

HORIZON PHARMA, INC.  
Form 10-K  
March 13, 2014  
Table of Contents

**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)

Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

**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:**

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
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.



---

**Table of Contents**

**HORIZON PHARMA, INC.**  
**FORM 10-K ANNUAL REPORT**  
**For the Fiscal Year Ended December 31, 2013**  
**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I</u></b>	
<u>Item 1. Business</u>	3
<u>Item 1A. Risk Factors</u>	37
<u>Item 1B. Unresolved Staff Comments</u>	73
<u>Item 2. Properties</u>	73
<u>Item 3. Legal Proceedings</u>	74
<u>Item 4. Mine Safety Disclosures</u>	76
<b><u>PART II</u></b>	
<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	76
<u>Item 6. Selected Financial Data</u>	78
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	81
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	98
<u>Item 8. Financial Statements and Supplementary Data</u>	99
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	99
<u>Item 9A. Controls and Procedures</u>	99
<u>Item 9B. Other Information</u>	100
<b><u>PART III</u></b>	
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	100
<u>Item 11. Executive Compensation</u>	108
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	128
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	132
<u>Item 14. Principal Accounting Fees and Services</u>	134
<b><u>PART IV</u></b>	
<u>Item 15. Exhibits, Financial Statement Schedules</u>	135

---

**Table of Contents**

**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,

**Table of Contents**

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
<b>Consolidated Statements of Comprehensive Loss for the Three Months Ended</b>			
<b>March 31, 2012</b>			
Sales discounts and allowances	(384)	(38)	(422)
Net Sales	2,523	(38)	2,485
Cost of goods sold	2,067	(38)	2,029
<b>Consolidated Statements of Comprehensive Loss for the Three Months Ended</b>			
<b>June 30, 2012</b>			
Sales discounts and allowances	(767)	(160)	(927)
Net Sales	3,841	(160)	3,681
Cost of goods sold	2,855	(160)	2,695
<b>Consolidated Statements of Comprehensive Loss for the Three Months Ended</b>			
<b>September 30, 2012</b>			
Sales discounts and allowances	(790)	(202)	(992)
Net Sales	6,521	(202)	6,319
Cost of goods sold	3,810	(202)	3,608
<b>Consolidated Statements of Comprehensive Loss for the Three Months Ended</b>			
<b>December 31, 2012</b>			
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
<b>Consolidated Statements of Comprehensive Loss for the Three Months Ended</b>			
<b>March 31, 2013</b>			
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
<b>Consolidated Statements of Comprehensive Loss for the Three Months Ended</b>			
<b>June 30, 2013</b>			
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
<b>Consolidated Statements of Comprehensive Loss for the Six Months Ended</b>			
<b>June 30, 2013</b>			
Sales discounts and allowances	(6,910)	(1,601)	(8,511)
Net Sales	21,425	(1,601)	19,824

Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

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

**Table of Contents**

	As Reported	Adjustment (in thousands)	As Revised
<b>Consolidated Statements of Comprehensive Loss for the Nine Months Ended</b>			
<b>September 30, 2013</b>			
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

## Table of Contents

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

## **Table of Contents**

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](http://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.

**Table of Contents**

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.

## **Table of Contents**

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

## **Table of Contents**

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.

**Table of Contents**

*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.

## **Table of Contents**

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;

## **Table of Contents**

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

## **Table of Contents**

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

---

## **Table of Contents**

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.

---

## **Table of Contents**

### **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,

## **Table of Contents**

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.

## **Table of Contents**

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.

## **Table of Contents**

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.

## **Table of Contents**

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.

## **Table of Contents**

### *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.

---

## **Table of Contents**

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

---

**Table of Contents**

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.

## **Table of Contents**

### *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

---

**Table of Contents**

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

---

**Table of Contents**

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.

---

**Table of Contents**

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.

---

## **Table of Contents**

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.

---

**Table of Contents**

*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.

---

## **Table of Contents**

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.

## **Table of Contents**

### **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

## **Table of Contents**

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:

## Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

*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.

---

## **Table of Contents**

*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

## Table of Contents

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.

## **Table of Contents**

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.

---

**Table of Contents**

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

---

**Table of Contents**

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.

---

**Table of Contents**

*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

## **Table of Contents**

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](http://www.horizonpharma.com). Information is also available through the Securities and Exchange Commission's website at [www.sec.gov](http://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

**Table of Contents**

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.

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.

---

## **Table of Contents**

*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

---

**Table of Contents**

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.

---

**Table of Contents**

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.



---

**Table of Contents**

*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

---

**Table of Contents**

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

## Table of Contents

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,

---

**Table of Contents**

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

Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

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

---

**Table of Contents**

*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<sup>®</sup>, 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

---

**Table of Contents**

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).

---

**Table of Contents**

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



## **Table of Contents**

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;

## Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

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.

## **Table of Contents**

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

---

**Table of Contents**

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,

---

**Table of Contents**

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.

## **Table of Contents**

*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.

---

**Table of Contents**

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

---

**Table of Contents**

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.

---

**Table of Contents**

*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.

## **Table of Contents**

*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

---

## **Table of Contents**

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.

## **Table of Contents**

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.

---

**Table of Contents**

**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;



---

**Table of Contents**

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

---

**Table of Contents**

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

## **Table of Contents**

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

---

**Table of Contents**

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.

---

**Table of Contents**

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

---

**Table of Contents**

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

## Table of Contents

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.

---

## **Table of Contents**

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

**Table of Contents**

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;

**Table of Contents**

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

## **Table of Contents**

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

---

**Table of Contents**

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;

---

**Table of Contents**

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

---

**Table of Contents**

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.

---

**Table of Contents**

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

**Table of Contents**

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
<b>2013</b>		
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
<b>2012</b>		
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.

## **Table of Contents**

### **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.

**Table of Contents**

**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.

**Table of Contents**

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	
<b>Statement of Operations Data</b>					
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.

**Table of Contents**

	As of December 31,				
	2013	2012	2011	2010	2009
<b>Selected Balance Sheet Data</b>					
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
<b>Selected Statement of Cash Flows Data</b>					
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

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

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

*The discussion below contains forward-looking statements, as defined in Section 21E of the 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.

---

**Table of Contents**

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.

---

**Table of Contents**

**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.

## **Table of Contents**

### *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.

**Table of Contents***Co-Pay Assistance*

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:

	<b>Customer Discounts and Rebates</b>	<b>Co-Pay Assistance</b>	<b>Government Rebates and Chargebacks</b>	<b>Returns and Prompt Pay Allowances</b>	<b>Total</b>
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

## **Table of Contents**

### *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

## **Table of Contents**

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.

**Table of Contents****RESULTS OF OPERATIONS****Year Ended December 31, 2013 Compared to Year Ended December 31, 2012**

	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.

## Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

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.

**Table of Contents**

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:

	<b>For the Years Ended December 31,</b>	
	<b>2013</b>	<b>2012 (Revised)</b>
Gross product sales	102,995	22,978
Customer discounts and rebates	8,176	1,772
Co-pay assistance	13,608	1,578
Government rebates and chargebacks	3,910	418
Product returns and prompt pay allowances	3,285	366
Sales discounts and allowances	28,979	4,134
Product sales, net	74,016	18,844

Sales discounts and allowances, as a percent of gross product sales 28% 18%

*Cost of Goods Sold.* Cost of goods sold increased \$2.7 million to \$14.6 million during the year ended December 31, 2013, from \$11.9 million during the year ended December 31, 2012. The increase in cost of goods sold was primarily attributable to a \$3.4 million increase in intangible amortization expense. The increase in amortization expense was related to the FDA approval of RAYOS in July 2012, which resulted in the reclassification and subsequent amortization of an indefinite-lived intangible asset to a finite-lived intangible asset, which resulted in additional intangible amortization expense of \$2.0 million during the year ended December 31, 2013 as a result of a full year of amortization as compared to 2012. Additionally, as a result of our asset purchase agreement with AstraZeneca, we capitalized \$67.7 million in intangible assets related to the VIMOVO intellectual property rights. This intangible asset will be amortized using a straight-line method over its estimated useful life of 61.5 months. During the year ended December 31, 2013, we recorded \$1.4 million in intangible amortization expense related to the intellectual property acquired in connection with our acquisition of the U.S. rights to VIMOVO. For the years ended December 31, 2013 and 2012, intangible amortization expense accounted for 56% and 40%, respectively, of total cost of goods sold.

