convertible preferred stock to common stock on April 1, 2010		(510,920)	215,213				
Cancellation of Treasury shares			(168,492)	(168,492)			
Issuance of warrants in connection with notes payable					2,136		2,136
Issuance of common stock in conjunction with option exercises			7				
Stock-based compensation					2,574		2,574
Comprehensive loss							
Net loss	$ (27,065)					(27,065)	(27,065)
Currency translation adjustment	(2,230)					(2,230)	(2,230)
Other comprehensive loss	(2,230)						
Comprehensive loss	$ (29,295)						

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HORIZON PHARMA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands, except share data)

	Total Comprehensive Loss	Convertible Preferred Stock		Special Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders Equity (Deficit)
		Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2010		24,961,340	$ 2		$	1,490,551	$		$	$ 206,336	$ (2,230)	$ (107,052)	$ 97,056
Common stock issuance in public offering, net of underwriting fees and issuance costs						5,500,000	1			41,744			41,745
Issuance of common stock in conjunction with the conversion of bridge notes payable						2,017,242				18,156			18,156
Conversion of convertible preferred stock to common stock		(24,961,340)	(2)			10,514,431	1			1			
Issuance of common stock in conjunction with option exercises and ESPP purchases						24,172				124			124
Stock-based compensation										2,530			2,530
Issuance of common stock in conjunction with warrant exercises						81,348							
Issuance of warrants in connection with notes payable										1,124			1,124
Comprehensive loss													
Net loss	$ (113,265)											(113,265)	(113,265)
Currency translation adjustment	(1,558)										(1,558)		(1,558)
Other comprehensive loss	(1,558)												
Total comprehensive loss	$ (114,823)												
Balances at December 31, 2011			$		$	19,627,744	$ 2		$	$ 270,015	$ (3,788)	$ (220,317)	$ 45,912

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

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HORIZON PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	For the Years Ended December 31,		
	2011	**2010**	**2009**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (113,265)	$ (27,065)	$ (20,500)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	4,199	2,973	77
Stock-based compensation	2,530	2,574	402
Intangible impairment charge	69,621		
Loss from debt extinguishment	1,977		
Amortization of interest payment on notes payable	246	140	105
Amortization of debt discount	485	826	663
Foreign exchange loss	1,023	273	
Loss on disposal of assets		42	
Bargain purchase gain		(19,326)	
Change in carrying value of warrant liabilities			(481)
Changes in operating assets and liabilities:			
Accounts receivable	(1,817)	(516)	
Inventories	(923)	1,010	
Prepaid expenses and other current assets	(1,897)	551	116
Accounts payable	5,643	(1,137)	137
Accrued expenses	3,215	(2,404)	1,089
Deferred revenues	3,237	5,734	
Deferred tax liabilities	(15,778)	(708)	
Other non-current assets and liabilities	(36)	(499)	
Net cash used in operating activities	(41,540)	(37,532)	(18,392)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(1,604)	(714)	(617)
Increase in restricted cash	(550)	(200)	
Acquisition of Nitec Pharma AG, net of cash acquired		6,489	
Proceeds from sale of manufacturing equipment			260
Net cash (used in) provided by investing activities	(2,154)	5,575	(357)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock in initial public offering, net of underwriting fees and issuance costs	44,678		
Proceeds from issuance of bridge notes payable to related parties	6,766	10,000	9,000
Proceeds from issuance of convertible preferred stock, net of issuance costs		20,683	7,022
Proceeds from the purchase of warrants			1
Proceeds from the issuance of notes payable	16,651	11,960	
Proceeds from the issuance of common stock	124		
Deferred financing expenses		(1,902)	
Repayment of notes payable	(13,067)	(10,981)	(4,181)
Net cash provided by financing activities	55,152	29,760	11,842
Effect of foreign exchange rate changes on cash	1,124	421	
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	12,582	(1,776)	(6,907)
CASH AND CASH EQUIVALENTS, beginning of the year	5,384	7,160	14,067
CASH AND CASH EQUIVALENTS, end of the year	$ 17,966	$ 5,384	$ 7,160

Supplemental cash flow information:			
Cash paid for interest	$ 2,757	$ 1,905	$ 657
Cash paid for income taxes		66	
Commitment fee paid on notes payable		120	
Non-cash investing and financing activities:			
Warrants issued in connection with notes payable	$ 1,124	$ 2,136	$
Conversion of bridge notes and accrued interest to common stock	18,156		
Unpaid deferred offering costs		583	
Convertible preferred stock and common stock issued to Nitec shareholders in connections with in connection with the Nitec acquisition		104,135	
Conversion of bridge notes and accrued interest of $894 to Series D convertible preferred stock			17,894
Deposit on manufacturing equipment			114
Warrants issued on related parties in connection with bridge notes			283

