HORIZON PHARMA, INC.
Form 10-K
March 18, 2013
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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, 2012

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	60015
(Address of principal executive offices)	(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 Website, 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	x
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

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

The aggregate market value of the registrant s voting common stock held by non-affiliates of the registrant, based upon the $7.13 per share closing sale price of the registrant s common stock on June 29, 2012 (the last business day of the registrant s most recently completed second quarter), was approximately $150,877,787. Solely for purposes of this calculation, the registrant s directors and executive officers and holders of 10% or more of the registrant s outstanding shares of common stock have been assumed to be affiliates and an aggregate of 12,585,513 shares of the registrant s voting common stock held by such persons on June 29, 2012 are not included in this calculation.

As of March 13, 2013, the registrant had outstanding 61,947,247 shares of its common stock.

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HORIZON PHARMA, INC.

FORM 10-K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2012

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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, or the Exchange Act, that reflect our current expectations regarding our future growth, results of operations, financial condition, cash flows, performance, 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 results to d 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 commercialize DUEXIS® and RAYOS® in the U.S.; our ability to obtain additional financing; our ability to maintain regulatory approvals for DUEXIS and RAYOS, known as LODOTRA® outside 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 RAYOS/LODOTRA, 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 management, sales and marketing, regulatory, clinical affairs, medical affairs or development 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 RAYOS/LODOTRA; 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 specialty pharmaceutical company that has developed and is commercializing DUEXIS and RAYOS/LODOTRA, both of which target unmet therapeutic needs in arthritis, pain and inflammatory diseases. Our strategy is to develop, acquire, in-license and/or co-promote additional innovative medicines where we can execute a targeted commercial approach in specific therapeutic areas while taking advantage of our commercial strengths and the infrastructure we have put in place.

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. In the second-half of 2011, we hired our initial commercial organization, including approximately eighty sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In the third quarter of 2012, we expanded our sales force to

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approximately one hundred fifty representatives and under a co-promotion agreement with Mallinckrodt LLC, or Mallinckrodt, the pharmaceutical business of Covidien plc, or Covidien, Mallinckrodt began calling on twenty five thousand exclusive physician targets. Our sales force expansion, along with the Mallinckrodt co-promotion agreement, expanded our called-on physician targets for DUEXIS from approximately ten thousand to approximately fifty thousand. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal S.A., or Grünenthal, a private company focused on the promotion of pain products. In March 2013, we announced that the United Kingdom, or UK, Medicines and Healthcare products Regulatory Agency, or MHRA, granted a National Marketing Authorization, or MA, for DUEXIS in the UK. We will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded non-steroidal anti-inflammatory drugs, or NSAIDs, we do not expect a material level of sales from DUEXIS in European markets.

Our other lead product, RAYOS, known as LODOTRA outside the U.S., is a proprietary delayed-release formulation of low-dose prednisone for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, polymyalgia rheumatica, or PMR, psoriatic arthritis, or PsA, ankylosing spondylitis, or AS, asthma and chronic obstructive pulmonary disease, or COPD, and a number of other conditions. We plan to focus our promotion of RAYOS in the U.S. on rheumatology indications, including RA and PMR. We began detailing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of rheumatologists and high-value primary care physicians. LODOTRA is currently marketed in Europe by our distribution partner, Mundipharma International Corporation Limited, or Mundipharma.

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 , RAYOS and LODOTRA 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.

Our Strategy

Our strategy is to utilize the commercial strengths and the infrastructure that we have put in place in creating a fully-integrated U.S.-focused specialty pharmaceutical company to successfully commercialize DUEXIS and RAYOS in the U.S. market and also to expand and leverage these capabilities by developing, acquiring, in-licensing or co-promoting additional products where we can execute a targeted commercial approach in specific therapeutic areas. 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 and our relationship with Grünenthal for the commercialization of DUEXIS in Latin America.

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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, or Merck Serono, 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, or Mundipharma Laboratories. We also entered into distribution agreements with Mundipharma for the exclusive distribution and marketing rights pertaining to LODOTRA for Europe (originally excluding Germany and Austria) and certain Asian, Latin American and other countries and a manufacturing and supply agreement with Mundipharma Medical Company, or Mundipharma Medical, pursuant to which we supply LODOTRA to Mundipharma Medical. We have also entered into a manufacturing and supply agreement with Jagotec AG, or Jagotec, an affiliate of SkyePharma AG, or SkyePharma, from whom we purchase LODOTRA. In May 2011, we entered into a manufacturing and supply agreement with sanofi-aventis U.S. to manufacture and supply DUEXIS. In August 2011, SkyePharma leased its entire pharmaceutical manufacturing business to Aenova France SAS, or Aenova, with our consent to allow Jagotec to subcontract the manufacture of LODOTRA to Aenova. In addition, we have entered into an exclusive agreement with Grünenthal for the commercialization of DUEXIS in Latin America.

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 RAYOS/LODOTRA 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; UK National MA approved in March 2013	Horizon	Worldwide excluding Latin America
		Registration	Grünenthal	Latin America
RAYOS/LODOTRA	Rheumatoid arthritis	NDA approved July 26, 2012, approved and marketed in Europe	Horizon	Worldwide, excluding Europe and certain Asian, Latin American and other countries
			Mundipharma	Europe and certain Asian, Latin American and other countries
	Polymyalgia rheumatica and other indications	NDA approved July 26, 2012	Horizon	Worldwide, excluding Europe and certain Asian, Latin American, and other countries

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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.

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-

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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 anti-rheumatic 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. 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. Interleukin 6, or IL-6, levels are substantially increased in patients with RA in general and show a significant circadian variation in these levels. 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.

Because RA has the potential to cause serious damage to joints and bones, 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.

Polymyalgia Rheumatica

PMR is an inflammatory disorder that causes significant muscle pain and stiffness. The pain and stiffness often occur in the shoulders, neck, upper arms and hip with pronounced morning stiffness lasting at least one hour. Symptoms of PMR usually begin within two weeks. Most people who develop PMR are older than 65 years of age. It rarely affects people younger than 50. There are approximately 1.1 million patients with PMR in the U.S. and it afflicts one in every 133 people over the age of 50. Prednisone is the standard of care for treating PMR and treatment is generally initiated at a relatively high dose (e.g., 10-20 mg per day) and reduced as clinical improvement is seen. Treatment usually lasts 18-24 months. Similar to RA, PMR is associated with circadian patterns of IL-6 elevation in early morning hours.

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, gastroesophageal reflux disease, or 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 both provide effective pain relief and decrease stomach acidity, thus reducing the risk of NSAID-induced upper GI ulcers.

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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 and 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 Source Healthcare Analytics (formerly Wolters Kluwer Pharmaceutical) Audit Suite Total Rx s 2002-2012 (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 Alimentary 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.

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

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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 Alimentary 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;
- 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

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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 a new drug application, or 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. 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 (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 RA and OA and to decrease the risk of developing GI ulcers in patients who are taking ibuprofen for these indications. In the second-half of 2011, we hired our initial commercial organization, including approximately eighty sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In the third quarter of 2012, we expanded our sales force to approximately one hundred fifty representatives and under a co-promotion agreement with Mallinckrodt, the pharmaceutical business of Covidien, Mallinckrodt began calling on twenty five thousand exclusive physician targets. Our sales force expansion, along with the Mallinckrodt co-promotion agreement, expanded our called-on physician targets for DUEXIS from approximately ten thousand to approximately fifty thousand. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal, a private company focused on the promotion of pain products. In March 2013, we announced that the UK MHRA granted a MA for DUEXIS in the UK. We will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded NSAIDs, we do not expect a material level of sales from DUEXIS in European markets.

RAYOS/LODOTRA

RAYOS, known as LODOTRA outside the U.S., is a proprietary delayed-release formulation of low-dose prednisone that is currently marketed in Europe by our distribution partner, Mundipharma, for the treatment of moderate to severe, active RA in adults particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, PMR, PsA, AS, asthma, COPD and a number of other conditions. We plan to focus our promotion of RAYOS in the U.S. on rheumatology indications, including RA and PMR. We began detailing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of rheumatologists and high-value primary care physicians. LODOTRA is currently marketed in Europe by our distribution partner, Mundipharma.

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 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 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.

RAYOS/LODOTRA Solution

The proprietary formulation technology of RAYOS/LODOTRA enables a delayed-release of prednisone approximately four hours after administration. As reflected in the chart below, RAYOS/LODOTRA 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 and PMR.

RAYOS/LODOTRA was developed utilizing SkyePharma s proprietary GeoClock and GeoMatrix technologies, for which we hold an exclusive worldwide license for the delivery of corticosteroids. RAYOS/LODOTRA 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. RAYOS/LODOTRA is intended to be administered at bedtime. At approximately four hours following bedtime administration of RAYOS/LODOTRA, 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.

Our pharmacokinetic studies have shown that the blood concentration of prednisone from RAYOS/LODOTRA is similar to immediate release prednisone except for the intended time delay of product release after administration. The administration of RAYOS/LODOTRA (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 RAYOS/LODOTRA (5 mg) compared to an immediate release prednisone 5 mg tablet.

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Clinical Trial Results

We have successfully completed two pivotal Phase 3 clinical trials evaluating RAYOS/LODOTRA for the treatment of RA. The Circadian Administration of Prednisone in Rheumatoid Arthritis-1, or CAPRA-1 trial, investigating the efficacy of RAYOS/LODOTRA in the treatment of RA, supported the marketing authorization application 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, supported 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 RAYOS/LODOTRA 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 RAYOS/LODOTRA were permitted to continue RAYOS/LODOTRA treatment and patients taking immediate release prednisone were permitted to switch to RAYOS/LODOTRA for a nine-month open label extension study for a total of 12 months. There were a total of 219 patients who completed the open label extension study.

The trial results demonstrated that bedtime administration of RAYOS/LODOTRA 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 RAYOS/LODOTRA 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 RAYOS/LODOTRA compared to approximately 0.4% for patients taking immediate release prednisone (p-value = 0.045) after 12 weeks.

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RAYOS/LODOTRA 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, RAYOS/LODOTRA 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 RAYOS/LODOTRA compared to 9.0% for immediate release prednisone), abdominal pain (3.5% for RAYOS/LODOTRA compared to 5.6% for immediate release prednisone), nasopharyngitis, or inflammation of the nasal passages (2.8% for RAYOS/LODOTRA compared to 5.6% for immediate release prednisone) headache (4.2% for RAYOS/LODOTRA compared to 2.8% for immediate release prednisone), and flushing (2.8% for RAYOS/LODOTRA and 4.2% for immediate release prednisone).

At the conclusion of the nine-month open label extension period, patients who continued treatment with RAYOS/LODOTRA experienced a 55% reduction in the duration of morning stiffness. In addition, patients who were newly assigned to RAYOS/LODOTRA 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 RAYOS/LODOTRA 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.

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CAPRA-2

The primary endpoint of CAPRA-2 was to show that RAYOS/LODOTRA 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 RAYOS/LODOTRA (5 mg) or placebo once daily at bedtime in addition to their existing therapy. Results showed that patients treated with RAYOS/LODOTRA 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 RAYOS/LODOTRA 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 RAYOS/LODOTRA 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 RAYOS/LODOTRA 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).

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

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PMR

In PMR, blood concentrations of the pro-inflammatory cytokine IL-6 have been shown to increase and reach a peak during the early hours of the morning, in parallel to patients symptoms of pain and stiffness. This is similar to results in RA, another inflammatory condition with marked circadian variation in symptoms. RAYOS/LODOTRA has been shown to better control the symptoms of RA than taking the same dose of prednisone in the morning and also to suppress the nocturnal rise in IL-6. Also, 7 mg of RAYOS/LODOTRA was shown to more successfully suppress the nocturnal rise in IL-6 in PMR than 7 mg of prednisolone taken in the morning.

Mean (95% CI) plasma IL-6 concentrations over 24 hours in 10 untreated patients with PMR, and in 6 of these patients treated for 2 weeks with 7 mg of prednisolone in the morning and 4 treated for 2 weeks with 7 mg of RAYOS/LODOTRA at night.

Further, although only a small study, symptoms of morning stiffness were also better suppressed with RAYOS/LODOTRA almost as well as 15 mg of prednisolone taken in the morning.

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Morning stiffness and plasma IL-6 as a proportion of baseline (Night A) after 2 weeks of treatment with 7 mg of prednisolone in the morning or 7 mg MR RAYOS/LODOTRA at night (Night B) and after a further 2 weeks of treatment with prednisolone 15 mg in the morning (Day C) ($P<0.05$ for differences at Night B).

This study suggested that 7 mg of RAYOS/LODOTRA had a similar efficacy to 15 mg of prednisolone in the morning, a standard treatment for PMR. This raises the possibility of using lower doses of RAYOS/LODOTRA to treat PMR, which would have profound implications for the reduction of adverse effects and the simplification of treatment regimens in clinical practice.

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 RAYOS/LODOTRA for the potential treatment for PMR outside the U.S, which we expect will be a Phase 3 clinical trial, beginning in the first quarter of 2013.

Regulatory and Commercial Status

LODOTRA received its first approval in Europe in March 2009 and is currently approved for marketing in 20 countries outside the U.S. where it is being commercialized by Mundipharma. RAYOS was approved in the U.S. in July 2012 where it is being commercialized by Horizon.

RAYOS/LODOTRA in Other Indications

We also conducted a small Phase 2 clinical trial to evaluate the potential use of RAYOS/LODOTRA to treat severe asthma compared to immediate-release prednisone. 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 RAYOS/LODOTRA. We currently do not have plans at this time to pursue commercialization of RAYOS for the treatment of severe asthma

Commercial Agreements

Merck Serono License Agreements (Assigned to Mundipharma Laboratories)

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

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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 Laboratories from Merck Serono and Merck GesmbH 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.

For the years ended December 31, 2012 and 2011, Merck Serono accounted for 0% and 20% of total gross 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. 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.

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

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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 and the manufacturing and supply 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, as amended, 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, 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 tablets of product to millions of tablets of product 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, as amended, 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

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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 years ended December 31, 2012, 2011 and 2010, Mundipharma and Mundipharma Laboratories accounted for approximately 39%, 79% and 0%, respectively, of our consolidated gross sales.

Grünenthal Agreement

In June 2012, we entered into a collaboration, license and supply agreement with Grünenthal for the potential commercialization of DUEXIS in certain Latin American and Caribbean countries. Under the terms of the agreement, we will supply DUEXIS to Grünenthal exclusively in the territory at an agreed upon price and they will have the exclusive right to distribute DUEXIS in the territory. Subject to early termination, the term of the agreement is 10 years from launch with certain automatic 2-year renewal provisions.

Mallinckrodt Agreement

In June 2012, we entered into a co-promotion agreement with Mallinckrodt, the pharmaceutical business of Covidien, pursuant to which we engaged Mallinckrodt on a non-exclusive basis to promote DUEXIS in the United States, excluding any territories or possessions and excluding Puerto Rico. Under the terms of the Mallinckrodt agreement, Mallinckrodt has agreed to use commercially reasonable efforts to promote DUEXIS to an agreed list of physician promotion targets. Mallinckrodt is required to achieve minimum levels of prescriptions from targeted physicians on a quarterly basis during the term of the Mallinckrodt agreement, and we agreed not to grant to any third party the right to co-promote DUEXIS to those targeted physicians in the agreed upon territory during the term, other than an existing third party agreement that has since been terminated. Under the terms of the Mallinckrodt agreement, we are responsible for the manufacture, supply and distribution of DUEXIS.

The term of the Mallinckrodt agreement continues through December 31, 2014 subject to automatic six-month renewals unless either party provides advance notice that it does not wish to renew, unless the agreement is terminated early. Either party may terminate the agreement early if any governmental authority takes any action that would prevent performance or make performance illegal, if any third party asserts that commercialization of DUEXIS infringes an issued U.S. patent, upon a change of control of the other party or upon an uncured material breach by the other party. In addition, Mallinckrodt may terminate the agreement upon notice if a third party launches a generic version of DUEXIS, upon specified supply failures that are not cured, or upon breach of our agreement not to grant rights to co-promote DUEXIS to targeted physicians. In addition, each party may terminate the agreement upon certain failures to achieve minimum levels of prescriptions for a specified period of time. Under certain circumstances, we may owe Mallinckrodt a residual fee payment upon termination.

SkyePharma and Jagotec Agreements

Development and License Agreement

In August 2004, we entered into a development and license agreement with SkyePharma and Jagotec, 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

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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 RAYOS/LODOTRA which we can exercise any time upon specified prior written notice, expiring no earlier than five years after the first launch of RAYOS/LODOTRA. We have exercised the option to acquire the manufacturing license, which license will become effective in April 2014.

In return for the grant of the license, Jagotec has the right to manufacture, package and supply RAYOS/LODOTRA 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 RAYOS/LODOTRA and on any sub-licensing income, which includes any payments not calculated based on the net sales of RAYOS/LODOTRA, such as license fees, and lump sum and milestone payments.

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 RAYOS/LODOTRA. 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 RAYOS/LODOTRA. Under the agreement, which was amended in March 2011, Jagotec or its affiliates manufacture and supply RAYOS/LODOTRA 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 RAYOS/LODOTRA, with our consent. We are required to purchase RAYOS/LODOTRA exclusively from Jagotec for an agreed period of time, after which we will be able to purchase RAYOS/LODOTRA from other manufacturers if we choose. As of December 31, 2012 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 RAYOS/LODOTRA.

We pay Jagotec, exclusive of any value added tax or similar governmental charges, a price for RAYOS/LODOTRA 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 RAYOS/LODOTRA 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 RAYOS/LODOTRA from Jagotec for a period of 24 months after termination by Jagotec, regardless of the reason for termination.

Pursuant to a letter agreement between Jagotec and us, Jagotec agreed to allow us to give Bayer Pharma AG, or Bayer, the right to manufacture, test and release quantities of LODOTRA in order to establish and maintain Bayer as a manufacturer of LODOTRA. Under certain circumstances, we may also purchase shortfall quantities of LODOTRA from Bayer to the extent Jagotec is unable to supply us. We have entered into an agreement with Bayer effective March 1, 2013 to allow us to purchase quantities of LODOTRA for these purposes. After our manufacturing license from Jagotec becomes effective, we may also purchase quantities of LODOTRA from Bayer pursuant to our agreement with Bayer.

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Manufacturing and Supply Agreement with sanofi-aventis U.S. LLC

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. 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 commercial manufacturer and supplier of 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.

Temmler Supply Agreement

We have entered into an agreement with Temmler Werke GmbH, or Temmler, for the packaging and assembling of RAYOS/LODOTRA. Pursuant to the agreement, we may order RAYOS/LODOTRA according to

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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 RAYOS/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 for successive renewal terms of three years each 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

Subsequent to the April 2011 FDA approval of DUEXIS we hired our initial commercial organization of approximately 80 field sales representatives and completed sales force training. We began detailing DUEXIS to physicians in December 2011 and held our launch meeting for DUEXIS in the U.S. in January 2012. In June 2012, to increase the number of called-on physicians for DUEXIS and in anticipation of the potential FDA approval of RAYOS, we began expanding our commercial organization and in early October 2012, we announced the expansion to approximately 150 field sales representatives was completed. Also in June 2012, we engaged Mallinckrodt, the pharmaceutical business of Covidien, to co-promote DUEXIS in the U.S. Our sales force expansion, along with the Mallinckrodt co-promotion agreement, expanded our called-on physician targets for DUEXIS from approximately ten thousand to approximately fifty thousand. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal, a private company focused on the promotion of pain products. In March 2013, we announced that the UK MHRA granted a MA for DUEXIS in the UK. We will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded NSAIDs, we do not expect a material level of sales from DUEXIS in European markets.

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 RAYOS/LODOTRA, 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

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World Intellectual Property Organization covering site- and time-controlled GI release of corticosteroids and 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. One of these, U.S. Patent application 13/428,548, has received a notice of allowance from the U.S. patent office and is expected to issue as a U.S. patent during the second quarter of 2013. 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 to 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, Israel, New Zealand, South Africa, Brazil, India, 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.

There are four issued U.S. patents listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, U.S. 8,067,451, U.S. 8,067,033, U.S. 8,309,127, and U.S. 8,318,202, all of which expire on July 18, 2026. Additionally, we recently received a notice of allowance from the U.S. patent office on U.S. 13/620,150, which also covers DUEXIS and is expected to issue as a U.S. patent in the second quarter of 2013. Further, DUEXIS is protected in Europe by EP 2043637, which was granted on January 4, 2012. Patents covering DUEXIS have also issued/granted in Australia, China, South Africa, and New Zealand.

In the U.S., in addition to any patent protection, DUEXIS has been granted three years of marketing exclusivity as a Section 505(b)(2) NDA. RAYOS also received 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 had 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. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS and seeking an injunction to prevent

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the approval of Par s ANDA and/or preventing Par from selling a generic version of DUEXIS. In January 2013, we filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par s ANDA and/or preventing Par from selling a generic version of DUEXIS. A trial date is currently set for the second quarter of 2014. 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 Book. Under the FDA s rules and regulations, because we initiated a patent infringement suit to defend a patent identified in the Paragraph IV notice within 45 days after the FDA s receipt of the notice, the FDA is prevented from approving the ANDA until the earlier of 30 months from the date of the first suit or a decision in the infringement case that the patent is not infringed or invalid.

On March 13, 2013, we received a Paragraph IV Patent Certification from Alvogen Pine Brook, Inc., or Alvogen, advising that Alvogen had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Alvogen has not advised us as to the timing or status of the FDA s review of its filing, and we believe Alvogen s Paragraph IV certification may be defective because the FDA had not accepted the ANDA prior to Alvogen sending the certification. If a patent infringement suit is initiated to defend the RAYOS 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. We are evaluating Alvogen s Paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to RAYOS, 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;
- 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 such as Par, 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 RAYOS/LODOTRA, as well as future drug

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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., Naprelan, marketed by Shionogi Inc., and Vimovo, developed by Pozen Inc. and marketed by AstraZeneca AB.

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.

Naprelan is a fixed once-daily dose of naproxen sodium NSAID indicated for the treatment of RA, OA, AS, tendinitis, bursitis, acute gout and may also be used to relieve mild to moderate pain and the treatment of primary dysmenorrhea (menstrual cramps). We believe that DUEXIS may offer competitive advantages over Naprelan as Naprelan may cause ulcers and bleeding in the stomach and intestines while DUEXIS has been shown to reduce the risk of NSAID-induced upper GI ulcers.

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.

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 DUEXIS. In addition, physicians could begin to prescribe both an NSAID and 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.

RAYOS/LODOTRA

RAYOS/LODOTRA competes in Europe and in the U.S. 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

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-

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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, European Medicines Agency, or EMA, and other internationally recognized regulatory authorities. In addition, these facilities have been audited by these agencies to confirm compliance. We do not plan to build manufacturing facilities and plan to 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 critical 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.

RAYOS/LODOTRA

We rely on well-established third-party manufacturers for the manufacture of RAYOS/LODOTRA. In Europe, we retain quality responsibilities for RAYOS/LODOTRA by controlling the final release of products. We purchase the primary active ingredients for RAYOS/LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and from Sanofi-Aventis SA in France.

We have contracted with Jagotec for the production of RAYOS/LODOTRA tablets. Jagotec produces RAYOS/LODOTRA operating through its affiliate SkyePharma. The SkyePharma 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 RAYOS/LODOTRA, with our consent. We consider Aenova an experienced and reliable contract manufacturer dedicated largely to advanced oral dosage forms. The commercial scale production of RAYOS/LODOTRA tablets was implemented prior to the launch of LODOTRA in Europe in 2009. Under our manufacturing and supply agreement, we are required to purchase RAYOS/LODOTRA exclusively from Jagotec for an agreed period of time, after which we will be able to purchase RAYOS/LODOTRA from other manufacturers if we choose.

Pursuant to a letter agreement between Jagotec and us, Jagotec agreed to allow us to give Bayer the right to manufacture, test and release quantities of LODOTRA in order to establish and maintain Bayer as a manufacturer of LODOTRA. Under certain circumstances, we may also purchase shortfall quantities of LODOTRA from Bayer to the extent Jagotec is unable to supply us. We have entered into an agreement with Bayer effective March 1, 2013 to allow us to purchase quantities of LODOTRA for these purposes. After our manufacturing license from Jagotec becomes effective, we may also purchase quantities of LODOTRA from Bayer pursuant to our agreement with Bayer.

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

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

Distribution

Finished tablets for DUEXIS and RAYOS 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 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. Finished tablets for LODOTRA in Europe are shipped directly to our distribution partner, Mundipharma, in accordance with their purchase order instructions.

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 adequate reimbursement for our product candidates, in whole or in part. These pricing and reimbursement pressures may create negative reactions to any product price increases, or limit the amount by which we may be able to increase our product prices, which may adversely affect our product sales and results of operations.

The U.S. market has seen a trend in which retail pharmacies have become increasingly aggressive in determining which prescriptions will be filled with the requested product or a substitute product. Pharmacists and pharmacies utilize opportunities to suggest substitutions based on the direct benefit to their stores or perceived cost and benefit for a patient. Pharmacies can direct patients to a number of substitutions, including generic, over the counter or alternative brands. Many states have in place requirements for prescribers to indicate in writing on their prescriptions if they do not want pharmacies to make substitutions; these requirements are varied and not consistent across states. We have put in place strategies and tactics, both at pharmacies and at prescribers offices, to protect prescriptions written by prescribers for our products. We may need to increasingly spend time and resources to ensure the prescriptions written for our products are filled as written. Even with these efforts, this trend by pharmacies can erode the impact of our strategies and tactics. We continue to evaluate innovative initiatives to demonstrate value and protect the prescriptions that prescribers have written based on the value of our products.