---

**Table of Contents**

*Research and Development Expenses.* Research and development expenses during the year ended December 31, 2013 were \$10.1 million, a decrease of \$6.7 million compared to research and development expenses of \$16.8 million during the year ended December 31, 2012. The decrease in research and development expenses during the year ended December 31, 2013 was primarily associated with the classification of \$5.0 million in medical affairs expenses to sales and marketing expenses, a \$0.9 million reduction in consulting fees and a \$0.8 million decrease in regulatory and clinical trial expenses. During the first quarter of 2013, in connection with the full commercial launch of RAYOS, we began to classify our medical affairs expenses, which now consist of expenses related to scientific publications, health outcomes, biostatistics, medical education and information, and medical communications, as sales and marketing expenses. Prior to the full commercial launch of RAYOS in late January 2013, medical affairs expenses were classified as part of research and development expenses.

*Sales and Marketing Expenses.* Sales and marketing expenses during the year ended December 31, 2013 were \$68.6 million, an increase of \$19.0 million compared to sales and marketing expenses of \$49.6 million during the year ended December 31, 2012. The increase in sales and marketing expenses was primarily attributable to an increase of \$13.6 million in salaries and benefits expenses due to the increase in staffing of our field sales force and the inclusion of \$5.0 million of medical affairs expenses in sales and marketing expenses.

*General and Administrative Expenses.* General and administrative expenses during the year ended December 31, 2013 were \$23.6 million, an increase of \$4.2 million compared to general and administrative expenses of \$19.4 million during the year ended December 31, 2012. The increase in general and administrative expenses was primarily due to \$1.9 million in additional salaries and related benefits expense associated with incremental finance and administrative staff compared to the prior year, \$1.8 million in higher legal expenses, which consisted of a \$1.1 million increase in legal fees incurred in connection with our VIMOVO asset acquisition and a \$0.7 million increase in legal fees associated with intellectual property related matters. Additionally, facilities expense increased \$0.7 million in the year ended December 31, 2013 as a result of additional information technology infrastructure expenses related to the expansion of our field sales force.

*Interest Expense, Net.* Interest expense, net was \$39.2 million during the year ended December 31, 2013, an increase of \$24.7 million compared to interest expense, net of \$14.5 million during the year ended December 31, 2012. The increase in interest expense, net was primarily attributable to higher debt extinguishment costs and interest expense related to the amortization of deferred financing and debt discount expenses. During the year ended December 31, 2013, we recorded a \$26.4 million charge related to the extinguishment of our senior secured loan facility with a group of institutional lenders, or the Senior Secured Loan, in November 2013 compared to loss on debt extinguishment of a prior debt facility of \$2.5 million during the year ended December 31, 2012.

*Foreign Exchange Gain.* During the years ended December 31, 2013 and 2012, we reported a foreign exchange gain of \$1.2 million and \$0.5 million, respectively. The foreign exchange gain in each period was primarily attributable to an increase in the value of the Euro against the U.S. dollar compared to the applicable prior year, which resulted in a favorable currency impact for our Swiss subsidiary, Horizon Pharma AG.

*Loss on Derivative Revaluation.* During the year ended December 31, 2013, we recorded a \$69.3 million non-cash charge related to the increase in the fair value of the embedded derivatives in the Convertible Senior Notes we issued in November 2013, principally due to an increase in the market value of our common stock during the period from issuance to December 31, 2013.

*Income Tax Benefit.* Income tax benefit was \$1.1 million during the year ended December 31, 2013, a decrease of \$4.1 million compared to an income tax benefit of \$5.2 million during the year ended December 31, 2012. The decrease in income benefit during the year ended December 31, 2013 was primarily attributable to the absence of a one-time tax benefit which was recorded during the year ended December 31, 2012. On July 26, 2012, the FDA approved RAYOS, which resulted in the reclassification of the entire asset balance of \$35.5 million, from an indefinite-lived intangible asset to a finite-lived intangible asset. The reclassification from an indefinite-lived intangible asset to a finite-lived intangible asset required us to amortize this asset over the useful

**Table of Contents**

life of the asset, which resulted in a corresponding reduction to our net deferred tax liabilities and the recognition of a one-time net income tax benefit of \$4.3 million that was recorded during the third quarter of 2012.

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

	For the Years Ended December 31,		Increase/ (Decrease)
	2012 (Revised)	2011	
Gross sales	\$ 22,978	\$ 6,939	\$ 16,039
Sales discounts and allowances (1)	(4,134)	(12)	4,122
Net sales	18,844	6,927	11,917
Cost of goods sold (1)	11,875	7,267	4,608
Gross profit (loss)	6,969	(340)	7,309
Operating expenses			
Research and development	16,837	15,358	1,479
Sales and marketing	49,561	20,314	29,247
General and administrative	19,444	15,008	4,436
Intangible impairment charge		69,621	(69,621)
Total operating expenses	85,842	120,301	(34,459)
Operating loss	(78,873)	(120,641)	(41,768)
Other income (expense)			
Interest expense, net	(14,525)	(6,284)	8,241
Foreign exchange gain (loss)	489	(1,023)	(1,512)
Other expense	(56)		56
Total other expense, net	(14,092)	(7,307)	6,785
Loss before benefit for income taxes	(92,965)	(127,948)	(34,983)
Benefit for income taxes	(5,171)	(14,683)	(9,512)
Net loss	\$ (87,794)	\$ (113,265)	\$ (25,471)

(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.* Gross sales for the year ended December 31, 2012 were \$23.0 million, an increase of \$16.1 million compared to gross sales of \$6.9 million for the year ended December 31, 2011. Net sales for the year ended December 31, 2012 were \$18.8 million, an increase of \$11.9 million compared to net sales of \$6.9 million for the year ended December 31, 2011.

DUEXIS gross sales were \$13.2 million during the year ended December 31, 2012, an increase of \$13.1 million compared to gross sales of \$0.1 million during the year ended December 31, 2011. Net sales of DUEXIS during the year ended December 31, 2012 were \$10.3 million, an increase of \$10.2 million compared to net sales of \$0.1 million during the year ended December 31, 2011. The increase in DUEXIS sales was

## Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

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

**Table of Contents**

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

Additionally, RAYOS gross and net sales were \$0.8 million and \$0.3 million, respectively, during the year ended December 31, 2012, as a result of our initial product launch during the fourth quarter of 2012 to a subset of high prescribing rheumatologists.

*Sales discounts and allowances.* During the year ended December 31, 2012, sales discounts and allowances were \$4.1 million and was 18% as a percentage of gross product sales. The increase in sales discounts and allowances was attributable to a full year of operating results of DUEXIS, as initial DUEXIS product sales did not occur until the fourth quarter of 2011. The following table presents our sales discounts and allowances for the years ended December 31, 2012 and 2011:

	<b>For the Years Ended December 31, 2012 (Revised)</b>	<b>2011</b>
Gross product sales	22,978	6,939
Customer discounts and rebates	1,772	10
Co-pay assistance	1,578	0
Government rebates and chargebacks	418	2
Product returns and prompt pay allowances	366	0
Sales discounts and allowances	4,134	12
Product sales, net	18,844	6,927

Sales discounts and allowances, as a percent of gross product sales 18% 0%

*Cost of Goods Sold.* Cost of goods sold during the year ended December 31, 2012 were \$11.9 million, an increase of \$4.6 million compared to \$7.3 million during the year ended December 31, 2011. The increase in cost of goods sold was primarily attributable to a \$2.6 million increase in DUEXIS product costs associated with full year commercial sales of DUEXIS compared to only one month of DUEXIS product sales in 2011, a \$1.0 million increase in LODOTRA product costs due to higher product sales and a \$1.0 million increase in amortization expense. The increase in amortization expense was related to the FDA approval of RAYOS in July 2012, which resulted in the reclassification and subsequent amortization of an indefinite-lived intangible asset to a finite-lived intangible asset. For the years ended December 31, 2012 and 2011, intangible amortization expense accounted for 40% and 52%, respectively, of total cost of goods sold.

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

*Sales and Marketing Expenses.* Sales and marketing expenses during the year ended December 31, 2012 were \$49.5 million, an increase of \$29.2 million compared to \$20.3 million during the year ended December 31, 2011. The increase in sales and marketing expenses was primarily attributable to salaries and related expenses for

**Table of Contents**

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

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

*Intangible Impairment Charge.* During the year ended December 31, 2011, we recorded an intangible impairment charge of \$69.6 million related to the impairment of our indefinite-lived in-process research and development, or IPR&D, asset consisting of our rights to RAYOS in the United States. Our impairment analysis concluded that as a result of the significant decline in our stock price in the fourth quarter of 2011, and the market value attributed to us in the public markets, along with an appropriate risk control premium, that the IPR&D's fair value calculated was less than its carrying value at December 31, 2011. Accordingly, during the year ended December 31, 2011, we recorded an intangible impairment charge of \$69.6 million to write down the value of our IPR&D asset to its fair value.