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

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HORIZON PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2011, 2010, and 2009

(in thousands, except share and per share data)

1. The Company

Horizon Pharma, Inc. (the Company) was incorporated in Delaware on March 23, 2010. On April 1, 2010, the Company became a holding company that operates primarily through its two wholly-owned subsidiaries, Horizon Pharma USA, Inc. (formerly known as Horizon Therapeutics, Inc.), a Delaware corporation, and Horizon Pharma AG (formerly known as Nitec Pharma AG, Nitec), a company organized under the laws of Switzerland which was acquired by the Company on April 1, 2010 in exchange for newly-issued shares of Horizon Pharma, Inc. Horizon Pharma AG owns all of the outstanding share capital of its wholly-owned subsidiary, Horizon Pharma GmbH, a company organized under the laws of Germany (formerly known as Nitec Pharma GmbH), through which Horizon Pharma AG conducts most of its European operations. Unless the context indicates otherwise, the Company refers to Horizon Pharma, Inc. and its subsidiaries taken as a whole.

The Company is a biopharmaceutical company that is developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases. On April 23, 2011, the U.S. Food and Drug Administration (FDA) approved DUEXIS (formerly HZT-501), a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis (RA) and osteoarthritis (OA) and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. On November 14, 2011, the Company and sanofi-aventis U.S. LLC (sanofi-aventis U.S.) announced the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. In December 2011, Valeant Pharmaceuticals International, Inc. (Valeant), acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, the manufacturing agreement remains with sanofi-aventis U.S. The Company has hired its initial commercial organization and completed sales force training, and it began detailing DUEXIS to physicians in December 2011 and held our launch meeting for DUEXIS in the U.S. in January 2012. In October 2010, the Company submitted a Marketing Authorization Application (MAA) for DUEXIS in the United Kingdom (UK), the Reference Member State, through the Decentralized Procedure. In February 2012, the Company modified the DUEXIS MAA submission to include the recently approved manufacturing site in Laval, Quebec through the National Procedure in the UK. The Company anticipates a decision on the MAA in the second half of 2012. The Company s other product, LODOTRA, known as RAYOS in the U.S., is a proprietary programmed release formulation of low-dose prednisone that is currently marketed in Europe by its distribution partner, Mundipharma International Corporation Limited (Mundipharma), for the treatment of moderate to severe, active RA in adults when accompanied by morning stiffness. The Company has successfully completed two Phase 3 clinical trials of RAYOS and submitted a new drug application (NDA) for RAYOS to the FDA on September 26, 2011. As a result, the Company has a Prescription Drug User Fee Act, or PDUFA, goal date for RAYOS of July 26, 2012. The Company has worldwide marketing rights for DUEXIS and has retained exclusive marketing rights in the U.S. for all of its products. The Company s strategy is to commercialize its products in the U.S., to explore co-promotion opportunities for DUEXIS in the U.S. and to enter into licensing or additional distribution agreements for commercialization of its products outside the U.S.

On July 7, 2011, the Company effected a 1-for-2.374 reverse stock split of its common stock and a proportional adjustment to the existing conversion ratios for each series of preferred stock. Accordingly, all share and per share amounts for all periods presented in these consolidated financial statements and notes thereto, have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

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On August 2, 2011, the Company closed its initial public offering of 5,500,000 shares of common stock at an offering price of $9.00 per share. The Company received net proceeds of approximately $41,885, after deducting underwriting discounts of $3,465 and offering costs of $4,150.

The Company has incurred net operating losses and negative cash flows from operations during every year since inception. In order to continue its operations, the Company must achieve profitable operations and/or obtain additional debt or equity financing. There can be no assurance, however, that such financing will be available on terms acceptable to the Company or at all.

These financial statements are prepared on a going concern basis that contemplates the realization of assets and discharge of liabilities in the normal course of business. The Company believes that it has sufficient resources, including cash and cash equivalents, and interest thereon, to operate into the second half of 2013. However, the Company is highly dependent in the near term on the commercial success of DUEXIS in the U.S. market, where it was only recently launched, and has insufficient commercial operating history to accurately predict its future performance. The Company has recently entered into a senior secured loan facility that includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end. Should the Company not meet these quarterly minimum revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. While the Company believes, based on its current estimates that it will meet the minimum quarterly revenue covenants under its loan facility, there can be no assurance that it will. The Company also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if the Company was unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on the Company s financial position and results of operations. These uncertainties and lack of commercial operating history raise substantial doubt about the Company s ability to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America (GAAP) and in accordance with the instructions for Form 10-K and Article 3 of Regulation S-X. The consolidated financial statements include the accounts of the Company and its wholly-owned consolidated subsidiaries.

