

HORIZON PHARMA, INC.
Form 10-K
March 13, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2013

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)

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Delaware
(State or other jurisdiction of
incorporation or organization)
520 Lake Cook Road, Suite 520

27-2179987
(I.R.S. Employer
Identification No.)

Deerfield, Illinois
(Address of principal executive offices)

60015
(zip code)

(224) 383-3000

(Registrant's telephone number, including area code)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value \$0.0001 per share	The NASDAQ Global Market

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

None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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. x

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 \$2.46 per share closing sale price of the registrant's common stock on June 28, 2013 (the last business day of the registrant's most recently completed second quarter), was approximately \$128,221,687. 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 11,187,697 shares of the registrant's voting common stock held by such persons on June 28, 2013 are not included in this calculation.

As of March 11, 2014, the registrant had outstanding 67,733,417 shares of its common stock.

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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, 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 differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to successfully execute our sales and marketing strategy, including continuing to successfully recruit and retain sales and marketing personnel in the United States, and to successfully build the market for DUEXIS®, VIMOVO® and RAYOS® in the United States; whether we will be able to realize the expected benefits of our acquisition of the U.S. rights to VIMOVO, including whether and when the acquisition will be accretive to our net income; 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 maintain regulatory approvals for DUEXIS, VIMOVO and RAYOS, known as LODOTRA® outside the United States; our need for and ability to obtain additional financing; the accuracy of our estimates regarding expenses, future revenues and time to profitability; our ability to successfully execute our strategy to develop, acquire or in-license additional products or acquire companies; 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, VIMOVO 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, licensees and manufacturers, over which we have limited control; our ability to obtain and maintain intellectual property protection for our products; our ability to defend our intellectual property rights with respect to our products and otherwise prevent the entry of generic versions of our products; our ability to operate our business without infringing the intellectual property rights of others; the loss of key commercial or management personnel; regulatory developments in the United States and other countries; 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.

Revision of Prior Period Financial Statements

In the course of preparing our Consolidated Statements of Comprehensive Loss for this Annual Report on Form 10-K, we determined that there had been a misclassification of certain fees in our financial statements for the previously reported quarters ended March 31, 2012 and 2013, June 30, 2012 and 2013 and September 30, 2012 and 2013, as well as our annual financial statements for the year ended December 31, 2012, or, collectively, the Affected Financial Statements.

The Affected Financial Statements classified wholesaler service fees as cost of goods sold. We determined that these fees should be classified as sales discounts and allowances, which are a reduction in revenue instead of an increase in cost of goods sold and have revised all identified prior period misclassifications in the periods in which they originated. The revision had no impact on our reported gross profit, net loss or cash flows.

In evaluating whether our previously issued consolidated financial statements were materially misstated, we considered the guidance in Financial Accounting Standards Board, or FASB, Accounting Standards Codification,

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or ASC, Topic 250, *Accounting Changes and Error Corrections*, ASC Topic 250-10-S99-1, *Assessing Materiality*, and ASC Topic 250-10-S99-2, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*. We concluded that these misstatements were not material, individually or in the aggregate, to any of the prior reporting periods, and therefore, amendments of previously filed reports were not required. As such, the revisions are reflected in the financial information of the applicable prior periods and will be reflected in future filings containing such financial information.

The following table includes selected line items from our financial statements illustrating the effect of the revision:

	As Reported	Adjustment (in thousands)	As Revised
Consolidated Statements of Comprehensive Loss for the Three Months Ended			
March 31, 2012			
Sales discounts and allowances	(384)	(38)	(422)
Net Sales	2,523	(38)	2,485
Cost of goods sold	2,067	(38)	2,029
Consolidated Statements of Comprehensive Loss for the Three Months Ended			
June 30, 2012			
Sales discounts and allowances	(767)	(160)	(927)
Net Sales	3,841	(160)	3,681
Cost of goods sold	2,855	(160)	2,695
Consolidated Statements of Comprehensive Loss for the Three Months Ended			
September 30, 2012			
Sales discounts and allowances	(790)	(202)	(992)
Net Sales	6,521	(202)	6,319
Cost of goods sold	3,810	(202)	3,608
Consolidated Statements of Comprehensive Loss for the Three Months Ended			
December 31, 2012			
Sales discounts and allowances	(1,405)	(388)	(1,793)
Net Sales	6,747	(388)	6,359
Cost of goods sold	3,931	(388)	3,543
Consolidated Statements of Comprehensive Loss for the Three Months Ended			
March 31, 2013			
Sales discounts and allowances	(1,527)	(478)	(2,005)
Net Sales	9,171	(478)	8,693
Cost of goods sold	4,247	(478)	3,769
Consolidated Statements of Comprehensive Loss for the Three Months Ended			
June 30, 2013			
Sales discounts and allowances	(5,383)	(1,123)	(6,506)
Net Sales	12,254	(1,123)	11,131
Cost of goods sold	3,517	(1,123)	2,394
Consolidated Statements of Comprehensive Loss for the Six Months Ended			
June 30, 2013			
Sales discounts and allowances	(6,910)	(1,601)	(8,511)
Net Sales	21,425	(1,601)	19,824

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Cost of goods sold	7,764	(1,601)	6,163
Consolidated Statements of Comprehensive Loss for the Three Months Ended			
September 30, 2013			
Sales discounts and allowances	(5,306)	(2,106)	(7,412)
Net Sales	26,218	(2,106)	24,112
Cost of goods sold	5,313	(2,106)	3,207

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	As Reported	Adjustment (in thousands)	As Revised
Consolidated Statements of Comprehensive Loss for the Nine Months Ended			
September 30, 2013			
Sales discounts and allowances	(12,216)	(3,707)	(15,923)
Net Sales	47,643	(3,707)	43,936
Cost of goods sold	13,077	(3,707)	9,370

Item 1. Business**Overview**

We are a specialty pharmaceutical company commercializing DUEXIS, VIMOVO and RAYOS/LODOTRA, each of which targets unmet therapeutic needs in arthritis, pain and inflammatory diseases. We developed DUEXIS and RAYOS/LODOTRA, and we acquired the U.S. rights to VIMOVO from AstraZeneca AB, or AstraZeneca, in November 2013. Our strategy is to develop, acquire or in-license additional innovative medicines or acquire companies where we can execute a targeted commercial approach among specific target physicians such as primary care physicians, orthopedic surgeons and rheumatologists, 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, 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, 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 80 sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. 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 the third quarter of 2012, we expanded our sales force to approximately 150 representatives and have subsequently further expanded our sales force to approximately 290 representatives, most recently by adding approximately 115 representatives in connection with our acquisition of the U.S. rights to VIMOVO in November 2013. 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 and inflammation 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 second approved product in the United States, RAYOS, known as LODOTRA outside the United States, is a proprietary delayed-release formulation of low-dose prednisone approved originally in Europe 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 are focusing our promotion of RAYOS in the United States 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 U.S. rheumatologists and key primary care physicians. LODOTRA is currently marketed outside the United States by our distribution partner, Mundipharma International Corporation Limited, or Mundipharma. In connection with our acquisition of the U.S. rights to VIMOVO, we increased our rheumatology sales force from 25 representatives to 40 representatives in January 2014.

On November 18, 2013, we entered into agreements with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other

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pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs in the United States. VIMOVO (naproxen/esomeprazole magnesium) is a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, or PPI, layer surrounding the core. VIMOVO was originally developed by Pozen Inc., or Pozen, together with AstraZeneca pursuant to an exclusive global collaboration and license agreement under which AstraZeneca and Pozen agreed to co-develop VIMOVO and AstraZeneca obtained exclusive rights to commercialize VIMOVO worldwide. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of OA, RA and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

Under the asset purchase agreement with AstraZeneca, we acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the investigational new drug application, or IND, and new drug application, or NDA, for VIMOVO in the United States, AstraZeneca's interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. In addition, AstraZeneca assigned to us its amended and restated collaboration and license agreement for the United States with Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States.

In December 2013, as a result of the acquisition of the U.S. rights to VIMOVO, we began the expansion of our sales force to approximately 250 primary care representatives and 40 rheumatology sales specialists and also recognized revenues under our transition agreement with AstraZeneca. We announced the availability of Horizon-labeled VIMOVO on January 2, 2014. We completed the hiring and training of our expanded sales force in January 2014 and began selling VIMOVO in early February 2014. Our primary care representatives will promote DUEXIS in a primary position to physician targets who are high branded NSAID prescribers and are also prescribers of DUEXIS and ibuprofen and they will promote VIMOVO in a second position among these target physicians. Our primary care representatives will promote VIMOVO in a primary position to physician targets who are high branded NSAID prescribers and are also prescribers of VIMOVO and naproxen and they will promote DUEXIS in a second position among these target physicians. Our analysis indicates that there is an approximate 30% overlap of physician targets who prescribe both DUEXIS and VIMOVO. In those cases, individual target-by-target promotional plans will be executed and both DUEXIS and VIMOVO will be promoted to these targets. Our strategy with respect to VIMOVO is to bring its pricing in-line with DUEXIS and thereby significantly increase the value realized per prescription while lowering the monthly out-of-pocket costs to patients taking VIMOVO. We have also expanded our rheumatology specialty sales force from 25 sales specialists to approximately 40 sales specialists, with these specialist representatives promoting RAYOS and VIMOVO to rheumatologists. We have also included VIMOVO in our *Prescriptions-Made-Easy*, or PME, specialty pharmacy program, along with DUEXIS and RAYOS, and offer co-pay assistance for all of our marketed products to ensure patients receive them at a reasonable out-of-pocket cost.

PME is a novel program that we have developed to address the impact of pharmacies switching from branded products prescribed by doctors to substitute products. In the fourth quarter of 2013, approximately 27% of DUEXIS prescriptions were processed through the three partner pharmacies that are contracted to run the PME pharmacy services. The three partner pharmacies are geographically located on the east coast, in the midwest and on the west coast. Physician offices can access PME either through electronic prescribing systems or a simple fax form that is linked to one of the partner pharmacies. Then, within four hours, the partner pharmacy places a call to the patient and the prescription is shipped overnight to the patient's home. We have initiated this program for DUEXIS, VIMOVO and RAYOS. Over 85% of prescriptions submitted through the PME program are filled and sent to the patient. In comparison, approximately 62% of prescriptions written at retail pharmacies are filled and received by the patient.

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

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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, Inc., 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, LODOTRA and VIMOVO are registered trademarks in the United States and/or 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 have been put in place in creating a fully-integrated U.S.-focused specialty pharmaceutical company to successfully commercialize DUEXIS, VIMOVO and RAYOS in the U.S. market and also to expand and leverage these capabilities by developing, acquiring or in-licensing additional products or acquiring companies where we can execute a targeted commercial approach among specific target physicians such as primary care physicians, orthopedic surgeons and rheumatologists. We intend to enter into licensing or additional distribution arrangements for the commercialization of our products outside the United States, such as our relationship with Mundipharma for the commercialization of LODOTRA outside of the United States, excluding Japan and Canada, and our relationship with Grünenthal for the commercialization of DUEXIS in Latin America.

Our Strategic Relationships

We have entered into several strategic relationships 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 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 March 2013, we entered into a back-up manufacturing agreement with Bayer Pharma AG, or Bayer.

In May 2011, we entered into a manufacturing and supply agreement with sanofi-aventis U.S. to manufacture and supply DUEXIS. In addition, we have entered into an exclusive agreement with Grünenthal for the commercialization of DUEXIS in Latin America.

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In November 2013, we entered into agreements with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO in the United States. In connection with these agreements, we entered into a supply agreement with AstraZeneca pursuant to which AstraZeneca agreed to supply VIMOVO to us for commercialization in the United States through December 31, 2014. Also in November 2013, we entered into a master manufacturing services agreement and product agreement with Patheon Pharmaceuticals, Inc., or Patheon, the contract manufacturer of VIMOVO, pursuant to which Patheon will manufacture VIMOVO for us from the end of the AstraZeneca supply agreement through December 31, 2019.

Our Products

We believe that our products address unmet therapeutic needs in arthritis, pain and/or inflammatory diseases and provide significant advantages over existing therapies.

Our current product portfolio consists of the following:

Products	Disease	Phase of		Marketing Rights	Territory
		Development			
DUEXIS	Signs and symptoms of OA and RA	NDA approved		Horizon	Worldwide excluding Latin America
		April 23, 2011; UK National MA approved on March 6, 2013			
		Registration		Grünenthal	Latin America
RAYOS/LODOTRA	RA	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
	PMR and other indications	NDA approved July 26, 2012		Horizon	Worldwide, excluding Europe and certain Asian, Latin American, and other countries
VIMOVO	Signs and symptoms of OA, RA and AS	FDA approved April 30, 2010		Horizon	United States

Market Overview

Pain is a serious and costly public health concern affecting more people in the United States 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.