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 healthcare industry. 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 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. Once the submission has been accepted for filing, the FDA s goal is to review applications within 12 months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, eight 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 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

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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 and RAYOS have 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 EMA (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) MAs 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 these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from

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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. 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 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 such that 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. 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. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, 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.

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. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes any request or demand for money or property presented to the U.S. government. 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 just a federal healthcare program.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including healthcare fraud, and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare 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 healthcare benefits, items or services.

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

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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. We may be a business associate of certain covered entities. 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 significant civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in U.S. federal or state healthcare 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, 2012, we had 247 full-time employees. Of our employees as of December 31, 2012, 38 were engaged in development, regulatory and manufacturing activities, 185 were engaged in sales and marketing and 24 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 our products will be subject to attaining significant market acceptance among physicians, patients and healthcare payers.

DUEXIS and RAYOS/LODOTRA, and other product candidates that we may develop, acquire, in-license or co-promote, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. In the U.S. market, we began selling DUEXIS in December 2011, we announced our co-promotion agreement with Mallinckrodt in June 2012 and we announced in October 2012 that we had completed the expansion of our sales force. We began commercial sales of RAYOS, which was approved by the FDA in July 2012, to a subset of rheumatologists in the fourth quarter of 2012 with the full launch to the majority of U.S. rheumatologists and high-value primary care physicians in late January 2013. Outside the U.S., LODOTRA has been sold in a limited number of European countries. Sales of DUEXIS and LODOTRA have been limited to date outside the U.S. and sales may not grow to expected levels, in part because, with respect to LODOTRA, we depend on our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for commercialization outside the U.S., and with respect to DUEXIS, we have only received marketing approval in the United Kingdom, or UK, thus far, and even if it is approved in other European countries, we do not expect the opportunity in Europe to be material to our business given the current state of the market in Europe for pain products and the revenue being generated by existing branded NSAIDs in Europe. We believe that the degree of market acceptance and our ability to generate revenues from our products 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;
- the performance of our distribution and co-promotion partners, over which we have limited control;
- 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 protective agents other than ibuprofen and famotidine, including those of our competitors, would be more

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effective for their patients. With respect to both DUEXIS and RAYOS/LODOTRA, their higher cost compared to the generic forms of their active ingredients alone may limit adoption by physicians, patients and healthcare payers. If DUEXIS, RAYOS/LODOTRA or any other product candidates that we may seek approval for, acquire, in-license or co-promote 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.

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 RAYOS/LODOTRA. 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 RAYOS in the U.S. market. We may not be able to successfully commercialize either DUEXIS or RAYOS in the U.S. Prior to 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. Although we announced in October 2012 the completion of our sales force expansion to approximately 150 sales representatives, we currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market these products and any additional products we may acquire, in-license or co-promote will be expensive and time-consuming and could delay any product launch. Nor can we be certain that we will be able to continue to successfully develop this capability. As a result of the evolving role of various constituents in the prescription decision making process, we adjusted the profile of the sales representatives we hire from those with traditional pharmaceutical sales experience to those with successful business to business experience. For example, we have faced challenges due to pharmacists increasingly switching a patient s intended prescription from DUEXIS to a generic or over the counter brand. We expect that we will face similar challenges for RAYOS. While we believe the new profile of our representatives is better suited for this evolving environment, we cannot be certain that our representatives will be able to successfully protect DUEXIS and RAYOS prescriptions or that we will be able to continue attracting and retaining sales representatives with our desired profile and skills. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain commercial personnel. 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 and maintain 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 RAYOS/LODOTRA, and we may not be able to successfully commercialize these products and failure to do so may adversely impact our existing debt facility and/or access to capital.

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. Our ability to generate significant product revenues and to achieve commercial success in the near term will initially depend almost entirely on our ability to successfully commercialize DUEXIS and RAYOS in the U.S. DUEXIS has been approved for marketing in

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the UK but is not yet approved in any other countries in Europe and therefore, unless we obtain regulatory approval in other countries DUEXIS may not be commercialized to any significant extent outside of the U.S. Even if DUEXIS is approved in other European countries, we do not expect the opportunity in Europe to be material to our business given the current state of the market in Europe for pain products and the revenue being generated by existing branded NSAIDs in Europe. Our initial strategy for RAYOS is to solely focus on the rheumatology indications approved for RAYOS where our Phase 3 clinical trial data supports our commercial plans. We initially launched RAYOS in the United States to a subset of rheumatologists in the fourth quarter of 2012, and the full launch to the majority of U.S. rheumatologists and high-value primary care physicians occurred in late January 2013. Although LODOTRA is approved for marketing in 20 countries outside the U.S., 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 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. Before we can market and sell these products in a particular jurisdiction, we 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 or our commercialization partners will obtain any additional regulatory approvals for our products. Even if we or our commercialization partners 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 condition and results of operations will be adversely affected.

Our $60.0 million senior secured loan that we entered into in February 2012 with a group of institutional lenders, or Senior Secured Loan, includes certain performance covenants, including minimum trailing twelve month revenue covenants at specified quarter ends beginning on June 30, 2012. Should we not meet these quarterly minimum trailing twelve month 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. There can be no assurance that we will be able to satisfy the operating and financial covenants under the Senior Secured Loan for future periods. 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 success of our efforts to commercialize DUEXIS in the United States will be partially dependent on our co-promotion agreement with Mallinckrodt.

Pursuant to our co-promotion agreement with Mallinckrodt, we engaged Mallinckrodt as a non-exclusive partner for the promotion of DUEXIS in the United States. We have limited control over the amount and timing of resources that Mallinckrodt may devote to the co-promotion of DUEXIS. If Mallinckrodt fails to adequately promote DUEXIS, or if Mallinckrodt s efforts are not effective for any other reason, our business may be negatively affected. In particular, we are relying on our co-promotion agreement with Mallinckrodt to reach a broader segment of the market than we could otherwise reach on our own. If Mallinckrodt is unsuccessful or the co-promotion agreement is terminated earlier than we expect, our ability to access these broader market segments may either be delayed or eliminated, and the revenues we may generate from sales of DUEXIS in the United States may be limited.

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We are subject to a number of other risks associated with our dependence on our co-promotion agreement with Mallinckrodt, including:

- Mallinckrodt could fail to devote sufficient resources to the promotion of DUEXIS, including by failing to maintain or train sufficient sales and marketing personnel to promote or provide information regarding DUEXIS;
- Mallinckrodt may not comply with applicable regulatory guidelines with respect to the promotion of DUEXIS, which could adversely impact sales of DUEXIS in the United States;
- we and Mallinckrodt may not be successful in coordinating our respective sales and promotion activities under the co-promotion agreement, which could lead to inefficiencies, the failure to maximize DUEXIS sales in the United States, and/or disagreements between us and Mallinckrodt; or
- business combinations or significant changes in Mallinckrodt s business strategy, including the acquisition or development by Mallinckrodt of other products, may adversely affect Mallinckrodt s ability or willingness to perform its obligations under our co-promotion agreement.

Our co-promotion agreement with Mallinckrodt is subject to early termination, including through Mallinckrodt s right to terminate if we experience certain supply failures in relation to the demand for DUEXIS in the United States, if monthly prescription volumes for DUEXIS in the United States do not meet certain amounts beginning one year after Mallinckrodt begins promotion of DUEXIS, or if any third party commercially launches a generic version of DUEXIS in the territory where Mallinckrodt is promoting DUEXIS. If the agreement is terminated early, we may not be able to find another partner to co-promote DUEXIS in the United States on acceptable terms, or at all, and we may be unable to sufficiently promote and commercialize DUEXIS in the United States on our own.

We are solely 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 have had disagreements with Mundipharma under our European agreements and may continue to have disagreements, which could harm commercialization of LODOTRA in Europe or result in the termination of our agreements with Mundipharma. 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.

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

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.

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To market any drugs outside of the U.S., we and current or future collaborators must comply with numerous and varying regulatory and compliance related 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.

Applications for regulatory approval, including a marketing authorization application, or MAA, for marketing new drugs in Europe, 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. The number and types of preclinical studies and clinical trials that will be required for regulatory 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. Regulatory 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.

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 regulatory authorities, or regulatory interpretation of these data and procedures may be unfavorable. 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.

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. Similarly, our ability to market DUEXIS outside of the U.S. will depend on obtaining regulatory and reimbursement approval in each country where we expect DUEXIS to be marketed. However, certain countries have a very difficult reimbursement environment and we may not obtain reimbursement approval in all countries where we expect DUEXIS to be marketed, or we may obtain reimbursement approval at a level that would make marketing DUEXIS in certain countries not viable.

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

We have two products approved in the U.S., one product with broad approval for commercial sale in Europe, and another product approved only for commercial sale in the UK thus far. RAYOS/LODOTRA has only been approved in the U.S., select countries within Europe, Australia, Korea and Israel 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 in March 2013 we announced we were granted marketing authorization for DUEXIS in the UK, and we have generated limited revenues for DUEXIS to date. We only recently began the commercial sale of RAYOS in the U.S. in the fourth quarter of 2012. We face considerable risks and difficulties as a company with limited commercial 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 commercial 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, our Senior Secured Loan includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end beginning in the first quarter of 2013. 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. There can be no assurance that we will be able to satisfy the operating and financial covenants under the Senior Secured Loan, as amended for future periods. 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.

We rely on third parties to manufacture commercial supplies of DUEXIS and RAYOS/LODOTRA, 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 sanofi-aventis U.S. LLC, or sanofi-aventis U.S., operating through Valeant Pharmaceuticals International, Inc., or Valeant, its manufacturing partner located in Laval, Canada for production of DUEXIS, and Jagotec AG, a wholly-owned subsidiary of SkyePharma PLC, 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 RAYOS/LODOTRA, with our consent. Bayer Schering Pharma AG in Germany has been qualified as a backup manufacturer for RAYOS/LODOTRA. 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. 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 RAYOS/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 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

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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 limited 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., operating through Valeant, 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 RAYOS/LODOTRA from Jagotec for a period of 24 months after termination, we would need to move our manufacturing to our alternate supplier of RAYOS/LODOTRA, Bayer Schering Pharma AG, in such an event and we may experience delays in implementing this transition.

In addition, we do not have the capability to package DUEXIS, RAYOS/LODOTRA or any other product candidates for distribution. Consequently, we have entered into an agreement with Temmler Werke GmbH for packaging of RAYOS/LODOTRA in certain European countries, Israel and in the U.S., as well as any additional countries as may be agreed to by the parties. We intend to sell drug product finished and packaged by either Temmler Werke GmbH or an alternate packager. Sanofi-aventis Canada Inc. manufactures and supplies DUEXIS to us in final, packaged form for the U.S. as well as any additional countries as may be agreed to by the parties.

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 commercialize DUEXIS and RAYOS 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 RAYOS/LODOTRA 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 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. As of December 31, 2011, and December 31, 2012, we employed 164 and 247 full-time employees, respectively, as a consolidated entity, including approximately 150 field sales representatives at December 31, 2012. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired in connection with the commercial launch of DUEXIS and RAYOS, requiring us to hire and train new sales representatives. 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 our commercialization plans and strategies develop, 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. We may also need to expand these capabilities, along with our field sales force size and capabilities if we develop, acquire, in-license or co-promote additional products. Our ability to manage any future growth effectively may require us to do, among other things, the following:

- continue to manage and expand the sales and marketing efforts for DUEXIS and RAYOS;
- enhance our operational, financial and management controls, reporting systems and procedures;
- expand our international resources;
- manage the MAA review process for DUEXIS to ensure additional approvals in Europe beyond the UK;
- 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 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 and RAYOS in the U.S. will be harmed.

As DUEXIS and RAYOS were not fully commercially launched until January 2012 and January 2013, respectively, the members of our sales force have limited experience promoting DUEXIS and almost no experience promoting RAYOS. 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 and RAYOS. In addition, we must train our sales force to ensure that a consistent and appropriate message about DUEXIS and RAYOS is being delivered to our potential customers. Our sales representatives

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may also experience challenges promoting two products when they call on physicians and their office staff, and our representatives may also be distracted from selling DUEXIS with the recent launch of RAYOS as all of our representatives were previously focused solely on selling DUEXIS. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired in connection with the commercial launch of DUEXIS and RAYOS, requiring us to train new sales representatives. As a result of the managed care environment and pharmacies switching patient s prescriptions to a generic or over the counter brand, we have had to adjust the profile of the sales representatives we hire from the traditional pharmaceutical representative to a representative with business to business experience that is focused on the total office call in order to protect the prescription the physician has written and ensure the patient receives what their doctor ordered. 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 RAYOS and their proper administration and label indication, our efforts to successfully commercialize DUEXIS and RAYOS 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 and we will have to find new ways to compete and may have to potentially merge with or acquire other businesses to stay competitive. 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 RAYOS/LODOTRA or any product candidates that we may develop.

DUEXIS faces competition from Celebrex®, marketed by Pfizer Inc., Vimovo®, marketed by AstraZeneca AB and Arthrotec®, marketed by Pfizer. DUEXIS also 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. Legislation enacted in most states in the United States allows or, in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded product, in the absence of specific instructions from the prescribing physician. Because pharmacists often have economic and other incentives to prescribe lower-cost generics, if physicians prescribe DUEXIS, those prescriptions may not result in sales. If we are unsuccessful in convincing physicians to provide prescribing instructions prohibiting the substitution of generic ibuprofen and famotidine separately as a substitution for DUEXIS, sales of DUEXIS may suffer despite any success we may have in promoting DUEXIS to physicians. 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 advising that Par had 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. In March 2012, we filed a patent infringement lawsuit against Par and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS. In January 2013, we filed a second suit against Par claiming patent infringement of additional patents that have been issued for DUEXIS. A trial date is currently set for the second quarter of 2014. 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 Book. Under the FDA s rules and

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regulations, because we initiated a patent infringement suit to defend a patent identified in the Paragraph IV notice within 45 days after the FDA s receipt of the notice, the FDA is prevented from approving the ANDA until the earlier of 30 months from the date of the first suit or a decision in the infringement case that the patent is not infringed or invalid. However, if we are unsuccessful on the patent litigation, we will likely face generic competition and our sales of DUEXIS will be substantially harmed.

RAYOS/LODOTRA competes 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 believe that RAYOS/LODOTRA s principal competition is prednisone, the active pharmaceutical ingredient in RAYOS/LODOTRA, or other oral corticosteriods, which, while they may be suboptimal, are less expensive than RAYOS/LODOTRA. 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.

On March 13, 2013, we received a Paragraph IV Patent Certification from Alvogen Pine Brook, Inc., or Alvogen, advising that Alvogen had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Alvogen has not advised us as to the timing or status of the FDA s review of its filing and we believe Alvogen s Paragraph IV certification may be defective because the FDA had not accepted the ANDA prior to Alvogen sending the certification. We are evaluating Alvogen s Paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to RAYOS, but we cannot predict the outcome of this matter. If we are unsuccessful in enforcing our intellectual property rights relating to RAYOS or Alvogen s ANDA is otherwise approved, we will likely face generic competition and our sales of RAYOS will be substantially harmed.

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

- Develop, acquire, in-license or co-promote medicines that are superior to other products in the market;
- attract qualified clinical, regulatory, 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.

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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, as well as in certain Asian and Latin American countries. Also, Grünenthal S.A. is in the registration process for the commercialization of DUEXIS in Latin America. 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, and certain Asian and Latin American countries, and commercialization of DUEXIS in Latin America, increased dependence on the commercialization efforts and regulatory compliance 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;
- 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.

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If we fail to develop, acquire, in-license or co-promote other product candidates or products, our business and prospects would be limited.

A key element of our strategy is to develop, acquire, in-license or co-promote and commercialize a portfolio of other product candidates in addition to DUEXIS and RAYOS/LODOTRA. 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, in-license or co-promote clinically enabled product candidates for the treatment of pain-related diseases, or for therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring, licensing or co-promoting promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition, license or co-promotion 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, license or co-promote 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, license or co-promote 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 is 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 RAYOS/LODOTRA, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates to follow our existing products, 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 or co-promotion 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 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 financial resources and 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.

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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., and our Executive Vice President and Chief Commercial Officer, Todd Smith. 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.

Despite our efforts to retain valuable employees, members of our management, sales and marketing, regulatory, clinical affairs, medical affairs 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 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.

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We are, with respect to DUEXIS and RAYOS, and will be, with respect to any other product candidate for which we obtain FDA approval, or acquire or in-license, subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense. Additionally, 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, or GLP, 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;
- 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, the imposition of civil or criminal penalties, or exclusions.

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.

Coverage and reimbursement may not be available, or reimbursement may be available at only limited levels, for DUEXIS, RAYOS/LODOTRA or any other product candidates that we develop, acquire, in-license or co-promote, which could make it difficult for us to sell our products profitably or to successfully execute planned product price increases.

Market acceptance and sales of DUEXIS, RAYOS/LODOTRA or any other product candidates that we may develop, acquire, in-license or co-promote will depend in large part on global coverage and 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 for healthcare. In particular, in the U.S., private health insurers and other third-party payers often provide reimbursement for products and services 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

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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. These pressures may create negative reactions to any product price increases, or limit the amount by which we may be able to increase our product prices, which may adversely affect our product sales and results of operations.

In Europe, the success of our products, including LODOTRA and, if widely approved, DUEXIS, will depend largely on obtaining and maintaining government coverage, because in many European countries patients are unlikely to use prescription drugs that are not covered by their government healthcare programs. To date, LODOTRA is approved in 20 countries outside the U.S., and reimbursement for LODOTRA has been obtained in Germany, Italy and Switzerland. Mundipharma is seeking coverage for LODOTRA in a number of countries in Europe and Israel and currently sells LODOTRA without coverage in a limited number of European countries. Negotiating coverage and reimbursement with governmental authorities can delay commercialization by 12 months or more. Coverage and 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 we 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.

In light of such policies and the uncertainty surrounding proposed regulations and changes in the coverage and reimbursement policies of governments and third-party payers, we cannot be sure that coverage and 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 coverage and reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize DUEXIS, RAYOS/LODOTRA 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.

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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 PPACA and its implementing regulations, including reporting any payment or transfer of value made or distributed to teaching hospitals, prescribers and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection to be required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services to be required by March 31, 2014 and by the 90th day of each subsequent calendar year;

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

expansion of healthcare 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.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, it remains unclear the full effect that the PPACA would have on our business. On June 28, 2012, the U.S. Supreme Court upheld the constitutionality of the PPACA, excepting certain provisions that would have required each state to expand its Medicaid programs or risk losing all of the state s Medicaid funding. At this time, it remains unclear whether there will be any further changes made to the PPACA, whether in part or in its entirety. Some states have indicated that they intend to not implement certain sections of the PPACA, and some members of the U.S. Congress are still working to repeal the PPACA. We anticipate that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in

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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, RAYOS/LODOTRA and any other products that we may develop, acquire, in-license or co-promote, 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 RAYOS/LODOTRA or any other product candidates that we may develop, acquire, in-license or co-promote. If we fail to successfully secure and maintain coverage and adequate 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 from payers concerning 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. If we are unsuccessful with our co-pay initiatives, we would be at a competitive disadvantage in terms of pricing versus preferred branded and generic competitors.

We are 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 RAYOS, and any of our other products or product candidates that are approved by the FDA and commercialized in the U.S. 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 educational 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 up to $25,000 per violation and imprisonment for not more than five years, or both, 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.

The federal False Claims Act prohibits persons from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to a federal healthcare program or knowingly making, using, or causing to

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be made or used, a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes any request or demand for money or property presented to the U.S. 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 of $5,500 to $11,000 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 marketing and promotional activities 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.

DUEXIS, RAYOS/LODOTRA 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 clinical 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 RAYOS/LODOTRA 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, RAYOS/LODOTRA 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.

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

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, including those required for post-marketing commitments. We may also have the need to enter into other such agreements in the future if we were to develop 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 Phase 3 clinical trial for LODOTRA for the potential treatment of PMR. 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 in Europe for LODOTRA 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 as a treatment for PMR on our own.

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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 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 potential 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 RAYOS/LODOTRA or we conduct clinical development of earlier stage product candidates or for additional indications for RAYOS/LODOTRA, we may experience delays in these clinical trials. A ten patient investigator-initiated Phase 2 study was recently completed to investigate LODOTRA as a potential treatment for PMR and a manuscript has been prepared by the investigator. Pursuant to a March 2011 letter agreement, Mundipharma has agreed to conduct a separate Phase 3 clinical trial for LODOTRA in this indication. While we are currently not focusing any resources on internal development of new 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.

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

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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.

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 Laval, Quebec, Canada and Lyon, France, and possibly elsewhere to produce our products in addition to a packaging provider, located in Munich, Germany. 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 RAYOS/LODOTRA 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 RAYOS and/or the potential commercial launches of DUEXIS and LODOTRA 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

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laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, 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 net losses of $87.8 million, $113.3 million and $27.1 million for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012, we had an accumulated deficit of $308.1 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 we will continue to incur operating losses in 2013 and into 2014 as we execute our plan to expand our development and commercialization activities of DUEXIS and RAYOS/LODOTRA, and seek other products or product candidates to develop, acquire, in-license or co-promote.

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.

Our $60.0 million 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. There can be no assurance that we will be able to satisfy the operating and financial covenants under the Senior Secured Loan for future periods. 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 March 2013, certain of our lenders notified us that they would require such prepayments for the second fiscal

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quarter of 2013 and we expect that we will continue to be required to make such prepayments in subsequent quarters. 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 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 revenues from sales of DUEXIS in late 2011 following the commercial launch in the U.S. LODOTRA is approved for marketing in 20 countries outside the U.S., and to date we have generated only limited revenues from sales of LODOTRA. RAYOS was approved by the FDA on July 26, 2012, and we began marketing it in the U.S through our full field sales force in late January 2013. We may never be able to successfully commercialize DUEXIS or RAYOS or develop or commercialize other products in the U.S., which we believe represents our most significant commercial opportunity, or sell DUEXIS in Europe, where we do not consider it to be material to our business. Our ability to generate future revenues depends heavily on our success in:

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

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.

We may need to obtain additional financing to successfully commercialize or further develop DUEXIS and RAYOS/LODOTRA, or to develop, acquire, in-license and/or co-promote other product candidates.

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

- launch and commercialize DUEXIS and RAYOS in the U.S.;
- complete the regulatory approval process, and any future required clinical development related thereto, for DUEXIS and RAYOS/LODOTRA;
- conduct clinical trials with respect to RAYOS/LODOTRA to generate clinical data in diseases beyond RA, such as PMR, or support our partner, Mundipharma, who is conducting such trials; and

potentially acquire, in-license and/or co-promote complementary products or products which augment our current therapeutic areas of focus.

We believe that our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations through 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, if we develop, acquire, in-license and/or co-promote additional products, or our revenues do not meet expectations.

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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. As of December 31, 2012, our Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. We will continue to monitor and review steps to address any 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 and could affect our ability to have sufficient cash at our U.S. subsidiary to meet its near term operating needs.

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 our use of the funds from our debt facility through debt covenants, we generally have broad discretion in the use of our cash 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 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 RAYOS, to fund additional regulatory approvals of DUEXIS and RAYOS/LODOTRA, to fund development of RAYOS/LODOTRA for other indications 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

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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. In September 2012, the sale of our common stock and warrants to purchase shares of our common stock in a public equity offering triggered an ownership change limitation and, as a result, we will be subject to annual limits on our ability to utilize net operating loss carryforwards. We estimate that these annual limits will be $27.9 million, $22.0 million and $22.0 million for the years 2013, 2014 and 2015, 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 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. While there has been some recent improvement in some of these financial metrics, 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 again, 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, 2012, we had $104.1 million of cash and cash equivalents consisting of cash and money market funds. 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, 2012, 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.

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

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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, RAYOS/LODOTRA and other product candidates in development. There is no assurance that 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 RAYOS/LODOTRA 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 had 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. In March 2012, we filed a patent infringement lawsuit against Par and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS. In January 2013, we filed a second suit against Par claiming patent infringement of additional patents that have been issued for DUEXIS. A trial date is currently set for the second quarter of 2014. 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 Book. Under the FDA s rules and regulations, because we initiated a patent infringement suit to defend a patent identified in Par s Paragraph IV notice within 45 days after the FDA s receipt of the notice, the FDA is prevented from approving Par s ANDA until the earlier of 30 months from the date of the first suit or a decision in the infringement case that the patent is not infringed or invalid. In addition, on March 13, 2013, we received a Paragraph IV Patent Certification from Alvogen advising that Alvogen had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Alvogen has not advised us as to the timing or status of the FDA s review of its filing and we believe Alvogen s Paragraph IV certification may be defective because the FDA had not accepted the ANDA prior to Alvogen sending the certification. If a patent infringement suit is initiated to defend the RAYOS 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 Alvogen s ANDA until the earlier of 30 months or a decision in the infringement case that each of the patents are not infringed or invalid.