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

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

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

---

**Table of Contents**

**Liquidity and Capital Resources**

We have incurred losses since our inception in June 2005 and, as of December 31, 2013, we had an accumulated deficit of \$457.1 million. We anticipate that we will continue to incur net losses until such time as the revenues we generate from DUEXIS, VIMOVO and RAYOS/LODOTRA or any products we may acquire or in-license are sufficient to cover our operating expenses. We expect that our sales and marketing expenses will continue to increase as a result of our commercialization of DUEXIS, VIMOVO and RAYOS/LODOTRA. As a result, we will need to generate significant net product sales, and royalty and other revenues to achieve profitability.

We have financed our operations to date through equity financings, debt financings and the issuance of convertible notes. As of December 31, 2013, we had \$80.5 million in cash and cash equivalents. In February 2012, we entered into the \$60.0 million Senior Secured Loan. Under the terms of the Senior Secured Loan, the outstanding principal was to accrue interest until maturity in January 2017 at a rate of 17% per annum, payable quarterly unless repaid earlier. The Senior Secured Loan allowed us to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt. We could prepay the loan at any time, subject to certain prepayment premiums. In connection with the Senior Secured Loan, we also issued warrants to the lenders to purchase up to an aggregate of approximately 3,277,191 shares of our common stock at an exercise price of \$0.01 per share, all of which have been exercised. The Senior Secured Loan was secured by a lien covering substantially all of our assets including intellectual property in addition to a pledge of all of our equity interests in Horizon Pharma USA, Inc. and 65% of our equity interests in Horizon Pharma AG.

During 2012, we elected to pay the 12% interest in cash, and the remaining 5% interest due of \$1.8 million was added to the principal loan balance as payment in kind borrowing. During 2013, we again elected to pay 12% interest in cash, and the remaining 5% interest due of \$3.0 million was added to the principal loan balance as payment in kind borrowing.

In September 2012, we and the lenders entered into an amendment of the Senior Secured Loan, or the Senior Secured Loan Amendment, whereby certain affirmative covenants under the Senior Secured Loan relating to minimum levels of liquidity and net revenue were modified. In lieu of paying a cash fee in consideration for entering into the Senior Secured Loan Amendment, we agreed to issue an aggregate of 1,250,000 shares of our common stock to the lenders.

Beginning in April 2013, and for each quarter thereafter, the lenders had the option to require us to repay \$4.0 million of the loan principal. In March 2013, one of the lenders notified us of its election to request a partial repayment of the loan principal, effective on the April 1, 2013 interest payment date and for each payment thereafter unless written notice was provided to us. In March 2013 and June 2013, a second lender notified us of its election to request a partial repayment of the loan principal, effective on the April 1, 2013 and July 1, 2013 interest payment dates, respectively. Accordingly, on April 1, 2013, we made a payment of \$5.8 million, which consisted of \$4.0 million in principal and \$1.8 million in interest. Additionally, on July 1, 2013, we made a payment of \$5.8 million, which consisted of \$4.0 million in principal and \$1.8 million in interest. In September 2013, we were notified by the first lender mentioned above of its election to rescind its on-going request of a partial repayment of the loan principal, effective starting with the fourth quarter of 2013.

On November 22, 2013, in connection with the closing of our offering of \$150.0 million aggregate principal amount of Convertible Senior Notes, as more fully described below, we used \$70.4 million of the proceeds to repay the Senior Secured Loan. As a result of the extinguishment of the Senior Secured Loan, we incurred a \$26.4 million loss on debt extinguishment from the write-off of the remaining debt discount and deferred financing costs, pre-payment penalty, interest and end of loan fees.

On November 18, 2013, we entered into note purchase agreements with investors to issue \$150.0 million aggregate principal amount of Convertible Senior Notes. The note purchase agreements contain customary

---

**Table of Contents**

representations, warranties, covenants and closing conditions. The Convertible Senior Notes were issued on November 22, 2013. We received net proceeds of \$124.9 million from the sale of the Convertible Senior Notes, after deducting fees and expenses of approximately \$6.4 million and \$18.7 million related to a capped call transaction. The Convertible Senior Notes are governed by an Indenture, dated as of November 22, 2013, between us and U.S. Bank National Association, as trustee. The Convertible Senior Notes bear interest at a rate of 5.00% per year, payable in arrears on May 15 and November 15 of each year, beginning on May 15, 2014. The Convertible Senior Notes will mature on November 15, 2018, unless earlier repurchased or converted. The Convertible Senior Notes were sold at a price equal to 100% of the principal amount thereof and 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 common stock or a combination of cash and shares of our common stock, at our election. If we undergo a fundamental change prior to the maturity date of the Convertible Senior Notes, the holders may require us to repurchase for cash all or any portion of their Convertible Senior Notes at a price equal to 100% of the principal amount of the Convertible Senior Notes to be repurchased, plus accrued and unpaid interest.

The conversion rate for the Convertible Senior Notes will initially be 186.4280 shares of common stock per \$1,000 principal amount of Convertible Senior Notes (equivalent to an initial conversion price of approximately \$5.36 per share of common stock); provided that unless and until we obtain stockholder approval to issue more than 13,164,951 shares of our common stock, which is 19.99% of our common stock outstanding on November 18, 2013, upon conversion of the Convertible Senior Notes in accordance with the listing standards of The NASDAQ Global Market, the number of shares of common stock deliverable upon conversion will be subject to a conversion share cap. Unless and until such stockholder approval is obtained, we are required to settle conversions of the Convertible Senior Notes in cash up to their principal amount, shares for any conversion spread, and, if the number of shares deliverable for the conversion spread exceeds the conversion share cap, cash in lieu of shares that would otherwise be deliverable. The conversion rate of the Convertible Senior Notes, and the corresponding conversion price, is subject to adjustment for certain events, but will not be adjusted for accrued and unpaid interest.

Additionally, pursuant to a number of factors outlined in FASB Accounting Standards Codification Topic 815 *Derivatives and Hedging*, or ASC Topic 815, the conversion option in the Convertible Senior Notes was deemed an embedded derivative that required bifurcation and separate accounting. As such, we ascertained the value of the conversion option as if separate from the convertible issuance and appropriately recorded that value as a derivative liability. Accordingly, a derivative liability and a corresponding debt discount in the amount of \$40.1 million were recorded at November 22, 2013. The debt discount will be charged to interest expense ratably over the life of the convertible debt.

The derivative liability will be subject to revaluation on a quarterly basis to reflect the market value change of the embedded conversion option. At December 31, 2013, we conducted a fair value assessment to ascertain the market value of the embedded derivative. Due primarily to changes in our common stock value, we recorded a \$69.3 million expense in our results of operations for the three and twelve months ended December 31, 2013 to properly reflect the fair value of the embedded derivative at \$109.4 million as of December 31, 2013.

In August 2012, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may sell common stock in at-the-market, or ATM, offerings under our registration statement on Form S-3, which became effective on August 9, 2012. Subject to the terms and conditions of the sales agreement, Cowen will use its commercially reasonable efforts to sell on our behalf any shares of common stock requested to be sold by us. Cowen and we each have the right, by giving written notice as specified in the sales agreement, to terminate the sales agreement in each party's sole discretion at any time. The aggregate compensation payable

**Table of Contents**

to Cowen as sales agent will not exceed 3.0% of the gross sales price of the shares sold through it pursuant to the sales agreement. On March 25, 2013, we requested that Cowen begin to make sales under the sales agreement and provided them both daily volume and minimum price restrictions under which they could sell our common stock. Cowen has not sold shares under the ATM since July 2013 and 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.

We are required to maintain compliance with applicable Swiss laws with respect to our Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. We review on a regular basis whether our Swiss subsidiary is overindebted. As of December 31, 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. As of December 31, 2013, Horizon Pharma AG had \$3.5 million in cash and cash equivalents. Based upon the cash and cash equivalents held by our Swiss subsidiary as of December 31, 2013 and its level of overindebtedness at such time, we do not expect that our financial position or results of operations will be materially affected by any need to address overindebtedness at our Swiss subsidiary. To date, the overindebtedness of our Swiss subsidiary has not resulted in the need to divert material cash resources from our U.S. subsidiary.