Principles of Consolidation

The consolidated financial statements include the Company s accounts and those of its wholly-owned subsidiaries: Horizon Pharma USA, Inc. in Deerfield, IL, Horizon Pharma AG in Reinach, Switzerland and Horizon Pharma GmbH in Mannheim, Germany. All intercompany accounts and transactions have been eliminated.

Segment Information

The Company operates as one segment. Management uses one measure of profitability and does not segment its business for internal reporting.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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Foreign Currency Translation and Transactions

The reporting currency of the Company and its subsidiaries is the U.S. dollar.

The U.S. dollar is the functional currency for the Company s U.S. based businesses and the Euro is the functional currency for its subsidiaries in Switzerland and Germany. Foreign currency-denominated assets and liabilities of these subsidiaries are translated into U.S. dollars based on exchange rates prevailing at the end of the period, revenues and expenses are translated at average exchange rates prevailing during the corresponding period, and stockholders equity accounts are translated at historical exchange rates as of the date of any equity transaction. The effects of foreign exchange gains and losses arising from the translation of assets and liabilities of those entities where the functional currency is not the U.S. dollar are included as a component of accumulated other comprehensive gain (loss).

Gains and losses resulting from foreign currency transactions are reflected within the Company s results of operations and have not had a material impact on the Company s operating results. The Company does not and has not in the past utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

Revenue Recognition

Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable and collectability is reasonably assured. Some of the Company s agreements contain multiple elements and in accordance with these agreements, the Company may be eligible for upfront license fees, marketing or commercial milestones and payment for product deliveries.

Revenue from up-front license fees

The Company recognizes revenues from the receipt of non-refundable, up-front license fees. In situations where the licensee is able to obtain stand-alone value from the license and no further performance obligations exist on the Company s part, revenues are recognized on the earlier of when payments are received or collection is reasonably assured. Where continuing involvement by the Company is required in the form of technology transfer, product manufacturing or technical support, revenues are deferred and recognized over the term of the agreement.

Revenue from milestone receipts

Milestone payments are recognized as revenue based on achievement of the associated milestones, as defined in the relevant agreements. Revenue from a milestone achievement is recognized when earned, as evidenced by acknowledgment from the Company s partner, provided that (1) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (2) the milestone represents the culmination of an earnings process and (3) the milestone payment is non-refundable. If all of these criteria are not met, revenue from the milestone achievement is recognized over the remaining minimum period of the Company s performance obligations under the agreement.

Revenue from product deliveries

The Company recognizes revenue from the delivery of its products to its distribution partners when delivery has occurred, title has transferred to the partner, the selling price is fixed or determinable, collectability is reasonably assured and the Company has no further performance obligations. Upon initial launch of a product, the Company recognizes revenues based on the amount of product sold through to the end user consumer until such time as a reasonable estimate of allowances for product returns, rebates and discounts can be made.

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As a result of the acquisition of Nitec in April 2010, the Company began recognizing revenues from the sale of LODOTRA. The Company anticipates revenues will continue to result from distribution, marketing, manufacturing and supply agreements with third parties in Europe and certain Asian, Latin American and other countries. The Company will also recognize revenues related to up-front license fees, milestone receipts and product deliveries. During the years ended December 31, 2011, 2010 and 2009, substantially all revenues recognized were related to the sale of LODOTRA to the Company s distribution partners under existing arrangements (Note 13).

Prior to 2011, revenues from the sale of LODOTRA made to the Company s distribution partner, Mundipharma, were accounted for using the sell-through method. Under the sell-through method, the Company recognizes revenue based on an estimate of the amount of product sold through to the customers of the Company s distribution partners and end users.

Under the manufacturing and supply agreements with Mundipharma Medical Company (Mundipharma Medical) discussed in Note 13, Mundipharma Medical agreed to purchase LODOTRA exclusively from the Company at the price, which is a specified percentage of the average net selling price, or ANSP, for sales in a given country, subject to a minimum price. Mundipharma Medical has a nine-month period from purchase date to request for an ANSP adjustment. If the ANSP is lower than the actual purchase price, then Mundipharma Medical would receive a price adjustment. Beginning in 2011, products sold to Mundipharma Medical were recognized upon delivery at the minimum price, as no contractual right of return exists. The difference between the actual selling price and the minimum price is recorded as deferred revenue until such time as adjustments for product returns, rebates and discounts can be reliably estimated or the nine-month period ANSP adjustment passes at which time any previously deferred revenue would be recognized as revenue.