We intend to vigorously defend our intellectual property rights relating to DUEXIS and RAYOS, but we cannot predict the outcome of the Par and Alvogen matters. Any adverse outcome in these matters could result in one or more generic versions of DUEXIS and/or RAYOS 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/or RAYOS 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 RAYOS/LODOTRA 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 RAYOS/LODOTRA 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 RAYOS/LODOTRA 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.

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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 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 RAYOS/LODOTRA 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 RAYOS/LODOTRA. 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 RAYOS/LODOTRA.

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 fully develop or be sustained even if it does. 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 report, these factors include:

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

- 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;

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unanticipated serious safety concerns related to the use of DUEXIS, RAYOS/LODOTRA 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, acquire, in-license and/or co-promote 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 management, commercial or regulatory 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;

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.

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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 officers, directors and funds affiliated with our directors own a significant percentage of our stock and will be able to influence matters subject to stockholder approval.

Our officers, directors and funds affiliated with our directors held in the aggregate approximately 22% and 23% of our outstanding voting stock as of December 31, 2012 and 2011, respectively. Therefore, these stockholders have the ability to influence us through this ownership position, including through matters requiring stockholder approval. For example, these stockholders may be able to influence the elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

We have incurred and will continue to 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 have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In particular, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by 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. These rules and regulations have substantially increased our legal and financial compliance costs and have made 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 continue to 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, these rules and regulations 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.

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 are required to perform annual system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our independent registered public accounting firm is also required to

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deliver a report on the effectiveness of our internal control over financial reporting. Our testing, or the 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 requires 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, as well as retain and work with consultants with such knowledge. Moreover, if we are not able to comply with the requirements of Section 404 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. 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 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 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 automatically increases on January 1 of each year 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

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reserved for issuance automatically increases on January 1 of each year 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 14, 2012, 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 1,474,304 shares and 200,000 shares, respectively, effective January 1, 2013.

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 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. 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.

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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 may 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 26,900 square feet of space in our headquarters in Deerfield, Illinois under lease agreements that expire on June 30, 2018. We also occupy approximately 5,000 square feet of office space in Mannheim, Germany under a lease that expires on December 31, 2014 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 advising that Par had 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. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par s ANDA and/or preventing Par from selling a generic version of DUEXIS. In January 2013, we filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par s ANDA and/or preventing Par from selling a generic version of DUEXIS. A trial date is currently set for the second quarter of 2014. 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 Book. Under the FDA s rules and regulations, because we initiated a patent infringement suit to defend a patent identified in the Paragraph IV notice within 45 days after the FDA s receipt of the notice, the FDA is prevented from approving the ANDA until the earlier of 30 months from the date of the first suit or a decision in the infringement case that the patent is not infringed or invalid.

On March 13, 2013, we received a Paragraph IV Patent Certification from Alvogen advising that Alvogen had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Alvogen has not advised us as to the timing or status of the FDA s review of its filing and we believe Alvogen s Paragraph IV certification may be defective because the FDA had not accepted the ANDA prior to Alvogen sending the certification. If a patent infringement suit is initiated to defend the RAYOS patents identified in the Paragraph IV notice within 45 days after the FDA s receipt of the notice, the FDA would be prevented from

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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. We are evaluating Alvogen s Paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to RAYOS, but we cannot predict the outcome of this matter.

Item 4. Mine Safety Disclosures

None.

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 periods indicated.

	Common Stock	
	High	**Low**
2012		
First quarter	$ 4.96	$ 3.05
Second quarter	7.47	3.50
Third quarter	8.72	3.29
Fourth quarter	3.50	2.03

	High	**Low**
2011		
Third quarter (commencing July 28, 2011)	$ 9.34	$ 6.85
Fourth quarter	8.99	3.86

Holders of Record

The closing price of our common stock on March 13, 2013 was $2.22. As of March 13, 2013, there were approximately 78 holders of record of our common stock.

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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 31, 2012, 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.

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. In addition, our ability to pay cash dividends is currently prohibited by the terms of our Senior Secured Loan so long as we owe any amounts to the lenders under the related loan agreements, subject to customary exceptions. 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.

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Recent Sales of Unregistered Securities

We completed the following issuances of unregistered securities during the year ended December 31, 2012:

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 to a group of institutional lenders. The warrants expire on January 22, 2017.

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.

In March 2012, we issued 41,797 shares of common stock to Kreos Capital III Limited upon the cashless exercise of a warrant to purchase an aggregate of 42,122 shares of common stock.

In July 2012, we issued 6,169 shares of common stock to Arivi Vermogensverwaltungs GmbH upon the cashless exercise of a warrant to purchase an aggregate of 13,807 shares of common stock.

In August 2012, we issued 34,518 shares of common stock to IB Invest GmbH upon the exercise of a warrant and we received proceeds of $148,703.55 representing the aggregate exercise price.

In August 2012, we issued 1,362,237 shares of common stock to FHP Pharma, L.L.C. upon the cashless exercise of a warrant to purchase an aggregate of 1,365,496 shares of common stock.

In September 2012, in connection with an amendment to our Senior Secured Loan, we issued an aggregate of 1,250,000 shares of common stock to a group of institutional lenders.

In October 2012, we issued 546,198 shares of common stock to Quaker BioVentures Capital II, L.P. upon the exercise of a warrant and we received proceeds of $5,462 representing the aggregate exercise price.

The offers, sales and issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D in that each issuance of securities was to an accredited investor under Rule 501 of Regulation D and 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 with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

Issuer Repurchases of Equity Securities

None.

Item 6. Selected Financial Data

The selected statement of operations data for the years ended December 31, 2012, 2011 and 2010, and the balance sheet data as of December 31, 2012 and 2011 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, 2009 and 2008, and the balance sheet data as of December 31, 2010, 2009 and

2008 have been derived from audited financial statements which are not included in this Annual Report on Form 10-K.

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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).

	For the Years Ended December 31,				
	2012	2011	2010	2009	2008
Statement of Operations Data					
Sale of goods	$ 22,761	$ 6,773	$ 2,376	$	$
Contract revenue	217	166			
Gross sales	22,978	6,939	2,376		
Sales discounts and allowances	(3,346)	(12)			
Net sales	19,632	6,927	2,376		
Cost of good sold	12,663	7,267	4,263		
Gross profit (loss)	6,969	(340)	(1,887)		
Operating expenses:					
Research and development	16,837	15,358	17,697	10,894	22,295
Sales and marketing	49,561	20,314	5,558	2,072	1,337
General and administrative	19,444	15,008	18,612	5,823	3,235
Intangible impairment charge		69,621			
Total operating expenses	85,842	120,301	41,867	18,789	26,867
Loss from operations	(78,873)	(120,641)	(43,754)	(18,789)	(26,867)
Other (expense) income, net:					
Interest expense, net	(14,525)	(6,284)	(3,024)	(2,189)	(529)
Bargain purchase gain			19,326		
Foreign exchange gain (loss)	489	(1,023)	(273)		
Other (expense) income	(56)			478	(503)
Loss before income tax benefit	(92,965)	(127,948)	(27,725)	(20,500)	(27,899)
Income tax benefit	(5,171)	(14,683)	(660)		
Net loss	(87,794)	(113,265)	(27,065)	(20,500)	(27,899)
Capital contribution				3,489	
Net loss attributable to common stockholders	$ (87,794)	$ (113,265)	$ (27,065)	$ (17,011)	$ (27,899)
Net loss per share - basic and diluted	$ (2.26)	$ (12.56)	$ (21.16)	$ (40.65)	$ (68.01)
Weighted average shares outstanding - basic and diluted	38,871,422	9,014,968	1,279,133	418,520	410,206

	As of December 31,				
	2012	2011	2010	2009	2008
Selected Balance Sheet Data					
Assets:					
Cash and cash equivalents	$ 104,087	$ 17,966	$ 5,384	$ 7,160	$ 14,067
Working capital (deficit)	79,983	1,065	(17,944)	(905)	(628)
Total assets	193,984	101,078	161,685	8,213	14,955
Long-term debt, net of current maturities	36,866	15,834	10,395	3,133	7,749
Accumulated deficit	(308,111)	(220,317)	(107,052)	(79,987)	(59,487)

Total stockholders equity (deficit)	105,978	45,912	97,056	(3,177)	(8,454)

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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.

Overview

We are a specialty pharmaceutical company that has developed and is commercializing DUEXIS and RAYOS/LODOTRA, both of which target unmet therapeutic needs in arthritis, pain and inflammatory diseases. Our strategy is to develop, acquire, in-license and/or co-promote additional innovative medicines where we can execute a targeted commercial approach in specific therapeutic areas while taking advantage of our commercial strengths and our existing infrastructure.

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. Between July and November 2011 we hired our initial commercial organization, including approximately eighty sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In June 2012, we engaged Mallinckrodt LLC, or Mallinckrodt, the pharmaceutical business of Covidien plc, pursuant to a co-promotion agreement to co-promote DUEXIS in the U.S. In the third quarter of 2012, we expanded our sales force to approximately one hundred fifty representatives. Our sales force expansion, along with the Mallinckrodt co-promotion agreement, expanded our called-on physician targets for DUEXIS from approximately ten thousand to approximately fifty thousand. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products. In March 2013, we announced that the United Kingdom, or UK, Medicines and Healthcare products Regulatory Agency, or MHRA, granted a National Marketing Authorization, or MA, for DUEXIS in the UK. We will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded non-steroidal anti-inflammatory drugs, we do not expect a material level of sales from DUEXIS in European markets.

Our other lead product, RAYOS, known as LODOTRA outside the U.S., is a proprietary delayed-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,

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active rheumatoid arthritis, or RA, in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the U.S. FDA approved RAYOS for the treatment of RA, Polymyalgia Rheumatica, or PMR, Psoriatic Arthritis, or PsA, Ankylosing Spondylitis, or AS, Asthma and Chronic Obstructive Pulmonary Disease, or COPD and a number of other conditions. We plan to focus our promotion of RAYOS in the U.S. on rheumatology indications, including RA and PMR. We began detailing RAYOS to a subset of rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of rheumatologists and high-value primary care physicians.

Critical Accounting Policies and Significant Judgments and Estimates

The methods, estimates and judgments that we use in applying our critical accounting policies have a significant impact on the results that we report in our financial statements. Some of our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates regarding matters that are inherently uncertain.

We have identified the accounting policies and estimates listed below as those that we believe require management s most subjective and complex judgments in estimating the effect of inherent uncertainties. This section should also be read in conjunction with Note 2, Summary of Significant Accounting Policies, in the notes to our condensed consolidated financial statements included in this report, which includes a discussion of these and other significant accounting policies.

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 product deliveries

We recognize revenue from the delivery of our products when delivery has occurred, title has transferred, the selling price is fixed or determinable, the right of return no longer exists (which is the earlier of product being dispensed through patient prescriptions or the expiration of the right of return) or product returns can be reasonably estimated, collectability is reasonably assured and we have no further performance obligations. Prior to October 2012, revenue for products sold in the U.S. to our wholesale pharmaceutical distributors and retail chains was recognized based on the amount of product sold through to the end user consumer. Beginning in October 2012, due to our ability to reasonably estimate and determine allowances for product returns, rebates and discounts, we began to recognize DUEXIS and RAYOS revenue at the point of sale to the wholesale pharmaceutical distributors and retail chains.

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

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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 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.

Cost of Goods Sold

Cost of goods sold for DUEXIS includes all costs directly related to the acquisition of product from our manufacturer, including freight charges and manufacturing overhead costs. Until we began recognizing revenue at the point of sale of DUEXIS to our wholesale pharmaceutical distributors and retail chains in the fourth quarter of 2012, we deferred the DUEXIS related cost of goods sold and recorded such amounts as other current assets until related revenue was recognized.

Cost of goods sold for 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, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

Cost of goods sold for RAYOS includes all costs directly related to the manufacture and delivery of product, including raw material costs, costs associated with third parties who manufacture RAYOS for us, supply chain costs, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

Inventories

Inventories are stated at the lower of cost or market value. Inventories consist of raw materials, work-in-process and finished goods. We have 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.

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.

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

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the vesting period. 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.

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. The fair value of equity awards granted to non-employees are re-measured at each reporting date, and the resulting change in the fair value associated with awards, if any, is recognized as a corresponding increase or reduction to stock-based compensation during the period.

RESULTS OF OPERATIONS

Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

	For the Years Ended December 31,		
	2012	2011	Increase / (Decrease)
Gross sales	$ 22,978	$ 6,939	$ 16,039
Sales discounts and allowances	(3,346)	(12)	3,334
Net sales	19,632	6,927	12,705
Cost of good sold	12,663	7,267	5,396
Gross profit (loss)	6,969	(340)	7,309
Operating expenses			
Research and development	16,837	15,358	1,479
Sales and marketing	49,561	20,314	29,247
General and administrative	19,444	15,008	4,436
Intangible impairment charge		69,621	(69,621)
Total operating expenses	85,842	120,301	(34,459)
Operating loss	(78,873)	(120,641)	(41,768)
Other income (expense)			
Interest expense, net	(14,525)	(6,284)	8,241
Foreign exchange gain (loss)	489	(1,023)	(1,512)
Other expense	(56)		56
Total other expense, net	(14,092)	(7,307)	6,785
Loss before benefit for income taxes	(92,965)	(127,948)	(34,983)
Benefit for income taxes	(5,171)	(14,683)	(9,512)
Net loss	$ (87,794)	$ (113,265)	$ (25,471)

Sales. Gross sales for the year ended December 31, 2012 increased $16.1 million to $23.0 million from $6.9 million for the year ended December 31, 2011. Net sales for the year ended December 31, 2012 increased $12.7 million to $19.6 million from $6.9 million for the year ended December 31, 2011.

DUEXIS gross sales increased $13.1 million, from $0.1 million during the year ended December 31, 2011, to $13.2 million during the year ended December 31, 2012. Net sales of DUEXIS increased $10.9 million, from $0.1 million during the year ended December 31, 2011, to $11.0 million during the year ended December 31, 2012. The increase in DUEXIS sales was attributable to the inclusion of a full year of sales during

the year ended December 31, 2012 compared to one month of product sales in the prior year. In addition, during the fourth quarter of 2012, as a result of a change in timing of DUEXIS revenue recognition to when product is sold into the wholesale and pharmacy channel instead of when product is dispensed through patient prescriptions, we recognized gross and net DUEXIS sales of $1.8 million and $1.4 million, respectively, that were previously deferred.

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LODOTRA gross sales increased $2.2 million, from $6.8 million during the year ended December 31, 2011, to $9.0 million year ended December 31, 2012. Net sales increased $1.4 million, from $6.8 million during the year ended December 31, 2011, to $8.2 million during the year ended December 31, 2012. The increase in LODOTRA sales was attributable to higher product shipments in 2012 in addition to a higher recognition of deferred revenues associated with product sales in prior periods to our distribution partner, Mundipharma.

Additionally, RAYOS gross and net sales were $0.8 million and $0.4 million, respectively, during the year ended December 31, 2012, as a result of our initial product launch during the fourth quarter of 2012 to a subset of high-value rheumatologists.

Cost of Goods Sold. Cost of goods sold increased $5.4 million, from $7.3 million during the year ended December 31, 2011, to $12.7 million during the year ended December 31, 2012. The increase in cost of goods sold was primarily attributable to a $3.4 million increase in DUEXIS product costs associated with full year commercial sales of DUEXIS compared to only one month of DUEXIS product sales in 2011, a $1.0 million increase in LODOTRA product costs due to higher product sales and a $1.0 million increase in amortization expense. The increase in amortization expense was related to the FDA approval of RAYOS in July 2012, which resulted in the reclassification and subsequent amortization of an indefinite-lived intangible asset to a finite-lived intangible asset. For the years ended December 31, 2012 and 2011, intangible amortization expense accounted for 37% and 52%, respectively, of total cost of goods sold.

Research and Development Expenses. Research and development expenses increased $1.5 million, from $15.3 million during the year ended December 31, 2011, to $16.8 million during the year ended December 31, 2012. The increase in research and development expenses was primarily associated with a $3.4 million increase in salaries and benefits expense as a result of additional staffing of our regulatory and medical affairs group, which supports scientific publications, health outcomes medical education and information and medical communications. The increase in payroll and benefits expense was partially offset by reductions in regulatory submission fees and clinical trial expenses of $1.8 million, and a reduction in legal fees of $0.2 million.

Sales and Marketing Expenses. Sales and marketing expenses increased $29.2 million, from $20.3 million during the year ended December 31, 2011, to $49.5 million during the year ended December 31, 2012. The increase in sales and marketing expenses was primarily attributable to salaries and related expenses for the full year for our initial 80 field sales representatives hired during the second half of 2011, incremental salaries and related expenses associated with increasing our field sales organization during the course of 2012 to approximately 150 sales representatives, salaries and related expenses associated with staffing the sales support functions to support a 150-person field sales force and an increase in marketing related expenses to launch and commercialize DUEXIS and RAYOS in the U.S. During the year ended December 31, 2012, personnel related costs increased approximately $17.5 million as a result of staffing our sales and marketing organization, expenses associated with marketing efforts for DUEXIS and RAYOS increased $9.0 million, consulting and outside service costs increased $1.9 million and other sales and marketing expenses increased $1.0 million.

General and Administrative Expenses. General and administrative expenses increased $4.4 million, from $15.0 million during the year ended December 31, 2011, to $19.4 million during the year ended December 31, 2012. The increase in general and administrative expenses was primarily due to $2.2 million in additional salaries and related benefits expense associated with incremental finance and administrative staff added during the second half of 2011 and during 2012 as we built out our corporate infrastructure, $1.0 million in higher legal fees associated with intellectual property and regulatory related matters and $1.1 million in higher facilities and information technology infrastructure expenses.

Intangible Impairment Charge. During the year ended December 31, 2011, we recorded an intangible impairment charge of $69.6 million related to the impairment of our indefinite-lived in-process research and development, or IPR&D, asset consisting of our rights to RAYOS in the U.S. 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

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attributed to us in the public markets, along with an appropriate risk control premium, that the IPR&D s fair value calculated was less than its carrying value at December 31, 2011. Accordingly, during the year ended December 31, 2011, we recorded an intangible impairment charge of $69.6 million to write down the value of our IRP&D asset to its fair value.

Interest Expense, Net. Interest expense, net increased $8.2 million, from $6.3 million during the year ended December 31, 2011, to $14.5 million during the year ended December 31, 2012. The increase in interest expense was primarily attributable to higher borrowing balances under our debt facilities compared to the prior year, higher debt extinguishment costs and amortization to interest expense of deferred financing and debt discount expenses. During the year ended December 31, 2012, we recorded a $2.5 million charge related to the extinguishment of prior debt facilities compared to a $1.9 million charge during the year ended December 31, 2011, related to the loss on extinguishment of another prior debt facility. Additionally, in the year ended December 31, 2012, we amortized to interest expense approximately $2.9 million in deferred financing and debt discount expenses associated with borrowings under our $60.0 million Senior Secured Loan.

Foreign Exchange Gain (Loss), Net. During the year ended December 31, 2012, we had a foreign exchange gain of $0.5 million compared to a foreign exchange loss of $1.0 million for the year ended December 31, 2011. The foreign exchange gain was primarily attributable to an increase in the value of the Euro against the U.S. dollar during the fourth quarter of 2012, which resulted in a favorable currency impact for our Swiss subsidiary, Horizon Pharma AG.

Income Tax Benefit. Income tax benefit decreased $9.5 million, from $14.7 million during the year ended December 31, 2011, to $5.2 million during the year ended December 31, 2012. The decrease in income tax benefit was primarily attributable to our IPR&D intangible asset impairment charge of $69.6 million during 2011, which reduced our deferred income tax positions and increased our income tax benefit. Benefit for income taxes during 2012 was primarily attributable to the amortization of our developed technology assets in addition to a one-time income tax benefit of $4.3 million recorded during the third quarter of 2012, which was associated with the reclassification of our IPR&D asset to developed technology as a result of the FDA approval of RAYOS.

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

	For the Years Ended December 31,		
	2011	2010	Increase / (Decrease)
Gross sales	$ 6,939	$ 2,376	$ 4,563
Sales discounts and allowances	(12)		12
Net sales	6,927	2,376	4,551
Cost of good sold	7,267	4,263	3,004
Gross loss	(340)	(1,887)	1,547
Operating expenses			
Research and development	15,358	17,697	(2,339)
Sales and marketing	20,314	5,558	14,756
General and administrative	15,008	18,612	(3,604)
Intangible impairment charge	69,621		69,621
Total operating expenses	120,301	41,867	78,434
Operating loss	(120,641)	(43,754)	76,887
Other income (expense)			
Interest expense, net	(6,284)	(3,024)	3,260
Foreign exchange gain (loss)	(1,023)	(273)	750
Bargain purchase gain		19,326	19,326
Other expense			
Total other expense, net	(7,307)	16,029	23,336
Loss before benefit for income taxes	(127,948)	(27,725)	100,223
Benefit for income taxes	(14,683)	(660)	14,023
Net loss	$ (113,265)	$ (27,065)	$ 86,200

Sales. Gross sales increased $4.5 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 sales was primarily attributable to higher product sales and the recognition of revenues from milestone receipts for LODOTRA during the fourth quarter of 2011. Additionally, sales 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

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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 our prior $12.0 million debt facility and our prior 7.5 million Euro debt facility, in addition to a higher borrowing base of debt as a result of our prior $17.0 million debt facility.

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 our deferred tax positions associated with the IPR&D intangible asset impairment charge of $69.6 million.

Liquidity and Capital Resources

We have incurred losses since our inception in June 2005 and, as of December 31, 2012, we had an accumulated deficit of $308.1 million. We anticipate that we will continue to incur net losses for at least the next few years. We expect that our sales and marketing expenses will continue to increase as a result of our commercialization of DUEXIS and RAYOS/LODOTRA. 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, 2012, we had $104.1 million in cash and cash equivalents. In February 2012, we entered into the $60.0 million Senior Secured Loan. We used $22.4 million of the loan proceeds to repay the remaining obligations under our previous debt facilities. 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

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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 3,277,191 shares of our common stock at an exercise price of $0.01 per share. The warrants became 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 a pledge of 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 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 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 12 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. During 2012, we elected to pay the 12% interest in cash and the remaining 5% interest of $1.8 million was added to the principal loan balance as incremental debt as payment in kind borrowings.

On September 7, 2012, we and the lenders entered into an amendment of the Senior Secured Loan, or the Senior Secured Loan Amendment, whereby affirmative covenants under the Senior Secured Loan with respect to minimum levels of liquidity and net revenue were modified. Under the Senior Secured Loan Amendment, we were required to have a minimum liquidity of $30.0 million as of December 31, 2012, rather than the $10.0 million required at all other times, and we were no longer required to achieve minimum net revenue levels for the trailing 12 month periods at the end of the third and fourth quarters of 2012, and the minimum trailing 12 month net revenues as of the end of each quarter of 2013 and the first quarter of 2014 were reduced. In lieu of paying a cash fee in consideration for entering into the Senior Secured Loan Amendment, we agreed to issue an aggregate of 1,250,000 shares of our common stock to the lenders. At December 31, 2012, the outstanding balance on the Senior Secured Loan was $61.8 million.

As of December 31, 2012, we were in compliance with all applicable financial covenants under the Senior Secured Loan as amended. 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. Additionally, our ability to comply with the operating and financial covenants under the Senior Secured Loan in future periods will be dependent on several factors including: the continued growth of the arthritis, pain and inflammation markets; acceptance of our products by patients, primary care specialists and other key specialists, including rheumatologists, orthopedic surgeons and pain specialists; the level of sales discounts and allowances we maintain for our products; 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.

Certain of the lenders under the Senior Secured Loan have required that we prepay the maximum $4.0 million of outstanding principal amounts for the quarter beginning April 1, 2013, and we expect that we will be

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required to prepay similar amounts for subsequent quarters as well. To the extent that we are required to make on-going quarterly prepayments of principal under the Senior Secured Loan, we may be required to seek additional funding earlier than we otherwise would in order to sustain our operations as well as maintain compliance with our minimum liquidity requirements under the Senior Secured Loan.

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 and received gross proceeds of $50.8 million. 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.

On August 1, 2012, we filed a registration statement on Form S-3, which became effective on August 9, 2012, that allows us to offer and sell up to an aggregate of $175.0 million worth of common stock, preferred stock, debt securities and/or warrants in public offerings. In September 2012, we received gross proceeds of $86.2 million from the sale of 24,638,750 shares of common stock and warrants to purchase an aggregate of 12,319,375 shares of common stock with an exercise price of $4.57 per share in a public offering under the registration statement. We currently have approximately $27.4 million worth of securities available for future issuance under the registration statement.

In August 2012, we entered into a sales agreement with Cowen and Company, LLC, pursuant to which we may sell, in at-the-market offerings, up to $75.0 million worth of common stock, of which $27.4 million is presently available for future issuance. Subject to the terms and conditions of the sales agreement, Cowen will use its commercially reasonable efforts to sell on our behalf any shares of common stock requested to be sold by us. Cowen and we each have the right, by giving written notice as specified in the sales agreement, to terminate the sales agreement in each party s sole discretion at any time. The aggregate compensation payable to Cowen as sales agent will not exceed 3.0% of the gross sales price of the shares sold through it pursuant to the sales agreement.