The following table provides a summary of our cash position and cash flows for the years ended December 31, 2013, 2012 and 2011, as follows (in thousands):

	<b>For the Years Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Cash and cash equivalents	\$ 80,480	\$ 104,087	\$ 17,966
Cash (used in) provided by:			
Operating activities	(52,287)	(76,641)	(41,540)
Investing activities	(36,135)	(1,386)	(2,154)
Financing activities	66,716	164,308	55,152

*Net Cash Used in Operating Activities*

During the years ended December 31, 2013, 2012 and 2011, net cash used in operating activities was \$52.3 million, \$76.6 million and \$41.5 million, respectively. The decrease in net cash used in operating activities during 2013 compared to 2012 was primarily attributable to an increase in cash flows associated with higher product sales and gross margins of DUEXIS and RAYOS during the year ended December 31, 2013, which was partially offset by additional cash used in operating activities related to increases in our working capital requirements, such as for accounts receivable and inventories due to our increased product sales.

Net cash used in operating activities during 2012 was primarily attributable to staffing our sales and marketing organization and expenses related to our product launches of DUEXIS and RAYOS. Additionally, cash used in operating activities during 2012 was for interest payments made on our Secured Senior Loan, additional staffing of support and administrative functions and for working capital purposes.

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

---

**Table of Contents**

*Net Cash (Used in) Provided by Investing Activities*

During the years ended December 31, 2013, 2012 and 2011, net cash used in investing activities was \$36.1 million, \$1.4 million and \$2.2 million, respectively. Net cash used in investing activities during 2013 was primarily attributable to our asset purchase agreement with AstraZeneca in November 2013, in which we paid \$35.0 million to acquire from AstraZeneca and its affiliates certain intellectual property and other assets related to U.S. rights to VIMOVO. Additionally, \$1.2 million of cash used in investing activities in 2013 was used for capital expenditures related to computer hardware and equipment purchases for the additional staffing of our sales function.

Net cash used in investing activities during 2012 and 2011 was primarily attributable to capital expenditures for computer hardware and equipment to support our sales and administrative functions. Additionally, during the year ended December 31, 2011, we were required to make restricted cash deposits of \$0.6 million for our new corporate facility lease and our company-sponsored employee credit card program.

*Net Cash Provided by Financing Activities*

During the years ended December 31, 2013, 2012 and 2011, net cash provided by activities was \$66.7 million, \$164.3 million and \$55.2 million, respectively. Net cash provided by financing activities in 2013 was primarily attributable to proceeds from the Convertible Senior Notes, net of issuance costs, partially offset by principal debt payments and the extinguishment of our Senior Secured Loan. In connection with our acquisition of the U.S. rights to VIMOVO, we issued \$150.0 million aggregate principal amount of Convertible Senior Notes and received net proceeds of \$143.6 million from the sale of the Convertible Senior Notes, after deducting fees and expenses of approximately \$6.4 million. In addition, we used \$18.7 million of the net proceeds to purchase capped calls and used \$70.4 million of the net proceeds to repay all obligations under our Senior Secured Loan. During the year ended December 31, 2013, we sold 2,448,575 shares of our common stock through ATM offerings for gross proceeds of \$6.2 million and net proceeds of \$6.0 million, after deducting \$0.2 million in commissions and other issuance costs.

Net cash provided by financing activities in 2012 was primarily the result of our debt refinancing and the equity offerings we completed. In February, we entered into our \$60.0 million Senior Secured Loan with a group of institutional lenders. As part of the closing of the Senior Secured Loan, we repaid outstanding principal under previous borrowings totaling \$19.8 million. In March 2012, we received gross proceeds of \$50.8 million and net proceeds of \$47.5 million, after deducting \$3.3 million in issuance costs, from the sale of 14,033,829 shares of our common stock and warrants to purchase an aggregate of 3,508,448 shares of our common stock to certain institutional and accredited investors in a private equity placement. In September 2012, we received gross proceeds of \$86.2 million and net proceeds of \$80.6 million after deducting \$5.6 million in issuance costs from the sale of 24,638,750 shares of common stock and warrants to purchase an aggregate of 12,319,375 shares of common stock to certain institutional and accredited investors in a public offering.

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

**Table of Contents***Contractual Obligations*

As of December 31, 2013, minimum future cash payments due under contractual obligations, including, among others, our Convertible Senior Notes, minimum purchase agreements and non-cancelable operating lease agreements, were as follows (in thousands including notes):

	2014	2015	2016	2017	2018	2019 & Thereafter	Total
Convertible Senior Notes (1)	\$ 7,372	\$ 7,500	\$ 7,500	\$ 7,500	\$ 157,500	\$	\$ 187,372
Purchase commitments (2)(3)(4)	12,174	1,151	1,117				14,442
Operating lease obligations (5)	681	662	624	623	341		2,931
Total contractual cash obligations	\$ 20,227	\$ 9,313	\$ 9,241	\$ 8,123	\$ 157,841	\$	\$ 204,745

- (1) Represents the minimum contractual obligation due under our \$150,000 Convertible Senior Notes, which includes quarterly interest payments beginning in May 2014 and repayment of the Convertible Senior Notes principal in November 2018.
- (2) Minimum purchase commitment for RAYOS/LODOTRA tablets from Jagotec through December 31, 2016 (the end of the minimum term), which is the firm commitment term under the contract.
- (3) Purchase commitment of \$6,614 for final packaged DUEXIS tablets from sanofi-aventis U.S. through February 2014.
- (4) Minimum purchase commitment for VIMOVO tablets from AstraZeneca through July 2014.
- (5) These amounts reflect payments due under the following operating leases:

Lease agreement for our corporate headquarters in Deerfield, Illinois with a lease term from December 1, 2011 to June 30, 2018, at the minimum rent of approximately \$30 per month during the first year, which will increase each year during the initial term, up to approximately \$35 per month after the sixth year. We have the option to extend the lease for an additional five-year term, which would commence upon the expiration of the initial term. In addition, includes a lease agreement entered in August 2012 and December 2013 for additional office space at our corporate headquarters. The August 2012 lease agreement requires initial rent of approximately \$7 per month during the first year and will increase each year during the initial term, up to approximately \$8 per month after the sixth year and expires in June 2018. The December 2013 lease agreement requires initial rent of approximately \$12 per month and will increase up to a maximum of \$14 per month after the fifth year.

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

Vehicle leases at our Reinach, Switzerland and Mannheim, Germany offices. As of December 31, 2013, payments of \$39, \$36, and \$17 are due in years 2014, 2015 and 2016, respectively.

**Off-Balance Sheet Arrangements**

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities, other than the indemnification agreements discussed in Note 12, *Commitments and Contingencies* in the consolidated financial statements included in this report.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

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



---

## **Table of Contents**

*Interest Rate Risk.* We are subject to interest rate fluctuation exposure through our investment in money market accounts which bear a variable interest rate. The goals of our investment policy are associated with the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market risk, we maintain our excess cash and cash equivalents in money market funds. Because of the short-term maturities of our cash equivalents, we do not believe that a decrease in interest rates would have any material negative impact on the fair value of our cash equivalents.

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

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

*Credit Risk.* Historically, our accounts receivable balances have been highly concentrated with a select number of customers, consisting primarily of large wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. For the year ended December 31, 2013, our top five customers, AmerisourceBergen, McKesson Corporation, Cardinal Health, Inc., Mundipharma and Rochester Drug Company, accounted for approximately 89% of total consolidated gross sales. For the year ended December 31, 2012, our top three customers, Mundipharma, McKesson Corporation and Cardinal Health, Inc., accounted for approximately 83% of total consolidated gross sales.

In addition, four customers, McKesson Corporation, AmerisourceBergen, Rochester Drug Company and Cardinal Health, Inc., accounted for approximately 85% of our total outstanding accounts receivable balances at December 31, 2013. As of December 31, 2012, three customers, Cardinal Health, Inc., Walgreen Company and McKesson Corporation, accounted for approximately 77% of our total outstanding accounts receivable balances. Historically, we have not experienced any losses related to our accounts receivable balances.

### **Item 8. Financial Statements and Supplementary Data**

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

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

None.