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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 U.S. 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 United States. 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 United States, 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 United States 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, 2.9 million people in the United States suffer from RA, of which 1.8 million are diagnosed and treated with various drugs. RA has no known cause, but unlike OA, RA is not associated with factors such as aging. RA occurs when the body's immune system malfunctions, attacking healthy tissue and causing inflammation, which leads to pain and swelling in the joints and may eventually cause permanent joint damage and painful disability. The primary symptoms of RA include progressive immobility and pain, especially in the morning, with long-term sufferers experiencing continual joint destruction for the remainder of their lives. There is no known cure for RA. Once the disease is diagnosed, treatment is prescribed for life to alleviate symptoms and/or to slow or stop disease progression.

RA treatments include medications, physical therapy, exercise, education and sometimes surgery. Early, aggressive treatment of RA can delay joint destruction. Treatment of RA usually includes multiple drug therapies taken concurrently. Disease-modifying 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

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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 control 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 United States 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 provide both effective pain relief and decrease stomach acidity, thus reducing the risk of NSAID-induced upper GI ulcers.

VIMOVO

VIMOVO is a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a PPI, layer surrounding the core. Naproxen has proven anti-inflammatory and analgesic properties and esomeprazole reduces the stomach acid secretions that can cause upper GI ulcers. Both naproxen and esomeprazole have well-documented and excellent long-term safety profiles in a significant number of patients worldwide. Based on Pozen's and AstraZeneca's clinical trial results, VIMOVO has been shown to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric 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 United States 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: Source Healthcare Analytics (formerly Wolters Kluwer Pharmaceutical) Audit Suite Total Rx's 2002-2013 (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.

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Despite the fact that GI ulcers are one of the most prevalent adverse events resulting from the use of NSAIDs in the United States, according to a 2006 article published in BMC Musculoskeletal Disorders, eleven observational studies indicated that physicians do not commonly co-prescribe GI protective agents to high-risk patients. Physicians prescribe concomitant therapy to only 24% of NSAID users, and studies show sub-optimal patient compliance with concomitant prophylaxis therapy. According to a 2003 article published in 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 or VIMOVO, creating a simple solution for both patients and physicians.

Horizon Solution

DUEXIS

Ibuprofen: One of the World's Most Widely Prescribed NSAIDs

Ibuprofen continues to be one of the most widely prescribed NSAIDs worldwide. According to Source Healthcare Analytics, or SHA, in the United States alone, there were over 37 million prescriptions written for ibuprofen in 2013. Ibuprofen prescription volumes in Europe approximately equal those in the United States. In the United States, 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;

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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

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 PPIs.

Despite these advantages, famotidine had not yet been approved to reduce the incidence of NSAID-induced upper GI ulcers in patients taking NSAIDs. As a result, we conducted two pivotal Phase 3 clinical trials demonstrating that treatment with DUEXIS significantly reduced the incidence of NSAID-induced upper GI ulcers in patients with mild to moderate pain or arthritis compared to ibuprofen alone. Based on the data from our Phase 3 clinical trials of DUEXIS, in March 2010 we submitted an NDA requesting approval to market DUEXIS in the United States. 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.

Commercial Status

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 80 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 150 representatives and under a co-promotion agreement with Mallinckrodt LLC, or Mallinckrodt, the pharmaceutical business of Covidien plc, or Covidien, Mallinckrodt began calling on 25,000 exclusive physician targets. Our sales force expansion, along with the Mallinckrodt co-promotion agreement, expanded our called-on physician targets for DUEXIS from approximately 10,000 to approximately 50,000. In June 2013, we provided written notice to Mallinckrodt of the termination of our co-promotion agreement with Mallinckrodt, effective 30 days after the date of such notice. The co-promotion agreement was terminated because Mallinckrodt did not achieve minimum levels of prescriptions from targeted physicians for two consecutive quarters during the period prior to September 30, 2013. We detail the physicians previously targeted by Mallinckrodt through the hiring of approximately 20 additional field sales representatives and reallocation of efforts of our existing sales force. As of January 2014, we had approximately 250 field sales representatives detailing DUEXIS to physicians in the United States. 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.

VIMOVO

Naproxen: One of the World's Most Widely Prescribed NSAIDs

Naproxen is one of the most widely prescribed NSAIDs worldwide. According to SHA, in the United States alone, there were over 15 million prescriptions written for naproxen in 2013. In the United States, the 375 mg

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and 500 mg doses together account for approximately 90% of total naproxen prescriptions. In addition, naproxen's twice daily dosing allows it to be used for chronic conditions such as arthritis and AS.

Esomeprazole: A Safe and Effective GI Agent

Esomeprazole, a gastroprotective agent, is a PPI that works by inhibiting the secretion of gastric acid thus decreasing the amount of acid in the stomach. PPIs are considered to be very potent inhibitors of acid secretion.

Benefits of a Fixed-Dose Combination Therapy

VIMOVO is specifically formulated to allow esomeprazole to achieve its gastroprotective impact before naproxen is released into the system. The product is a single-tablet formulation comprising an enteric coated naproxen core surrounded by an immediate release esomeprazole mantle. VIMOVO's design is intended to produce a sequential delivery of gastroprotective esomeprazole before systemic (or local) exposure to naproxen.

Commercial Status

On April 30, 2010, the FDA approved VIMOVO delayed release tablets, 375 mg/20 mg and 500 mg/20 mg for relief of signs and symptoms of OA, RA and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers. In December 2013, as a result of our acquisition of U.S. rights to VIMOVO, we began the expansion of our sales force to approximately 250 primary care representatives and 40 rheumatology sales specialists, all of which began promoting VIMOVO in early February 2014.

RAYOS/LODOTRA

RAYOS, known as LODOTRA outside the United States, 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, PMR, PsA, AS, asthma, COPD and a number of other conditions. We focus our promotion of RAYOS in the United States 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 outside the United States by our distribution partner, Mundipharma.

Market Opportunity and Limitations of Existing Treatments

According to DataMonitor, there are approximately 4.9 million RA patients in the United States, Japan, France, Italy, Spain, Germany and the UK, of which approximately 3.1 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 United States, 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 United States, Japan, France, Italy, Spain, Germany and the UK 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

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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.

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. 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. The 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.

Commercial Status

LODOTRA received its first approval in Europe in March 2009 and is currently approved for marketing in over 30 countries outside the United States where it is being commercialized by Mundipharma.

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 mg 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.

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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 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, 2013, 2012 and 2011, Merck Serono accounted for 0%, 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. As of December 31, 2013, we have received 4.9 million Euros in milestone payments under the distribution agreement.

Under the distribution agreement, we granted Mundipharma the exclusive distribution and marketing rights pertaining to LODOTRA for: Albania, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Liechtenstein, Lithuania, Luxemburg, Macedonia, Malta, Montenegro, Netherlands, Norway, Poland, Portugal,

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Romania, Serbia, former Soviet Union countries, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the UK. We also granted Mundipharma an exclusive license to use our trademark for LODOTRA in these countries, and Mundipharma is allowed to commercialize LODOTRA under the LODOTRA trademark. Mundipharma is obligated to use commercially reasonable efforts to market LODOTRA in the territory and is prohibited from launching other oral corticosteroids during the term of the distribution agreement. If Mundipharma does not meet specified minimum sales targets, which range from single digit millions of Euros to tens of millions of Euros on a country by country basis, over specified periods of time, the marketing rights granted under the distribution agreement will become nonexclusive with respect to the applicable country unless Mundipharma pays us the shortfall.

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

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

In November 2010, we entered into a second distribution agreement with Mundipharma for the commercialization of LODOTRA in several Asian countries, Australia, New Zealand and South Africa, and a second manufacturing and supply agreement with Mundipharma Medical. Under the distribution agreement, we received an upfront payment of \$3.5 million and may be entitled to additional aggregate milestone payments of up to \$4.5 million. In March 2012, we amended the distribution agreement and the manufacturing and supply agreement to include certain Latin American countries. Under the March 2012 amendment to the distribution agreement, we may receive aggregate upfront and milestone payments of up to \$2.0 million. In October 2013, we further amended the distribution agreement and the manufacturing and supply agreement to include an additional 55 countries in the Middle Eastern and African regions. As of December 31, 2013, under our distribution agreement we have received \$0.2 million in milestone payments and \$1.2 million associated with an upfront payment under the March 2012 amendment.

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, Honduras and the Middle Eastern and African regions. Mundipharma will be responsible for obtaining regulatory approvals in these countries. We also granted 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.

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

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

For the years ended December 31, 2013, 2012 and 2011, Mundipharma and Mundipharma Laboratories accounted for approximately 8%, 39% and 79%, 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.

AstraZeneca and Pozen Agreements

AstraZeneca Asset Purchase Agreement

In November 2013, we entered into an asset purchase agreement with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs in the United States. Pursuant to the transactions contemplated by the asset purchase agreement, we acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the IND and NDA for VIMOVO in the United States, AstraZeneca's interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. Under the asset purchase agreement, we are also entitled to the benefit of a covenant not to sue granted by Merck Sharp & Dohme Corp. and certain of its affiliates, or collectively Merck, to AstraZeneca, with respect to certain patents owned by AstraZeneca but exclusively licensed to Merck, that cover the manufacture and commercialization of VIMOVO in the United States. In addition, under the asset purchase agreement, AstraZeneca assigned to us its amended and restated collaboration and license agreement for the United States with Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States. The terms of the amended and restated collaboration and license agreement for the United States with Pozen, or the Pozen license agreement, are described below.

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In November 2013, in connection with the closing of the transactions contemplated by the asset purchase agreement, we also entered into a license agreement with AstraZeneca, a supply agreement with AstraZeneca's affiliate, AstraZeneca LP, and certain other agreements that are described below. We also executed a transition agreement with AstraZeneca pursuant to which AstraZeneca transitioned to us regulatory and commercial responsibility for VIMOVO in the United States. From the closing of the transaction until December 31, 2013, AstraZeneca continued to commercialize VIMOVO in the United States under AstraZeneca's existing pricing and paid to us the net profits recognized on sales of VIMOVO in the United States. Beginning January 1, 2014, we commenced commercialization of VIMOVO in the United States on our own behalf and under new pricing for VIMOVO.

In consideration for the U.S. rights to VIMOVO, we paid to AstraZeneca a one-time upfront cash payment of \$35.0 million.

Following the closing of the transactions contemplated by the asset purchase agreement, we became responsible for and will control matters relating to VIMOVO in the United States, including responsibility for commercialization of VIMOVO in the United States, responsibility for ongoing developmental and regulatory activities with respect to VIMOVO in the United States and responsibility for the current VIMOVO litigation with respect to the patents we purchased under the asset purchase agreement and the patents we licensed from Pozen under the Pozen license agreement. AstraZeneca continues to be responsible for and will retain control of VIMOVO outside the United States.

AstraZeneca License Agreement

In November 2013, in connection with the closing of the transactions contemplated by the asset purchase agreement, we entered into a license agreement with AstraZeneca, or the AstraZeneca license agreement, pursuant to which AstraZeneca granted us an exclusive license under certain intellectual property (including patents, know-how, trademarks, copyrights and domain names) of AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States. AstraZeneca also granted us a non-exclusive license under certain intellectual property of AstraZeneca and its affiliates to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States. In addition, AstraZeneca granted us a non-exclusive right of reference and use under certain regulatory documentation controlled by AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States and to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States.

Under the AstraZeneca license agreement, we granted AstraZeneca a non-exclusive sublicense under such licensed intellectual property and a non-exclusive right of reference under certain regulatory documentation controlled by us to manufacture, import, export and perform research and development activities with respect to VIMOVO in the United States but solely for purposes of commercializing VIMOVO outside the United States.

Under the AstraZeneca license agreement, we and our affiliates are subject to certain limitations and restrictions on our ability to develop, commercialize and seek regulatory approval with respect to VIMOVO or other products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs (excluding DUEXIS). These limitations and restrictions include, among other things, restrictions on indications for which we may commercialize VIMOVO or any such other products, restrictions on our ability to develop or seek regulatory approval with respect to such other products that contain esomeprazole, restrictions on our ability to develop or seek regulatory approval for VIMOVO for any indications other than the indications for which NSAIDs are indicated, and restrictions on our marketing activities with respect to VIMOVO and any such other products.

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The AstraZeneca license agreement continues in full force and effect until terminated in accordance with its terms. Under the AstraZeneca license agreement, the parties may terminate upon mutual written agreement by the parties, or either party may terminate rights granted to us with respect to licensed trademarks and licensed domain names under the AstraZeneca license agreement upon uncured material breach by the other party of certain specified provisions of the AstraZeneca license agreement.

Amended and Restated Collaboration and License Agreement with Pozen; Letter Agreement with AstraZeneca and Pozen

Under the Pozen license agreement, Pozen granted us an exclusive, royalty-bearing license under certain of Pozen's intellectual property in the United States to manufacture, develop and commercialize VIMOVO and other products controlled by us that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs, excluding DUEXIS, in the United States.