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. As of December 31, 2012 and 2011, our Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. We will continue to monitor and review steps to address any overindebtedness until such time as our Swiss subsidiary may generate 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 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 years December 31, 2012, 2011 and 2010, as follows:

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

	For the Years Ended December 31,		
	2012	2011	2010
Cash and cash equivalents	$ 104,087	$ 17,966	$ 5,384
Cash (used in) provided by:			
Operating activities	(76,641)	(41,540)	(37,532)
Investing activities	(1,386)	(2,154)	5,575
Financing activities	164,308	55,152	29,760

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Net Cash Used in Operating Activities

During the years ended December 31 2012, 2011 and 2010, net cash used in operating activities was $76.6 million, $41.5 million and $37.5 million, respectively. Net cash used in operating activities during 2012 was primarily attributable to staffing our sales and marketing organization and expenses related to our product launches of DUEXIS and RAYOS. Additionally, cash used in operating activities during 2012 was used for interest payments made on our Secured Senior Loan, additional staffing of support and administrative functions and for working capital purposes.

Net cash used in operating activities during 2011 was primarily due to costs related to our product launch of DUEXIS, staffing of our sales and marketing functions during the fourth quarter of 2011 and higher consulting and outside service costs associated with pre-commercialization efforts.

Net cash used in operating activities during 2010 was primarily due to the inclusion of operating costs for Nitec as a result of our acquisition in April 2010, investment banking and consulting fees associated with the acquisition of Nitec, and regulatory expenses in preparation for the submission for our NDA for DUEXIS.

Net Cash (Used in) Provided by Investing Activities

During the years ended December 31 2012 and 2011, net cash used in investing activities was $1.4 million and $2.2 million, respectively, compared to net cash provided by investing activities of $5.6 million for the year ended December 31, 2010. Net cash used in investing activities during 2012 and 2011 was primarily attributable to capital expenditures for computer hardware and equipment to support our sales and administrative functions. Additionally, during the year ended December 31, 2011, we were required to make restricted cash deposits of $0.6 million for our new corporate facility lease and our company-sponsored employee credit card program. During the year ended December 31, 2010, net cash provided by investing activities was $5.6 million and the increase was primarily due to $6.5 million of cash acquired in connection with our Nitec acquisition, partially offset by capital expenditures and restricted cash payments.

Net Cash Provided by Financing Activities

During the years ended December 31 2012, 2011 and 2010, net cash provided by activities was $164.3 million, $55.2 million and $29.8 million, respectively. Net cash provided by financing activities in 2012 was primarily the result of our debt refinancing and the equity offerings we completed. In February, we entered into our $60.0 million Senior Secured Loan with a group of institutional lenders. As part of the closing of the Senior Secured Loan, we repaid outstanding principal under previous debt facilities totaling $19.8 million. In March 2012, we received gross proceeds of $50.8 million and net proceeds of $47.5 million, after deducting $3.3 million in issuance costs, 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 to certain institutional and accredited investors in a private equity placement. In September 2012, we received gross proceeds of $86.2 million and net proceeds of $80.6 million after deducting $5.6 million in issuance costs from the sale of 24,638,750 shares of common stock and warrants to purchase an aggregate of 12,319,375 shares of common stock to certain institutional and accredited investors in a public offering.

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 convertible promissory notes in January and April 2011 and $16.7 million in net proceeds from new borrowings, net of repayments made on outstanding loan amounts of $13.1 million.

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

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the issuance of 2010 notes payable to related parties in the principal amount 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.

Contractual Obligations

As of December 31, 2012, minimum future cash payments due under contractual obligations, including, among others, our debt agreement, minimum purchase agreements and non-cancelable operating lease agreements, were as follows (in thousands including notes):

	2013	2014	2015	2016	2017	2018 & Thereafter	Total
Debt agreements (1)	$ 19,157	$ 21,660	$ 20,008	$ 18,275	$ 10,269	$	$ 89,369
Purchase commitments (2)(3)	10,772	1,072	1,072				12,916
Operating lease obligations (4)	586	595	478	450	462	258	2,829
Total contractual cash obligations	$ 30,515	$ 23,327	$ 21,558	$ 18,725	$ 10,731	$ 258	$ 105,114

(1) Represents minimum interest payments and quarterly principal debt repayments of $3,978 beginning in April 2013 under our Senior Secured Loan.
(2) Minimum purchase commitment for RAYOS/LODOTRA tablets from Jagotec through December 31, 2013 (the end of the minimum term), which is the firm commitment term under the contract.
(3) Purchase commitment of $9,700 for final packaged DUEXIS tablets from sanofi-aventis U.S. through December 31, 2013.
(4) These amounts reflect payments due under the following operating leases:

Lease agreement 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, which will increase each year during the initial term, up to approximately $35 per month after the sixth year. We have the option to extend the lease for an additional five-year term, which would commence upon the expiration of the initial term. In addition, includes a lease agreement entered in August 2012 for additional office space at our corporate headquarters. The August 2012 lease agreement requires initial rent of approximately $7 per month during the first year and will increase each year during the initial term, up to approximately $8 per month after the sixth year and expires in June 2018.

Leases for our offices in Reinach, Switzerland and in Mannheim, Germany. The Reinach office lease rate is approximately $7 (6 CHF) per month and expires on May 31, 2015. The Mannheim office lease rate is approximately $6 (5 EUR) per month, expiring on December 31, 2014.

Vehicle leases at our Reinach, Switzerland and Mannheim, Germany offices. As of December 31, 2012, payments of $26, $9, and $6 are due in years 2013, 2014 and 2015, respectively.

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 12, Commitments and Contingencies in the consolidated financial statements included in this report.

Recent Accounting Pronouncements

In January 2012, we adopted the Financial Accounting Standards Board, or FASB, Accounting Standards Update 2011-05, *Presentation of Comprehensive Income*, or ASU 2011-05, which eliminated our previous

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election to present other comprehensive income within the consolidated statements of changes in equity, and provided the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. The standard is reflected in our consolidated statement of comprehensive income and was retrospectively applied to all prior periods presented.

In February 2013, the FASB issued Accounting Standards Update 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income,* or ASU 2013-02. ASU 2013-02 requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under generally accepted accounting principles, or GAAP, to be reclassified in its entirety to net income. For other amounts that are not required under GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under GAAP that provide additional detail about those amounts. We adopted this standard on December 31, 2012 and it had no material impact on our consolidated financial condition, results of operations or cash flows.

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 third party borrowings under our Senior Secured Loan bear interest at fixed interest rates; therefore, we have limited interest rate exposure through our debt. However, we are subject to interest rate fluctuation exposure through our investment in money market accounts which bear a variable interest rate. The goals of our investment policy are associated with the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market 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 our 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 RAYOS, which was approved on July 26, 2012, 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 condensed consolidated financial statements are presented in this report.

Credit Risk. Historically, our accounts receivable balances are highly concentrated with a select number of customers, consisting primarily of large wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. During the years ended December 31, 2012, 2011 and 2010, sales to three or fewer customers accounted for approximately 83%, 98% and 100%, respectively, of our consolidated gross sales. In addition, as of December 31, 2012 and 2011, three or fewer customers comprised approximately 77% and 81%, respectively, of our total outstanding accounts receivable balances. Historically, we have not experienced any losses related to our accounts receivable balances.

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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

Our Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, or the Act), have concluded that, as of December 31, 2012, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the 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 by an issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer s management, including its principal executive officer or officers and principal financial officer or officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, there inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in *Internal Control Integrated Framework*. Based on its assessment, management concluded that, as of December 31, 2012, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) promulgated under the Act) identified in connection with the evaluation required by Rule 13a-15(d) promulgated under the Act that occurred during the fiscal quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Item 9B. Other Information

On March 14, 2013, our board of directors determined that going forward, Michael Adatto, our Senior Vice President, Managed Care and Commercial Development, would increasingly focus his efforts on managed care and commercial development and, as a result, would no longer retain his prior policy making functions and status as an executive officer at Horizon.

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 14, 2013:

Name	Age	Position with the Company
Directors		
Timothy P. Walbert	45	President, Chief Executive Officer and Chairman of the Board of Directors
Jeffrey W. Bird, M.D., Ph.D. (3)	52	Director
Jean-François Formela, M.D. (3)	56	Director
Michael Grey (1,2)	60	Lead Independent Director
Jeff Himawan, Ph.D. (2)	48	Director
Ronald Pauli (1,2)	52	Director
Gino Santini (1,3)	56	Director
Executive Officers (other than Mr. Walbert)		
Robert J. De Vaere	55	Executive Vice President, Chief Financial Officer
Jeffrey W. Sherman, M.D., FACP	58	Executive Vice President, Development, Regulatory Affairs, Manufacturing and Chief Medical Officer
Todd N. Smith	43	Executive Vice President, Chief Commercial Officer

(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, which exceeded $9.0 billion in 2012 sales, and divisional vice president, global cardiovascular strategy at Abbott, a broad-based healthcare company, now AbbVie. 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,

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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 from Muhlenberg College, in Allentown, Pennsylvania. Mr. Walbert also serves on the board of directors of XOMA Ltd. (NASDAQ: XOMA), Raptor Pharmaceutical Corp. (NASDAQ: RPTP), the Biotechnology Industry Organization (BIO), the Illinois Biotechnology Industry Organization (iBIO), ChicagoNEXT, a World Business Chicago (WBC) led council of technology leaders 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, and CEO of Verinata Health since May 2012. 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.

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. He also serves on the boards of directors of Annovation Biopharma, Inc., ARCA Biopharma, Inc., Arteaus Therapeutics, LLC and F-Star GmbH, and is the chairman of Egalet Ltd. as well as RaNA Therapeutics Inc., which he co-founded. Dr. Formela has been involved in the formation of companies such as Adnexus Therapeutics, Inc., which was acquired by Bristol-Myers Squibb Company, Archemix Corp., ArQule, Inc., Cellzome AG, which was acquired by GlaxoSmithKline plc, deCODE genetics, Inc., which was acquired by Amgen Inc, Exelixis, Inc., MorphoSys AG, NxStage Medical, Inc., and SGX, which was acquired by Lilly in 2008. He was also a board member of Biochem Pharma Inc., which was acquired by Shire Pharmaceuticals Group, and Novexel SA, which was acquired by Astrazeneca PLC in 2010. 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 and as lead independent director of the Company since August 2012. Mr. Grey currently serves as president and chief executive officer at Lumena Pharmaceuticals, Inc. and is a venture partner at Pappas 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 biopharmaceutical companies will bring important strategic insight to our board as we plan Horizon s future growth.

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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 a financial consultant for the pharmaceutical and life science industries. Prior to that, Mr. Pauli held senior positions at a number of biopharmaceutical companies, including chief financial officer at Sagent Pharmaceuticals, Inc. and NeoPharm, Inc. and corporate controller and interim chief financial officer at Abraxis BioScience, Inc. (formerly American Pharmaceutical Partners, Inc.). In addition, Mr. Pauli previously served as corporate controller for Applied Power, Inc. and R.P. Scherer Corporation, held multiple finance positions at Kmart Corporation and began his career at Ernst & Whinney. 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 currently serves on the board of directors of AMAG Pharmaceuticals, Inc. and Allena Pharmaceuticals, Inc. and is 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, 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.

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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 now a past president of DIA and serves as DIA liaison to the Clinical Trial Transformation Initiative, a public-private partnership founded by the FDA and Duke University to improve the quality and efficiency of clinical trials. He also serves on the Board of Advisors of the Center for Information and Study on Clinical Research Participation, a nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process. 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 our executive vice president and chief commercial officer since February 2012. Prior to that, Mr. Smith served as our 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, now AbbVie, 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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Board Composition

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

- Class I, which consists of Mr. Grey and Mr. Pauli, and whose term will expire at our 2015 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.

Board Committees

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

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Audit Committee

Our audit committee consists of 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 the 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;
- as appropriate, reviewing 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

During 2012 our compensation committee consisted of Dr. Formela, Mr. Grey and Dr. Himawan, with Dr. Formela serving as the chair of the compensation committee. Effective as of January 1, 2013, our compensation committee consists of Mr. Pauli, Mr. Grey and Dr. Himawan. Dr. Himawan now serves as the chair of the compensation committee, effective January 1, 2013. 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 outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as

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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

During 2012 our nominating and corporate governance committee consisted of Dr. Bird, Mr. Pauli and Mr. Santini, with Dr. Bird serving as the chair of the nominating and corporate governance committee. Since January 1, 2013, our nominating and corporate governance committee

consists of Dr. Formela, Dr. Bird and Mr. Santini. Dr. Formela now serves as the chair of the corporate governance and nominating committee, effective January 1, 2013. Our board of directors has determined that each of the members of this committee satisfies the NASDAQ independence requirements. Mr. Santini 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;

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

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, 2012, with the exception of Michael Grey, Ronald Pauli and Gino Santini, who each received an annual stock option grant on June 8, 2012 and each filed a Form 4 late on February 22, 2013.

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 discusses the compensation philosophy, policies and principles underlying our executive compensation decisions for the 2012 fiscal year. It provides qualitative information on the factors relevant to these decisions and the manner in which compensation is awarded to our executive officers who have been named in the Summary Compensation Table included in this Item 11 and whom we refer to as our named executive officers.

Our board of directors has delegated responsibility for creating, reviewing and making recommendations regarding 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 who approve all compensation decisions relating to our executive officers.

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Consideration of Stockholder Advisory Votes. Our say-on-pay vote held at our 2012 annual meeting of stockholders was supported by 99.7% of the votes affirmatively cast, excluding abstentions and broker non votes. While this vote was only advisory, our compensation committee interpreted it to be a very positive affirmation from our stockholders that they strongly endorse our historical compensation philosophy, policies and decisions. Accordingly, the compensation committee determined to not make any significant changes in setting 2012 or 2013 compensation levels for our executives. When determining how often to hold an advisory vote on executive compensation, our board of directors recommended and our stockholders agreed upon, an annual vote. In addition to holding an annual advisory vote on executive compensation, we are committed to ongoing engagement with our stockholders on executive compensation and corporate governance issues.

Executive Summary

Our compensation committee believes that our executive compensation program is appropriately designed and reasonable in light of the executive compensation programs of our industry group and peer group companies in that it both encourages our named executive officers to work for our long-term prosperity and reflects a pay-for-performance philosophy, without encouraging our employees to assume excessive risks. The major aspects of our executive compensation program include the following:

No Guaranteed Salary Increases or Bonus Awards. We do not provide our named executive officers with guaranteed salary increases or bonuses. Our named executive officers are employed at-will and are expected to demonstrate strong performance in order to continue serving as members of the executive team.

No Excessive Perquisites. We do not provide personal lifestyle perquisites, such as country club memberships, vacation units, personal use of aircraft, personal entertainment accounts, or similar perquisites, nor do we provide tax-gross ups for any executive perquisites.

Responsible Severance and Change in Control Compensation. Our executive employment agreements and our Severance Benefit Plan, in all cases require an involuntary or constructive termination of employment for our named executive officers to be eligible for any non-change of control related severance benefits or change of control related severance benefits. The severance benefits are less than two times the annual base salary for any of our named executive officers and we do not provide any tax gross-ups.

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 to manage our business to meet our long-term objectives;

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

align the interests of our executive officers and stockholders by motivating executive officers to achieve performance objectives that will increase stockholder value;

provide a competitive compensation package in which total compensation is determined in part by market factors, key performance objectives and milestones and the achievement level of these performance objectives and milestones by our executive officers; and

reward the achievement of key corporate and individual performance measures.

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Our compensation committee believes that our executive compensation programs should include short- and long-term performance incentive 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 total 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 and a review of historic compensation levels, including prior equity award gains and losses.

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, or Radford survey, together with other information made available to it such as compensation analysis performed by independent, third party, compensation specialists. 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 our executive compensation decisions. Our compensation committee has not benchmarked our executive compensation against a particular group of companies included in the Radford survey data.

Although our compensation committee has used the Radford survey data as a tool in determining executive compensation, it typically has applied its subjective discretion to make compensation decisions and has not targeted our executive compensation against any specific percentile or used a formula to set our executives compensation in relation to this survey data.

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 as well as market factors 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, to assist the compensation committee in making compensation decisions. In 2012, we engaged Compensia Inc., an executive compensation specialist to analyze our overall executive compensation practices against the practices of an industry peer group of twenty-two pharmaceutical

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companies with similar market capitalizations, number of employees and revenue levels. The following table shows the companies that made up our benchmark peer group.

Peer Group	
Affymax	Pacira Pharmaceuticals
Astex Pharma	POZEN
BioCryst Pharmaceuticals	Progencis Pharmaceutical
Cadence Pharmaceuticals	Sangamo BioSciences
Corcept Therapeutics	Santarus
Cornerstone Therapeutics	Sucampo Pharmaceuticals
Depomed	Synta Pharmaceuticals
Dyax	Transcept Pharmaceuticals
GTx	Vanda Pharmaceuticals
Neurocrine Biosciences	XenoPort
Orexigen Therapeutics	Zogenix

The compensation committee may make adjustments to certain components of our executive compensation levels as a result of this more formal compensation benchmarking process as it did in 2012.

In 2012, the compensation committee conducted an independence assessment with respect to Compensia Inc. s role in recommending or determining the amount and form of executive compensation during the fiscal year ended December 31, 2012. In conducting this assessment, the compensation committee considered the following factors: whether Compensia Inc. provided any other services to the Company; the amount of fees received by Compensia Inc. from Horizon during 2012 as a percentage of Compensia Inc. s total revenues for the 12 months ended December 31, 2012; the policies and procedures of Compensia Inc. that are designed to prevent conflicts of interest; any business or personal relationship of the individual representative of Compensia Inc. who worked directly with the compensation committee; any stock of Horizon owned by the individual representative of Compensia Inc. who worked directly with the compensation committee; and any business or personal relationship of the individual representative of Compensia Inc. who worked directly with the compensation committee, or of Compensia Inc., with any of our executive officers. After conducting this assessment, the compensation committee concluded that Compensia Inc. s role in recommending or determining the amount and form of executive compensation during the fiscal year ended December 31, 2012 did not raise any conflict of interest.

Role of the Compensation Committee

After considering the survey data and all other information available to it, including any analysis provided by the compensation consultant, the compensation committee exercises subjective discretion in recommending salary adjustments and discretionary cash and equity-based awards for all executive officers for final approval to the board of directors.

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 equity awards for the other executives. The chief executive officer is not present during deliberations or voting with respect to the compensation for himself.

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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 equity awards, as well as severance protection for certain of our executive officers through employment agreements with those executive officers and our Severance Benefit Plan. As discussed in more detail below, recommended base salary levels are determined in the compensation committee s discretion after taking into consideration market factors. Annual cash incentive compensation is a target percentage of base salary, with the actual amount awarded determined in the compensation committee s discretion based upon its determination of the level of attainment of performance goals. 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.

Historically, we have not specified a target percentage of the overall compensation to be represented by the various compensation elements. The compensation committee s intention was that performance based cash incentive bonuses and long-term equity compensation should be a significant part of the executive s compensation and historically, it has represented a significant portion of an executive s total pay package, so that approximately 30% to 60% of our executive officers total potential compensation is at risk. This helps with implementing a culture in which our named executive officers know that their take home pay, to a large extent, depends upon our performance. Employees in more senior roles have an increasing proportion of their potential compensation at risk and tied to performance because they are in a position to have greater influence on our performance results. For example, 60% of our chief executive officer s total potential 2012 compensation was at risk. For purposes of such calculations, with respect to stock unit award values, the value of the underlying shares on the date of grant was used.

We have selected each of the executive compensation components for the following reasons:

Taken as a whole, the components of the executive compensation program (base pay, annual cash incentive compensation, long-term compensation in the form of equity grants and our severance benefit protections) are comparable to the programs offered by other companies of our size in the life sciences and healthcare services industries; therefore, our compensation program generally helps us attract new executive talent and retain, motivate, and reward the executives that we currently employ.

The annual cash incentive program rewards executives for the satisfaction of our pre-established annual corporate performance goals. Compensation under this program directly rewards satisfaction of our corporate objectives and individual performance. We provide this program so that our executives will focus their efforts on annual and longer-term company goals, and to take actions that maximize stockholder value. Our compensation committee rewards executives only in the event of satisfactory corporate and individual performance.

Equity awards serve several purposes: first, they are a retention device, because the executive must continue employment with us for the awards to vest, and second, our performance restricted stock unit awards that vest upon satisfaction of corporate performance goals incentivize our executives to satisfy key performance objectives that will maximize stockholder value.

Base Salary. Base salaries for our executives are established based on the scope of their responsibilities, individual experience and market factors. Base salaries are reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with current market levels as reflected by the Radford survey data after taking into account individual responsibilities, performance and experience., and making a subjective determination as to whether and what extent base salaries should be increased based upon those factors. The compensation committee does not apply specific formulas to determine its recommendations for increases to base salary, although it has generally recommended increases as a percentage of an executive officer s then current base salary.

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The base salaries for each of 2013, 2012, 2011 and 2010 are as follows:

	Base Salary			
Named Executive Officer	**2013**	**2012**	**2011**	**2010**
Timothy P. Walbert	$ 589,160	$ 572,000	$ 550,000	$ 450,625
Robert J. DeVaere	$ 374,920	$ 364,000	$ 350,000	$ 324,450
Jeffrey W. Sherman	$ 396,340	$ 384,800	$ 370,000	$ 333,900
Todd N. Smith	$ 375,950	$ 365,000	$ 274,275	$ 265,000
Michael Adatto	$ 304,500	$ 300,000	$ 274,275	$ 265,000

In December 2011, our compensation committee approved increases to the base salaries for our executive officers, effective January 1, 2011 based on the 2011 Radford survey data which indicated a 4% average level of base salary increases. The compensation committee generally recommended and the Board approved a 4% increase to the annual base salaries of certain of our named executive officers because their levels of individual responsibility and performance warranted an increase in base salary consistent with the average levels of base salary increase reflected in the Radford survey, while certain other named executive officers were provided a 9% salary increase to better align their salaries within the ranges of the Radford survey data for their levels of individual responsibility and performance.

In December 2012, our compensation committee approved increases to the base salaries for our executive officers, effective January 1, 2013 based on the 2012 Radford survey data which indicated a 3% average level of base salary increases. The compensation committee generally recommended and the Board approved a 3% increase to the annual base salary of Mr. Walbert, Mr. De Vaere, and Dr. Sherman and a $1\,^{1}/_{2}\%$ increase to the annual base salary of Mr. Adatto to reflect their levels of individual responsibility and performance relative to the average levels of base salary increase reflected in the Radford survey. Also, in February 2012, Mr. Smith was promoted from senior vice president, sales, marketing and business development to executive vice president and chief commercial officer. As a result of this promotion and in light of his increased responsibilities, Mr. Smith s base salary was increased during 2012 from an annualized base salary of $300,000 to $365,000. Mr. Smith s base salary was increased from $274,275 to $300,000 during 2011, to reflect increased responsibilities and to align his salary within the Radford survey data for those levels of responsibility. Additionally, as part of its annual review of base salaries, in December 2012 our compensation committee approved a further increase in the annual base salary of Mr. Smith of 3% effective January 1, 2013, consistent with the levels of increase generally approved for our named executive officers.

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: 60% for Mr. Walbert, 40% for Mr. De Vaere, Dr. Sherman and Mr. Smith and 30% for Mr. Adatto. These established target bonus percentages were deemed market competitive based on Radford data at the time of hire of the executive officers and based on then current data. 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, Dr. Sherman and Mr. Smith such percentages may not be reduced without the consent of the executive.

At the beginning of each calendar year, the compensation committee determines corporate goals and milestones for the executive officers. At the end of each year, the compensation committee reviews and determines the level of achievement for each corporate goal and milestone. Each of these corporate objectives and milestones are assigned a certain weight and bonus payments are determined based on achievement of the various objectives. 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

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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 and individual performance.

Actual bonus award levels are determined in the compensation committee s discretion and recommended to the board of directors for approval. At the close of the applicable fiscal year, the compensation committee comes to a general, subjective conclusion as to whether the corporate goals were met, whether the executive has performed his duties in a satisfactory manner, and whether there were any other extraordinary factors that should be considered in determining the amount of bonus earned for the year. The compensation committee may decide to pay bonuses to the executive officers even if the specified corporate performance goals are not met, in recognition of the officer s efforts throughout the year in meeting other objectives not contemplated at the beginning of the performance period. In making the final decision on the amount of bonuses earned, if any, the compensation committee considers the review of the year-end corporate results as well as the performance of the executive officers. In sum, the amount of variable compensation that is actually earned by our named executive officers is a subjective, entirely discretionary, determination made by the compensation committee without the use of pre-determined formulas. The compensation committee believes that maintaining discretion to evaluate our and the executive s performance at the close of the year based on the totality of the circumstances, and to award or fail to award bonus compensation without reliance on rote calculations under set formulas, is appropriate in responsibly discharging its duties. Payouts of awarded bonuses, if any, are generally made in the year following the year of performance.

The 2012 corporate objectives established by the compensation committee at the beginning of 2012 were:

- raising sufficient capital to fund operations;
- continued execution of the DUEXIS launch plan, including comprehensive sales operations plans with the hiring and training of the additional sales representatives;
- achieving certain specified sales targets;
- specific performance objectives relating to clinical development and regulatory milestones including obtaining marketing approval from the FDA for RAYOS in the U.S.; and
- timely response to questions from the MHRA in the UK to ensure the DUEXIS MAA review remained on schedule.