In December 2011, the Company began recognizing revenues from the sale of DUEXIS following its commercial launch in the U.S. DUEXIS is currently sold to wholesale pharmaceutical distributors and to several national and regional retail chains. Until the Company can reliably estimate returns, the Company has determined that shipment of products to wholesale distributors and retail chains do not meet the criteria for revenue recognition at the time of shipment. The Company is currently deferring DUEXIS revenue recognition until the right of return no longer exists, which is the earlier of DUEXIS being dispensed through patient prescriptions or the expiration of the right of return (twelve months after the expiration date of the product). The Company also defers the related cost of goods sold and records such amounts as other current assets until revenue is recognized. As of December 31, 2011 and 2010, the Company has deferred cost of goods sold totaling $290 and $0, respectively.

Product Sales Discounts and Allowances

The Company records DUEXIS sales to wholesale pharmaceutical distributors and national and regional retail chains net of allowances for product returns, rebates and discounts. The Company is required to make significant judgments and estimates in determining some of these allowances. If actual results differ from its estimates, the Company will be required to make adjustments to these allowances in the future.

Prompt Pay Discounts. As an incentive for prompt payment, the Company offers a 2% cash discount to customers. The Company expects that all customers will comply with the contractual terms to earn the discount. The Company records the discount as an allowance against accounts receivable and a reduction of deferred revenue.

Product Launch Discounts. The Company offers additional discounts to wholesale distributors for product purchased. The Company records the discount as an allowance against accounts receivable and a reduction of deferred revenue based on orders placed.

Patient Discount Programs. The Company offers discount card programs to patients under which the patient receives a discount on his or her prescription. The Company reimburses pharmacies for this discount through a third-party vendor. The Company records the total amount of discounts issued in the period as a reduction of deferred revenue.

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Distribution Service Fees. The Company pays distribution services fees to each wholesaler for distribution and inventory management services. The Company accrues for the fees based on contractually defined terms with each wholesaler and records the expense as deferred cost of goods sold.

Chargebacks. The Company provides discounts to federal government qualified entities with whom the Company has contracted. These federal entities purchase products from the wholesalers at a discounted price, and the wholesalers then charge back to the Company the difference between the current retail price and the contracted price the federal entity paid for the product. The Company accrues estimated chargebacks based on contract prices and sell-through sales data obtained from third party information.

Rebates. The Company participates in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, the Company pays a rebate to the third-party administrator of the program. The Company accrues estimated rebates based on contract prices, estimated percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel.

At December 31, 2011 the total accrual for sales discounts and allowances related to the sale of DUEXIS, following its commercial launch in the U.S. was not material.

Cost of Goods Sold

As a result of the acquisition of Nitec in April 2010, the Company began to recognize cost of goods sold in connection with its sale of LODOTRA. Cost of sales of LODOTRA includes all costs directly related to the manufacture and delivery of product and out-licensing of distribution and marketing rights to third parties. The cost in connection with product delivery to the Company s distribution partners consists of raw material costs, costs associated with third parties who manufacture LODOTRA for the Company, supply chain costs, royalty payments to third parties for the use of certain licensed patents and applicable taxes. Cost of goods sold also includes amortization of developed technology related to the acquisition of Nitec.

As a result of the commercial launch of DUEXIS in the U.S. in December 2011, the Company began to recognize cost of goods sold in connection with its sale of DUEXIS. Cost of sales of DUEXIS includes all costs directly related to the acquisition of product from the Company s third party manufacturers, including freight charges. The Company also defers the related DUEXIS cost of goods sold and records such amounts as other current assets until revenue is recognized.

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market value. Inventories consist of raw materials, work-in-process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. The Company s inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs.

Inventories exclude product sample inventory, which are included in other current assets and are expensed as a component of sales and marketing expense when provided to physicians or healthcare providers. As of December 31, 2011 and 2010, the Company had product sample inventory of $629 and $0, respectively.

Preclinical Study and Clinical Trial Accruals

The Company s preclinical studies and clinical trials have been conducted by third-party contract research organizations and other vendors. Preclinical study and clinical trial expenses are based on the services received from these contract research organizations and vendors. Payments depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients and site initiation. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts the accrual accordingly. To date, the Company has had no significant adjustments to accrued clinical expenses.

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Fair Value of Financial Instruments

Carrying amounts of the Company s financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their s