Under the Pozen license agreement, we are required to pay Pozen a flat 10% royalty based on net sales of VIMOVO and such other products sold by us, our affiliates or sublicensees during the royalty term, subject to minimum annual royalty obligations of \$5.0 million in 2014 and \$7.5 million each year thereafter, which minimum royalty obligations will continue for each year during which one of Pozen's patents covers such products in the United States and there are no competing products in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing products. Our obligation to pay royalties to Pozen will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in the United States. In addition, we will be obligated to reimburse Pozen for costs, including attorneys' fees, incurred by Pozen in connection with VIMOVO patent litigation moving forward, subject to agreed caps.

We are responsible for and will be required to use diligent and reasonable efforts to commercialize VIMOVO or another qualified product in the United States. We will also own and maintain all regulatory filings and marketing approvals in the United States for any such products, including all INDs and NDAs for VIMOVO. Pozen covenanted that it will not at any time prior to the expiration of the royalty term, and will ensure that its affiliates do not, directly or indirectly, develop or commercialize or license any third party to develop or commercialize certain competing products in the United States.

The Pozen license agreement, unless earlier terminated, will expire upon expiration of the royalty term for all such products in the United States. Either party has the right to terminate the agreement upon uncured material breach by the other party or upon the bankruptcy or similar proceeding of the other party. We also have the right to terminate the Pozen license agreement for cause upon certain defined product failures.

In November 2013, in connection with the asset purchase agreement and the Pozen license agreement, we, AstraZeneca and Pozen entered into a letter agreement in which Pozen consented to AstraZeneca's assignment of the Pozen license agreement to us and that addresses the rights and responsibilities of the parties in relation to the Pozen license agreement and the amended and restated collaboration and license agreement between Pozen and AstraZeneca for territories outside the United States, or the Pozen-AstraZeneca license agreement. Under the letter agreement, we and AstraZeneca agreed to pay Pozen milestone payments upon the achievement by us and AstraZeneca, collectively, of certain annual aggregate global net sales thresholds ranging from \$550.0 million to \$1.25 billion with respect to products licensed by Pozen to us under the Pozen license agreement and to AstraZeneca under the Pozen-AstraZeneca license agreement. The aggregate milestone payment amount that may be owed by AstraZeneca and us, collectively, under the letter agreement is \$260.0 million, with the amount payable by each of us and AstraZeneca with respect to each milestone to be based upon the proportional sales achieved by each of us and AstraZeneca, respectively, in the applicable year.

The letter agreement will terminate with respect to Pozen and us upon the termination of the Pozen license agreement and will terminate with respect to Pozen and AstraZeneca upon the termination of the Pozen-AstraZeneca license agreement.

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Supply Agreement with AstraZeneca

In November 2013, in connection with the asset purchase agreement, we entered into a supply agreement with AstraZeneca pursuant to which AstraZeneca agreed to supply VIMOVO to us for commercialization in the United States through December 31, 2014. Under the supply agreement, AstraZeneca will supply the quantity of VIMOVO that we order, both for our own use and for use by our sublicensees, on a transitional basis through December 31, 2014. We will pay a set transfer price agreed by us and AstraZeneca for quantities of VIMOVO supplied by AstraZeneca under the supply agreement.

The supply agreement will expire on December 31, 2014, unless terminated earlier as described herein. The supply agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party. Additionally, we have the right to terminate the supply agreement at any time upon 120 days prior written notice to AstraZeneca or immediately upon written notice if the existing regulatory approval of VIMOVO is suspended for any reason or if any regulatory authority provides a warning letter or other official documentation expressing major and significant concerns from a regulatory perspective with AstraZeneca's or its affiliates' or third party manufacturer's manufacturing of VIMOVO. Additionally, the supply agreement will automatically terminate upon any termination of the AstraZeneca license agreement.

Patheon Agreement

In November 2013, we entered into a master manufacturing services agreement and product agreement, or, collectively, the Patheon manufacturing agreement, with Patheon, who is AstraZeneca's contract manufacturer of VIMOVO, for the manufacture and supply of VIMOVO. Under the Patheon manufacturing agreement, we agreed to purchase a specified percentage of our VIMOVO requirements for the United States from Patheon or its affiliates. In addition, under the terms of the Patheon manufacturing agreement, we are able to enter into individual product agreements with Patheon for the manufacture of specific products in addition to VIMOVO if agreed by us and Patheon.

Pursuant to the Patheon manufacturing agreement, we are required to supply Patheon with any active materials for VIMOVO. We must pay an agreed price for final, packaged VIMOVO supplied by Patheon as set forth in the Patheon manufacturing agreement, subject to adjustments, including certain unilateral adjustments by Patheon, such as annual adjustments for inflation and adjustments to account for certain increases in the cost of components of VIMOVO other than active materials.

The Patheon manufacturing agreement will be effective until December 31, 2019 and will automatically renew for successive terms of three years each if there is any product agreement in effect, unless either party gives written notice to the other party of its intention to terminate the agreement at least 24 months prior to the end of the then current term. Either party may terminate the Patheon manufacturing agreement or any product agreement early for uncured material breach by the other party or upon the other party's bankruptcy or insolvency. We may terminate any product agreement if any regulatory authority takes any action or raises any objection that prevents us from commercializing the product. Additionally, Patheon may terminate the Patheon manufacturing agreement or any product agreement early if we assign our rights or obligations under the Patheon manufacturing agreement or such product agreement to a competitor of Patheon or to a party that, in the reasonable opinion of Patheon, is not a credit worthy substitute for us, or in certain other circumstances where we assign the Patheon manufacturing agreement or product agreement without Patheon's consent.

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.

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Under the agreement, which was amended in August 2007, we received an exclusive, sub-licensable worldwide license to the oral formulation of any corticosteroid, including prednisone, prednisolone, methylprednisolone and/or cortisone, with delayed release technology covered by intellectual property rights and know-how owned by SkyePharma. We were also granted an option to acquire a royalty-free, exclusive and sub-licensable right to license and manufacture 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, which patent rights will expire between 2024 and 2028. 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 for the purchase of 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, and 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 through April 2014, after which we will be able to purchase RAYOS/LODOTRA from other manufacturers if we choose. As of December 31, 2013 our total remaining minimum purchase commitment was approximately \$3.4 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, or API, 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 the right to manufacture, test and release quantities of RAYOS/LODOTRA in order to establish and maintain Bayer as a manufacturer of RAYOS/LODOTRA. Under certain circumstances, we may also purchase shortfall quantities of RAYOS/LODOTRA from Bayer to the extent Jagotec is unable to supply us. In March 2013, we entered into an agreement with Bayer to allow us to purchase quantities of RAYOS/LODOTRA

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for these purposes. After our manufacturing license from Jagotec becomes effective, we may also purchase quantities of RAYOS/LODOTRA from Bayer pursuant to our agreement with Bayer.

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 APIs 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.

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 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. In December 2012, Temmler was acquired by the Aenova Group.

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BASF Sales Contract

In July 2010, we entered into a sales contract with BASF Corporation, or BASF, 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.

Mallinckrodt Agreement

In June 2012, we entered into a co-promotion agreement with Mallinckrodt, pursuant to which we engaged Mallinckrodt on a non-exclusive basis to promote DUEXIS in the United States, excluding Puerto Rico and any other territories or possessions. Under the terms of the Mallinckrodt agreement, Mallinckrodt agreed to use commercially reasonable efforts to promote DUEXIS to an agreed list of physician promotion targets. Mallinckrodt was required to achieve minimum levels of prescriptions from targeted physicians on a quarterly basis during the term of the 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 were responsible for the manufacture, supply and distribution of DUEXIS. Each party could terminate the agreement early upon certain failures to achieve minimum levels of prescriptions for a specified period of time. In June 2013, we provided written notice to Mallinckrodt of the termination of the Mallinckrodt agreement, effective 30 days after the date of such notice. The Mallinckrodt agreement was terminated as a result of Mallinckrodt not achieving minimum levels of prescriptions from targeted physicians for two consecutive quarters during the period prior to September 30, 2013.

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 United States 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. In December 2013, as a result of the acquisition of U.S. rights to VIMOVO from AstraZeneca, we began the expansion of our sales force to approximately 250 primary care representatives and 40 rheumatology sales specialists. We announced the availability of Horizon-labeled VIMOVO on January 2, 2014. We completed the hiring and training of our expanded sales force in January 2014 and began selling VIMOVO in early February 2014. We have, and expect to continue to, entered into agreements with third parties for commercialization of our products outside the United States.

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 United States and foreign patent applications from SkyePharma. We also have

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licenses to United States patents and patent applications and trademarks covering VIMOVO from Pozen and AstraZeneca. 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.

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.

With respect to RAYOS/LODOTRA, there are five issued U.S. patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Three of those patents were in-licensed from SkyePharma, U.S. 8,168,218 (listed for the 5 mg dosage form only), U.S. 8,309,124, and U.S. 8,394,407, each of which expires between 2024 and 2028. In addition, we purchased from a third party two issued U.S. patents, which are listed for the 1 mg and 2 mg dosage forms and which are anticipated to expire in 2020 (U.S. 6,488,960 and U.S. 6,667,326).

Prosecution is ongoing for our own pending patent applications in the United States and those in-licensed from SkyePharma to obtain broader patent coverage on RAYOS. We have filed our own patent applications related to delayed release corticosteroid treatment of RA and delayed release treatment of asthma. 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 pending patent applications pending from SkyePharma for its proprietary drug delivery technology, GeoClock, which cover tablet geometry and design.

On March 13, 2013, we received purported Notice Letters that a Paragraph IV Patent Certification had been filed by Alvogen Pine Brook, Inc., or Alvogen, advising that Alvogen had filed an Abbreviated New Drug Application, or ANDA, with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. In the Notice Letters, Alvogen noted that as of March 13, 2013, the FDA had not accepted the ANDA for review. Alvogen has agreed that their Notice Letters do not constitute Notice as described in 21 U.S.C. 355(j)(2)(B).

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc., Florida, or Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA's review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc., or collectively WLF. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

On or about August 12, 2013, we received a Notice of Opposition to a European patent covering LODOTRA, EP 2049123, filed by Laboratorios Liconsa, S.A. In the European Union, the grant of a patent may be opposed by one or more private parties.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Par Pharmaceutical, Inc. has not advised us as to the timing or status of the

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FDA's review of its filing. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., or collectively Par. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

With regard to DUEXIS, there are six issued U.S. patents listed in the FDA's Orange Book, U.S. 8,067,451, U.S. 8,067,033, U.S. 8,309,127, U.S. 8,318,202, U.S. 8,449,910, and U.S. 8,501,228, all of which expire on July 18, 2026. 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.

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 United States, 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.

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par 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.

On August 21, 2013, we entered into a settlement agreement, or Par settlement agreement, and license agreement, or Par license agreement, with Par relating to our patent infringement litigation. Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par's generic version of DUEXIS in the United States after the generic entry date and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par's generic version of DUEXIS prior to the generic entry date. The generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. If any of the events that permit Par to enter the market with its generic version of DUEXIS prior to January 1, 2023 were to occur, we will likely face generic competition from Par shortly after the event, and our sales of DUEXIS would be substantially harmed. Also, despite our Par settlement agreement and Par license agreement, additional third parties may file ANDAs with the FDA for their own generic versions of DUEXIS and we may not be successful in preventing any other generic products from entering the market.

On November 18, 2013 we entered into an asset purchase agreement with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs in the United States.

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With respect to VIMOVO, there are eight issued VIMOVO U.S. patents listed in the FDA's Orange Book: U.S. 5,714,504, U.S. 5,900,424, U.S. 6,369,085, U.S. 6,875,872, U.S. 6,926,907, U.S. 7,411,070, U.S. 7,745,466, and U.S. 8,557,285. These patents expire between May 2014 and February 2023. There are also five issued U.S. patents, although not allowed to be listed in the Orange Book, that are directed to manufacturing processes of VIMOVO. Furthermore, there are currently three pending U.S. applications directed to further patent coverage of VIMOVO.

In connection with our acquisition of the U.S. rights to VIMOVO, we received the benefit of a covenant not to sue under AstraZeneca's patent portfolio with respect to Nexium (esomeprazole), which will automatically become a license under such patent portfolio if and when AstraZeneca reacquires control of such patent portfolio from Merck Sharp & Dohme Corp. and certain of its affiliates. AstraZeneca also assigned the Pozen license agreement to us, under which AstraZeneca had in-licensed exclusive rights under certain of Pozen's patents with respect to VIMOVO, and assigned to us AstraZeneca's ownership interest in certain U.S. patents covering VIMOVO that are jointly owned with Pozen.