The compensation committee selected these goals because it believed that they are the best indicators of the achievement of the execution of our operating plan and are the factors that are most critical to increasing the value of our common stock. These goals, therefore, best align the financial interests of the named executive officers with those of our stockholders.

In December 2012, based on management s recommendations and the compensation committee s own review, deliberation and determination of achievement of the corporate objectives and milestones listed above, along with determination of achievement of personal goals, our compensation committee recommended and our Board approved bonus percentages for our named executive officers for 2012 as follows: 48% of base salary for Mr. Walbert (80% of the 60% target); 37% of base salary for Dr. Sherman (92.5% of the 40% target); 33% of base salary for Mr. De Vaere (82.5% of the 40% target); 29% of base salary for Mr. Smith (72.5% of the 40% target); and 12% of base salary for Mr. Adatto (35% of the 35% target), which resulted in the awarding of discretionary incentive bonus amounts of $275,000 for Mr. Walbert, $142,000 for Dr. Sherman, $120,000 for Mr. De Vaere, $106,000 for Mr. Smith and $37,000 for Mr. Adatto for 2012 performance. Payment of the discretionary bonuses was made in January 2013.

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

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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. These equity awards are generally approved in December of each year and granted at the beginning of the subsequent year.

In January 2012, based on the recommendation of the compensation committee, the Board granted performance-based restricted stock units covering an aggregate of 510,000 shares of common stock to our named executive officers as part of their overall compensation package and to incentivize our executives to meet certain performance objectives. The award level for each of our named executive officers related to the performance-based restricted stock unit grants were as follows: 140,000 restricted stock units for Mr. Walbert; 110,000 restricted stock units for Mr. De Vaere; 110,000 restricted stock units for Dr. Sherman; 75,000 restricted stock units for Mr. Smith; and 75,000 restricted stock units granted to Mr. Adatto. These award levels were determined by the compensation committee to be levels sufficiently large to incentivize our named executive officers to attain our performance objectives and at levels competitive with the long-term incentive compensation levels provided by our peers.

These performance objectives included capital raising goals, revenue growth and market penetration targets. The Board determined these were critical objectives in meeting the corporate goals. Vesting of the performance-based restricted stock units was contingent upon the achievement of certain performance objectives being met during 2012, with vested performance-based restricted stock resulting in the issuance of a related number of shares of common stock on December 31, 2012. The performance objectives included the completion of an equity financing transaction, a specific DUEXIS net sales target, FDA approval of RAYOS, a specific number of new DUEXIS prescriptions and access to reimbursement for DUEXIS through healthcare plans of a targeted percentage of total U.S. lives. The compensation committee selected these goals as they believed that these goals were the best indicators in executing our 2012 operating plan and were the objectives that were most critical to increasing the value of our common stock.

During 2012, performance objectives associated with the completion of an equity financing transaction, FDA approval of RAYOS and access to reimbursement for DUEXIS through healthcare plans of a targeted percentage of total U.S. lives were achieved, resulting in the vesting of a total of 225,000 performance-based restricted stock units. The remaining 285,000 performance-based restricted stock units were cancelled at December 31, 2012 as a result of not meeting the other defined performance objectives.

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 further 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.

Mr. Walbert, Mr. DeVaere, Dr. Sherman and Mr. Smith each have severance benefit protection under the terms of their employment agreements which provide for up to 12 months base salary and COBRA health insurance premiums in the event of an involuntary or constructive termination. In addition, stock option and other equity awards are subject to acceleration under the terms of their employment agreements in the event of a qualifying termination within 90 days prior to or within 18 months following a change in control. Mr. Walbert also receives his target annual bonus amount for the preceding year in the event of his involuntary termination. Each of Mr. Walbert, Mr. DeVaere, Dr. Sherman and Mr. Smith must enter into a non-competition agreement that is to be effective during the period that the severance benefits are payable.

Our Severance Benefit Plan provides severance benefit protection for executives employed by Horizon Pharma, Inc. and its affiliates that do not have executive employment agreements, for a period of at least three months for vice president level and above. Mr. Adatto does not have severance benefit protection in his employment agreements and instead is eligible to receive severance benefits under the Severance Benefit Plan,

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which provide for six months base salary and COBRA health insurance premiums. 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 to our executives are payable only if the executive s employment is involuntarily terminated without cause or constructively terminated under certain circumstances. The compensation committee believes that these benefits are an important element of the named executive officers retention and motivation and consistent with compensation arrangements provided in a competitive market for executive talent, and that the benefits of such severance rights agreements, including generally requiring a release of claims against Horizon as a condition to receiving any severance benefits are in our best interests. The severance benefits are also intended to eliminate, or at least reduce, the reluctance of our executive officers to diligently consider and pursue potential change of control transactions that may be in the best interests of our stockholders.

Other Compensation. All of our executive officers are eligible to receive our standard employee benefits such as our 401(k) Plan, medical, dental, vision coverage, short-term disability, long-term disability, group life insurance, cafeteria plan, and the 2011 Employee Stock Purchase Plan, in each case on the same basis as our other The compensation committee periodically reviews the levels of benefits provided to executive officers to ensure they remain reasonable and consistent with its compensation philosophy.

Risk Analysis. The compensation committee has reviewed our compensation policies as generally applicable to our employees and believes that our policies do not encourage excessive and unnecessary risk-taking, and that the level of risk that they do encourage is not reasonably likely to have a material adverse effect on the company. The design of our compensation policies and programs encourage our employees to remain focused on both the short-and long-term goals of the company. For example, while our cash incentive plan measures performance on an annual basis, our equity awards typically vest over a number of years, which we believe encourages our employees to focus on sustained potential stock price appreciation, thus limiting the potential value of excessive risk-taking.

Accounting and Tax Considerations. We account for stock-based awards exchanged for employee services in accordance with the Compensation Stock Compensation topic of the Financial Accounting Standards Board Accounting Standards Codification. In accordance with the topic, we are required to estimate and record an expense for each award of equity compensation over the vesting period of the award. Accounting rules also require us to record cash compensation as an expense over the period during which it is earned.

Section 162(m) of the Internal Revenue Code of 1986 as amended (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.

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Summary Compensation Table

The following table provides information regarding the compensation earned during the years ended December 31, 2012, 2011 and 2010 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; Executive Vice President and Chief Commercial Officer; and Senior Vice President, Managed Care and Commercial Development, whom 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 [10]	Total
Timothy P. Walbert	2012	$ 572,000	$ 0	$ 0	$ 588,000	$ 275,000[3]	$ 1,218	$ 1,436,218
	2011	$ 550,000	$ 0	$ 797,744	$ 658,883	$ 363,000[3]	$ 1,218	$ 2,370,845
President and Chief Executive Officer	2010	$ 450,625	$ 0	$ 2,182,343	$ 0	$ 337,969[3]	$ 1,077	$ 2,972,014
Robert J. De Vaere	2012	$ 364,000	$ 0	$ 0	$ 462,000	$ 120,000[4]	$ 1,156	$ 947,156
	2011	$ 350,000	$ 0	$ 197,170	$ 162,843	$ 162,800[4]	$ 1,156	$ 873,969
Executive Vice President and Chief Financial Officer	2010	$ 324,450	$ 0	$ 813,744	$ 0	$ 162,225[4]	$ 1,657	$ 1,302,076
Jeffrey W. Sherman	2012	$ 384,800	$ 0	$ 0	$ 462,000	$ 142,000[5]	$ 1,070	$ 989,870
	2011	$ 370,000	$ 0	$ 197,170	$ 162,843	$ 162,800[5]	$ 1,070	$ 893,883
Executive Vice President and Chief Medical Officer	2010	$ 333,900	$ 0	$ 813,744	$ 0	$ 125,213[5]	$ 3,139	$ 1,275,996
Todd Smith	2012	$ 332,583	$ 0	$ 0	$ 315,000	$ 106,000[6]	$ 824	$ 754,407
	2011	$ 274,275	$ 0	$ 80,455	$ 66,448	$ 96,250[6]	$ 824	$ 518,252
Executive Vice President and Chief Commercial Officer	2010	$ 66,250[8]	$ 0	$ 182,835	$ 0	$ 21,863[6]	$ 127	$ 271,075
Michael Adatto	2012	$ 300,000	$ 0	$ 0	$ 315,000	$ 37,000[7]	$ 1,331	$ 653,331
	2011	$ 274,275	$ 0	$ 80,455	$ 66,448	$ 96,250[7]	$ 1,331	$ 518,759
Senior Vice President, Managed Care and Commercial Development	2010	$ 110,417[9]	$ 0	$ 173,233	$ 0	$ 36,440[7]	$ 324	$ 320,414

(1) Amounts shown in this column do not reflect actual compensation received by our named executive officers. The amounts reflect the grant date fair value of stock option awards and calculated in accordance with the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification Topic 718 *Compensation Stock Compensation (ASC Topic 718)* and assume no forfeiture rate derived in the calculation of the grant date fair value of these awards. Assumptions used in the calculation of these awards are included in Note 16, Equity Incentive Plans in Part IV, Item 15 in 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) Amounts shown in this column do not reflect actual compensation received by our named executive officers. The amounts reflects the grant date fair values of restricted stock units issued in accordance with the provisions of ASC Topic 718 and were based on the closing stock price of our common stock on the date of grant and assume no forfeiture rate derived in the calculation of the grant date fair value of these awards. Stock awards granted to our named executive officers during 2012 were performance-based restricted stock units and vested only upon the achievement of certain performance objectives during 2012. Stock awards granted to our named executive officers during 2011 were restricted stock units that vest equally in four annual installments commencing on the anniversary date of the grant. See Note 16 Equity Incentive Plans in the notes to our consolidated financial statements for further information on our restricted stock units.

(3) Mr. Walbert s target bonus amount for 2010 was $337,969, but payment was deferred until August 2011 upon the completion of the Company s initial public offering. In December 2011, our board approved

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Mr. Walbert s 2011 bonus in the amount of $363,000, but deferred payment until completion of a debt financing, which occurred in February 2012. Mr. Walbert s target bonus amount for 2012 was $343,200, or 60% of base salary. In December 2012, our board approved Mr. Walbert s bonus in the amount of $275,000, which was paid in January 2013.

(4) 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. Mr. De Vaere s target bonus amount for 2012 was $145,600, or 40% of base salary. In December 2012, our board approved Mr. De Vaere s bonus in the amount of $120,000, which was paid in January 2013.

(5) 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. Dr. Sherman s target bonus amount for 2012 was $153,920, or 40% of base salary. In December 2012, our board approved Dr. Sherman s bonus in the amount of $142,000, which was paid in January 2013.

(6) Mr. Smith s target bonus amount for 2010 was $79,500, which was pro-rated to $21,863, based on his hire date. Our compensation committee approved Mr. Smith s 2010 bonus in the amount of $21,863, but deferred payment of the bonus until August 2011, upon completion of the initial public offering. In December 2011, our board 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. Mr. Smith s target bonus for 2012 was $146,000, or 40% of base salary. In December 2012, our board approved Mr. Smith s bonus in the amount of $106,000, which was paid in January 2013.

(7) Mr. Adatto s target bonus amount for 2010 was $79,500, which was pro-rated to $36,440 based on his hire date. Our compensation committee approved Mr. Adatto s 2010 bonus in the amount of $36,440, but deferred payment of the bonus until August 2011, upon completion of the initial public offering. In December 2011, our board 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. Mr. Adatto s target bonus amount for 2012 was $105,000, or 35% of base salary. In December 2012, our board approved Mr. Adatto s bonus in the amount of $37,000, which was paid in January 2013.

(8) Mr. Smith joined us on October 1, 2010. If Mr. Smith had been employed for the complete fiscal year 2010, Mr. Smith would have earned an annual base salary of $265,000.

(9) Mr. Adatto joined us on August 2, 2010. If Mr. Adatto had been employed for the complete fiscal year 2010, Mr. Adatto would have earned an annual base salary of $265,000.

(10) 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

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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 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.

In June 2012, we entered into an employment agreement with Mr. Smith, our executive vice president and chief commercial officer, that provides if we terminate Mr. Smith without cause or if Mr. Smith 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. Smith 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. Smith 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 willful and deliberate breach of the executive s obligations under the employment agreement that causes injury to us. Resignation for good reason is defined as a material reduction in executive duties, authority

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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. Smith 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 agreement with Mr. Adatto does not include provisions for potential payments upon termination or change in control. However, because Mr. Adatto is a senior vice president who has been employed for at least six months he is 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, Dr. Sherman and Mr. Smith 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, Dr. Sherman and Mr. Smith 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 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 named executive officers assuming their employment was terminated on December 31, 2012 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	Cash Severance	Continuation of Medical Benefits	Bonus	Value of Accelerated Vesting [2]	Total	Cash Severance	Continuation of Medical Benefits	Bonus	Value of Accelerated Vesting [2]	Total
Timothy P. Walbert	$ 589,160	$ 26,758	$ 353,496	$ 0	$ 969,414	$ 589,160	$ 26,758	$ 353,496	$ 232,140	$ 1,201,554
Robert J. De Vaere	$ 374,920	$ 26,758	$ 0	$ 0	$ 401,678	$ 374,920	$ 26,758	$ 0	$ 57,374	$ 459,052
Jeffrey W. Sherman	$ 396,340	$ 26,758	$ 0	$ 0	$ 423,098	$ 396,340	$ 26,758	$ 0	$ 57,374	$ 480,472
Todd N. Smith	$ 375,950	$ 26,758	$ 0	$ 0	$ 402,708	$ 375,950	$ 26,758	$ 0	$ 23,412	$ 426,120
Michael Adatto	$ 152,250	$ 13,379	$ 0	$ 0	$ 165,629	$ 152,250	$ 13,379	$ 0	$ 23,412	$ 189,041

(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 price of $2.33 for our common stock on December 31, 2012, multiplied by the number of shares subject to accelerated vesting, less the stock option exercise price, if applicable.

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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 2012.

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards Target	All Other Stock Awards: Number of Shares of Stock or Units (#)	Grant Date Fair Value of Stock and Options Awards ($)[7]
Timothy P. Walbert	N/A	$ 275,000[1]		
	1/3/2012		140,000[6]	$ 588,000
Robert J. De Vaere	N/A	$ 120,000[2]		
	1/3/2012		110,000[6]	$ 462,000
Jeffrey W. Sherman	N/A	$ 142,000[3]		
	1/3/2012		110,000[6]	$ 462,000
Todd Smith	N/A	$ 106,000[4]		
	1/3/2012		75,000[6]	$ 315,000
Michael Adatto	N/A	$ 37,000[5]		
	1/3/2012		75,000[6]	$ 315,000

(1) Mr. Walbert s target bonus for 2012 was $343,200 or 60% of his base salary. In December 2012, our compensation committee approved Mr. Walbert s bonus in the amount of $275,000, which was paid in January 2013.

(2) Mr. De Vaere s target bonus for 2012 was $145,600 or 40% of his base salary. In December 2012, our compensation committee approved Mr. De Vaere s bonus in the amount of $120,000, which was paid in January 2013.

(3) Dr. Sherman s target bonus for 2012 was $153,920 or 40% of his base salary. In December 2012, our compensation committee approved Dr. Sherman s bonus in the amount of $142,000, which was paid in January 2013.

(4) Mr. Smith s target bonus for 2012 was $146,000 or 40% of his base salary. In December 2012, our compensation committee approved Mr. Smith s bonus in the amount of $106,000, which was paid in January 2013.

(5) Mr. Adatto s target bonus for 2012 was $105,000 or 35% of his base salary. In December 2012, our compensation committee approved Mr. Adatto s bonus in the amount of $37,000, which was paid in January 2013.

(6) On January 3, 2012, our named executive officers were granted performance-based restricted stock units. Vesting of the performance-based restricted stock units was contingent upon the achievement of certain performance goals, with vested performance-based restricted stock units resulting in the issuance of a related number of shares of common stock. On January 3, 2013, common stock associated with vested performance-based restricted stock units was issued as follows: 70,000 shares of common stock were issued to Mr. Walbert; 55,000 shares of common stock were issued to each of Mr. De Vaere and Dr. Sherman; and 22,500 shares of the Company s common stock were issued to each of Messrs. Smith and Adatto.

(7) 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 and were calculated in accordance with the provisions of ASC Topic 718 and assume no forfeiture rate derived in the calculation of the grant date fair value of these awards. Assumptions used in the calculation of these amounts are included in Note 16, Equity Incentive Plans, in the notes to our consolidated financial statements for further information on our restricted stock units.

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Outstanding Equity Awards at December 31, 2012

The following table sets forth certain information regarding outstanding stock options and restricted stock units held by our named executive officers on December 31, 2012.

		Option Awards					Stock Awards			
Name	Award Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested [5]	Market Value of Stock that Has Not Vested [6]	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that Have not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that Have Not Vested ($)
Timothy P. Walbert	7/16/2008	121,701[1][2]			$ 10.43	7/15/2018				
	2/3/2010	91,330[3]	37,607[3]		$ 5.20	2/2/2020				
	6/16/2010	70,491[3]	42,296[3]		$ 12.94	6/15/2020				
	12/8/2011	54,238[4]	162,717[4]		$ 4.96	12/7/2021	99,631	$ 232,140		$
		337,760	242,620				99,631	$ 232,140		$
Robert J. De Vaere	10/6/2008	46,335[1][2]			$ 10.43	10/5/2018				
	2/3/2010	33,754[3]	13,900[3]		$ 5.20	2/2/2020				
	6/16/2010	26,434[3]	15,861[3]		$ 12.94	6/5/2020				
	12/8/2011	13,405[4]	40,216[4]		$ 4.96	12/7/2021	24,624	$ 57,374		$
		119,928	69,977				24,624	$ 57,374		$
Jeffrey W. Sherman	6/23/2009	46,335[1][2]			$ 13.47	6/22/2019				
	2/3/2010	33,754[3]	13,900[3]		$ 5.20	2/2/2020				
	6/16/2010	26,434[3]	15,861[3]		$ 12.94	6/15/2020				
	12/8/2011	13,405[4]	40,216[4]		$ 4.96	12/7/2021	24,624	$ 57,374		$
		119,928	69,977				24,624	$ 57,374		$
Todd Smith	12/2/2010	10,266[2]	8,689[2]		$ 20.78	12/1/2020				
	12/8/2011	5,470[4]	16,410[4]		$ 4.96	12/7/2021	10,048	$ 23,412	$	$
		15,736	25,099				10,048	$ 23,412		$
Michael Adatto	6/16/2010	9,214[2]	5,529[2]		$ 12.94	6/15/2020				
	12/8/2011	5,470[4]	16,410[4]		$ 4.96	12/7/2021	10,048	$ 23,412	$	$
		14,684	21,939				10,048	$ 23,412		$

(1) The initial option award grant for each officer was early exercisable; as such, 100% of the option award is exercisable.

(2) 1/4th of the shares vest one year after the vesting commencement date and 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 award grant date and 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 four years following the vesting commencement date, which is the grant date.
(5) Stock awards represent restricted stock units granted and vest in four equal annual installments on the anniversary of the grant date.
(6) The market value of stock awards that have not vested is based on the closing stock price of our common stock of $2.33 per share on December 30, 2012.

Option Exercises and Stock Vested

Our named executive officers did not exercise any stock option awards during the fiscal year ended December 31, 2012. However, performance and service based restricted stock units covering an aggregate of 281,325 shares of common stock vested in December 2012 and the underlying shares were issued to our named executive officers. Additionally, each of our named executive officers sold shares of common stock pursuant to a previously-established trading plan under Rule 10b5-1 to satisfy certain withholding tax obligations.

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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, 2012.

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 in July 2011. Prior to August 1, 2012 the policy provided 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 would receive a stock option grant for 10,530 shares, vesting in equal installments over 36 month from the date of grant. Thereafter, at each Annual Meeting of our stockholders, eligible non-employee directors would automatically receive stock option grants of 5,265 shares, vesting in equal installments over 12 months from the date of grant.

Effective August 1, 2012, our board approved an amendment to the non-employee director compensation policy providing for an annual Board service retainer, payable in quarterly installments, of $50,000 for a non-executive Chairman of the Board or lead independent director and $40,000 for all other eligible non-employee directors, and committee member service fees ranging from $3,750 to $20,000 per year. On December 14, 2012 our board approved a further amendment to the non-employee director compensation policy providing that eligible non-employee directors elected to the Board would receive a stock option grant for 40,000 shares, vesting in equal installments over 36 month from the date of grant. Thereafter, at each Annual Meeting of our stockholders, eligible non-employee directors would automatically receive stock option grants of 20,000 shares, vesting in equal installments over 12 months from the date of grant.

Also, we have reimbursed and will continue to reimburse our non-employee directors for their travel-related expenses, including lodging and other reasonable expenses incurred in attending meetings of our Board of Directors and committees of the Board of Directors.

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The following table sets forth compensation information for our non-employee directors who earned or received compensation under our non-employee director compensation policy in 2012:

Name	Fees Earned or Paid in Cash	Stock Awards	Total
Ronald Pauli	$ 68,524	$ 14,759	$ 83,283
Michael Grey	$ 60,208	$ 14,759	$ 74,967
Gino Santini	$ 39,125	$ 30,849	$ 69,974

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.

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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.

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

Jeff Himawan, Ph.D., Chairman

Michael Grey

Ronald Pauli

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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, 2012, with respect to shares of our common stock that may be issued under our existing equity compensation plans:

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrant, and rights	(b) Weighted-average exercise price of outstanding options, warrant, and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by stockholders:			
2005 Stock Plan	1,218,665[(1)]	$ 13.78	
2011 Equity Incentive Plan	1,760,411[(1)]	$ 4.27	754,910
2011 Employee Stock Purchase Plan		$ 0.00	438,625
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 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

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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 stock option or a non-qualified stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted typically vest over a four-year period and the term can be up to ten years. As of December 31, 2012, there were 754,910 shares available for future grants under the 2011 EIP. On December 6, 2012, 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 1,474,304 shares, effective January 1, 2013.

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, 2012, there were 438,625 shares available for future grants under the 2011 purchase plan. On December 6, 2012, 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 200,000 shares, effective January 1, 2013.

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 11, 2013 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 10, 2013, which is 60 days after March 11, 2013.

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Percentage of beneficial ownership is based on 61,947,247 shares of common stock outstanding as of March 11, 2013. 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:		
Fidelity and its affiliates [1]	8,895,482	13.7%
82 Devonshire St.		
Boston, Massachusetts 02109		
Essex Woodlands Health Ventures Fund VII, L.P [2]	5,815,940	9.3%
335 Bryant St., 3rd Floor		
Palo Alto, CA 94301		
Quaker Bioventures Capital II, LLC [3]	4,206,378	6.7%
2929 Arch St., 3rd Floor, the Cira Centre		
Philadelphia, PA 19104-2857		
DiscoveryGroup [4]	3,972,860	6.4%
191 N. Wacker Dr., Suite 1685		
Chicago, IL 60606		
CD-Venture and its affiliates [5]	3,957,575	6.3%
Bergheimer St. 89/1		
69115 Heidelberg, Germany		
Atlas Venture Fund VI, L.P. and its affiliates [6]	3,895,404	6.3%
25 First Street, Suite 303		
Cambridge, MA 02141		
Directors and named executive officers:		
Jeff Himawan, Ph.D. [7]	5,815,940	9.3%
Jean-François Formela, M.D. [8]	3,895,404	6.3%
Jeffrey W. Bird, M.D., Ph.D. [9]	2,692,057	4.3%
Michael Grey [10]	10,383	*
Ronald Pauli [11]	10,383	*
Gino Santini [12]	8,921	*
Timothy P. Walbert [13]	486,752	*
Robert J. De Vaere [14]	190,225	*
Jeffrey W. Sherman, M.D., FACP [15]	192,301	*
Todd N. Smith [16]	47,643	*
Michael Adatto [17]	41,764	*
All executive officers and directors as a group (11 persons) [18]	13,391,773	20.9%

* Represents beneficial ownership of less than one percent.

(1) Includes (a) 6,032,626 shares and (b) 2,862,856 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on October 9, 2012 by FMR LLC, which reflects beneficial ownership as of September 30, 2012. FMR LLC reported that it had beneficial ownership of, and sole dispositive power with respect to, 6,032,626 shares of our common stock, including 2,862,856 shares issuable upon exercise of warrants. The Schedule 13G includes shares beneficially owned by Edward C. Johnson, III 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 common stock and the execution of a stockholders voting agreement, may be deemed a controlling group with respect to FMR

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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 383,835 shares of our common stock, including 79,400 shares of warrants, as a result of its serving as investment manager of institutional accounts owning such shares. Mr. Johnson III and FMR LLC, through its control of PGATC, each has sole dispositive power and sole power to vote or to direct the voting of 383,835 shares managed by PGATC.

(2) 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.

(3) Includes (a) 3,516,009 shares and (b) 690,369 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on February 14, 2013 by Quaker Bio Ventures Capital II, LLC.

(4) Includes 3,972,860 shares held by Discovery Group. This information is based on the Schedule 13D filed with the SEC on October 25, 2012. Discovery Group is the sole general partner of Discovery Equity Partners and has sole discretionary investment authority with respect to Discovery Equity Partners investment in the common stock. Messrs. Donoghue and Murphy are the sole managing members of Discovery Group. As a consequence, Discovery Group and Messrs. Donoghue and Murphy may be deemed to share beneficial ownership of all of the shares of common stock owned by both Discovery Group and Discovery Equity Partners, while Discovery Equity Partners shares beneficial ownership with Discovery Group and Messrs. Donoghue and Murphy of only the shares of common stock owned by it.