### **Item 9A. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

Our Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act), have concluded that, as of December 31, 2013, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that

**Table of Contents**

information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive officer or officers and principal financial officer or officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

**Management Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance to management and our board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2013. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control Integrated Framework (1992)*. Based on its assessment, management believes that, as of December 31, 2013, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2013 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) promulgated under the Exchange Act) identified in connection with the evaluation required by Rule 13a-15(d) promulgated under the Exchange Act that occurred during the fiscal quarter ended December 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

**PART III****Item 10. Directors, Executive Officers and Corporate Governance****Directors and Executive Officers**

The following table sets forth information regarding our directors and executive officers as of March 11, 2014:

<b>Name</b>	<b>Age</b>	<b>Position with the Company</b>
<b>Directors</b>		
Timothy P. Walbert	46	President, Chief Executive Officer and Chairman of the board of directors
Jeffrey W. Bird, M.D., Ph.D. (3)	53	Director
Jean-François Formela, M.D. (3)	57	Director
Michael Grey (1,2)	61	Lead Independent Director
Jeff Himawan, Ph.D. (2)	49	Director
Ronald Pauli (1,2)	53	Director
Gino Santini (1,3)	57	Director

**Table of Contents**

Name	Age	Position with the Company
<b>Executive Officers (other than Mr. Walbert)</b>		
Robert F. Carey	55	Executive Vice President, Chief Business Officer
Robert J. De Vaere	56	Executive Vice President, Chief Financial Officer
Jeffrey W. Sherman, M.D., FACP	59	Executive Vice President, Development, Manufacturing and Regulatory Affairs,
		Chief Medical Officer
Todd N. Smith	44	Executive Vice President, Chief Commercial Officer

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

*Directors*

**Timothy P. Walbert.** Mr. Walbert has served as chairman of our board of directors and our president and chief executive officer since our inception in March 2010. Mr. Walbert has also served as the president and chief executive officer of Horizon Pharma USA since June 2008 and on its board of directors since July 2008. From May 2007 to June 2009, Mr. Walbert served as president, chief executive officer and director of IDM Pharma, Inc., or IDM, a biopharmaceutical company which was acquired by Takeda America Holdings, Inc., or Takeda, in June 2009. From January 2006 to May 2007, Mr. Walbert served as executive vice president, commercial operations of NeoPharm, Inc., a biopharmaceutical company. From June 2001 to August 2005, Mr. Walbert served as divisional vice president and general manager, Immunology, where he led the global development and launch of HUMIRA, which exceeded \$9.0 billion in 2012 sales, and divisional vice president, global cardiovascular strategy at Abbott, a broad-based healthcare company, now AbbVie. From April 1998 to June 2001, Mr. Walbert served as director, Celebrex North America and arthritis team leader, Asia Pacific, Latin America and Canada at G.D. Searle & Company, or G.D. Searle, a pharmaceutical company. From 1991 to 1998, Mr. Walbert also held sales and marketing roles with increasing responsibility at G.D. Searle, Merck & Co., Inc. and Wyeth. Mr. Walbert received his B.A. in business from Muhlenberg College, in Allentown, Pennsylvania. Mr. Walbert also serves on the board of directors of XOMA Ltd. (NASDAQ: XOMA), Raptor Pharmaceutical Corp. (NASDAQ: RPTP), Egalet Corporation (NASDAQ: EGLT), the Biotechnology Industry Organization (BIO), the Illinois Biotechnology Industry Organization (iBIO), ChicagoNEXT, a World Business Chicago (WBC) led council of technology leaders and the Greater Chicago Arthritis Foundation. Our board believes that Mr. Walbert's business expertise, including his prior executive level leadership, give him the operational expertise, breadth of knowledge and valuable understanding of our industry, which qualify him to serve as a director and to lead our board as chairman.

**Jeffrey W. Bird, M.D., Ph.D.** Dr. Bird has served on our board of directors since our inception in March 2010 and has served on the board of directors of Horizon Pharma USA since July 2007. Dr. Bird has been a managing director of the general partner of Sutter Hill Ventures, a California Limited Partnership, a venture capital firm, since July 2003, and CEO of Verinata Health since May 2012. Dr. Bird also serves on the boards of directors of Artemis Health, Inc., Drais Pharmaceuticals, Inc., NuGen Technologies, Inc., Portola Pharmaceuticals, Inc., Restoration Robotics, Inc., Threshold Pharmaceuticals, Inc. and ViroBay, Inc. From 1988 to 1990 and from 1992 to 2000, Dr. Bird served as a Senior Vice President, Business Operations at Gilead Sciences, Inc., a biopharmaceutical company, where he oversaw business development and commercial activities. Dr. Bird received his B.S. in biological sciences from Stanford University and his doctorate in cancer biology and M.D. from Stanford Medical School. Our board believes that Dr. Bird's drug development and commercialization expertise and experience as a successful venture capitalist will bring important strategic insight and drug commercialization expertise to our board, as well as provide experience working with the investment community.

**Table of Contents**

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

**Michael Grey.** Mr. Grey has served on our board of directors since September 2011 and as our lead independent director since August 2012. Mr. Grey currently serves as president and chief executive officer at Lumena Pharmaceuticals, Inc. and is a venture partner at Pappas Ventures. Mr. Grey holds over 30 years of experience in the pharmaceutical and biotechnology industries, and has held senior positions at a number of companies, including president and chief executive officer of SGX Pharmaceuticals, Inc., which was acquired by Eli Lilly in 2008, president and chief executive officer of Trega Biosciences, Inc., which was acquired by Lion Bioscience in 2001, and president of BioChem Therapeutic Inc. For approximately 20 years, Mr. Grey served in various roles with Glaxo, Inc. and Glaxo Holdings, P.L.C., culminating in his position as vice president, corporate development and director of international licensing. Mr. Grey also serves on the board of directors of BioMarin Pharmaceutical Inc. and Selventa, Inc. Mr. Grey received a B.S. in chemistry from the University of Nottingham in the United Kingdom. Our board believes that Mr. Grey's extensive experience managing pharmaceutical and biopharmaceutical companies will bring important strategic insight to our board as we plan Horizon's future growth.

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

**Ronald Pauli.** Mr. Pauli has served on our board of directors since September 2011. Mr. Pauli is currently a financial consultant for the pharmaceutical and life science industries. Prior to that, Mr. Pauli held senior positions at a number of biopharmaceutical companies, including chief financial officer at Sagent Pharmaceuticals, Inc. and NeoPharm, Inc. and corporate controller and interim chief financial officer at Abraxis BioScience, Inc. (formerly American Pharmaceutical Partners, Inc.). In addition, Mr. Pauli previously served as corporate controller for Applied Power, Inc. and R.P. Scherer Corporation, held multiple finance positions at Kmart Corporation and began his career at Ernst & Whinney. Mr. Pauli received a B.S. in accounting from Michigan State University and a master's degree in finance from Walsh College. Our board believes that Mr. Pauli's financial experience at numerous biotechnology and pharmaceutical companies will add valuable expertise in guiding the strategic direction of the company and working with the investment community.

**Table of Contents**

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

*Executive Officers (other than Mr. Walbert)*

**Robert F. Carey.** Mr. Carey has served as our executive vice president and chief business officer since March 2014. Prior to joining Horizon, Mr. Carey spent more than 11 years as managing director and head of the life sciences investment banking group at JMP Securities LLC, a full-service investment bank. Prior to JMP, Mr. Carey was a managing director in the healthcare groups at Dresdner Kleinwort Wasserstein and Vector Securities. Mr. Carey also has held roles at Red Hen Bread, InStadium, Shearson Lehman Hutton and Ernst & Whinney. Mr. Carey received his B.S. in accounting from the University of Notre Dame.

**Robert J. De Vaere.** Mr. De Vaere has served as our executive vice president and chief financial officer since our inception in March 2010 and as the executive vice president and chief financial officer of Horizon Pharma USA since October 2008. From May 2007 to June 2009, Mr. De Vaere served as senior vice president, finance and administration and chief financial officer at IDM, which was acquired by Takeda in 2009. From August 2006 to April 2007, Mr. De Vaere served as chief financial officer at Nexa Orthopedics, Inc., a medical device company, which was acquired by Tornier, Inc. in February 2007. From August 2005 to March 2006, Mr. De Vaere served as vice president, finance and administration and chief financial officer at IDM. From May 2000 to August 2005, Mr. De Vaere served as vice president and chief financial officer at Epimmune Incorporated, a pharmaceutical company focused on the development of vaccines, which was combined with IDM in August 2005. Prior to 2000, Mr. De Vaere served as vice president of finance and administration and chief financial officer at Vista Medical Technologies, Inc., a medical device company. Mr. De Vaere received his B.S. from the University of California, Los Angeles.