Currently, patent litigation is pending against five generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the District of New Jersey and are grouped in three sets: (i) Dr. Reddy's Laboratories, Inc., or Dr. Reddy's; Lupin Pharmaceuticals Inc., or Lupin; Anchen Pharmaceuticals Inc., or Anchen, or collectively, the DRL cases; (ii) Mylan Laboratories Limited, or collectively, the Mylan cases; and (iii) Watson Pharma, Inc., or collectively, the Watson cases. We understand that Dr. Reddy's has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy's will not be able to commercialize VIMOVO under AstraZeneca's Nexium patent rights until May 28, 2014. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The DRL cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy's notice letters were dated March 11, 2011 and November 12, 2012; the Lupin notice letter was dated June 10, 2011; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order. The DRL cases do not have a trial date set. We understand Anchen has recertified under Paragraph III and has filed a motion to dismiss on that basis.

The Watson cases were filed on May 10, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a March 29, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date for the Watson cases.

The Mylan cases were filed on June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a May 16, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date for the Mylan cases.

In the United States, in addition to any patent protection, DUEXIS, VIMOVO and RAYOS have been granted three years of marketing exclusivity as a Section 505(b)(2) NDA. This marketing exclusivity period for each product began upon marketing approval of such product and runs in parallel with any patents that have issued or we expect to be issued protecting such product. 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, on a country by country basis.

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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 United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States 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;

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 be successful in any patent litigation to enforce our patent rights, including our pending patent litigation regarding VIMOVO;

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 commercial success of DUEXIS, VIMOVO and RAYOS/LODOTRA, as well as future drug candidates that we may develop, are efficacy, safety and tolerability profile, convenience in dosing, price and reimbursement.

DUEXIS and VIMOVO

DUEXIS and VIMOVO compete with other branded NSAIDs, including Celebrex, marketed by Pfizer Inc. 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.

In general, DUEXIS and VIMOVO 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 and VIMOVO. 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' and VIMOVO's 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 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 and that VIMOVO

will be the only product containing a PPI with an indication to reduce the risk of NSAID-induced ulcers.

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RAYOS/LODOTRA

RAYOS/LODOTRA competes in Europe and in the United States 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 United States. We have contracted with internationally recognized pharmaceutical companies with operations in North America and Europe for contract manufacturing and packaging. In May 2011, we entered into a long-term supply and manufacturing agreement with sanofi-aventis U.S. for the manufacture of DUEXIS. In November 2011, the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. In December 2011, Valeant acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. All of the facilities contracted by us are registered with the FDA, 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 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.

VIMOVO

In November 2013, in connection with our asset purchase agreement with AstraZeneca for VIMOVO, we entered into a transitional supply agreement with AstraZeneca pursuant to which AstraZeneca will supply VIMOVO to us for commercialization in the United States through December 31, 2014. AstraZeneca relies on well-established third party manufacturers for the manufacture of VIMOVO, with the exception of final packaging which AstraZeneca does internally. We are transitioning the supply chain to these third parties (including the packaging) during the transition period.

As part of this transition, in November 2013, we entered into the Patheon manufacturing agreement with Patheon, who is AstraZeneca's contract bulk supply manufacturer of VIMOVO, pursuant to which Patheon will manufacture and package VIMOVO for us from the end of the AstraZeneca supply agreement through December 31, 2019.

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The APIs in VIMOVO are manufactured by Patheon into finished tablets for AstraZeneca and will be manufactured into finished packaged products for us after the transition from AstraZeneca. The first API in VIMOVO is naproxen, which is supplied to AstraZeneca by Divis Laboratories Limited in India. The second API in VIMOVO is esomeprazole magnesium trihydrate and is supplied to AstraZeneca by Minakem Holding SAS in France. We plan to continue to purchase APIs from these companies after the transition from AstraZeneca and we are currently negotiating long-term supply agreements with them, although we cannot guarantee that we will reach definitive agreements on acceptable terms.

RAYOS/LODOTRA

We rely on well-established third-party manufacturers for the manufacture of RAYOS/LODOTRA. In Europe, we retain quality responsibility 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 Chimie 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, and 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 through April 2014, 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 RAYOS/LODOTRA in order to establish and maintain Bayer as a manufacturer of RAYOS/LODOTRA. Under certain circumstances, we may also purchase shortfall quantities of RAYOS/LODOTRA from Bayer to the extent Jagotec is unable to supply us. In March 2013, we entered into an agreement with Bayer to allow us to purchase quantities of RAYOS/LODOTRA for these purposes. After our manufacturing license from Jagotec becomes effective, we may also purchase quantities of RAYOS/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. Temmler was acquired by the Aenova Group in December 2012. Catalent Pharma Solutions, or Catalent, in Schorndorf, Germany is registered as a second site for Europe supplies. A CBE 30 has been submitted to the FDA notifying the FDA of our intent to include Catalent as the second packaging site for RAYOS in the United States.

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 United States, including the FDA.

Distribution

Finished tablets for DUEXIS, VIMOVO 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 United States and Europe.

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Third-Party Coverage and Reimbursement

In both U.S. and foreign markets, our ability to commercialize our products successfully depends in significant part on the availability of coverage and adequate reimbursement to healthcare providers from third-party payers, including, in the United States, 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. Even if coverage is made available by a third-party payer, the reimbursement rates paid for covered products might not be adequate. For example, third-party payers may use tiered coverage and may adversely affect demand for our products by not covering our products or by placing them in a more expensive formulary tier relative to competitive products (where patients have to pay relatively more out of pocket than for products in a lower tier). We cannot be certain that our products will be covered by third-party payers or that such coverage, where available, will be adequate, or 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. The industry competition to be included on such formularies and preferred drug lists often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other therapeutic alternative is available. In addition, because each third-party payer individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payer separately with no assurance that approval would be obtained, and 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 competitive products, and third-party payers may not provide coverage and adequate reimbursement for our products or our product candidates. These pricing and reimbursement pressures may create negative perceptions to any product price increases, or limit the amount we may be able to increase our product prices, which may adversely affect our product sales and results of operations. Where coverage and reimbursement are not adequate, physicians may limit how much or under what circumstances they will prescribe or administer such products, and patients may decline to purchase them. This, in turn, could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

The U.S. market has seen a trend in which retail pharmacies have become increasingly involved in determining which prescriptions will be filled with the requested product or a substitute product, based on a number of factors, including potentially perceived product costs and benefits, as well as payer substitution policies. 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 may need to increasingly spend time and resources to ensure the prescriptions written for our products are filled as written, where appropriate.

Coverage policies, third-party reimbursement rates and product pricing regulation may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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

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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 United States, 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 United States generally involves the following:

submission to the FDA of an 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 United States.

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:

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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.

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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 postmarketing 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 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, VIMOVO and RAYOS NDAs were submitted under Section 505(b)(2) of the FDCA. 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, VIMOVO 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

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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, payment of product and manufacturing establishment fees 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 products 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.

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, VIMOVO and RAYOS 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.

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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 an 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 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.

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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, 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 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 may have been violated, and enforcement will depend on the relevant facts and circumstances. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute to state that a person or entity needs not 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. In addition, where such activities involve foreign government officials, they may also potentially be subject to the Foreign Corrupt Practices Act. 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 prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes any

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request or demand for money or property presented to the U.S. government. In addition, the PPACA specified 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. The federal False Claims Act has been the basis for numerous enforcement actions and settlements by pharmaceutical and other healthcare companies in connection with various alleged financial relationships with customers. In addition, a number of pharmaceutical manufacturers have reached substantial financial settlements in connection with allegedly causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. 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 similar fraud and abuse statutes or regulations, including, without limitation, false claims laws analogous to the False Claims Act, and laws analogous to the federal Anti-Kickback Statute, that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

Separately, there are a number of other fraud and abuse laws that pharmaceutical manufacturers must be mindful of, particularly after a product candidate has been approved for marketing in the United States. For example, a federal criminal law enacted as part of, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, 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, as amended by the Health Information Technology and Clinical Health Act and their respective implementing regulations, which established uniform standards for certain covered entities (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. Among other things, HIPAA's privacy and security standards are directly applicable to business associates, independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. In addition to possible civil and criminal penalties for violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Sunshine and Marketing Disclosure Laws. There are an increasing number of state sunshine laws that require pharmaceutical manufacturers to make reports to states on pricing and marketing information. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, and make periodic public disclosures on sales and marketing activities, and prohibiting certain other sales and marketing practices. In addition, a similar recently implemented federal requirement requires manufacturers, including pharmaceutical manufacturers, to track and report to the federal government certain payments and other transfers of value made to physicians and other healthcare professionals and teaching hospitals and ownership or investment interests held by physicians and their immediate family members. The federal government will disclose the reported information on a publicly available website beginning in 2014. These laws may adversely affect our sales, marketing, and other activities with respect to our products in the United States by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

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Government Price Reporting. For those marketed products which are covered in the United States by the Medicaid programs, we have various obligations, including government price reporting and rebate requirements, which generally require products be offered at substantial rebates/discounts to Medicaid and certain purchasers (including covered entities purchasing under the 340B Drug Discount Program). We are also required to discount such products to authorized users of the Federal Supply Schedule of the General Services Administration, under which additional laws and requirements apply. These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial penalties.

In General. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities, in the U.S., could be subject to challenge under one or more of such laws. 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, sunshine, government price reporting, and fraud laws may prove costly.

Impact of Healthcare Reform on Coverage, Reimbursement, and Pricing. In the United States and other potentially significant markets for our products, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country-specific 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 future 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.

The United States and some foreign jurisdictions are considering or have enacted a number of additional 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 United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, the PPACA. The PPACA, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial new provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, and impose additional health policy reforms, any or all of which may affect our business. A significant number of provisions are not yet, or have only recently become, effective, but the PPACA is likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Other legislative changes have also been proposed and adopted since the PPACA was

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enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws may result in additional reductions in Medicare and other healthcare funding. In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Employees

As of December 31, 2013, we had 304 full-time employees. Of our employees as of December 31, 2013, 28 were engaged in development, regulatory and manufacturing activities, 244 were engaged in sales and marketing and 32 were engaged in administration, including business development, finance, information systems, facilities and human resources. None of our employees is 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.

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, VIMOVO and RAYOS/LODOTRA, and other product candidates that we may develop, acquire, or in-license, 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 began commercial sales of RAYOS, which was approved by the U.S. Food and Drug Administration, or 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 key primary care physicians in late January 2013. Outside the United States, LODOTRA has been sold in a limited number of countries and sales may not grow to expected levels, in part because we depend on our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for commercialization outside the United States. 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

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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 non-steroidal anti-inflammatory drugs, or NSAIDs, in Europe. There have been no sales of DUEXIS in the UK thus far. VIMOVO was launched in the U.S. market in the fourth quarter of 2010 by AstraZeneca AB, or AstraZeneca, under its license from Pozen Inc., or Pozen. Following our acquisition of the U.S. rights to VIMOVO in November 2013, we began selling VIMOVO in the first quarter of 2014 and have completed the expansion of our sales force to approximately 250 primary care representatives and approximately 40 rheumatology sales specialists. 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 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;

impact of past and future product price increases;

our ability to maintain a continuous supply of product for commercial sale;

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 FDA or other regulatory authorities.

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With respect to DUEXIS and VIMOVO, studies indicate that physicians do not commonly co-prescribe gastrointestinal, or 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 and VIMOVO will be limited. Some physicians may also be reluctant to prescribe DUEXIS or VIMOVO due to the inability to vary the dose of ibuprofen and naproxen, respectively, or if they believe treatment with NSAIDs or GI protective agents other than those contained in DUEXIS and VIMOVO, including those of our competitors, would be more effective for their patients. With respect to each of DUEXIS, VIMOVO and RAYOS/LODOTRA, their higher cost compared to the generic or branded forms of their active ingredients alone may limit adoption by physicians, patients and healthcare payers. If DUEXIS, VIMOVO, RAYOS/LODOTRA or any other product that we may seek approval for, acquire or in-license fail to attain market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

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Our current business plan is highly dependent upon our ability to successfully execute on our sales and marketing strategy for the commercialization of DUEXIS, VIMOVO 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 commercialization of DUEXIS, VIMOVO and RAYOS in the U.S. market. We may not be able to successfully commercialize DUEXIS, VIMOVO or RAYOS in the United States. Prior to our commercial launch of DUEXIS in the United States 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 have expanded our sales force to approximately 290 sales representatives in connection with our November 2013 acquisition of the U.S. rights to VIMOVO, 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 or in-license will be expensive and time-consuming and could delay any product launch or our success in assuming commercialization for VIMOVO in the United States. 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 have faced similar challenges for RAYOS with respect to generic brands and expect to face similar challenges with respect to VIMOVO. 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, VIMOVO 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, 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.

Our future prospects are highly dependent on the success of DUEXIS, VIMOVO and RAYOS/LODOTRA, and we may not be able to successfully commercialize these products. Failure to do so would adversely impact our financial condition and prospects.