(5) Includes (a) 3,395,714 shares and (b) 561,861 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on October 5, 2012 by Christoph F. Boehringer and CD-Venture GmbH, which reflects beneficial ownership as of October 5, 2012. Mr. Boehringer is the beneficial owner of 3,957,575 shares of our common stock, including 2,357,575 shares of our common stock beneficially owned by CD-Venture. Mr. Boehringer is also the record holder of a warrant to purchase up to 561,861 shares of our common stock, which includes a warrant to purchase up to 276,147 shares of common stock beneficially owned by CD-Venture.

(6) 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 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.

(7) Includes the shares referred to in footnote (2) above. Dr. Himawan disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.

(8) Includes the shares referred to in footnote (4) above. Dr. Formela disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.

(9) Includes (a) 99,912 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, (b) 21,685 shares issuable upon exercise of warrants held by the Bird Trust, (c) 2,096,558 shares held by Sutter Hill Ventures, a California Limited Partnership, or SHV, (d) 458,902 shares issuable upon exercise of warrants held by SHV, (e) 5,000 shares held by Dr. Bird in a Roth IRA account, (f) l,250 shares issuable upon the exercise of warrants held by Dr. Bird in a Roth IRA account, (g) 7,000 shares held by NestEgg Holdings, a Limited Partnership and (h) 1,750 shares issuable upon exercise of warrants held by NestEgg Holdings. Dr. Bird disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.

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(10) Includes 10,383 shares that Mr. Grey has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
(11) Includes 10,383 shares that Mr. Pauli has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
(12) Includes 8,921 shares that Mr. Santini has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
(13) Includes (a) 88,962 shares and (b) 397,790 shares that Mr. Walbert has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
(14) Includes (a) 51,092 shares and (b) 139,133 shares that Mr. De Vaere has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
(15) Includes (a) 55,099 shares and (b) 137,202 shares that Dr. Sherman has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
(16) Includes (a) 22,570 shares and (b) 25,073 shares that Mr. Smith has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
(17) Includes (a) 21,761 shares and (b) 20,003 shares that Mr. Adatto has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options. On March 14, 2013, our board of directors determined that going forward, Mr. Adatto, would increasingly focus his efforts on managed care and commercial development and, as a result, would no longer retain his prior policy making functions and status as an executive officer at Horizon.
(18) Includes the following held by our executives and directors, in the aggregate: (a) 11,200,979 shares, (b) 748,888 shares that can be acquired within 60 days of March 11, 2013 pursuant to the exercise of stock options and (c) 1,441,906 shares issuable upon the 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 2012, 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**.**

Financings

In March 2012, we closed a private investment in public equity, 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.

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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.

In September 2012, we closed a public offering, with a select group of institutional and accredited investors. Upon the closing of the offering, we received gross proceeds of approximately $86.2 million resulting from the sale of 24,638,750 units at a price of $3.50 per unit. Each unit consisted of one share of our common stock and a warrant to purchase 0.50 shares of our common stock at an exercise price of $4.57 per share.

Purchasers in the offering 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 offering:

Participants	Proceeds	Common Stock	Warrants
5% or Greater Stockholders			
Fidelity	$ 19,801,040	5,657,440	2,828,720
Tang Capital Partners, L.P.	$ 14,700,000	4,200,000	2,100,000

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.

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

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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. 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.

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

Director	Principal Stockholder
Jean-François Formela, M.D.	Atlas Venture Fund VI, L.P.
Jeff Himawan, Ph.D.	Essex Woodlands Health Ventures Fund VII, 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 2012 and 2011 in the following categories:

	2012	2011
Audit fees [(1)]	$ 1,021,000	$ 847,000
Tax fees [(2)]	13,000	36,000
Total	$ 1,034,000	$ 883,000

(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 equity finance offerings, 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, 2012 and 2011. 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-34 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
The exhibits listed on the Index to Exhibits are filed as part of this Annual Report on Form 10-K.

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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 18, 2013

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	Chairman, President and Chief Executive Officer *(Principal Executive Officer)*	March 18, 2013
/s/ Robert J. De Vaere Robert J. De Vaere	Executive Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 18, 2013
/s/ Jeffrey Bird, M.D., Ph.D. Jeffrey Bird, M.D., Ph.D.	Director	March 18, 2013
/s/ Jean-Francois Formela, M.D. Jean-François Formela, M.D.	Director	March 18, 2013
/s/ Michael Grey Michael Grey	Director	March 18, 2013
/s/ Jeff Himawan, Ph.D. Jeff Himawan, Ph.D.	Director	March 18, 2013

/s/ Ronald Pauli	Director	March 18, 2013
Ronald Pauli		
/s/ Gino Santini	Director	March 18, 2013
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 comprehensive loss, stockholders equity (deficit) and cash flows present fairly, in all material respects, the financial position of Horizon Pharma, Inc. and its subsidiaries at December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the Management Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company s internal control over financial reporting based on our audits (which was an integrated audit in 2012). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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.

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

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

/s/ PricewaterhouseCoopers LLP

Chicago, Illinois

March 18, 2013

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HORIZON PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	As of December 31, 2012	2011
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 104,087	$ 17,966
Restricted cash	800	750
Accounts receivable, net	3,463	2,372
Inventories, net	5,245	1,195
Prepaid expenses and other current assets	3,323	2,763
Total current assets	116,918	25,046
Property and equipment, net	3,725	3,245
Developed technology, net	68,892	35,602
In-process research and development		36,638
Other assets	4,449	547
TOTAL ASSETS	$ 193,984	$ 101,078
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,986	$ 8,170
Accrued expenses	16,784	8,926
Deferred revenues current portion	2,230	3,281
Notes payable current portion	11,935	3,604
Total current liabilities	36,935	23,981
LONG-TERM LIABILITIES:		
Notes payable, net of current	36,866	15,834
Deferred revenues, net of current	9,554	5,666
Deferred tax liabilities, net	4,408	9,561
Other long term liabilities	243	124
Total long-term liabilities	51,071	31,185
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 61,722,247 and 19,627,744 shares issued and outstanding at December 31, 2012 and 2011, respectively	6	2
Additional paid-in capital	417,455	270,015
Accumulated other comprehensive loss	(3,372)	(3,788)
Accumulated deficit	(308,111)	(220,317)
Total stockholders equity	105,978	45,912
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 193,984	$ 101,078

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

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HORIZON PHARMA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands, except share data)

	For the Years Ended December 31,		
	2012	**2011**	**2010**
REVENUES:			
Sale of goods	$ 22,761	$ 6,773	$ 2,376
Contract revenue	217	166	
Gross sales	22,978	6,939	2,376
Sales discounts and allowances	(3,346)	(12)	
Net sales	19,632	6,927	2,376
Cost of goods	12,663	7,267	4,263
Gross profit (loss)	6,969	(340)	(1,887)
OPERATING EXPENSES:			
Research and development	16,837	15,358	17,697
Sales and marketing	49,561	20,314	5,558
General and administrative	19,444	15,008	18,612
Intangible impairment charge		69,621	
Total operating expenses	85,842	120,301	41,867
Operating loss	(78,873)	(120,641)	(43,754)
OTHER (EXPENSE) INCOME, NET:			
Interest expense, net	(14,525)	(6,284)	(3,024)
Foreign exchange gain (loss)	489	(1,023)	(273)
Bargain purchase gain			19,326
Other, net	(56)		
Total other (expense) income, net	(14,092)	(7,307)	16,029
Loss before benefit for income taxes	(92,965)	(127,948)	(27,725)
BENEFIT FOR INCOME TAXES	(5,171)	(14,683)	(660)
NET LOSS	$ (87,794)	$ (113,265)	$ (27,065)
NET LOSS PER COMMON SHARE - Basic and diluted	$ (2.26)	$ (12.56)	$ (21.16)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING - Basic and diluted	38,871,422	9,014,968	1,279,133
OTHER COMPREHENSIVE INCOME (LOSS), NET OF TAX			
Foreign currency translation adjustments	416	(1,559)	(2,230)
Other comprehensive income (loss)	416	(1,559)	(2,230)
COMPREHENSIVE LOSS..	$ (87,378)	$ (114,824)	$ (29,295)

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)

	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 options to purchase up to 328,074 shares of common stock in April 2010 in connection with acquisition of Nitec 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
Conversion of common stock to preferred stock on April 1, 2010	1,007,830				(424,527)							
Conversion of special convertible preferred stock to common stock on			(510,920)		215,213							

April 1, 2010									
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
Currency translation adjustment						(2,230)			(2,230)
Net loss							(27,065)		(27,065)
Balances at December 31, 2010	24,961,340	$ 2	$ 1,490,551	$	$	$ 206,336	$ (2,230)	$ (107,052)	$ 97,056

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) (Continued)

(In thousands, except share data)

	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				
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 conjuction 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 conjuction with warrant exercises					81,348							
Issuance of warrants in connection with notes payable amendment									1,124			1,124
Currency translation adjustment										(1,558)		(1,558)
Net loss											(113,265)	(113,265)
Balances at December 31, 2011	$	$	$	$	$ 19,627,744	$ 2	$	$	$ 270,015	$ (3,788)	$ (220,317)	$ 45,912
Issuance of common stock in conjunction with equity financing offerings, net of underwriting fees and issuance costs.					38,672,579	4			128,075			128,079
Issuance of common stock in conjunction with vesting of restricted stock units					74,050							
Issuance of common stock in conjunction with ESPP purchases					106,955				287			287
Stock-based compensation									4,661			4,661
Issuance of common stock in conjuction with warrant exercises					1,990,919				154			154
Issuance of warrants in connection with notes payable									9,188			9,188

Issuance of common stock in connection with notes payable amendment				1,250,000				5,075				5,075
Currency translation adjustment									416			416
Net loss										(87,794)		(87,794)
Balances at December 31, 2012	$	$	$	$ 61,722,247	$ 6	$	$	$ 417,455	$ (3,372)	$ (308,111)	$	105,978

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,		
	2012	**2011**	**2010**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (87,794)	$ (113,265)	$ (27,065)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	5,538	4,199	2,973
Stock-based compensation	4,661	2,530	2,574
Intangible impairment charge		69,621	
Paid in kind interest expense	2,607		
Non-cash interest expense	2,740	2,708	966
Foreign exchange (gain) loss	(489)	1,023	273
Loss on disposal of assets	76		42
Bargain purchase gain			(19,326)
Changes in operating assets and liabilities:			
Accounts receivable	(1,087)	(1,817)	(516)
Inventories	(4,022)	(923)	1,010
Prepaid expenses and other current assets	(543)	(1,897)	551
Accounts payable	(2,209)	5,643	(1,137)
Accrued expenses	7,052	3,215	(2,404)
Deferred revenues	2,616	3,237	5,734
Deferred tax liabilities	(5,206)	(15,778)	(708)
Other non-current assets and liabilities	(581)	(36)	(499)
Net cash used in operating activities	(76,641)	(41,540)	(37,532)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(1,336)	(1,604)	(714)
Increase in restricted cash	(50)	(550)	(200)
Acquisition of Nitec Pharma AG, net of cash acquired			6,489
Net cash (used in) provided by investing activities	(1,386)	(2,154)	5,575
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
Proceeds from issuance of convertible preferred stock, net of issuance costs			20,683
Proceeds from equity finance offerings, net of offering costs	128,077		
Proceeds from the issuance of notes payable, net of issuance costs	55,578	16,651	10,058
Proceeds from the issuance of common stock	441	124	
Repayment of notes payable	(19,788)	(13,067)	(10,981)
Net cash provided by financing activities	164,308	55,152	29,760
Effect of foreign exchange rate changes on cash	(160)	1,124	421
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS..	86,121	12,582	(1,776)
CASH AND CASH EQUIVALENTS, beginning of the year	17,966	5,384	7,160
CASH AND CASH EQUIVALENTS, end of the year	$ 104,087	$ 17,966	$ 5,384

Supplemental cash flow information:

Cash paid for interest	$ 7,554	$ 2,757	$ 1,905
Cash paid for income taxes	57		66
Commitment fee paid on notes payable	600		120
Non-cash investing and financing activities:			
Common stock issued in connection with debt amendment	$ 5,075	$	$
Payment in kind incremental borrowings	1,843		
Conversion of bridge notes and accrued interest to common stock		18,156	
Convertible preferred stock and common stock issued to Nitec shareholders in connections with in connection with the Nitec acquisition			104,135

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, 2012, 2011 and 2010

(in thousands, except share and per share data)

NOTE 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 specialty pharmaceutical company that has developed and is commercializing DUEXIS and RAYOS/LODOTRA, both of which target unmet therapeutic needs in arthritis, pain and inflammatory diseases. The Company s strategy is to develop, acquire, in-license and/or co-promote additional innovative medicines where it can execute a targeted commercial approach in specific therapeutic areas while taking advantage of its commercial strengths and the infrastructure the Company has put in place.

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), osteoarthritis (OA) and to decrease the risk of developing upper gastrointestinal (GI) ulcers in patients who are taking ibuprofen for these indications. In the second-half of 2011, the Company hired its initial commercial organization, including approximately eighty sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In the third quarter of 2012, the Company expanded its sales force to approximately one hundred fifty representatives and under a co-promotion agreement with Mallinckrodt LLC (Mallinckrodt), the pharmaceutical business of Covidien plc, Mallinckrodt began calling on twenty five thousand exclusive physician targets. The Company s sales force expansion, along with the Mallinckrodt co-promotion agreement, expanded the called-on physician targets for DUEXIS from approximately ten thousand to approximately fifty thousand. In June 2012, the Company licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products. In March 2013, the Company announced that the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA) granted a National Marketing Authorization (MA) for DUEXIS in the UK. The Company will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded non-steroidal anti-inflammatory drugs (NSAIDs), the Company does not expect a material level of sales from DUEXIS in European markets.

The Company s other lead product, RAYOS, known as LODOTRA outside the U.S., is a proprietary delayed-release formulation of low-dose prednisone for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, polymyalgia rheumatica (PMR), psoriatic arthritis (PsA), ankylosing spondylitis (AS), asthma and chronic obstructive pulmonary disease (COPD) and a number of other conditions. The Company plans to focus its promotion of RAYOS in the U.S. on rheumatology indications, including RA and PMR. The Company began detailing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of rheumatologists and high-value primary care physicians. LODOTRA is currently marketed in Europe by the Company s distribution partner, Mundipharma International Corporation Limited (Mundipharma).

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The Company s strategy is to utilize the commercial strengths and the infrastructure that have been put in place in creating a fully-integrated U.S.-focused specialty pharmaceutical company to successfully commercialize DUEXIS and RAYOS in the U.S. market and also to expand and leverage these capabilities by developing, acquiring, in-licensing or co-promoting additional products where the Company can execute a targeted commercial approach in specific therapeutic areas. The Company intends to enter into licensing or additional distribution arrangements for the commercialization of its products outside the U.S., such as its relationship with Mundipharma for the commercialization of LODOTRA in Europe, Asia and Latin America and the Company s relationship with Grünenthal for the commercialization of DUEXIS in Latin America.

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. In connection with the closing of the initial public offering, all of the Company s convertible preferred stock was converted to common stock.

In February 2012, the Company entered into a $60,000 loan facility with a group of institutional investors (the Senior Secured Loan), which includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end, beginning in the second quarter of 2012. In September 2012, the Company entered into an amendment of the Senior Secured Loan (the Senior Secured Loan Amendment), which modified affirmative covenants under the Senior Secured Loan with respect to minimum levels of liquidity and net revenue. Under the Senior Secured Loan Amendment, the Company was required to have a minimum liquidity of $30,000 as of December 31, 2012. The Company is no longer required to achieve minimum net revenue levels for the trailing 12 month periods at the end of the third and fourth quarters of 2012, and the minimum trailing 12 month net revenues as of the end of each quarter of 2013 and the first quarter of 2014 have been reduced. No other terms of the Senior Secured Loan were modified. As of December 31, 2012, the Company was in compliance with all financial loan covenants pursuant to the Senior Secured Loan.

In March 2012, the Company sold 14,033,829 shares of its common stock and warrants to purchase an aggregate of 3,508,448 shares of its 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 the Company s common stock is greater than the per share exercise price, by surrender of a portion of the warrant in a cashless exercise.

On August 1, 2012, the Company filed a registration statement on Form S-3, which became effective on August 9, 2012, that allows the Company to offer and sell up to an aggregate of $175,000 worth of common stock, preferred stock, debt securities and/or warrants in public offerings. In September 2012, the Company received gross proceeds of $86,236 from the sale of 24,638,750 shares of common stock and warrants to purchase an aggregate of 12,319,375 shares of common stock with an exercise price of $4.57 per share in a public offering under the registration statement.

The financial statements are prepared on a going concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business. As of December 31, 2012, the Company had cash and cash equivalents totaling $104,087. The Company believes that it has sufficient liquidity and capital resources to operate through 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 fully launched in January 2012, and the commercial success of RAYOS in the U.S. market, which was fully launched in late January 2013 to the majority of U.S. rheumatologists and high-value primary care physicians, and has insufficient commercial operating history to accurately predict its future performance. The Company has incurred net operating losses and negative cash flows from operations since its inception. In order to continue its operations, the Company must generate sufficient revenue to meet the trailing twelve month net revenue covenant and achieve profitable operations or may be required to obtain additional debt or equity financing. There can be no assurance, however, that such financing will be available or on terms acceptable to the Company. Should the Company not meet these quarterly minimum trailing twelve month net revenue covenants, in addition to an increase in the interest rate payable

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under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. 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 trailing twelve month net 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.

NOTE 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.

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 generally not had a material impact on the Company s operating results. During the year ended December 31, 2012, the Company recorded a gain from foreign currency transactions of $489 compared to losses during the years ended December 31, 2011 and 2010 of $1,023 and $273, respectively. The Company does not currently utilize and has not in the past utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

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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.

In June 2012, the Company received a non-refundable and non-creditable upfront payment associated with its entry into a collaboration, license and supply agreement with Grünenthal for the potential commercialization of DUEXIS in Latin America. The upfront payment was deferred and recorded on the balance sheet as long-term deferred revenue. As of December 31, 2012, deferred revenues under the collaboration, license and supply agreement was $1,650.

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 when delivery has occurred, title has transferred, the selling price is fixed or determinable, collectability is reasonably assured and the Company has no further performance obligations. In addition, revenue is only recognized when the right of return no longer exists (which is the earlier of the product being dispensed through patient prescriptions or the expiration of the right of return) or when product returns can be reasonably estimated. Prior to October 2012, revenue from products sold to the Company s wholesale distributors and retail chains was recognized based on the amount of product sold through to the end user consumer. Since October 2012, due to the Company s ability to reasonably estimate and determine allowances for product returns, rebates and discounts, the Company has begun recognizing DUEXIS and RAYOS revenue at the point of sale to wholesale pharmaceutical distributors and retail chains, which resulted in the recognition of $1,786 and $1,353 in gross and net deferred revenues, respectively.

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 with respect to LODOTRA. The Company also recognizes revenues related to up-front license fees, milestone receipts and product deliveries.

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.

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Under the manufacturing and supply agreements with Mundipharma Medical Company (Mundipharma Medical), Mundipharma Medical agreed to purchase LODOTRA exclusively from the Company at a price based on a specified percentage of the average net selling price (ANSP) for sales in a given country, subject to a minimum price. Mundipharma Medical has a nine-month period from purchase date to request 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 have been 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 ANSP adjustment period passes, at which time any previously deferred revenue would be recognized as revenue. As of December 31, 2012 and 2011, deferred revenues related to the sale of LODOTRA were $10,114 and $7,430, respectively.

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 could reliably estimate returns, the Company determined that shipment of products to wholesale pharmaceutical distributors and regional retail chains did not meet the criteria for revenue recognition at the time of shipment. The Company therefore deferred DUEXIS revenue recognition until the right of return no longer existed, which was 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).

During the fourth quarter of 2012, the Company changed from recognizing revenue upon product being dispensed through patient prescriptions to recognizing revenue when product is sold into the wholesale pharmaceutical distributor and retail chain channel. Based on approximately one year of minimal product return quantities and an enhanced ability and historical experience upon which to monitor DUEXIS inventory levels in the distribution channel and to assess the relative risk of potential product returns, the Company believes it now has the ability to reliably estimate returns and began recognizing revenue on the sale of DUEXIS and RAYOS at the point of sale to the wholesaler.

As of December 31, 2012 and 2011, the Company had $20 and $1,517, respectively, in deferred revenue on its balance sheet related to DUEXIS shipments.

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, 2012 and 2011, the Company had a deferred cost of goods sold balance of $0 and $1,067, respectively.

DUEXIS Product Sales Discounts and Allowances

Prior to the fourth quarter of 2012, the Company recorded DUEXIS sales to wholesale pharmaceutical distributors and retail chains as deferred revenue. Allowances for product returns, rebates and discounts were also deferred at the time of sale to wholesale pharmaceutical distributors and national and regional retail chains. These deferred expenses were recognized to arrive at net product sales at the time revenue was recognized. Beginning in the fourth quarter of 2012 the Company began recognizing revenue at the point of sale to its wholesale pharmaceutical distributors and retail chains and the allowances for product returns, rebates and allowances were also recognized at the point of sale. 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 revenue.

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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 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 revenue.

Distribution Service Fees

The Company pays distribution services fees to each wholesaler for distribution and inventory management services. The Company accrues the fees based on contractually defined terms with each wholesaler and records the expense as 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 wholesale pharmaceutical distributors at a discounted price, and the wholesale pharmaceutical distributors then charge back to the Company the difference between the current retail price and the contracted price the federal entities paid for the product. The Company accrues estimated chargebacks based on contract prices and sell-through sales data obtained from third party information and records the expense as a reduction of revenue.

Rebates

The Company participates in certain rebate programs. 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 and records the expense as a reduction of revenue.

Cost of Goods Sold

As a result of the commercial launch of DUEXIS in the U.S. in December 2011, and RAYOS in December 2012, the Company also began to recognize cost of goods sold in connection with its sale of DUEXIS and RAYOS. Cost of goods sold of DUEXIS includes all costs directly related to the acquisition of product from the Company s third party manufacturers, including freight charges as well as costs of distribution. Cost of goods sold of RAYOS includes all costs directly related to the manufacture and delivery of product, including raw material costs, costs associated with third parties who manufacture RAYOS for the Company, supply chain costs, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes. Until the Company began recognizing revenue at the point of sale of DUEXIS to the wholesaler in the fourth quarter of 2012, it also deferred the related DUEXIS cost of goods sold and recorded such amounts as other current assets until revenue was recognized.

Cost of goods sold of LODOTRA includes 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.

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Inventories

Inventories are stated at the lower of cost 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 is included in other current assets and is expensed as a component of sales and marketing expense when provided to physicians or healthcare providers. As of December 31, 2012 and 2011, the Company had product sample inventory of $875 and $629, respectively.

Preclinical Studies 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.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. For the periods presented, the Company s potential dilutive shares, which include shares issuable upon the exercise of outstanding stock options, unvested restricted stock units and warrants to purchase common stock, have not been included in the computation of diluted net loss per share for the periods presented in which there is a net loss as the result would be anti-dilutive. Such potentially dilutive shares are excluded when the effect would be to reduce net loss per share.

In circumstances where there has been a stock dividend, stock split or reverse stock split subsequent to the close of an accounting period but prior to issuance of financial statements, ASC 260 (Earnings Per Share) requires the computation of loss per share to give retroactive recognition to an appropriate equivalent change in capital structure for all periods presented based on the new number of shares. The Company s April 2010 recapitalization resulted in a similar change in capital structure and therefore the Company has applied the guidance in ASC 260 in order to show loss per share amount calculated on a basis that is more comparable to the basis on which it is expected to be calculated in future periods. In the recapitalization, the existing common stock, which had a liquidation preference relative to a special class of preferred stock, was exchanged for a mixture of common stock and Series A preferred stock.

Fair Value of Financial Instruments

The 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 short maturities. The estimated fair value of the Company s Senior Secured Loan was determined using Level 2 inputs and was based on the notional amounts of the outstanding debt instrument and borrowing rates of recent debt transactions. At December 31, 2012, the fair value of the Senior Secured Loan approximated its carrying value.

Cash and Cash Equivalents

Cash and cash equivalents primarily consist of cash balances and money market funds. Cash and cash equivalents were $104,087 and $17,966 as of December 31, 2012 and 2011, respectively. The Company s policy is to invest excess cash in money market funds, which are generally of a short-term duration based upon operating requirements.

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Restricted Cash

Restricted cash consists of balances included in interest-bearing money market accounts required by a vendor for the Company s sponsored employee credit card program and by the lessor for the Company s corporate office. As of December 31, 2012 and 2011, the Company had restricted cash in the amounts of $800 and $750, respectively.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation. Depreciation is recognized using the straight-line method over the estimated useful lives of the related assets for financial reporting purposes and an accelerated method for income tax reporting purposes. Upon retirement or sale of an asset, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operations. Repair and maintenance costs are charged to expenses as incurred and improvements are capitalized.