**Jeffrey W. Sherman, M.D., FACP.** Dr. Sherman has served as our executive vice president, development, manufacturing and regulatory affairs and chief medical officer since June 2011, as our executive vice president, development and regulatory affairs and chief medical officer since our inception in March 2010 and as the executive vice president, development and regulatory affairs and chief medical officer of Horizon Pharma USA since June 2009. From June 2009 to June 2010, Dr. Sherman served as president and board member of the Drug Information Association, or DIA, a nonprofit professional association of members who work in government regulatory, academia, patient advocacy, and the pharmaceutical and medical device industry. Dr. Sherman is now a past president of DIA and serves as DIA liaison to the Clinical Trial Transformation Initiative, a public-private partnership founded by the FDA and Duke University to improve the quality and efficiency of clinical trials. He also serves on the Board of Advisors of the Center for Information and Study on Clinical Research Participation, a nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process. Dr. Sherman is an adjunct assistant professor of Medicine at the Northwestern University Feinberg School of Medicine and is a member of a number of professional societies as well as a diplomat of the National Board of Medical Examiners and the American Board of Internal Medicine. From August 2007 to June 2009, Dr. Sherman served as senior vice president of research and development and chief medical officer at IDM which was acquired by Takeda in 2009. From June 2007 to August 2007, Dr. Sherman served as vice president of clinical science at Takeda, a pharmaceutical research and development center. From September 2000 to June 2007,

---

## **Table of Contents**

Dr. Sherman served as chief medical officer and executive vice president at NeoPharm, Inc., a biopharmaceutical company. From October 1992 to August 2000, Dr. Sherman served as director, senior director and executive director of clinical research and head of oncology global medical operations at Searle/Pharmacia, or Searle, a pharmaceutical company. Prior to joining Searle, Dr. Sherman worked in clinical pharmacology and clinical research at Bristol-Myers Squibb Company, a biopharmaceutical company. Dr. Sherman received his M.D. from the Rosalind Franklin University/Chicago Medical School. Dr. Sherman completed an internal medicine internship, residency and chief medical residency at Northwestern University as well as fellowship training at the University of California, San Francisco, or UCSF. Dr. Sherman was also a research associate at the Howard Hughes Medical Institute at UCSF.

**Todd N. Smith.** Mr. Smith has served as our executive vice president and chief commercial officer since February 2012. Prior to that, Mr. Smith served as our senior vice president, sales, marketing and business development of Horizon Pharma USA since October 1, 2010. From January 2009 to August 2010, Mr. Smith served as vice president, global marketing, strategy and business development at Fenwal, Inc., a global medical device technology company, and managed a team of approximately 100 people located in the United States and abroad. Mr. Smith also served as vice president of automated business from May 2008 to January 2009, and amicus category business unit director from November 2007 to May 2008 at Fenwal. From April 2006 to November 2007, Mr. Smith served as director of marketing, virology franchise, at Abbott, now AbbVie, and managed marketing and field teams of approximately 85 people. From March 2004 to April 2006, Mr. Smith served as director of sales, virology franchise, at Abbott Laboratories managing a sales and training team of approximately 200 people. From April 2003 to April 2004, Mr. Smith served as deputy director product management, segment markets and managed care, at Bayer Biological Products, a pharmaceutical company. At Bayer Biological Products, Mr. Smith also served as associate director of coagulation products from April 2002 to April 2003. From April 2001 to April 2002, Mr. Smith served as associate director of business development at Achillion Pharmaceuticals, Inc., a biopharmaceutical company focused on infectious disease. Prior to April 2001, Mr. Smith served as a regional sales manager, product manager and sales specialist at Agouron Pharmaceuticals, Inc., a pharmaceutical company, which was acquired by Pfizer Inc. in February 2000. Mr. Smith received his B.A. from Norwich University.

## **Board Composition**

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

Class I, which consists of Mr. Grey and Mr. Pauli, and whose term will expire at our 2015 annual meeting of stockholders;

Class II, which consists of Dr. Formela and Dr. Himawan, and whose term will expire at our 2016 annual meeting of stockholders;  
and

Class III, which consists of Dr. Bird, Mr. Santini and Mr. Walbert, and whose term will expire at our 2014 annual meeting of stockholders.

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

## **Table of Contents**

### **Director Independence**

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

### **Role of the Board in Risk Oversight**

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

### **Board Committees**

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

### **Audit Committee**

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

evaluating the performance, independence and qualifications of our independent registered public accounting firm and determining whether to retain our existing independent registered public accounting firm or engage a new independent registered public accounting firm;

reviewing and approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;

monitoring the rotation of partners of our independent registered public accounting firm on our engagement team as required by law;

reviewing our annual and quarterly financial statements and reports and discussing the statements and reports with our independent registered public accounting firm and management;

reviewing with our independent registered public accounting firm and management significant issues that arise regarding accounting principles and financial statement presentation, and matters concerning the scope, adequacy and effectiveness of our financial controls;

## Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

reviewing with management any earnings announcements and other public announcements regarding material developments;

establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;

## **Table of Contents**

preparing the report that the SEC requires in our annual proxy statement;

reviewing and providing oversight with respect to any related party transactions and monitoring compliance with our code of business conduct and ethics;

reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;

reviewing our investment policy on a periodic basis; and

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

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

## **Compensation Committee**

Our compensation committee consists of Mr. Pauli, Mr. Grey and Dr. Himawan, with Dr. Himawan serving as the chair of the compensation committee. Each member of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the IRC, and satisfies the NASDAQ independence requirements. The functions of this committee include, among other things:

reviewing and recommending to our board of directors the compensation and other terms of employment of our executive officers;

reviewing and recommending to our board of directors performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;

evaluating and approving the equity incentive plans, compensation plans and similar programs advisable for us, as well as modification or termination of existing plans and programs;

evaluating and recommending to our board of directors the type and amount of compensation to be paid or awarded to non-employee board members;

administering our equity incentive plans;

establishing policies with respect to equity compensation arrangements;

reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;

Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

reviewing and recommending to our board of directors the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;

reviewing with management our disclosures under the caption "Compensation Discussion and Analysis" and recommending to the full board its inclusion in our periodic reports to be filed with the SEC;

preparing the report that the SEC requires in our annual proxy statement;

reviewing the adequacy of our compensation committee charter on a periodic basis;

## **Table of Contents**

reviewing and evaluating, at least annually, the performance of the compensation committee; and

evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us.

### **Business Development Committee**

Our business development committee consists of Mr. Grey, Dr. Himawan, Mr. Santini and Mr. Walbert, with Mr. Grey serving as the chair of the business development committee. Our board of directors has determined that each of the members of this committee, with the exception of Mr. Walbert, satisfies the NASDAQ independence requirements. The functions of this committee include, among other things:

reviewing proposed product or business acquisitions, licensing, distribution, promotion, collaboration and other commercial agreements and arrangements, joint ventures, and any other business development transactions;

monitoring negotiations and other communications with third parties in connection with potential business development transactions;

considering historical and current information regarding our business, prospects, financial condition, operations, capabilities, products, management, advisors, competitive position and industry, and how these factors may affect business development opportunities;

considering general economic, industry and financial market conditions and trends, and how these factors may affect business development opportunities;

meeting with management to identify and develop board focus on issues that will further our business development strategy; and

periodically reviewing and evaluating prior transactions for consistency with, and achievement of, our strategic business goals, objectives or plans.

### **Nominating and Corporate Governance Committee**

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

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

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

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

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

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

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

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

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

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

## **Table of Contents**

### **Section 16(a) Beneficial Ownership Reporting Compliance**

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

Based solely on our review of the copies of such forms received and the written representations from certain reporting persons, we have determined that no officer, director or 10% beneficial owner known to us was delinquent with respect to their reporting obligations as set forth in Section 16(a) of the Exchange Act during the fiscal year ended December 31, 2013.

### **Code of Ethics**

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

### **Item 11. Executive Compensation**

#### **Compensation Discussion and Analysis**

##### *Overview*

This Compensation Discussion and Analysis discusses the compensation philosophy, policies and principles underlying our executive compensation decisions for the 2013 fiscal year and those we made in January 2014. It provides qualitative information on the factors relevant to these decisions and the manner in which compensation is awarded to our executive officers who have been named in the Summary Compensation Table included in this Item 11 and whom we refer to as our named executive officers.

Our board of directors has delegated responsibility for creating, reviewing and making recommendations regarding the compensation of our executive officers to the compensation committee of our board of directors, which is composed of independent directors under SEC regulations and the NASDAQ Listing Rules. The role of the compensation committee is to oversee our compensation and benefit plans and policies, to administer our equity incentive plans and to annually review and make recommendations to our board of directors who approve all compensation decisions relating to our executive officers.