A substantial majority of our resources are focused on the commercialization of DUEXIS and RAYOS in the United States and we expect to devote significant additional resources to the commercialization of VIMOVO in the United States. 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, VIMOVO and RAYOS in the United States. DUEXIS has been approved for marketing in 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 United States. 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. Following our acquisition of the U.S. rights to VIMOVO in November 2013, we

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began selling VIMOVO in the first quarter of 2014. Our strategy with respect to VIMOVO included bringing its pricing in-line with DUEXIS and thereby significantly increasing the value realized per prescription. While we have recently employed a similar strategy for DUEXIS, we cannot guarantee a similar result for VIMOVO, including due to the past declines in VIMOVO prescriptions and our need to re-negotiate managed care contracts for VIMOVO. 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 key primary care physicians occurred in late January 2013. Although LODOTRA is approved for marketing in more than 30 countries outside the United States, to date it has only been marketed in a limited number of countries. While we anticipate that LODOTRA will be marketed in additional countries as our distribution partner, Mundipharma, formulates its reimbursement strategy, the ability to market LODOTRA in additional 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 United States 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, VIMOVO 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.

We are solely dependent on Mundipharma to commercialize LODOTRA in Europe and certain Asian, Latin American, Middle Eastern, African 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, Middle Eastern, African 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, Middle Eastern, African 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 are subject to extensive regulation, and we may not obtain additional regulatory approvals for our products.

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 United States, 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 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 countries as Mundipharma formulates its reimbursement strategy, the ability to market LODOTRA in additional 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 United States will depend on obtaining regulatory and reimbursement approval in any country where DUEXIS may be marketed. However, certain countries have a very difficult reimbursement environment and we may not obtain reimbursement approval in all countries where DUEXIS may 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.

Following our acquisition of the U.S. rights to VIMOVO in November 2013, we have three products approved in the United States, 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 been approved in the United States and over 30 other countries, including Australia, Korea, Israel and select countries within Europe. However, we have a limited history of marketing LODOTRA through our distribution partners, and LODOTRA is not yet marketed in all of the countries where it has been approved. DUEXIS was approved in the United States 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 began the commercial sale of RAYOS in the United States in the fourth quarter of 2012 and the commercial sale of VIMOVO in the United States in the first quarter of 2014. 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 and our lack of any history commercializing VIMOVO makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. For example, we may underestimate the resources we will require to successfully commercialize VIMOVO or not realize the benefits we expect to derive from the acquisition.

We only have U.S. rights to VIMOVO and have no control over the activities of AstraZeneca to commercialize VIMOVO outside of the United States, which could adversely impact commercialization of VIMOVO in the United States.

AstraZeneca has retained its existing rights to VIMOVO in territories outside of the United States, including the right to use the VIMOVO name and related trademark. We have little or no control over AstraZeneca's activities with respect to VIMOVO outside of the United States, even though those activities could impact our ability to successfully commercialize VIMOVO in the United States. For example, AstraZeneca or its assignees can make statements or use promotional materials with respect to VIMOVO outside of the United States that are inconsistent with our positioning of the product in the United States, and can sell VIMOVO in foreign countries, including Canada, at prices that are dramatically lower than the prices we expect to charge in the United States. These activities and decisions, while occurring outside of the United States, could harm our commercialization strategy in the United States, in particular because AstraZeneca is continuing to market the product outside the United States under the same VIMOVO brand name that we are using in the United States. In addition, product recalls or safety issues with VIMOVO outside the United States, even if not related to the commercial product we sell in the United States, could result in serious damage to the brand in the United States and impair our ability to successfully market VIMOVO. We also rely on AstraZeneca to provide us with timely and accurate safety information regarding the use of VIMOVO outside of the United States, as we have limited access to this information ourselves.

We rely on third parties to manufacture commercial supplies of DUEXIS, VIMOVO 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

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Valeant, its manufacturing partner located in Laval, Canada for production of DUEXIS, and Jagotec AG, or Jagotec, a wholly-owned subsidiary of SkyePharma PLC, located in Lyon, France, for production of RAYOS/LODOTRA. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to Aenova France SAS, or Aenova. As such, Aenova is now a subcontractor for Jagotec for the manufacture of RAYOS/LODOTRA, with our consent. Sanofi Winthrop Industrie in France has been qualified as a backup manufacturer for DUEXIS. Bayer 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 in India, and the primary active ingredient for RAYOS/LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and Sanofi Chimie in France. With respect to VIMOVO, we rely on AstraZeneca, including through its existing third party manufacturing arrangements, to supply finished VIMOVO product through 2014. After 2014, AstraZeneca will no longer be obligated to supply VIMOVO to us and we will need to rely on our own third-party manufacturing arrangements to ensure continued supply. In connection with our acquisition of the U.S. rights to VIMOVO, we have entered into a long-term master manufacturing services and product agreement with Patheon Pharmaceuticals Inc., or Patheon, for the supply of finished VIMOVO product. We are also in the process of negotiating long-term supply agreements with Divis Laboratories Limited and Minakem Holding SAS for the supply of the active pharmaceutical ingredients, or APIs, of VIMOVO, but cannot guarantee that we will be able to reach definitive agreements on acceptable terms. In addition, we are required to obtain AstraZeneca's consent prior to engaging any third-party manufacturers for esomeprazole, one of the APIs in VIMOVO, other than the third-party manufacturer(s) currently used by AstraZeneca or its affiliates or licensees. To the extent such manufacturers are unwilling or unable to manufacture esomeprazole for us on commercially-acceptable terms, we cannot guarantee that AstraZeneca would consent to our use of alternate sources of supply. 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 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. To the extent any third-party manufacturers that we engage with respect to VIMOVO are different than those used by AstraZeneca, the FDA will need to approve the facilities of those third-party manufacturers used in the manufacture of VIMOVO prior to our sale of any VIMOVO product using these facilities. If we cannot agree to terms with third-party manufacturers of VIMOVO APIs or the third party suppliers we engage do not have their facilities approved by the FDA with sufficient time to transition commercial supply of VIMOVO after 2014, we may experience supply shortages and our commercialization of VIMOVO would be substantially harmed.

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 master manufacturing services and product agreement with Patheon for finished VIMOVO product, either we or Patheon may terminate the agreement for uncured material breach by the other party or upon the other party's bankruptcy or insolvency, we may terminate the agreement if any regulatory authority takes any action or raises any objection that prevents us from commercializing the VIMOVO product and Patheon may terminate the agreement if we assign our rights or obligations under the agreement to a competitor of Patheon or to a party that, in the reasonable opinion of Patheon, is not a credit worthy substitute for us, or in certain other circumstances where we assign the agreement without Patheon's consent. Under our manufacturing and supply agreement with

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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 Pharma AG, in such an event and we would have to qualify a new back-up manufacturer.

In addition, we do not have the capability to package DUEXIS, VIMOVO, RAYOS/LODOTRA or any other product candidates for distribution. Consequently, we have entered into an agreement with Temmler Werke GmbH, or Temmler, for packaging of RAYOS/LODOTRA in certain European countries, Israel and in the United States, 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 or an alternate packager. At the end of 2012, Temmler was acquired by the Aenova Group. Valeant manufactures and supplies DUEXIS to us in final, packaged form for the United States as well as any additional countries as may be agreed to by the parties. During 2014, AstraZeneca is obligated to supply us VIMOVO in final, packaged form under a transition agreement and will work with us to transfer product packaging to Patheon. After 2014, we expect that Patheon will supply final, packaged VIMOVO product pursuant to the master manufacturing services and product agreement we executed in connection with our acquisition of the U.S. rights to VIMOVO.

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 our products in the United States 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 our products 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.

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 have expanded the size of our organization substantially in connection with our acquisition of the U.S. rights to VIMOVO in November 2013, 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, 2012 and December 31, 2013, we employed 247 and 304 full-time employees, respectively, as a consolidated entity. In connection with our acquisition of the U.S. rights to VIMOVO, we hired approximately 115 additional employees as part of our commercial organization, and as of February 28, 2014, we employed 401 employees. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire in connection with the commercialization of our products, requiring us to hire and train new sales representatives. Our management,

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personnel, systems and facilities currently in place may not be adequate to support this recent and anticipated 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 further expand these capabilities, along with our field sales force size and capabilities, if we develop, acquire or in-license 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 our existing products;

enhance our operational, financial and management controls, reporting systems and procedures;

expand our international resources;

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

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

expand our facilities and equipment; and

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

Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities and towards managing these growth activities. Our future financial performance and our ability to 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 our products in the United States will be harmed.

As DUEXIS and RAYOS were not fully commercially launched in the United States until January 2012 and January 2013, respectively, and we did not begin commercializing VIMOVO in the United States until the first quarter of 2014, the members of our sales force have limited experience promoting any of our products. 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 our products. In addition, we must train our sales force to ensure that a consistent and appropriate message about our products is being delivered to our potential customers. Our sales representatives may also experience challenges promoting multiple products when they call on physicians and their office staff, and our representatives may also be distracted from selling DUEXIS and RAYOS now that we are commercializing VIMOVO as all of our representatives have to date been focused solely on selling DUEXIS and RAYOS. This is particularly true with respect to DUEXIS, since VIMOVO is approved for similar indications and prescribed to similar patients, and our sales representatives have previously been incentivized to increase DUEXIS market share at the expense of VIMOVO. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire, 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 our products and their proper administration and label indication, our efforts to successfully

commercialize our products could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.

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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 United States 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 our products.

DUEXIS and VIMOVO face competition from Celebrex[®], marketed by Pfizer, and several other branded NSAIDs. DUEXIS and VIMOVO also face 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 or VIMOVO. 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 or VIMOVO, 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 or generic naproxen and branded Nexium (esomeprazole) as a substitute for VIMOVO, sales of DUEXIS and VIMOVO may suffer despite any success we may have in promoting DUEXIS or VIMOVO to physicians. In addition, other product candidates that contain ibuprofen and famotidine in combination or naproxen and esomeprazole in combination, while not currently known to us, may be developed and compete with DUEXIS or VIMOVO, respectively, in the future.

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. 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. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., or collectively Par, for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par's ANDA and/or prevent 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 prevent Par from selling a generic version of DUEXIS.

On August 21, 2013, we entered into a settlement agreement, or Par settlement agreement, and license agreement, or Par license agreement, with Par relating to our patent infringement litigation. Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par's generic version of DUEXIS in the United States after the generic entry date and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par's generic version of DUEXIS prior to the generic entry date. The generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. If any of the events that permit Par to enter the market with its generic version of DUEXIS prior to January 1, 2023 were to occur, we

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will likely face generic competition from Par shortly after the event, and our sales of DUEXIS would be substantially harmed. Also, despite our Par settlement agreement and Par license agreement with Par, additional third parties may file ANDAs with the FDA for their own generic versions of DUEXIS and we may not be successful in preventing any other generic products from entering the market.

Currently, patent litigation is pending against five generic companies intending to market VIMOVO before the expiration of patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. These cases are in the District of New Jersey and are grouped in three sets: (i) Dr. Reddy's Laboratories, Inc., or Dr. Reddy's; Lupin Pharmaceuticals Inc., or Lupin; Anchen Pharmaceuticals Inc., or Anchen, or collectively, the DRL cases; (ii) Mylan Laboratories Limited or collectively, the Mylan cases; and (iii) Watson Pharma, Inc., or collectively, the Watson cases. We understand that Dr. Reddy's has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy's will not be able to commercialize VIMOVO under AstraZeneca's Nexium patent rights until May 28, 2014. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The DRL cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy's notice letters were dated March 11, 2011 and November 12, 2012; the Lupin notice letter was dated June 10, 2011; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order. The DRL cases do not have pretrial deadlines or a trial date set. We understand Anchen has recertified under Paragraph III and has filed a motion to dismiss on that basis.

The Watson cases were filed on May 10, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a March 29, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Watson cases.

The Mylan cases were filed on June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a May 16, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Mylan cases.

RAYOS/LODOTRA competes with a number of pharmaceuticals on the market to treat rheumatoid arthritis, or RA, including corticosteroids, 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 API in RAYOS/LODOTRA, or other oral corticosteroids, which, while they may be suboptimal, are less expensive than RAYOS/LODOTRA. In addition, other product candidates that contain prednisone or other oral corticosteroids 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 purported Notice Letters that a Paragraph IV Patent Certification had been filed by 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. In the Notice Letters, Alvogen noted that as of March 13, 2013, the FDA had not accepted the ANDA for review. Alvogen has agreed that their Notice Letters do not constitute Notice as described in 21 U.S.C. 355(j)(2)(B).