Leasehold improvements are amortized on a straight-line basis over the term of the applicable lease, or the useful life of the assets, whichever is shorter. Depreciation and amortization periods for the Company s property and equipment are as follows:

Machinery and equipment	5 to 7 years
Furniture and fixtures	3 to 7 years
Computer equipment	3 years
Software	5 years
Trade show equipment	3 years

Software includes internal-use software acquired and modified to meet the Company s internal requirements. Amortization commences when the software is ready for its intended use.

Intangible Assets

The Company s intangible assets consist of developed technology related to two of its approved products, LODOTRA outside the U.S and RAYOS in the U.S. On July 26, 2012, the FDA approved RAYOS for the treatment of a broad range of indications, which resulted in the Company reclassifying its indefinite-lived in-process research and development (IPR&D) asset to developed technology and commencing amortization during the third quarter of 2012. The Company amortizes these intangible assets over twelve years, which is the estimated useful life of the underlying LODOTRA and RAYOS patents.

The Company reviews its intangible assets when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. The Company measures fair value based on the estimated future discounted cash flows associated with these assets in addition to other assumptions and projections that the Company deems to be reasonable and supportable.

Research and Development Expenses

Research and development expenses include, but are not limited to, payroll and other personnel expenses, consultant expenses, expenses incurred under agreements with contract research organizations to conduct clinical trials and expenses incurred to manufacture clinical trial materials. Costs related to medical affairs, which consist of scientific publications, health outcomes, biostatistics, medical education and information, and medical communications are also charged to research and development expense as incurred.

Sales and Marketing Expenses

Sales and marketing expenses consist principally of payroll of sales representatives and marketing and support staff, travel and other personnel-related expenses, marketing materials and distributed sample inventories.

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Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that may potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents. The Company s cash and cash equivalents are invested in deposits with various banks in the U.S., Switzerland and Germany that management believes are creditworthy. At times, deposits in these banks may exceed the amount of insurance provided on such deposits. To date, the Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company s LODOTRA sales contracts are principally denominated in Euros and therefore, its revenues are subject to significant foreign currency risk.

To achieve profitable operations, the Company must successfully develop, obtain regulatory approval for, manufacture and market its products and product candidates, or acquire, in-license or co-promote products from third parties. There can be no assurance that any additional products can be developed, will be approved for marketing by the regulatory authorities, or can be manufactured at an acceptable cost and with appropriate performance characteristics or that any products will be successfully marketed, in-licensed or co-promoted by the Company. These factors could have a material adverse effect on the Company s operations.

The Company relies on third parties to manufacture its commercial supplies of DUEXIS and RAYOS/LODOTRA. The commercialization of any of its products or product candidates could be stopped, delayed or made less profitable if those third parties fail to provide the Company with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

The Company is required to maintain compliance with applicable Swiss laws with respect to its 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. The Company reviews on a regular basis whether its Swiss subsidiary is overindebted. As of December 31, 2012 and 2011, the Company s Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. The Company will continue to monitor and review steps to address any overindebtedness, until such time as its Swiss subsidiary generates positive income at a statutory level, which could require the Company to have cash at its Swiss subsidiary in excess of its near term operating needs and could affect the Company s ability to have sufficient cash at its U.S. subsidiary to meet its near term operating needs.

Historically, the Company s accounts receivable balances have been highly concentrated with a select number of customers, consisting primarily of large wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. The Company s top four customers, which includes Munipharma, Merck & Co., Inc., McKesson Corporation and Cardinal Heath, Inc. during the years ended December 31, 2012, 2011 and 2010 accounted for approximately 83%, 98% and 100%, respectively, of total consolidated sales. In addition, revenues to three customers, which included Mundipharma, Walgreen Company and McKesson Corporation as of December 31, 2012 and 2011, comprised approximately 77% and 81%, respectively, of the Company s total outstanding accounts receivable balances. Historically, the Company has not experienced any losses related to its accounts receivable balances.

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss) (OCI). OCI includes certain changes in stockholders equity (deficit) that are excluded from net income (loss), which consist of foreign currency translation adjustments. As of December 31, 2012 and 2011, accumulated other comprehensive loss was $3,372 and $3,788, respectively.

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NOTE 3 EARNINGS PER SHARE

The following table presents basic and diluted earnings per share for the years ended December 31, 2012, 2011 and 2010:

	For the Years Ended December 31,		
	2012	2011	2010
Basic and diluted earnings per share calculation:			
Net loss	$ (87,794)	$ (113,265)	$ (27,065)
Weighted average of common shares outstanding	38,871,422	9,014,968	1,279,133
Basic and diluted net loss per share	$ (2.26)	$ (12.56)	$ (21.16)

The following dilutive securities were excluded from the computation of diluted earnings per share for the years ended December 31, 2012, 2011 and 2010 due to the anti-dilutive effects resulting from the Company s net loss for the periods presented:

Outstanding stock options to purchase an aggregate of 2,746,918, 2,532,262 and 1,348,444 shares of common stock at December 31, 2012, 2011 and 2010, respectively, outstanding and unvested restricted stock units covering an aggregate of 232,158 and 304,890 shares of common stock at December 31, 2012 and 2011, respectively, and 225,000 vested restricted stock units outstanding at December 31, 2012.

Outstanding common stock warrants to purchase an aggregate of 17,480,243 and 377,370 shares of common stock at December 31, 2012, and 2011, respectively.

Outstanding preferred stock warrants to purchase an aggregate of 346,067 shares of common stock at December 31, 2010.

Outstanding convertible preferred stock of 10,514,431 at December 31, 2010. Additionally, the outstanding convertible preferred stock was excluded from the computation of diluted earnings per share for the period of January 2011 through July 2011. Upon the closing of the Company s initial public offering on August 2, 2011, the outstanding shares of convertible preferred stock were converted into shares of the Company s common stock, which were then included as part of the computation of diluted earnings per share.

NOTE 4 INVENTORIES

The components of inventories as of December 31, 2012 and 2011 consisted of the following:

	As of December 31,	
	2012	2011
Raw materials	$ 40	$ 75
Work-in-process	824	488
Finished goods	4,381	632
Net inventories	$ 5,245	$ 1,195

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NOTE 5 ALLOWANCE FOR DOUBTFUL ACCOUNTS

Allowance for doubtful accounts for the years ended December 31, 2012, 2011 and 2010 consisted of the following:

	For the Years Ended December 31,		
	2012	2011	2010
Balance at beginning of year	$ 170	$	$
Bad debt expense (1)	(94)	170	
Write-offs			
Balance at end of year	$ 76	$ 170	$

(1) As a result of the Company s revenue recognition policy, allowance for doubtful accounts was accrued, but the corresponding bad debt expense for the years ended December 31, 2012 and 2011 was not expensed, but offset against deferred revenues until actual revenues from these product shipments are realized. At December 31, 2012, the allowance for doubtful accounts reserve was reduced based upon the Company s product return history in 2012.

NOTE 6 PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets as of December 31, 2012 and 2011 consisted of the following:

	As of December 31,	
	2012	2011
Deferred cost of goods sold	$	$ 1,067
Product samples inventory	875	629
Prepaid clinical trial studies	661	
Prepaid marketing expenses	607	509
Prepaid insurance	265	230
Prepaid FDA product and manufacturing fees	139	139
Other prepaid expenses	745	115
Other current assets	31	74
Total prepaid and other current assets	$ 3,323	$ 2,763

NOTE 7 PROPERTY AND EQUIPMENT

Property and equipment as of December 31, 2012 and 2011 consisted of the following:

	As of December 31,	
	2012	2011
Machinery and equipment	$ 2,248	$ 1,797
Furniture and fixtures	116	158
Computer equipment	1,211	677
Software	646	286
Trade show equipment	228	228
Leasehold improvement	783	705
Construction in progress		165

	5,232	4,016
Less-accumulated depreciation	(1,507)	(771)
Total property and equipment	$ 3,725	$ 3,245

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Depreciation expense for the years ended December 31, 2012, 2011 and 2010 was $806, $446 and $237, respectively.

NOTE 8 INTANGIBLE ASSETS

The Company s intangible assets consist of developed technology related to the Company s approved and/or marketed products: LODOTRA in Europe and RAYOS in the U.S. On July 26, 2012, the FDA approved RAYOS for the treatment of a broad range of indications, which resulted in the Company reclassifying the entire asset balance of $35,456 from its indefinite-lived IPR&D asset to a finite-lived developed technology asset and commencing amortization. At December 31, 2012, the Company had no remaining IPR&D intangible assets.

In connection with the reclassification of IPR&D to developed technology in the third quarter of 2012, the Company conducted a fair value assessment related to the carrying value of this asset. The analysis indicated that the fair value of the developed technology asset exceeded its carrying value, which resulted in no impairment. Developed technology is amortized on a straight-line basis over its estimated useful life of twelve years for both RAYOS and LODOTRA.

The Company tests its intangible assets for impairment when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. During the fourth quarter of 2011, the Company performed its annual test of its indefinite-lived intangible assets for impairment. The Company utilized a fair value approach by calculating its business enterprise value, which equated to the market value of the Company s common stock as of December 31, 2011, and included an appropriate control risk premium. The result of this analysis indicated that the carrying value of its IPR&D asset was impaired. Additionally, the Company calculated the business enterprise value, which included its IPR&D asset, using a discounted cash flow approach. The fair value of the IPR&D utilizing this method was estimated to be $36,638 as of December 31, 2011. Accordingly, the Company recorded an intangible impairment charge related to its IPR&D asset of $69,621 during the fourth quarter of 2011.

As of December 31, 2012 and 2011, intangible assets consisted of the following:

	Developed Technology	In-Process Research and Development	Total Intangibles
Net book value at December 31, 2010	$ 39,990	$ 108,746	$ 148,736
Amortization expense	(3,753)		(3,753)
Currency translation adjustment	(635)	(2,487)	(3,122)
Impairment charge		(69,621)	(69,621)
Net book value at December 31, 2011	35,602	36,638	72,240
Amortization expense	(4,732)		(4,732)
Currency translation adjustment	2,566	(1,182)	1,384
Transfer to Developed Technology	35,456	(35,456)	
Net book value at December 31, 2012	$ 68,892	$	$ 68,892

Amortization expense of the Company s developed technology for the years ended December 31, 2012, 2011 and 2010 was $4,732, $3,753 and $2,634, respectively. As of December 31, 2012, estimated future amortization expense was as follows:

2013	$ 6,482
2014	6,482
2015	6,482
2016	6,482
2017 and thereafter	42,964
Total	$ 68,892

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NOTE 9 OTHER ASSETS

Other assets as of December 31, 2012 and 2011, consisted of the following:

	As of December 31,	
	2012	2011
Deferred financing costs	$ 3,195	$
Long-term clinical study deposits	661	
Long-term inventory deposits	505	505
Other	88	42
Total other assets	$ 4,449	$ 547

NOTE 10 ACCRUED LIABILITIES

Accrued liabilities as of December 31, 2012 and 2011, consisted of the following:

	As of December 31,	
	2012	2011
Payroll related expenses	$ 6,290	$ 4,237
Sales and marketing expenses	1,265	1,199
Deferred rent	876	811
Accrued rebates and royalties	2,704	694
Clinical and regulatory expenses	652	439
Professional services	399	394
Contract manufacturing expenses	1,094	220
Taxes and licenses	52	196
Interest expense	2,538	163
Consulting services	228	150
Accrued other	686	423
Total accrued liabilities	$ 16,784	$ 8,926

NOTE 11 FAIR VALUE MEASUREMENTS

The following tables set forth the Company s financial instruments that are measured at fair value on a recurring basis within the fair value hierarchy. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 - Observable inputs such as quoted prices in active markets for identical assets or liabilities.

Level 2 - Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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The Company utilizes the market approach to measure fair value for its money market funds. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities.

Assets measured at fair value on a recurring basis

The following table sets forth the Company s financial assets and liabilities at fair value on a recurring basis as of December 31, 2012 and 2011:

	2012			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 97,670	$	$	$ 97,670
Total assets at fair value	$ 97,670	$	$	$ 97,670

	2011			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 15,448	$	$	$ 15,448
Total assets at fair value	$ 15,448	$	$	$ 15,448

NOTE 12 COMMITMENTS AND CONTINGENCIES

Lease Obligations

In September 2011, the Company entered into an office lease agreement for approximately 22,000 square feet of office space in Deerfield, Illinois, which was effective August 31, 2011. The initial term of the lease commenced on December 1, 2011, and expires on June 30, 2018. The minimum net rent is initially 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. In August 2012, the Company entered into an additional lease agreement to expand the office space available to it by an additional 4,900 square feet in the same Deerfield, Illinois facility as its existing office space. The lease term coincides with its original lease in this facility and runs through June 30, 2018. The initial rent on the additional lease will be $7 per month and will increase up to a maximum of $8 per month after the sixth year.

The Company also leases its offices in Reinach, Switzerland and in Mannheim, Germany. The Reinach office lease rate is $7 (6 CHF) per month, expiring on May 31, 2015. The Mannheim office lease rate is approximately $6 (5 Euros) per month, expiring on December 31, 2014.

The Company recognizes rent expense on a monthly basis over the lease term based on a straight-line method. Rent expense was $458, $507 and $355 for the years ended December 31, 2012, 2011 and 2010, respectively.

Purchase Commitments

In August 2007, the Company entered into a manufacturing and supply agreement with Jagotec AG (Jagotec). Under the agreement, Jagotec or its affiliates are required to manufacture and supply RAYOS/LODOTRA exclusively to the Company in bulk. The Company committed to a minimum purchase of RAYOS/LODOTRA tablets from Jagotec for five years from the date of first launch of RAYOS/LODOTRA in a major country, as defined in the agreement, which was in April 2009. At December 31, 2012, the minimum remaining

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purchase commitment based on tablet pricing in effect under the agreement was $3,217. The purchase agreement automatically renews on a yearly basis until either party provides two years advance written notice of termination. The earliest the agreement can expire according to this advance notice procedure is April 15, 2015.

In May 2011, the Company 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 the Company in final, packaged form, and the Company is obligated to purchase DUEXIS exclusively from sanofi-aventis U.S. for the 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. At December 31, 2012, the Company had a $9,700 blanket purchase commitment to sanofi-aventis U.S. for DUEXIS to be delivered through December 2013, of which $70 represented a binding purchase order issued from the Company to sanofi-aventis U.S. for DUEXIS to be delivered in the first quarter of 2013.

Royalty Agreement

In connection with the August 2004 development and license agreement with SkyePharma AG (SkyePharma) and Jagotec, a wholly-owned subsidiary of SkyePharma, regarding certain proprietary technology and know-how owned by SkyePharma, Jagotec is entitled to receive a single digit percentage royalty on net sales of RAYOS/LODOTRA and on any sub-licensing income, which includes any payments not calculated based on the net sales of LODOTRA, such as license fees, and lump sum and milestone payments. Royalty expense recognized in cost of goods sold for the years ended December 31, 2012, 2011 and 2010 was $539, $455 and $352, respectively.

Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company s management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company s business, financial condition, results of operations or cash flows.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company s request in such capacity. Additionally, the Company has entered, and intends to continue to enter, into separate indemnification agreements with its directors and executive officers. These agreements, among other things, require the Company to indemnify its 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 the Company s directors or executive officers, or any of the Company s subsidiaries or any other company or enterprise to which the person provides services at the Company s request. There have been no claims to date and the Company has a director and officer insurance policy that enables it to recover a portion of any amounts paid for future potential claims.

NOTE 13 LEGAL PROCEEDINGS

On February 15, 2012, the Company received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. (Par) advising that Par had filed an Abbreviated New Drug Application (ANDA) with the FDA for a

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generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par has not advised the Company 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. In March 2012, the Company filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par s ANDA and/or preventing Par from selling a generic version of DUEXIS. In January 2013, the Company filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par s ANDA and/or preventing Par from selling a generic version of DUEXIS. A trial date is currently set for the second quarter of 2014. All of the Company s issued U.S. patents covering DUEXIS are listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Under the FDA s rules and regulations, because the Company initiated a patent infringement suit to defend a patent identified in the Paragraph IV notice within 45 days after the FDA s receipt of the notice, the FDA is prevented from approving the ANDA until the earlier of 30 months from the date of the first suit or a decision in the infringement case that the patent is not infringed or invalid.

NOTE 14 DEBT AGREEMENTS

The Company s outstanding debt balances as of December 31, 2012 and 2011, consisted of the following:

	As of December 31,	
	2012	2011
Senior Secured Loan	$ 61,843	$
Oxford Facility		16,598
Kreos Facility		2,840
	61,843	19,438
Current debt maturities	(11,935)	(3,604)
Debt discount	(13,042)	
Long-term debt, net of current maturities	$ 36,866	$ 15,834

On April 1, 2010, in connection with the acquisition of Nitec, the Company, Horizon Pharma USA, and Horizon Pharma AG entered into a Loan and Security Agreement (the Kreos-SVB Facility) with two financial institutions, which allowed for borrowings of up to $12,000 at a 12.9% interest rate. The first loan of $7,000 was advanced on April 1, 2010, with 36 equal monthly payments of $233 for principal and interest. The Company issued warrants to purchase 150,602 shares of Series B convertible preferred stock at an exercise price of $0.01 per share (Note 10). On September 3, 2010, the second loan for $5,000 was advanced with 36 equal monthly payments of $166 of principal and interest. In June 2011, in connection with the debt facility with Oxford Finance LLC (Oxford) and Silicon Valley Bank (SVB) described below (the Oxford Facility), the Company repaid all $8,455 due under the Kreos-SVB Facility (including principal and interest), which included $7,842 of principal, $443 of interest and $170 of loan fees.

Also, Horizon Pharma AG had renegotiated the payment terms of an existing 7,500 Euro debt facility (the Kreos Facility). Furthermore, the lender s warrant to purchase up to 37,244 shares of Nitec capital stock was cancelled and exchanged for a warrant to purchase up to 118,496 shares of the Company s Series A convertible preferred stock at an exercise price of $0.01 per share. In June 2011, in connection with the Oxford Facility, the Company paid Kreos $1,450 (1,000 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. The Company also issued a warrant to Kreos to purchase an aggregate of 100,000 shares of its Series B convertible preferred stock with an exercise price of $0.01 per share, which will expire on June 2, 2021, unless earlier terminated as a result of certain acquisitions or changes in control, in exchange for Kreos consent to enter into the Oxford Facility.

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As a result of the extinguishment of the Kreos-SVB Facility and the partial pay down of the Kreos Facility, the Company incurred a total of $1,977 of extinguishment loss from the write-off of remaining debt discount, prepayment penalty interest and loan fees. The loss on the extinguishment of debt is included in interest expense in the consolidated statement of operations for the year ended December 31, 2011.

In June 2011, the Company entered into the Oxford Facility and borrowed the full $17,000 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. With the loan proceeds, the Company repaid all $8,455 due under the Kreos-SVB Facility (including principal and interest). The Company also paid Kreos the $1,450 (1,000 Euros), described above. The remaining loan proceeds of $6,880, net of $215 of loan fees, was being used to fund the Company s operations. In connection with the Oxford Facility, the Company issued warrants to Oxford and SVB to initially purchase an aggregate of 80,007 shares of its Series B convertible preferred stock which became warrants to purchase an aggregate of 70,833 shares of common stock upon the completion of the Company s initial public offering. The warrants have a per share exercise price of $9.00.

In February 2012, the Company entered into the Senior Secured Loan with a group of institutional investors. The Company used $22,381 of the Senior Secured Loan proceeds to repay the Oxford Facility and the Kreos Facility. As a result of the extinguishment of the Oxford Facility and Kreos Facility, the Company incurred a $2,973 loss on debt extinguishment from the write-off of the remaining debt discount, pre-payment penalty, interest and end of loan fees. The loss on the extinguishment of debt is included in interest expense in the consolidated statement of comprehensive income for the year ended December 31, 2012.

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 the Company 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 (i.e., payment in kind borrowings). Beginning in April 2013, and each quarter thereafter, the lenders may require the Company to repay $3,978 of the loan principal. Accordingly, the Company has classified $11,935 of the principal balance as current borrowings in its consolidated balance sheets at December 31, 2012. The Company may also prepay the loan at any time, subject to certain prepayment premiums.

In connection with the Senior Secured Loan, the Company also issued warrants to the lenders to purchase up to an aggregate of 3,277,191 shares of common stock at an exercise price of $0.01 per share. The warrants became 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 on substantially all of the Company s assets including intellectual property, and the Company pledged all of its equity interests in Horizon Pharma USA, Inc. and 65% of its equity interests in Horizon Pharma AG.

The Senior Secured Loan restricts the Company s ability to incur additional indebtedness, incur liens, pay dividends and engage in significant business transactions, such as a change of control, so long as the Company owes any amounts to the lenders under the related loan agreements. If the Company defaults under its Senior Secured Loan, its lenders may accelerate all of its repayment obligations and take control of the pledged assets. The Company s lenders could declare the Company in default under its debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect upon it as defined under the loan agreements, thereby requiring the Company to repay the loan immediately or to attempt to reverse the lenders declaration through negotiation or litigation. Among other loan covenant requirements, the Senior Secured Loan also requires the Company to maintain a minimum level of liquidity of at least $10,000 at all times during the term of the loan unless its quarterly consolidated EBITDA is at least $6,000 and to meet specified minimum net revenues during a trailing twelve-month period, which commenced on June 30, 2012. The negative covenants include, among other things, restrictions on transferring or licensing the Company s assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on the Company s

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assets, in each case subject to customary exceptions. During 2012, the Company elected to pay the 12% interest in cash, and the remaining 5% interest due of $1,843 was added to the principal loan balance as a payment in kind borrowing.

On September 7, 2012, the Company and lenders entered into the Senior Secured Loan Amendment, whereby affirmative covenants under the Senior Secured Loan with respect to minimum levels of liquidity and net revenue were modified. Under the Senior Secured Loan Amendment, the Company was required to have a minimum liquidity of $30,000 as of December 31, 2012. The Company is no longer required to achieve minimum net revenue levels for the trailing 12 month periods at the end of the third and fourth quarters of 2012, and the minimum trailing 12 month net revenues as of the end of each quarter of 2013 and the first quarter of 2014 have been reduced.

In lieu of paying a cash fee in consideration for entering into the Senior Secured Loan Amendment, the Company agreed to issue an aggregate of 1,250,000 shares of the Company s common stock to the lenders. The fair value of the common stock issued in connection with the Senior Secured Loan Amendment was $5,075 and was classified as debt discount in the Company s consolidated balance sheets and will be amortized to interest expense over the remaining life of the Senior Secured Loan. At December 31, 2012, the outstanding balance on the Senior Secured Loan was $61,843 and the Company was in compliance with all applicable financial loan covenants.

NOTE 15 STOCKHOLDERS EQUITY

In February 2012, in connection with the Senior Secured Loan, the Company issued warrants to purchase an aggregate of 3,277,191 shares of the Company s common stock at an exercise price of $0.01 per share. The warrants expire on January 22, 2017.

In March 2012, the Company received gross proceeds of $50,820 from the sale of 14,033,829 shares of common stock and warrants to purchase an aggregate of 3,508,448 shares of common stock with an exercise price of $4.308 per share to certain institutional and accredited investors in a private equity 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 expire on March 2, 2017.

In March 2012, warrants to purchase an aggregate of 42,122 shares of the Company s common stock were exercised in a cashless exercise resulting in the issuance of 41,797 shares of common stock.

In July 2012, warrants to purchase an aggregate of 13,807 shares of the Company s common stock were exercised in a cashless exercise resulting in the issuance of 6,169 shares of common stock.

In August 2012, the Company issued 34,518 shares of common stock upon the exercise of a warrant and the Company received proceeds of $149 representing the aggregate exercise price.

In August 2012, warrants to purchase an aggregate of 1,365,496 shares of the Company s common stock were exercised in a cashless exercise resulting in the issuance of 1,362,237 shares of common stock.

In September 2012, in connection with the Senior Secured Loan Amendment, the Company issued an aggregate of 1,250,000 shares of the Company s common stock.

In September 2012, the Company received gross proceeds of $86,236 from the sale of 24,638,750 shares of common stock and warrants to purchase an aggregate of 12,319,375 shares of common stock with an exercise price of $4.57 per share to certain institutional and accredited investors in a public offering. For each share of common stock purchased, the investors received a warrant to purchase 0.5 of a share of the Company s common stock. The warrants expire on September 24, 2017.

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In October 2012, the Company issued 546,198 shares of common stock upon the exercise of a warrant and received proceeds of $5 representing the aggregate purchase price.

NOTE 16 EQUITY INCENTIVE PLANS

Employee Stock Purchase Plan

In July 2010, the Company s Board of Directors adopted an Employee Stock Purchase Plan (ESPP) and in June 2011, the Company s stockholders approved the 2011 Purchase Plan (the 2011 Purchase Plan), and it became effective upon the signing of the underwriting agreement related to the Company s initial public offering in July 2011. The Company reserved a total of 463,352 shares of common stock for issuance under the 2011 Purchase Plan. The 2011 Purchase Plan provides that an additional number of shares will automatically be added annually to the shares authorized for issuance under the 2011 Purchase Plan on January 1, from 2012 until 2021. The number of shares added each year will be equal to the least of: (a) 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (b) 1,053,074 shares of common stock; or (c) a number of shares of common stock that may be determined each year by the Company s Board of Directors that is less than (a) and (b). Subject to certain limitations, the Company s employees may elect to have 1% to 15% of their compensation withheld through payroll deductions to purchase shares of common stock under the 2011 Purchase Plan. Employees purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of the six-month offering period.