Consideration of Stockholder Advisory Votes. Our say-on-pay vote held at our 2013 annual meeting of stockholders was supported by 93.5% of the votes affirmatively cast, excluding abstentions and broker non votes. While this vote was only advisory, our compensation committee interpreted it to be a very positive affirmation from our stockholders that they strongly endorse our historical compensation philosophy, policies and decisions. Accordingly, the compensation committee determined to not make any significant changes in how it went about reviewing and setting compensation levels for our executives. When determining how often to hold an advisory vote on executive compensation, the board recommended and our stockholders agreed upon, an annual vote. In addition to holding an annual advisory vote on executive compensation, we are committed to ongoing engagement with our stockholders on executive compensation and corporate governance issues.

## **Table of Contents**

### **2013 Performance Highlights and Executive Summary**

We had strong corporate performance during 2013, including:

Total stockholder return of 227%.

Total annual net revenues increased from \$18.8 to \$74.0.

Total prescriptions for DUEXIS® increased 128% over 2012 to 214,690.

Total prescriptions for RAYOS® were 8,987 in its first full year of launch.

Executed the initial launch of RAYOS®.

We completed the acquisition of the U.S. rights to VIMOVO from AstraZeneca.

Our cash and cash equivalents at December 31, 2013 were approximately \$80.5 million.

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

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

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

**Responsible Severance and Change in Control Compensation.** Our executive employment agreements and our Severance Benefit Plan, in all cases require an involuntary or constructive termination of employment for our named executive officers to be eligible for any non-change of control related severance benefits or change of control related severance benefits. The severance benefits are less than two times the annual base salary of our named executive officers, other than for our chief executive officer, who as a result of changes approved by our board of directors in January 2014 would receive in a change in control related termination two times the sum of his annual base salary and target bonus, plus twelve months of COBRA premiums. We do not provide any tax gross-ups for any severance or change in control benefits.

#### *Compensation Objectives*

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

## Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

compensation programs are designed to achieve the following objectives:

attract and retain talented and experienced executives to manage our business to meet our long-term objectives;

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

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

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

reward the achievement of key corporate and individual performance measures.

**Table of Contents**

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

*Setting Executive Compensation*

The compensation committee reviews and determines generally on an annual basis the compensation to be paid to our chief executive officer and other executive officers. As part of this process, we conduct an annual review of the aggregate level of our executive compensation, the mix of elements used to compensate our executive officers and of historic compensation levels, including prior equity award gains and losses.

When setting executive compensation, the compensation committee generally considers compensation paid by life sciences companies included in the Radford Global Life Sciences Survey, together with other information made available to it such as compensation analysis performed by independent, third party compensation specialists. The compensation committee generally believes that gathering this information is an important part of our compensation-related decision-making process and typically provides additional context and validation for our executive compensation decisions. Although our compensation committee has used this survey data as a tool in determining executive compensation, it typically has not used a formula to set our executives' compensation in relation to this survey data. In addition, our compensation committee has typically taken into account advice from other non-employee members of our board of directors and publicly available data relating to the compensation practices and policies of other companies within and outside our industry.

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

Our compensation committee retains the services of third-party executive compensation specialists and consultants from time to time, as it sees fit, in connection with the establishment of cash and equity compensation and related policies. In 2012 and again in 2013, we engaged Compensia Inc., an executive compensation specialist to analyze our executive compensation practices against the practices of an industry peer group of twenty-two pharmaceutical companies with similar market capitalizations, number of employees and revenue levels. The following table shows the companies that made up our benchmark peer group. These peer group companies have market capitalization ranging from approximately \$176 million to \$1.4 billion, as compared to our current market capitalization of approximately \$900 million at March 11, 2014.

<b>Peer Group</b>	
Acorda Therapeutics	Neurocrine Biosciences
AMAG Pharmaceuticals	Orexigen Therapeutics
Antares Pharma	Pacira Pharmaceuticals
Arena Pharmaceuticals	Progenics Pharmaceutical
Auxillium Pharma	Sangamo Biosciences
Avanir Pharmaceuticals	Spectrum Pharmaceuticals
BioDelivery Sciences	Sucampo Pharmaceuticals
Cadence Pharmaceuticals	Supernus Pharmaceuticals
Corcept Therapeutics	Synta Pharmaceuticals
Depomed	Vanda Pharmaceuticals
Dyax	VIVUS
INSYS Therapeutics	Zogenix
Ironwood Pharmaceuticals	

## **Table of Contents**

Compensia Inc. was engaged in 2013 to analyze and present competitive ongoing market base salaries, discretionary annual bonuses, and long-term incentive grant practices provided by these peer group companies with respect to their employees, including executive management.

### *Benchmarking*

In December 2013, our compensation committee reviewed our compensation philosophy. The philosophy is to attract and retain top talent with experience in building and leading a successful specialty pharmaceutical organization, provide competitive compensation and benefits opportunities that motivate appropriate risk taking to achieve success, clearly communicate the drivers of business success to create a sense of urgency and ownership among employees, create a direct, meaningful link between business results, individual performance and rewards to motivate over achievement, to provide flexibility in our compensation plans to allow differentiation for our employees with the highest performance and potential, to create opportunities for equitable pay opportunities for management and high-level individual contributors and to align interests of management, employees and stockholders to set priorities and focus. The overall compensation goal is to target the 50<sup>th</sup> percentile of the total compensation of comparable companies and selectively the 75<sup>th</sup> percentile for employees with the highest performance and potential. In December 2013, our board of directors determined that due to their exceptional performance during 2013, the 2014 compensation of all of our named executive officers would be targeted at the 75<sup>th</sup> percentile of our peer group.

### *Independence of Compensation Consultant*

In September 2013, the compensation committee conducted an independence and performance assessment of Compensia Inc. In conducting the independence assessment, the compensation committee considered the following factors: whether Compensia Inc. provided any other services to us; the amount of fees received by Compensia Inc. from us as a percentage of Compensia Inc.'s total revenues; the policies and procedures of Compensia Inc. that are designed to prevent conflicts of interest; any business or personal relationship of the individual representative of Compensia Inc. who worked directly with the compensation committee; any of our stock owned by the individual representative of Compensia Inc. who worked directly with the compensation committee; and any business or personal relationship of the individual representative of Compensia Inc. who worked directly with the compensation committee, or of Compensia Inc., with any of our executive officers. After conducting this assessment, the compensation committee concluded that the retention of Compensia Inc. did not raise any conflict of interest and that Compensia Inc. has consistently provided valuable advice and services to the compensation committee so that it would continue to retain Compensia Inc. as its independent compensation consultant.

### *Role of Chief Executive Officer in Compensation Decisions*

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

### *Elements of Executive Compensation*

The compensation program for our executive officers consists principally of base salary, annual cash incentive compensation and long-term compensation in the form of equity awards, as well as severance protection for certain of our executive officers through employment agreements with those executive officers and

---

**Table of Contents**

our Severance Benefit Plan. As discussed in more detail below, base salary is based primarily on market factors and annual cash incentive compensation is a target percentage of base salary, with the actual amount awarded determined in the compensation committee's discretion based upon its determination of the level of attainment of performance goals. The amount of cash compensation and the amount of equity awards granted to our executives are both considered in determining total compensation for our executive officers.

Historically, we have not specified a target percentage of the overall compensation to be represented by the various compensation elements. The compensation committee's intention was that performance based cash incentive bonuses and long-term equity compensation should be a significant part of the executive's compensation and historically, it has represented a significant portion of an executive's total pay package, so that approximately 30% to 70% of our executive officers' total potential compensation is at risk. This helps with implementing a culture in which our named executive officers know that their take home pay, to a large extent, depends upon our performance. Employees in more senior roles have an increasing proportion of their potential compensation at risk and tied to performance because they are in a position to have greater influence on our performance results. For example, approximately 70% of our chief executive officer's total potential 2013 compensation was at risk. For purposes of such calculations, with respect to stock unit award values, the value of the underlying shares on the date of grant was used.

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

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

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

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

*Base Salary.* Base salaries for our executives are established based on the scope of their responsibilities, individual experience and market factors. Base salaries are reviewed annually, typically in connection with our annual performance review process. In December 2012, the board of directors approved the 2013 base salaries to align with 2013 market levels as reflected by the Radford survey data after taking into account individual responsibilities, performance and experience, and making a subjective determination as to whether and what extent 2013 base salaries should be increased based upon those factors.