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On July 15, 2013, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc., Florida, or Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA's review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc., or collectively WLF. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

On or about August 12, 2013, we received a Notice of Opposition to a European patent covering LODOTRA, EP 2049123, filed by Laboratorios Licons, S.A. In the European Union, the grant of a patent may be opposed by one or more private parties.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Par Pharmaceutical, Inc. has not advised us as to the timing or status of the FDA's review of its filing. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par. The lawsuit alleges that Par has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

If we are unsuccessful in any of the on-going patent litigations, we will likely face generic competition with respect to VIMOVO and/or RAYOS and our sales of VIMOVO and/or 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 our products. We will not successfully execute on our business objectives if the market acceptance of our products is inhibited by price competition, if physicians are reluctant to switch from existing products to our products, or if physicians switch to other new products or choose to reserve our products 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 or in-license 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

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competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, obtaining FDA approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business. The inability to compete with existing products or subsequently introduced products would have a material adverse impact on our business, financial condition and prospects.

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

In addition to our U.S. operations, we have operations in Switzerland and Germany. Moreover, LODOTRA is currently being marketed in a limited number of countries outside the United States, 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, Latin American, Middle Eastern and African 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, Latin American, Middle Eastern and African 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;

United States and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;

anti-corruption laws, including the Foreign Corrupt Practices Act;

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;

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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 United States;

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 United States.

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

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

A key element of our strategy is to develop, acquire or in-license and commercialize a portfolio of other product candidates in addition to DUEXIS and RAYOS/LODOTRA, such as our November 2013 acquisition of the U.S. rights to VIMOVO. Because we do not have proprietary drug discovery technology, the success of this strategy depends in large part upon the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license clinically enabled product candidates for the treatment of pain-related diseases, or 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 promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects will be limited.

Moreover, any product candidate we identify, select and acquire or license may require additional, time-consuming development or regulatory 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 our products, 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.

Our November 2013 acquisition of the U.S. rights to VIMOVO and any other strategic transactions that we may pursue in the future could have a variety of negative consequences, and we may not realize the benefits of such transactions or attempts to engage in such transactions.

We acquired the U.S. rights to VIMOVO in November 2013 and from time to time, we may seek to engage in additional strategic transactions with third parties, such as acquisitions of companies or divisions of companies, asset purchases or in-licensing of product candidates or technologies that we believe will complement or augment our existing business. We may also consider a variety of other business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business 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, create additional tax, legal, accounting and operational complexities in our business, require additional expertise, result in dilution to our existing stockholders and disrupt our management and business, which could harm our operations and financial results. For example, in connection with our acquisition of the U.S. rights to VIMOVO, we assumed primary responsibility for the existing patent infringement litigation with respect to VIMOVO, and have also agreed to reimburse certain legal expenses of Pozen with respect to its continued involvement in such litigation, and we expect that this will result in substantial on-going expenses and potential distractions to our management team. Because VIMOVO is approved for similar indications and prescribed to similar patients compared to DUEXIS, we may also experience lower prescriptions of DUEXIS as we seek to commercialize VIMOVO, particularly from the approximately 30% of physicians that currently prescribe both products. Moreover, we face significant competition in seeking appropriate strategic partners and transactions, and the

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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. We may not be able to expand our business or realize our strategic goals if we do not have sufficient funding or cannot borrow or raise additional capital. There is no assurance that following our acquisition of the U.S. rights to VIMOVO or any other strategic transaction, we will achieve the anticipated revenues or net income that we believe to justify 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.

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, Manufacturing and Regulatory Affairs 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 United States 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,

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those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others.

We are, with respect to DUEXIS, VIMOVO 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 regulations, and good laboratory practices, or GLPs, 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 formulation for DUEXIS and conduct two clinical studies of the drug product for pediatric populations. In addition, in connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we assumed responsibility for completing an ongoing Pediatric Research Equity Act post-marketing requirement study in children 12 years to 16 years and 11 months of age with Juvenile RA for which the FDA recently granted an extension with a final report due date of December 2015. 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.

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Coverage and reimbursement may not be available, or reimbursement may be available at only limited levels, for our products, 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 our products will depend in large part on global coverage and reimbursement policies and may be affected by future healthcare reform measures, both in the United States 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 United States, 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 United States, the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States 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.

Outside of the United States, the success of our products, including LODOTRA and, if widely approved, DUEXIS, will depend largely on obtaining and maintaining government coverage, because in many countries patients are unlikely to use prescription drugs that are not covered by their government healthcare programs. To date, LODOTRA is approved in over 30 countries outside the United States, and reimbursement for LODOTRA has been obtained in Germany, Italy, Sweden and Switzerland. Mundipharma is seeking coverage for LODOTRA in a number of countries and currently sells LODOTRA without coverage in a limited number of 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 or 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 our products.

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We expect to experience pricing pressures in connection with the sale of our products, 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, VIMOVO and RAYOS/LODOTRA or any other product candidates that we may develop, acquire or in-license. 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 to federal, state and foreign healthcare laws and regulations and implementation or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

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

If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to civil and/or criminal penalties, damages, fines, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. An expansion in the government's role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using our products, reduce product utilization and adversely affect our business and results of operations. It is unclear whether and to what extent, if at all, other anticipated developments resulting from the federal healthcare reform legislation, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us additional revenue to offset the annual excise tax (on certain drug product sales) enacted under the PPACA, subject to limited exceptions. It is possible that the tax burden, if we are not excepted, would adversely affect our financial performance, which in turn could cause the price of our stock to decline. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our current products and/or those for which we may receive regulatory approval in the future.

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.

In the United States, we are subject directly, or indirectly through our customers, to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims

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Act, federal and state privacy and security laws, sunshine laws, government price reporting laws, and other fraud laws, as described in greater detail in the Government Regulation Section of this report. These laws may impact, among other things, our proposed sales, marketing and educational programs, as well as other possible relationships with customers, payers, and patients.

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. Even if we structure our programs with the intent of compliance with such laws, there can be no certainty that we would not need to defend our business activities against enforcement or litigation, in light of the fact that there is significant enforcement interest in pharmaceutical companies in the United States, and some of the applicable laws are quite broad in scope with very narrow exceptions.

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.

Our products 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, result in product re-labeling or withdrawal from the market 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. In Phase 3 endoscopic registration clinical trials with VIMOVO, the most commonly reported treatment-emergent adverse events were erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain, nausea 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 we or others identify undesirable side effects caused by our products or any other product candidate that we may develop that receives marketing approval, or if there is a perception that the product is associated with undesirable side effects:

regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;

regulatory authorities may withdraw their approval of the product or place restrictions on the way it is prescribed; and

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product or implement a risk evaluation and mitigation strategy.

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

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

We have agreements with third-party contract research organizations, or CROs, to conduct our clinical programs, 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 initiated a separate Phase 3 clinical trial for LODOTRA for the potential treatment of polymyalgia rheumatica, or PMR. We had limited control over the timing and implementation of the planned clinical trial and in February 2014, Mundipharma informed us that they had terminated the clinical trial primarily due to recruitment difficulties based on the inclusion criteria and as a result of the cessation of production of the comparator product Decortin® 1mg.

We also, as part of the April 23, 2011 FDA approval of DUEXIS, have a commitment under the Pediatric Research Equity Act to conduct an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients. In addition, in connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we assumed responsibility for completing an ongoing Pediatric Research Equity Act post-marketing requirement study in children 12 years to 16 years and 11 months of age with Juvenile RA for which the FDA recently granted an extension with a final report due date of December 2015. Although we are committed to carrying out these commitments, there are challenges in conducting studies in pediatric patients including availability of study sites, patients, and obtaining parental informed consent.

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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, VIMOVO 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. 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 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 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

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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 and have implemented disaster management plans and contingencies, 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 and suppliers to produce our products. Our ability to obtain commercial supplies of our products could be disrupted and our results of operations and financial condition could be materially and adversely affected if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The ultimate impact of such events on us, our significant suppliers and our general infrastructure is unknown.

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

We face an inherent risk of product liability as a result of the commercial sales of our products and the clinical testing of our product candidates. For example, we may be sued if any of our products or product candidates 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 a 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;

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;

the inability to commercialize our products or product candidates; and

a decline in our stock price.

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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 \$20 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 on-going commercialization of DUEXIS, VIMOVO and RAYOS in the United States 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 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.

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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 \$149.0 million, \$87.8 million and \$113.3 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of \$457.1 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, commercialization activities related to our product launches and costs associated with derivative liability accounting. We anticipate that we will continue to incur operating losses until such time as the revenues we generate from the sale of our products are sufficient to cover our operating expenses.

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 United States. LODOTRA is approved for marketing in over 30 countries outside the United States, 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 United States through our full field sales force in late January 2013. Following our November 2013 acquisition of the U.S. rights to VIMOVO, we began commercialization efforts in the United States in the first quarter of 2014. We may never be able to successfully commercialize DUEXIS, VIMOVO or RAYOS or develop or commercialize other products in the United States, 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, VIMOVO, RAYOS/LODOTRA and any other product candidates for which we obtain approval;

securing additional foreign regulatory approvals for LODOTRA and DUEXIS; and

developing, acquiring or in-licensing and commercializing a portfolio of other product candidates in addition to DUEXIS, VIMOVO 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, VIMOVO and RAYOS/LODOTRA, or to develop, acquire or in-license other products.

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

commercialize DUEXIS, VIMOVO and RAYOS in the United States, including the substantial expansion of our sales force in connection with our November 2013 acquisition of the U.S. rights to VIMOVO;

complete the regulatory approval process, and any future required clinical development related thereto, for DUEXIS, VIMOVO and RAYOS/LODOTRA;

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conduct clinical trials with respect to RAYOS/LODOTRA to generate clinical data in diseases beyond RA, such as PMR; and

potentially acquire or in-license additional complementary products or products that augment our current therapeutic areas of focus. While we believe that our existing cash and cash equivalents at December 31, 2013, of \$80.5 million, together with interest thereon, will be sufficient to fund our operations to the point of generating positive cash flow based on our current expectations of continued revenue growth, we may need to raise additional funds if we choose to expand our commercialization or development efforts more rapidly than we presently anticipate, if we develop, acquire or in-license additional products or acquire companies, or if our revenues do not meet expectations.

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, 2013, 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.

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.

In August 2012, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may sell our common stock through Cowen in at-the-market, or ATM, offerings. Subject to the terms

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and conditions of the sales agreement, Cowen may sell the shares by methods deemed to be an ATM offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including sales made through The NASDAQ Global Market, on any other existing trading market for our common stock or to or through a market maker. The sale of additional shares of our common stock pursuant to the sales agreement will have a dilutive impact on our existing stockholders and could cause the market price of our common stock to be lower than it would otherwise be absent sales activities by Cowen. Sales of our common stock under the sales agreement, or the perception that such sales will occur, could also encourage short sales by third parties, which could contribute to a decline of our stock price.

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, VIMOVO 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 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 a cumulative carryforward of \$49.9 million in 2014, and at a minimum, \$22.0 million for each of 2015 and 2016 assuming only the carryforward limitation. The net operating loss carryforward limitation is 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

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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, 2013, we had \$80.5 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, 2013, 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, Inc. 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.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

In November 2013, we issued \$150.0 million aggregate principal amount of 5.00% Convertible Senior Notes due 2018, or the Convertible Senior Notes, to investors pursuant to note purchase agreements with such investors. As of March 13, 2014, all \$150.0 million principal amount of the Convertible Senior Notes remained outstanding. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Convertible Senior Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the United States or in other foreign countries. If this were to occur, early generic competition could be expected against DUEXIS, VIMOVO, 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

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particular, because the APIs in DUEXIS, VIMOVO 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 March 13, 2013, we received purported Notice Letters that a Paragraph IV Patent Certification had been filed by Alvogen, advising that Alvogen had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. In the Notice Letters, Alvogen noted that as of March 13, 2013, the FDA had not accepted the ANDA for review. Alvogen has agreed that their Notice Letters do not constitute Notice as described in 21 U.S.C. 355(j)(2)(B).

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA's review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against WLF. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Par Pharmaceutical, Inc. has not advised us as to the timing or status of the FDA's review of its filing. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

Currently there are patent litigations pending against five generics intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the District of New Jersey and are grouped in three sets: (i) the DRL cases; (ii) the Mylan cases; and (iii) the Watson cases. We understand that Dr. Reddy's has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy's will not be able to commercialize VIMOVO under AstraZeneca's Nexium patent rights until May 28, 2014. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The DRL cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy's notice letters were dated March 11, 2011 and November 12, 2012; the Lupin notice letter was dated June 10, 2011; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order. The case does not have pretrial deadlines or a trial date set. We understand Anchen has recertified under Paragraph III and has filed a motion to dismiss on that basis.

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The Watson cases were filed on May 10, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a March 29, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Watson cases.

The Mylan cases were filed on June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a May 16, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Mylan cases.