On December 15, 2011, pursuant to the terms of the 2011 Purchase Plan, the Company s Board of Directors approved for issuance 100,000 shares under the ESPP, effective January 1, 2012. On December 6, 2012, the Company s Board of Directors approved for issuance 200,000 shares under the ESPP, effective January 1, 2013. As of December 31, 2012, 124,727 shares have been issued and an aggregate of 438,625 shares of common stock were authorized and available for issuance under the ESPP.

Stock-Based Compensation Plans

In October 2005, the Company adopted the 2005 Stock Plan (the 2005 Plan). The 2005 Plan provides for the granting of stock options to employees and consultants of the Company. Options granted under the 2005 Plan may be either incentive stock options or nonqualified stock options. Upon the signing of the underwriting agreement related to the Company s initial public offering, on July 28, 2011, no further option grants were made under the 2005 Plan. As of July 28, 2011, the 460,842 shares of common stock reserved for future issuance and the 1,304,713 shares of common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan were transferred to the 2011 Equity Incentive Plan (the 2011 Plan), as described below. All stock options granted under the 2005 Plan prior to the offering continue to be governed by the terms of the 2005 Plan.

In July 2010, the Company s Board of Directors adopted the 2011 Plan and in June 2011, the Company s stockholders approved the 2011 Plan, and it became effective upon the signing of the underwriting agreement related to the Company s initial public offering, on July 28, 2011. The 2011 Plan has an initial reserve of 3,366,228 shares of common stock, including 460,842 shares of common stock previously reserved for future issuance under the 2005 Plan, 1,304,713 shares of common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan as of the 2011 Plan s effective date and 1,600,673 new shares of common stock reserved. The 2011 Plan provides that an additional number of shares will automatically be added annually to the shares authorized for issuance on January 1, from 2012 until 2021. The number of shares added each year will be equal to the least of: (a) 5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (b) 1,474,304 shares of common stock; or (c) a number of shares of common stock that may be determined each year by the Company s Board of Directors that is less than (a) and (b). As of December 31, 2012, there were 754,910 shares available for future grants under the 2011 Plan. On December 6, 2012, pursuant to the terms of the 2011 Plan, the Company s board of directors approved an increase in the number of shares available for issuance under the 2011 Plan of 1,474,304 shares, effective January 1, 2013.

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Under the 2011 Plan, the board of directors, or a committee of the board of directors, may grant incentive and nonqualified stock options, stock appreciation rights, restricted stock units, or restricted stock awards to employees, directors and consultants to the Company or any subsidiary of the Company. Under the terms of the 2011 Plan, the exercise price of stock options may not be less than 100% of the fair market value on the date of grant and their term may not exceed ten years.

The following table summarizes stock options activity under the 2011 Plan for the year ended December 31, 2012:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2011	2,532,262	$ 9.93		
Granted	516,325	$ 3.44		
Forfeited	(301,669)	$ 8.59		
Outstanding as of December 31, 2012	2,746,918	$ 8.85	8.0 years	$ 17.9
Exercisable as of December 31, 2012	1,295,921	$ 12.40	7.0 years	$ 16.4

The following table summarizes the Company s outstanding stock options at December 31, 2012:

	Options Outstanding			Options Exercisable	
Exercise Price Ranges	Number of options outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Number Exercisable	Weighted Average Exercise Price
$1.36 - $3.97	434,673	$ 3.24	9.5 years	27,667	$ 2.30
$4.10 - $5.20	1,117,493	4.97	8.5 years	401,109	5.07
$7.48 - $12.94	837,228	10.56	7.4 years	531,830	10.99
$13.47 - $17.22	107,160	13.92	6.6 years	94,167	13.81
$20.78 - $28.83	250,364	28.05	6.1 years	241,148	28.33
	2,746,918	$ 8.85	8.0 years	1,295,921	$ 12.40

During the years ended December 31, 2012, 2011 and 2010, the Company granted stock options to purchase an aggregate of 516,325, 1,256,339 and 1,082,917 shares of common stock, respectively, with a weighted average grant date fair value of $3.44, $5.77 and $15.39, respectively.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The determination of the fair value of each stock option is affected by the Company s stock price on the date of grant, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company s expected stock price volatility over the expected life of the awards and actual and projected stock option exercise behavior. The weighted average fair value per share of stock option awards granted during the years ended December 31, 2012, 2011 and 2010, and assumptions used to value stock options, are as follows:

	For the Years Ended December 31,		
	2012	2011	2010
Dividend yield			
Risk-free interest rate	1.0%	1.2%	2.3%
Weighted average volatility	89.0%	89.3%	80.1%
Expected life (in years)	5.96	6.00	5.11

Weighted average grant date fair value per share of options granted	$ 2.5	$ 4.2	$ 7.8

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Dividend yields

The Company has never paid dividends and does not anticipate paying any dividends in the near future. The loan agreements governing the Senior Secured Loan contain covenants that include, among other things, restrictions on paying dividends, subject to customary exceptions.

Risk-Free Interest Rate

The Company determined the risk-free interest rate by using a weighted average assumption equivalent to the expected term based on the U.S. Treasury constant maturity rate as of the date of grant.

Volatility

The Company used an average historical stock price volatility of comparable companies to be representative of future stock price volatility, as the Company did not have sufficient trading history for its common stock.

Expected Term

Given the Company s limited historical exercise behavior, the expected term of options granted was determined using the simplified method since the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. Under this approach, the expected term is presumed to be the average of the vesting term and the contractual life of the option.

Forfeitures

As stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures based on actual forfeiture experience, analysis of employee turnover and other factors. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Restricted Stock Units

The following table summarizes restricted stock unit activity for the year ended December 31, 2012:

	Number of Units	Weighted Average Grant-Date Fair Value Per Units
Outstanding as of December 31,2011	304,890	$ 4.96
Granted	520,000	$ 4.20
Vested	(299,050)	$ 4.39
Forfeited	(293,682)	$ 4.22
Outstanding as of December 31, 2012.	232,158	$ 4.92

In December 2011, the Company granted 304,890 restricted stock units to acquire shares of the Company s common stock to its employees. The restricted stock units vest over a four-year period on each anniversary of the vesting commencement date. Prior to December 2011, the Company did not grant any restricted stock units.

In January 2012, the Compensation Committee of the Board of Directors of the Company granted 510,000 restricted stock units to senior management of the Company. The restricted stock units were performance based and required the achievement of certain Company defined milestones, with awards being granted in the form of common stock on the earlier of termination of service or December 31, 2012. During 2012, certain performance goals related to these defined milestones were met, which resulted in the vesting of 299,050 restricted stock units

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and a corresponding acceleration of stock-based compensation expense related to these units during the month the milestone was achieved. At December 31, 2012, 285,000 restricted stock units were cancelled as a result of not achieving these milestones.

The following table summarizes share-based compensation expense included in the Company s consolidated statements of operations for the years ended December 31, 2012, 2011 and 2010:

	For the Years Ended December 31,		
	2012	2011	2010
Share-based compensation expense:			
Research and development	$ 1,186	$ 760	$ 867
Sales and marketing	1,090	451	195
General and administrative	2,385	1,319	1,512
Net effect of share-based compensation expense on net loss	$ 4,661	$ 2,530	$ 2,574

No income tax benefit has been recognized relating to stock-based compensation expense and no tax benefits have been realized from exercised stock options, due to the Company s net loss position. As of December 31, 2012, the Company estimates that pre-tax compensation expense of $6,929 for all unvested share-based awards, including both stock options and restricted stock units will be recognized through the fourth quarter of 2015, with $3,987 in pre-tax compensation expense estimated to be recognized during the year ended December 31, 2013. The Company expects to satisfy the exercise of stock options and future distribution of shares of restricted stock by issuing new shares of its common stock which have been reserved under the 2011 Plan.

NOTE 17 RELATED PARTY TRANSACTIONS

The Company has entered into consulting agreements with three stockholders, two of whom previously served as directors of Horizon Pharma USA. Two of the consulting agreements terminated as of December 31, 2011, while one remained in effect until December 31, 2012. In addition, the Company s wholly-owned subsidiary, Horizon Pharma AG, has entered into a consulting agreement with a former owner and majority shareholder of Nitec. For the years ended December 31, 2012, 2011 and 2010, the Company paid $716, $678 and $996, respectively, in consulting fees to the related parties.

NOTE 18 INCOME TAXES

The Company accounts 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.

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The components of the benefit for income taxes were as follows for the years ended December 31, 2012, 2011 and 2010:

	For the Years Ended December 31,		
	2012	2011	2010
Current provision			
Federal	$	$	$
State	4	3	1
Foreign	35	28	46
Total current provision	39	31	47
Deferred benefit			
Federal			
State			
Foreign	(5,210)	(14,714)	(707)
Total deferred benefit	(5,210)	(14,714)	(707)
Total benefit for income taxes	$ (5,171)	$ (14,683)	$ (660)

Total benefit for income taxes was $5,171 and $14,683 for the years ended December 31, 2012 and 2011, respectively. The $9,512 decrease in the income tax benefit during the year ended December 31, 2012 was primarily attributable to the intangible asset impairment charge of $69,621 associated with the Company s IPR&D asset during 2011, which reduced the Company s deferred income tax liability and increased the income tax benefit for the period. Additionally, the decrease in income tax benefit in 2012 was partially offset by higher income tax benefits associated with the reclassification of the Company s IPR&D asset to developed technology. On July 26, 2012, the FDA approved RAYOS, which resulted in the reclassification of the entire asset balance of $35,456, from an indefinite-lived intangible asset to a finite-lived intangible asset. The reclassification to a finite-lived intangible asset requires the Company to amortize this asset over the useful life of the asset, which results in an additional income tax benefit.

A reconciliation between the statutory federal income tax and the Company s effective tax is as follows:

	For the Years Ended December 31,		
	2012	2011	2010
U.S. federal income taxes at statutory tax rate	$ (32,538)	$ (44,781)	$ (9,704)
Stock based compensation	1,063	658	614
Foreign tax rate differential	4,376	14,994	4,532
Deferred taxes not benefited	21,715	14,499	10,620
Research and development credit	(5)	(79)	(154)
Other	218	26	196
Bargain purchase gain			(6,764)
Effective income taxes	$ (5,171)	$ (14,683)	$ (660)

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	As of December 31,		
	2012	2011	2010
Deferred tax assets:			
Net operating loss carryforwards	$ 97,724	$ 68,689	$ 54,011
Research and development credits	2,445	2,447	2,230
Accruals and reserves	5,144	1,906	2,652
Foreign intangible assets	76	90	141
Total deferred tax assets	105,389	73,132	59,034
Valuation allowance	(95,970)	(68,194)	(53,981)
Deferred tax assets, net of valuation allowance	9,419	4,938	5,053
Deferred tax liabilities:			
In-process research and development	$	$ 7,354	$ 21,825
Developed technology	13,827	7,145	8,026
Total deferred tax liabilities	13,827	14,499	29,851
Net deferred income tax liability	$ 4,408	$ 9,561	$ 24,798

The increase in the deferred tax valuation allowance was $27,776 and $14,213 for the years ended December 31, 2012 and 2011, respectively. The increase in the deferred tax valuation allowance in 2012 was primarily the result of higher federal and state net operating losses, which were fully reserved for due to the uncertainty surrounding the realization of these assets. A reconciliation of the beginning and ending amounts of the valuation allowance for the years ended December 31, 2012, 2011 and 2010 were as follows:

Valuation allowance as of December 31, 2009	$ (32,655)
Gross increase for current year activity	(21,326)
Valuation allowance as of December 31, 2010	$ (53,981)
Gross increase for current year activity	(14,213)
Valuation allowance as of December 31, 2011	(68,194)
Increase for current year activity	(32,034)
Release in valuance allowance[(1)]	4,258
Valuation allowance as of December 31, 2012	$ (95,970)

(1) In connection with the FDA approval of RAYOS on July 26, 2012, the Company reclassified its indefinite-lived IPR&D intangible asset to a finite-lived developed technology intangible asset and began amortizing the asset to cost of goods during the third quarter of 2012. The reclassification to developed technology required the Company to reassess its deferred tax positions, which indicated that it was more likely than not that a greater portion of the Company s deferred tax assets would be realized as a result of the reclassification of its intangible asset from indefinite-lived to finite-lived. As a result of this assessment, the Company reduced its deferred tax asset valuation allowances, which resulted in a corresponding reduction to the Company s net deferred tax liabilities and the recognition of a one-time net income tax benefit of $4,258 that was recorded as an additional benefit for income taxes during the third quarter of 2012.

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As of December 31, 2012, the Company had net operating loss carryforwards of approximately $209,672, $121,134 and $89,693 available to reduce future taxable income, if any, for federal, state, and foreign income tax purposes, respectively. Net operating loss carryforwards for state and federal income tax purposes will begin to expire in 2015 and 2025, respectively. 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. In December 2012, $3,801 of Horizon Pharma AG s net operating loss carryforwards expired as a result of this statutory limitation.

In September 2012, the sale of the Company s common stock and warrants to purchase shares of the Company s common stock in a public equity offering triggered an ownership change as prescribed by Section 382 of the Internal Revenue Code of 1986, as amended, which generally imposes an annual limitation on the amount of net operating loss carryforwards and associated built-in losses that may be used to offset taxable income when a corporation has undergone certain changes in stock ownership. The Company estimates that these annual limits will be $27,892, $22,001 and $22,001 for the years 2013, 2014 and 2015, 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.

The Company accounts 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. The changes in the Company s uncertain income tax positions for the years ended December 31, 2012 and 2011 consisted of the following:

	For the Years Ended December 31,		
	2012	2011	2010
Beginning balance	$ 442	$ 424	$ 370
Tax positions related to current year:			
Additions	2	34	75
Reductions			
	2	34	75
Tax positions related to prior years:			
Additions			
Reductions	(2)	(16)	(21)
Settlements			
Lapses in statutes of limitations			
Additions from current year acquisitions			
	(2)	(16)	(21)
Ending balance	$ 442	$ 442	$ 424

The Company has assessed that its liability for unrecognized income tax benefits will not significantly change within the next twelve months. If these unrecognized tax benefits are recognized, the impact on the Company s effective tax rate would be immaterial. Additionally, there was no interest or penalties accrued at December 31, 2012 and 2011, respectively, due to the Company s net operating loss position.

The Company files income tax returns in the U.S. federal and in various state and foreign jurisdictions. At December 31, 2012, all open tax years in the federal and some state jurisdictions date back to 2005 due to the taxing authorities ability to adjust operating loss carryforwards. No changes in settled tax years have occurred through December 31, 2012 and the Company does not anticipate there will be a material change in the total amount of unrecognized tax benefits within the next 12 months.

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NOTE 19 EMPLOYEE BENEFIT PLANS

The Company sponsors a defined contribution 401(k) retirement savings plan covering all of its U.S. employees, whereby an eligible employee may elect to contribute a portion of his or her salary on a pre-tax basis, subject to applicable federal limitations. Under the terms of the plan, the Company is not required to make any discretionary matching of employee contributions. For the years ended December 31, 2012, 2011 and 2010, the Company did not record any expense under the plan.

The Company s wholly-owned subsidiary, Horizon Pharma AG, sponsors a defined benefit savings plan covering all of its employees in Switzerland and a defined contribution plan for its employees in Germany. For the years ended December 31, 2012, 2011 and 2010, the Company recognized expenses of $55, $162, and $51, respectively, under these plans.

NOTE 20 RECENT ACCOUNTING PRONOUNCEMENTS

In January 2012, the Company adopted the Financial Accounting Standards Board (FASB), Accounting Standards Update 2011-05, *Presentation of Comprehensive Income* (ASU 2011-05), which eliminated a previous election to present other comprehensive income within the consolidated statements of changes in equity, and provided the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. The standard is reflected in the Company s consolidated statement of comprehensive income and was retrospectively applied to all prior periods presented.

In February 2013, the FASB issued Accounting Standards Update 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* (ASU 2013-02). ASU 2013-02 requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under GAAP to be reclassified in its entirety to net income. For other amounts that are not required under GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under GAAP that provide additional detail about those amounts. The Company adopted this standard on December 31, 2012 and it had no material impact on its consolidated financial condition, results of operations or cash flows.

NOTE 21 SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table provides a summary of selected financial results of operations by quarter for the years ended December 31, 2012 and 2011:

2012	First	Second	Third	Fourth
Net sales	$ 2,523	$ 3,841	$ 6,521	$ 6,747
Gross profit	456	986	2,711	2,816
Loss from operations	(19,788)	(18,345)	(18,714)	(22,026)
Net loss	(23,726)	(22,782)	(16,953)	(24,333)
Net loss per common share-basic and diluted	$ (0.98)	$ (0.68)	$ (0.47)	$ (0.40)

2011	First	Second	Third	Fourth
Net sales	$ 1,793	$ 1,335	$ 273	$ 3,526
Gross (loss) profit	(46)	(769)	(976)	1,451
Loss from operations	(6,990)	(8,748)	(15,655)	(89,248)
Net loss	(7,671)	(11,637)	(17,231)	(76,726)
Net loss per common share-basic and diluted	$ (5.14)	$ (7.78)	$ (1.30)	$ (3.92)

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NOTE 22 SUBSEQUENT EVENTS

On March 13, 2013, the Company received a Paragraph IV Patent Certification from Alvogen Pine Brook, Inc. (Alvogen), advising that Alvogen had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. The Company is evaluating Alvogen s Paragraph IV certification and intends to vigorously enforce our intellectual property rights relating to RAYOS.

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INDEX TO EXHIBITS

Exhibit Number	Description of Document
3.1(2)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated Bylaws.
4.1(1)	Form of Common Stock Certificate.
4.2(1)	Form of Warrant issued by Horizon Pharma, Inc. to bridge financing investors.
4.3(1)	Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Comerica Bank.
4.4(1)	Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Hercules Technology Growth Capital, Inc.
4.5(1)	Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Comerica Bank.
4.6(1)	Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Hercules Technology Growth Capital, Inc.
4.7(1)	Warrant issued by Horizon Pharma, Inc. on April 1, 2010 to Silicon Valley Bank.
4.8(1)	Investors Rights Agreement, dated April 1, 2010, by and among Horizon Pharma, Inc. and certain of its stockholders.
4.9(1)	Form of Warrant issued by Horizon Pharma, Inc. on June 2, 2011 to Oxford Finance LLC.
4.10(1)	Warrant issued by Horizon Pharma, Inc. on June 2, 2011 to Silicon Valley Bank.
4.11(1)	Conversion and Amendment Agreement, dated June 16, 2011, by and among Horizon Pharma, Inc. and certain of its stockholders.
4.12(4)	Form of Warrant issued by Horizon Pharma, Inc. pursuant to the Loan and Security Agreement, dated February 22, 2012, by and among Horizon Pharma USA, Inc., Horizon Pharma, Inc., Cortland Capital Market Services, LLC, as administrative agent, and the Lenders listed therein.
4.13(4)	Form of Warrant issued by Horizon Pharma, Inc. pursuant to the Securities Purchase Agreement, dated February 28, 2012, by and among Horizon Pharma, Inc. and the Purchasers and Warrant Holders listed therein.
4.14(4)	Amendment to Investors Rights Agreement, dated February 22, 2012.
4.15(8)	Form of Warrant issued in Public Offering of Units.
10.1(1)	Form of Indemnity Agreement.
10.2+(1)	2005 Stock Plan and Form of Stock Option Agreement thereunder.
10.3+(1)	2011 Equity Incentive Plan and Form of Option Agreement and Form of Stock Option Grant Notice thereunder.
10.4+(1)	2011 Employee Stock Purchase Plan and Form of Offering Document thereunder.
10.5*(1)	Development and License Agreement, dated August 20, 2004, by and among Horizon Pharma AG, Jagotec AG and SkyePharma AG.
10.6*(1)	Amendment to Development and License Agreement, dated August 3, 2007, by and among Horizon Pharma AG, Jagotec AG and SkyePharma AG.
10.7*(1)	Manufacturing and Supply Agreement, dated August 3, 2007, by and between Horizon Pharma AG and Jagotec AG.

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Exhibit Number	Description of Document
10.8*(1)	Technology Transfer Agreement, dated August 2, 2004, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck KgaA.
10.9*(1)	Transfer, License and Supply Agreement, dated December 21, 2006, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH (which was subsequently assigned to Mundipharma Laboratories GmbH in April 2011).
10.10*(1)	Amendment to Transfer, License and Supply Agreement, dated December 17, 2008, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH (which was subsequently assigned to Mundipharma Laboratories GmbH in April 2011).
10.11*(1)	Transfer, License and Supply Agreement, dated March 26, 2009, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck GesmbH.
10.12+(1)	Form of Employee Proprietary Information and Inventions Agreement.
10.13*(1)	Manufacturing and Supply Agreement, dated March 24, 2009, by and between Horizon Pharma AG and Mundipharma Medical Company.
10.14*(1)	Exclusive Distribution Agreement, dated March 24, 2009, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.
10.15(1)	Amendment to Exclusive Distribution Agreement, dated July 7, 2009, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.
10.16+(1)	Amended and Restated Executive Employment Agreement, dated July 27, 2010, by and between Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Timothy P. Walbert.
10.17+(1)	Amended and Restated Executive Employment Agreement, dated July 27, 2010, by and between Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Robert J. De Vaere.
10.18+(1)	Amended and Restated Executive Employment Agreement, dated July 27, 2010, by and between Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D. FACP.
10.19*(1)	Amendment to Manufacturing and Supply Agreement, dated March 4, 2011, by and between Horizon Pharma AG and Jagotec AG.
10.20*(1)	Master Services Agreement, dated September 11, 2008, by and between Horizon Pharma USA, Inc. and Pharmaceutics International, Inc.
10.21+	Non-Employee Director Compensation Policy.
10.22*(1)	Sales Contract, dated July 1, 2010, by and between Horizon Pharma USA, Inc. and BASF Corporation.
10.23*(1)	Manufacturing and Supply Agreement, dated November 4, 2010 by and between Horizon Pharma AG and Mundipharma Medical Company.
10.24*(1)	Exclusive Distribution Agreement, dated November 4, 2010 by and between Horizon Pharma AG and Mundipharma International Corporation Limited.
10.25*(1)	Letter Agreement, dated March 2, 2011, by and among Horizon Pharma AG, Horizon Pharma GmbH, Mundipharma International Corporation Limited and Mundipharma Medical Company.
10.26*(1)	Manufacturing and Supply Agreement, dated May 25, 2011, by and between Horizon Pharma USA, Inc. and sanofi-aventis U.S. LLC.
10.27*(3)	Standard Office Lease, effective August 31, 2011, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.

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Exhibit Number	Description of Document
10.28(4)	Loan and Security Agreement, dated as of February 22, 2012, by and among Horizon Pharma USA, Inc. and Horizon Pharma, Inc., Cortland Capital Market Services, LLC, as administrative agent and the Lenders listed therein.
10.29(4)	Guaranty and Security Agreement, dated as of February 22, 2012, by and among Horizon Pharma USA, Inc., Horizon Pharma, Inc. and Cortland Capital Markets Services LLC, as administrative agent.
10.30*(5)	Amendment No. 1 to Exclusive Distribution Agreement, dated March 5, 2012, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.
10.31(5)	Amendment No. 1 to Manufacturing and Supply Agreement, dated March 5, 2012, by and between Horizon Pharma AG and Mundipharma Medical Company.
10.32+(6)	Form of Restricted Stock Unit Purchase Agreement.
10.33+(6)	Amended and Restated Severance Benefit Plan Dated March 1, 2012.
10.34+(7)	Executive Employment Agreement, dated June 1, 2012, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Todd N. Smith.
10.35*(7)	Co-Promotion Agreement, dated June 14, 2012, by and between Horizon Pharma USA, Inc. and Mallinckrodt LLC.
10.36*(9)	First Amendment to Lease, dated July 31, 2012, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.
10.37(10)	Sales Agreement, dated August 14, 2012, between Horizon Pharma, Inc. and Cowen and Company, LLC.
10.38(11)	Consent and Amendment, dated September 7, 2012, by and among Horizon Pharma USA, Inc. and Horizon Pharma, Inc., Cortland Capital Market Services, LLC, as administrative agent, and the Lenders listed therein.
10.39*(11)	Second Letter Agreement, dated October 6, 2011, by and among Horizon Pharma AG, Mundipharma International Corporation Limited and Mundipharma Medical Company.
21.1	Subsidiaries of Horizon Pharma, Inc.
23.1	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document

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Exhibit Number	Description of Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.
* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.
(1) Incorporated by reference to Horizon Pharma, Inc. s Registration Statement on Form S-1 (No. 333-168504), as amended.
(2) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on August 2, 2011.
(3) Incorporated by reference to Horizon Pharma, Inc. s Quarterly Report on Form 10-Q, filed on November 14, 2011.
(4) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on March 1, 2012.
(5) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on March 8, 2012.
(6) Incorporated by reference to Horizon Pharma, Inc. s Annual Report on Form 10-K, filed on March 23, 2012.
(7) Incorporated by reference to Horizon Pharma, Inc. s Quarterly Report on Form 10-Q, filed on August 10, 2012.
(8) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on September 20, 2012.
(9) Incorporated by reference to Horizon Pharma, Inc. s Quarterly Report on Form 10-Q, filed on November 13, 2012.
(10) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on August 14, 2012.
(11) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on September 7, 2012.