We intend to vigorously defend our intellectual property rights relating to DUEXIS, VIMOVO and RAYOS, but we cannot predict the outcome of the Alvogen or WLF matters related to RAYOS or the DRL cases, the Mylan cases, or the Watson cases related to VIMOVO. Any adverse outcome in these matters or any new generic challenges that may arise could result in one or more generic versions of DUEXIS, VIMOVO 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, VIMOVO 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, VIMOVO or 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, VIMOVO and RAYOS/LODOTRA under patent protection could be reduced. Since patent applications in the United States 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, VIMOVO and RAYOS/LODOTRA or our other product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

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

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on

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September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or U.S. PTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the U.S. PTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. 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 United States and Canada. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. 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 United States, 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, VIMOVO, 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

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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.

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.

In connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we (i) received the benefit of a covenant not to sue under AstraZeneca's patent portfolio with respect to Nexium (which shall automatically become a license under such patent portfolio if and when AstraZeneca reacquires control of such patent portfolio from Merck Sharp & Dohme Corp. and certain of its affiliates), (ii) were assigned AstraZeneca's amended and restated collaboration and license agreement for the United States with Pozen under which AstraZeneca has in-licensed exclusive rights under certain of Pozen's patents with respect to VIMOVO, and (iii) acquired AstraZeneca's co-ownership rights with Pozen with respect to certain joint patents covering VIMOVO, all for the commercialization of VIMOVO in the United States. If we fail to comply with our obligations under our agreements with AstraZeneca or if we fail to comply with our obligations under our agreements with Pozen as we take over AstraZeneca's agreements with Pozen, our rights to commercialize VIMOVO in the United States may be adversely affected or terminated by AstraZeneca or Pozen.

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.

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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 United States.

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.

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

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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 market price of our common stock historically has been volatile and 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 commercialization of DUEXIS, VIMOVO and RAYOS in the United States;

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

unanticipated serious safety concerns related to the use of our products;

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, and/or in-license 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 or our inability to otherwise comply with financial reporting requirements;

adverse U.S. and foreign tax exposure;

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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.

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. 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 17% of our outstanding voting stock as of December 31, 2013. 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

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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 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 may 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 ATM sales agreement, our convertible notes or equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price.

Additional capital may 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

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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.

In August 2012, we entered into a sales agreement with Cowen pursuant to which we may sell common stock in ATM offerings under our registration statement on Form S-3, which became effective on August 9, 2012. As of December 31, 2013, Cowen had sold a cumulative total of 2,448,575 shares of our common stock with gross proceeds to us of \$6.2 million.

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 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 5, 2013, 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 1,053,074 shares, respectively, effective January 1, 2014.

In addition, (i) on November 7, 2013, November 16, 2013 and March 3, 2014, our board of directors approved amendments to the 2011 EIP to reserve an additional 200,000 shares, 800,000 shares and 730,000 shares, respectively, of our common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of ours (or following a bona fide period of non-employment with us), as an inducement material to the individual's entry into employment with us within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules and (ii) on January 10, 2014, our board of directors approved an amendment to the 2011 EIP to increase the number of shares available for issuance under the 2011 EIP by 703,400 shares, or the January 2014 amendment, with such increase to the number of shares available for issuance under the 2011 EIP subject to stockholder approval of the January 2014 amendment.

In November 2013, we issued \$150.0 million aggregate principal amount of the Convertible Senior Notes. The Convertible Senior Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding August 15, 2018 only under certain conditions. On or after August 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date for the Convertible Senior Notes, holders will be able to convert their Convertible Senior Notes at their option at the conversion rate then in effect at any time, regardless of these conditions. Subject to certain limitations, we may settle conversions of the Convertible Senior Notes by paying or delivering, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

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;

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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 depress the market price of 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.

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 34,460 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

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office space in Reinach, Switzerland under a lease that expires on May 31, 2015. We have no laboratory, research or manufacturing facilities. We believe that our current facilities are adequate for our needs and that, should it be needed, suitable additional space or renewal of our existing leases will be available to accommodate expansion of our operations on commercially reasonable terms.

Item 3. Legal Proceedings

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an Abbreviated New Drug Application, or ANDA, with the U.S. Food and Drug Administration, or FDA, for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., or collectively Par, for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par's ANDA and/or prevent 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 prevent Par from selling a generic version of DUEXIS.

On August 21, 2013, we entered into a settlement agreement, or Par settlement agreement, and license agreement, or Par license agreement, with Par relating to our patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both us and Par of all claims that were or could have been asserted in the litigation and that arise out of the specific patent issues that were the subject of the litigation, including all resulting damages or other remedies.

Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par's generic version of DUEXIS in the United States after the generic entry date (as defined below) and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par's generic version of DUEXIS prior to the generic entry date, or collectively the license. The license covers all patents owned or controlled by us during the term of the Par license agreement that would, absent the license, be infringed by the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States. Unless terminated sooner pursuant to the terms of the Par license agreement, the license will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. Only in the event that Par enters the DUEXIS market due to the specified changes in DUEXIS market conditions will the license become royalty-bearing, with the royalty obligations ceasing upon the occurrence of one of the other events that would have allowed Par to enter the DUEXIS market.

Under the Par license agreement, we also agreed not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by us during the term of the Par license agreement based on the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States.

The Par license agreement may be terminated by us if Par commits a material breach of the agreement that is not cured or curable within 30 days after we provide notice of the breach. We may also terminate the Par license agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the Par license agreement will terminate automatically upon termination of the Par settlement agreement.

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On March 13, 2013, we received purported Notice Letters that a Paragraph IV Patent Certification had been filed by 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. In the Notice Letters, Alvogen noted that as of March 13, 2013, the FDA had not accepted the ANDA for review. Alvogen has agreed that their Notice Letters do not constitute Notice as described in 21 U.S.C. 355(j)(2)(B).

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc. Florida, or Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA's review of its filing. On August 26, 2013, we, together with Jagotec AG, or Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc., or collectively WLF, seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

On or about August 12, 2013, we received a Notice of Opposition to a European patent covering LODOTRA, EP 2049123, filed by Laboratorios Licons, S.A. In the European Union, the grant of a patent may be opposed by one or more private parties.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Par Pharmaceutical, Inc. has not advised us as to the timing or status of the FDA's review of its filing. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

Currently there are patent litigations pending against five generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the District of New Jersey and are grouped in three sets: (i) Dr. Reddy's Laboratories, Inc., or Dr. Reddy's; Lupin Pharmaceuticals Inc., or Lupin; Anchen Pharmaceuticals Inc., or Anchen, or collectively, the DRL cases; (ii) Mylan Laboratories Limited, or collectively, the Mylan cases; and (iii) Watson Pharma, Inc., or collectively, the Watson cases. These cases seek an injunction preventing any infringing activity until the expiration of the patents. We understand that Dr. Reddy's has entered into a settlement with AstraZeneca AB, or AstraZeneca, with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy's will not be able to commercialize VIMOVO under AstraZeneca's Nexium patent rights until May 28, 2014. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The DRL cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We

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understand the Dr. Reddy's notice letters were dated March 11, 2011 and November 12, 2012; the Lupin notice letter was dated June 10, 2011; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order. The DRL cases do not have pretrial deadlines or a trial date set. We understand Anchen has recertified under Paragraph III and has filed a motion to dismiss on that basis.

The Watson cases were filed on May 10, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a March 29, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Watson cases.

The Mylan cases were filed on June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a May 16, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Mylan cases.

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
2013		
First quarter	\$ 2.95	\$ 1.97
Second quarter	2.75	2.23
Third quarter	3.55	2.11
Fourth quarter	7.80	3.21
	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

Holders of Record

The closing price of our common stock on March 11, 2014 was \$13.33. As of March 11, 2014, there were approximately 68 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, 2013, 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 of 1933, as amended, or the Securities Act, or the Securities Exchange Act of 1934, as amended, 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. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

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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.

Issuer Repurchases of Equity Securities

None.

Item 6. Selected Financial Data

The selected statement of operations data for the years ended December 31, 2013, 2012 and 2011, and the balance sheet data as of December 31, 2013 and 2012 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, 2010 and 2009, and the balance sheet data as of December 31, 2011, 2010 and 2009 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).

	2013	For the Years Ended December 31,			2009
		2012 (Revised)	2011	2010	
Statement of Operations Data					
Gross sales	\$ 102,995	\$ 22,978	\$ 6,939	\$ 2,376	\$
Sales discounts and allowances (1)	(28,979)	(4,134)	(12)		
Net sales	74,016	18,844	6,927	2,376	
Cost of goods sold (1)	14,625	11,875	7,267	4,263	
Gross profit (loss)	59,391	6,969	(340)	(1,887)	
Operating expenses:					
Research and development	10,084	16,837	15,358	17,697	10,894
Sales and marketing	68,595	49,561	20,314	5,558	2,072
General and administrative	23,566	19,444	15,008	18,612	5,823
Intangible impairment charge			69,621		
Total operating expenses	102,245	85,842	120,301	41,867	18,789
Loss from operations	(42,854)	(78,873)	(120,641)	(43,754)	(18,789)
Other (expense) income, net:					
Interest expense, net	(39,178)	(14,525)	(6,284)	(3,024)	(2,189)
Loss on derivative revaluation	(69,300)				
Bargain purchase gain				19,326	
Foreign exchange gain (loss)	1,206	489	(1,023)	(273)	
Other (expense) income		(56)			478
Loss before income tax benefit	(150,126)	(92,965)	(127,948)	(27,725)	(20,500)
Income tax benefit	(1,121)	(5,171)	(14,683)	(660)	
Net loss	(149,005)	(87,794)	(113,265)	(27,065)	(20,500)
Capital contribution					3,489
Net loss attributable to common stockholders	\$ (149,005)	\$ (87,794)	\$ (113,265)	\$ (27,065)	\$ (17,011)
Net loss per share basic and diluted	\$ (2.34)	\$ (2.26)	\$ (12.56)	\$ (21.16)	\$ (40.65)
Weighted average shares outstanding basic and diluted	63,657,924	38,871,422	9,014,968	1,279,133	418,520

- (1) For the year ended December 31, 2012, the reported amount for sales discounts and allowances has been revised from (\$3.3) million to (\$4.1) million, the reported amount for net sales has been revised from \$19.6 million to \$18.8 million, and the reported amount for cost of goods sold has been revised from \$12.7 million to \$11.9 million, reflecting reclassification of wholesaler service fees from cost of goods sold to sales discounts and allowances. See Note 1 The Company in the notes to our consolidated financial statements included in this Annual Report on Form 10-K.

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	As of December 31,				
	2013	2012	2011	2010	2009
Selected Balance Sheet Data					
Assets:					
Cash and cash equivalents	\$ 80,480	\$ 104,087	\$ 17,966	\$ 5,384	\$ 7,160
Working capital (deficit)	67,455	79,983	1,065	(17,944)	(905)
Total assets	252,596	193,984	101,078	161,685	8,213
Long-term debt, net of current maturities	150,000	36,866	15,834	10,395	3,133
Accumulated deficit	(457,116)	(308,111)	(220,317)	(107,052)	(79,987)
Total stockholders (deficit) equity	(49,802)	105,978	45,912	97,056	(3,177)

	For the Years Ended December 31,				
	2013	2012	2011	2010	2009
Selected Statement of Cash Flows Data					
Net cash used in operating activities	\$ (54,287)	\$ (76,641)	\$ (41,540)	\$ (37,532)	\$ (18,392)
Net cash (used in) provided by investing activities	(36,135)	(1,386)	(2,154)	5,575	(357)
Net cash provided by financing activities	66,716	164,308	55,152	29,760	11,842

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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 Securities Exchange Act of 1934, as amended, 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 commercializing DUEXIS, VIMOVO and RAYOS/LODOTRA, each of which targets unmet therapeutic needs in arthritis, pain and inflammatory diseases. We developed DUEXIS and RAYOS/LODOTRA, and we acquired the U.S. rights to VIMOVO from AstraZeneca AB, or AstraZeneca, in November 2013. Our strategy is to develop, acquire or in-license additional innovative medicines or acquire companies where we can execute a targeted commercial approach among specific target physicians such as primary care physicians, orthopedic surgeons and rheumatologists, 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, 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, osteoarthritis, or OA, and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. In the second half of 2011, we hired our initial commercial organization, including approximately 80 sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. 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 the third quarter of 2012, we expanded our sales force to approximately 150 representatives and have subsequently further expanded our sales force to approximately 290 representatives, most recently by adding approximately 115 representatives in connection with our acquisition of the U.S. rights to VIMOVO in November 2013. In March 2013, we announced that the United Kingdom, or UK, Medicines and Healthcare Products Regulatory Agency granted a National Marketing Authorization 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.

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Our second approved product in the United States, RAYOS, known as LODOTRA outside the United States, 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 rheumatic, or PMR, psoriatic arthritis, ankylosing spondylitis, or AS, asthma and chronic obstructive pulmonary disease and a number of other conditions. We are focusing our promotion of RAYOS in the United States 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 U.S. rheumatologists and key primary care physicians. LODOTRA is currently marketed outside the United States by our distribution partner, Mundipharma International Corporation Limited, or Mundipharma.

On November 18, 2013, we entered into agreements with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs in the United States. VIMOVO (naproxen/esomeprazole magnesium) is a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, layer surrounding the core. VIMOVO was originally developed by Pozen Inc., or Pozen, together with AstraZeneca pursuant to an exclusive global collaboration and license agreement under which AstraZeneca and Pozen agreed to co-develop VIMOVO and AstraZeneca obtained exclusive rights to commercialize VIMOVO worldwide. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of OA, RA, and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

Under the asset purchase agreement with AstraZeneca, we acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the investigational new drug application and new drug application for VIMOVO in the United States, AstraZeneca's interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. In addition, AstraZeneca assigned to us its amended and restated collaboration and license agreement for the United States with Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States.

In December 2013, as a result of the acquisition of the U.S. rights to VIMOVO, we began the expansion of our sales force to approximately 250 primary care representatives and 40 rheumatology sales specialists and recognized revenues under our transition agreement. We announced the availability of Horizon-labeled VIMOVO on January 2, 2014. We completed the hiring and training of our expanded sales force in January 2014 and began selling VIMOVO in early February 2014. Our primary care representatives will promote DUEXIS in a primary position to physician targets who are high branded NSAID prescribers and are also prescribers of DUEXIS and ibuprofen and they will promote VIMOVO in a second position among these target physicians. Our primary care representatives will promote VIMOVO in a primary position to physician targets who are high branded NSAID prescribers and are also prescribers of VIMOVO and naproxen and they will promote DUEXIS in a second position among these target physicians. Our analysis indicates that there is an approximate 30% overlap of physician targets who prescribe both DUEXIS and VIMOVO. In those cases, individual target-by-target promotional plans will be executed and both DUEXIS and VIMOVO will be promoted to these targets. We have also expanded our rheumatology specialty sales force from 25 sales specialists to approximately 40 sales specialists, with these specialist representatives promoting RAYOS and VIMOVO to rheumatologists. We have also included VIMOVO in our *Prescriptions-Made-Easy* specialty pharmacy program, along with DUEXIS and RAYOS, and offer co-pay assistance for all of our marketed products to ensure patients receive them at a reasonable out-of-pocket cost.

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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 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 United States to our wholesale pharmaceutical distributors and retail chains was recognized based on the amount of product sold through to the end 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. Beginning in 2014, we began to recognize VIMOVO revenue at the point of sale, consistent with our revenue recognition of DUEXIS and RAYOS, given the availability of prior VIMOVO product return data.

Revenue from upfront license fees

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

Revenue from milestone receipts

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

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Customer-Related Accruals and Allowances

DUEXIS, VIMOVO and RAYOS Product Sales Discounts and Allowances

Prior to the fourth quarter of 2012, we 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 the related revenue was recognized. In the fourth quarter of 2012, we began recognizing revenue at the point of sale to our wholesale pharmaceutical distributors and retail chains, at which point the associated allowances for product returns, rebates and allowances were also recognized. We are required to make significant judgments and estimates in determining some of these allowances. If actual results differ from our estimates, we will be required to make adjustments to these allowances in the future. Beginning in 2014, in connection with our marketing of VIMOVO in the United States, we will also recognize VIMOVO revenue at the point of sale to our wholesale pharmaceutical distributors and retail chains.

Customer Discounts and Rebates

Product Launch Discounts

We have offered additional discounts to wholesale distributors for product purchased at the time of product launch. We have recorded these discounts as an allowance against accounts receivable and a reduction of revenue when orders were placed.

Customer Rebates

We participate in certain commercial rebate programs. Under these rebate programs, we pay a rebate to the commercial entity or third-party administrator of the program. We accrue estimated rebates based on contract prices, estimated percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel and record the rebate as a reduction of revenue.

Distribution Service Fees

We include distribution service fees paid to our wholesalers for distribution and inventory management services as a reduction to revenue. The estimates are based on contractually determined fees, typically as a percentage of revenue.

Government Rebates and Chargebacks

Government Rebates

We participate in certain federal government rebate programs, such as Medicare and Medicaid. We accrue estimated rebates based on estimated percentages of product sold to qualified patients, estimated rebate percentages and estimated levels of inventory in the distribution channel that will be sold to qualified patients and record the rebate as a reduction of revenue.

Government Chargebacks

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

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We offer discount card programs to patients under which the patient receives a discount on his or her prescription. We reimburse pharmacies for this discount through a third-party vendor. We record the total amount of estimated discounts for sales recorded in the period as a reduction of revenue.

*Returns and Prompt Pay Allowances**Sales Returns*

Consistent with industry practice, we maintain a return policy that allows customers to return product within a specified period prior to and subsequent to the product expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date and up to one year after its expiration date. The right of return expires on the earlier of one year after the product expiration date or the time that the product is dispensed to the patient. The majority of our product returns are the result of product dating, which falls within the range set by our policy, and are settled through the issuance of a credit to the customer. Our estimate of the provision for returns is based upon our historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which our customer may return product. This period is known to us based on the shelf lives of our products at the time of shipment. We record sales returns as an allowance against accounts receivable and a reduction of revenue.

Prompt Pay Discounts

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

The following table summarizes our customer-related accruals and allowances as of December 31, 2013 and 2012:

	Customer Discounts and Rebates	Co-Pay Assistance	Government Rebates and Chargebacks	Returns and Prompt Pay Allowances	Total
Balance at December 31, 2011	\$ 796	\$ 4	\$ 62	\$ 170	\$ 1,032
Current provisions relating to sales in current year	1,773	1,578	418	365	4,134
Adjustments relating to prior years					
Payments/returns relating to sales in current year	(757)	(1,160)	(159)	(419)	(2,495)
Payments/returns relating to sales in prior years				(39)	(39)
Balance at December 31, 2012	\$ 1,812	\$ 422	\$ 321	\$ 77	\$ 2,632
Current provisions relating to sales in current year	8,191	13,609	3,909	3,270	28,979
Adjustments relating to prior years					
Payments/returns relating to sales in current year	(4,781)	(11,641)	(2,785)	(2,723)	(21,930)
Payments/returns relating to sales in prior years	(763)	(132)	(38)	(193)	(1,126)
Balance at December 31, 2013	\$ 4,459	\$ 2,258	\$ 1,407	\$ 431	\$ 8,555

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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 RAYOS includes all costs directly related to the acquisition of product from our third party manufacturers, including freight charges, manufacturing overhead 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 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, manufacturing overhead 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 VIMOVO in the fourth quarter of 2013, following our acquisition in November 2013 of certain assets and rights necessary to commercialize VIMOVO in the United States, includes only intangible amortization expense. Beginning in 2014, in connection with our marketing of VIMOVO in the United States, cost of goods sold for VIMOVO will include all costs directly related to the acquisition of product from AstraZeneca and/or the third-party manufacturer.

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.

Intangible Assets

Our intangible assets consist of developed technology related to three of our approved products: LODOTRA outside the United States, RAYOS in the United States and intellectual property rights related to our acquisition of the U.S. rights to VIMOVO. We amortize LODOTRA and RAYOS intangible assets over twelve years, which is the estimated useful life of the underlying patents, and we amortize the U.S. intellectual property rights of the VIMOVO intangible asset over 61.5 months. We review our intangible assets when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. We measure fair value based on the estimated future discounted cash flows associated with our assets in addition to other assumptions and projections that we deem to be reasonable and supportable.

Fair Value of Financial Instruments

The carrying amounts of our 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 our derivative liability related to the convertible portion of our 5.00% Convertible Senior Notes due 2018, or the Convertible Senior Notes, was derived utilizing the binomial lattice approach for the valuation of convertible instruments. Assumptions used in the calculation included, among others, determining the appropriate credit spread using benchmarking analysis and solving for the implied

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credit spread, calculating the fair value of the stock component using a discounted risk free rate and borrowing cost and calculating the fair value of the note component using a discounted credit adjusted discount rate. Based on the assumptions used to determine the fair value of the derivative liability associated with the Convertible Senior Notes, we concluded that these inputs were Level 3 inputs. We will continue to derive the fair value of the derivative liability using the binomial lattice approach and these assumptions in all future reporting periods.

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 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.

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	For the Years Ended December 31,		Increase / (Decrease)
	2013	2012 (Revised)	
Gross sales	\$ 102,995	\$ 22,978	\$ 80,017
Sales discounts and allowances (1)	(28,979)	(4,134)	24,845
Net sales	74,016	18,844	55,172
Cost of goods sold (1)	14,625	11,875	2,750
Gross profit	59,391	6,969	52,422
Operating expenses			
Research and development	10,084	16,837	(6,753)
Sales and marketing	68,595	49,561	19,034
General and administrative	23,566	19,444	4,122
Total operating expenses	102,245	85,842	16,403
Operating loss	(42,854)	(78,873)	(36,019)
Other income (expense)			
Interest expense, net	(39,178)	(14,525)	24,653
Foreign exchange gain	1,206	489	(717)
Loss on derivative revaluation	(69,300)		69,300
Other expense		(56)	(56)
Total other expense, net	(107,272)	(14,092)	93,180
Loss before benefit for income taxes	(150,126)	(92,965)	57,161
Benefit for income taxes	(1,121)	(5,171)	(4,050)
Net loss	\$ (149,005)	\$ (87,794)	\$ 61,211

(1) For the year ended December 31, 2012, the reported amount for sales discounts and allowances has been revised from (\$3.3) million to (\$4.1) million, the reported amount for net sales has been revised from \$19.6 million to \$18.8 million, and the reported amount for cost of goods sold has been revised from \$12.7 million to \$11.9 million, reflecting reclassification of wholesaler service fees from cost of goods sold to sales discounts and allowances. See Note 1 The Company in the notes to our consolidated financial statements included in this Annual Report on Form 10-K.

Sales. During the year ended December 31, 2013, gross and net sales were \$103.0 million and \$74.0 million, respectively, compared to \$23.0 million and \$18.8 million, respectively, during the year ended December 31, 2012. DUEXIS gross and net sales during the year ended December 31, 2013 were \$85.5 million and \$59.0 million, respectively, after deducting sales discounts and allowances of \$26.5 million, including co-pay assistance costs of \$12.8 million, compared to gross and net sales of \$13.2 million and \$10.3 million, respectively, during the year ended December 31, 2012. The increase in DUEXIS sales during the year ended December 31, 2013 compared to the prior year was primarily the result of product price increases implemented during the course of 2013 and increased volume driven by the expansion of our sales force.

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RAYOS gross and net sales were \$7.8 million and \$5.8 million, respectively, during the year ended December 31, 2013 after deducting sales discounts and allowances of \$2.0 million, including co-pay assistance costs of \$0.8 million, compared to gross and net sales of \$0.8 million and \$0.3 million, respectively, during the year ended December 31, 2012. The increase in RAYOS sales during the year ended December 31, 2013 compared to the prior year was primarily attributable to the inclusion of a full year of sales during the year ended December 31, 2013 following the RAYOS launch in December 2012.

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LODOTRA gross and net sales during the year ended December 31, 2013 were \$8.7 million and \$8.2 million, respectively, after deducting trade allowances of \$0.5 million, compared to gross and net sales of \$9.0 million and \$8.2 million, respectively, during the year ended December 31, 2012. The decrease in LODOTRA sales during the year ended December 31, 2013 compared to the prior year was the result of lower product shipments to our European distribution partner, Mundipharma, partially offset by an increase in the recognition of deferred revenues related to product previously shipped and invoiced to Mundipharma at contract minimum prices and where the contractual price adjustment period has passed. LODOTRA sales to Mundipharma occur at the time we ship product to Mundipharma based on its estimated requirements. Accordingly, LODOTRA sales are not linear or tied to Mundipharma sales to the market and can therefore fluctuate from year to year.

VIMOVO net sales during the year ended December 31, 2013 were \$1.0 million and represented net profits paid to us by AstraZeneca in the fourth quarter of 2013 under a transition services agreement in connection with our acquisition of certain assets and commercial rights to VIMOVO in the United States on November 18, 2013.

Sales discounts and allowances. During the year ended December 31, 2013, sales discounts and allowances were \$29.0 million compared to \$4.1 million during the year ended December 31, 2012. As a percentage of gross product sales, sales discounts and allowances increased to 28% during the year ended December 31, 2013 compared to 18% during the year ended December 31, 2012. The increase in sales discounts and allowances was attributable to a significant increase in product sales during the year ended December 31, 2013, which resulted in a corresponding increase in customer discounts and rebates, including distribution service fees and prompt pay allowances. Co-pay assistance costs increased \$12.0 million during the year ended December 31, 2013 compared to the prior year as a result of a larger number of prescriptions being filled by patients and product price increases implemented during the course of 2013, which resulted in us increasing the amount of co-pay assistance we would provide to a patient. The following table presents our sales discounts and allowances for the years ended December 31, 2013 and 2012:

For the Years Ended December 31,