In December 2013, our compensation committee recommended increases to the base salaries for our executive officers, effective January 1, 2014, after a review of the 2013 Radford Global Life Sciences survey data for comparable companies and executive officer positions, executive officer salaries at the peer group companies, and individual and company performance. The compensation committee recommended and the board approved a 3.0% increase to the annual base salary of Mr. De Vaere, Dr. Sherman and Mr. Smith, and a 9.3% increase for Mr. Walbert. These increases were approved in order to align their base salaries with the 75<sup>th</sup> percentile of the peer group companies because our board of directors determined that our named executive officers should be rewarded for our above target performance during 2013 and their individual efforts in contributing to such performance.

**Table of Contents**

The base salaries for each of our named executive officers for 2014, 2013 and 2012 are as follows:

Named Executive Officer	Base Salary		
	2014	2013	2012
Timothy P. Walbert	\$ 644,100	\$ 589,160	\$ 572,000
Robert F. Carey <sup>(1)</sup>	\$ 400,000		
Robert J. De Vaere	\$ 386,168	\$ 374,920	\$ 364,000
Jeffrey W. Sherman	\$ 408,234	\$ 396,340	\$ 384,800
Todd N. Smith	\$ 387,229	\$ 375,950	\$ 365,000
Mike Adatto <sup>(2)</sup>		\$ 304,500	\$ 300,000

(1) Mr. Carey began employment with us on March 5, 2014.

(2) Mr. Adatto terminated employment with us on June 17, 2013.

Mr. Carey began his employment with us on March 5, 2014. Mr. Carey's base salary was set at \$400,000 annually with a bonus target set at 50% of his base salary.

*Annual Cash Incentive Compensation.* In addition to base salaries, we provide performance-based cash bonuses as an incentive for our executives to achieve defined annual corporate goals.

*2013 Incentive Compensation.* For 2013, pursuant to their employment agreements, each executive officer had an established target cash bonus represented as a percentage of base salary as follows: 60% for Mr. Walbert and 40% for Mr. De Vaere, Dr. Sherman and Mr. Smith and 30% for Mr. Adatto. These established target bonus percentages were deemed market competitive based on Radford data at the time of hire of the executive officers and based on then current data. Bonus target percentages are reviewed annually and may be adjusted by the compensation committee in its discretion, although pursuant to the respective employment agreements with Mr. Walbert, Mr. De Vaere, Dr. Sherman and Mr. Smith such percentages may not be reduced without the consent of the executive.

At the beginning of each calendar year, the compensation committee, in consultation with management, determines corporate goals and milestones for the executive officers. At the end of each year, the compensation committee reviews and determines the level of achievement for each corporate goal and milestone. Each of these corporate objectives and milestones are assigned a certain weight and bonus payments are determined based on achievement of the various objectives. Final determinations as to discretionary bonus levels are based in part on the achievement of these corporate goals or milestones, as well as the compensation committee's assessment as to the overall development of our business and corporate accomplishments. These corporate goals and milestones, and the proportional emphasis placed on each goal and milestone will vary over time depending on our overall strategic objectives and stage of development as a company, but relate generally to factors such as achievement of clinical, regulatory, manufacturing, commercialization and sales milestones for products or product candidates, financial factors such as achieving sales and income levels, raising or preserving capital, performance against our operating budget and individual performance.

Actual bonus award levels are determined at the compensation committee's discretion and recommended to the board of directors for approval. At the close of the applicable calendar year, the compensation committee comes to a general, subjective conclusion as to whether the corporate goals were met, whether the executive has performed his duties in a satisfactory manner, and whether there were any other extraordinary factors that should be considered in determining the amount of bonus earned for the year. The compensation committee may decide to pay bonuses to the executive officers even if the specified corporate performance goals are not met, in recognition of the officer's efforts throughout the year in meeting other objectives not contemplated at the beginning of the performance period. In making the final recommendation on the amount of bonuses earned, if any, the compensation committee considers the review of the year-end corporate results as well as the performance of the individual executive officers. In sum, the amount of variable compensation that is actually

---

**Table of Contents**

earned by our named executive officers is a subjective, entirely discretionary, determination made by the compensation committee without the use of pre-determined formulas. The compensation committee believes that maintaining discretion to evaluate our and the executive s performance at the close of the year based on the totality of the circumstances, and to recommend or fail to recommend bonus compensation without reliance on rote calculations under set formulas, is appropriate in responsibly discharging its duties. Payouts of awarded bonuses, if any, are generally made in the year following the year of performance.

The 2013 corporate objectives established by the compensation committee at the beginning of 2013 were:

1. achieve certain specified DUEXIS and RAYOS/LODOTRA sales targets;
2. achieve a certain specified earnings before interest, taxes, depreciation and amortization (EBITDA) target;
3. end the year with a certain specified minimum cash level;
4. achieve certain specified commercial objectives relating to product prescriptions and managed care approval rates; and
5. achieve certain specified business development and alliance management goals.

The compensation committee selected these goals because it believed that they were the best indicators of the achievement of the execution of our operating plan and are the factors that were most critical to increasing the value of our common stock. These goals, therefore, best aligned the financial interests of the named executive officers with those of our stockholders. In December 2013, the board of directors determined that these 2013 corporate objectives had been attained at a level of 125% of the targeted levels.

In December 2013, based on management s recommendations and the compensation committee s own review, deliberation and determination of achievement of the corporate objectives and milestones listed above, along with determination of achievement of personal goals, our compensation committee recommended and our board approved bonus percentages for our named executive officers at 125% of target bonus amount for 2013, which resulted in the awarding of discretionary incentive bonus amounts of \$441,870 for Mr. Walbert (125% of the 60% target), \$198,172 for Dr. Sherman (125% of the 40% target), \$187,460 for Mr. De Vaere (125% of the 40% target) and \$187,975 for Mr. Smith (125% of the 40% target). Payment of the discretionary bonuses was made in January 2014.

In addition to the annual cash incentive bonuses described above, in December 2013 our compensation committee recommended and our board of directors approved a one-time bonus payment related to the completion of the acquisition of the U.S. rights to VIMOVO from AstraZeneca in November 2013. The compensation committee deliberated and determined that the VIMOVO acquisition was a significant value creation event for us and that the executive officers should be compensated separately for their completion of the acquisition. The one-time bonus amounts approved were \$300,000 for Mr. Walbert, \$150,000 for Mr. De Vaere, and \$125,000 for each of Dr. Sherman and Mr. Smith. The compensation committee and the board further determined that the bonus payments should be made in the form of fully vested stock units for a number of shares of our common stock with a value equal to the bonus payment amounts as of the award date, so that the board of directors approved 43,290 stock units for Mr. Walbert; 21,640 stock units for Mr. De Vaere; and 18,037 stock units each for Dr. Sherman and Mr. Smith. Shares of common stock are scheduled to be issued in settlement of the stock units on May 15, 2014.

*2014 Cash Incentive Compensation.* In December 2013, our compensation committee recommended changes to the target cash bonuses for our executive officers, effective for 2014, after a review of the 2013 Radford Global Life Sciences survey data for comparable companies and executive officer positions, and after reviewing executive officer cash incentive compensation at the peer group companies. The compensation committee recommended and the board of directors approved 2014 target cash bonuses expressed as a percentage

**Table of Contents**

of base salary as reflected in the table below. The board of directors approved these increases in target cash bonus percentages for 2014 in order to bring the executive s total target cash compensation to the 75<sup>th</sup> percentile of the peer group.

Named Executive Officer	2013 Target Bonus	2014 Target Bonus
Timothy P. Walbert	60%	70%
Robert F. Carey <sup>(1)</sup>		50%
Robert J. De Vaere	40%	50%
Jeffrey W. Sherman	40%	45%
Todd N. Smith	40%	45%
Mike Adatto <sup>(2)</sup>	30%	

(1) Mr. Carey began employment with us on March 5, 2014.

(2) Mr. Adatto terminated employment with us on June 17, 2013.

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

In January 2013, based on the recommendation of the compensation committee, the board granted restricted stock units covering an aggregate of 273,700 shares of common stock to our named executive officers as part of their overall compensation package. The award level for each of our named executive officers related to the restricted stock unit grants were as follows: 128,700 restricted stock units for Mr. Walbert; 45,000 restricted stock units for Mr. De Vaere and Dr. Sherman; 55,000 restricted stock units for Mr. Smith; and 18,900 restricted stock units granted to Mr. Adatto (who terminated his employment with us in June 2013). These award levels were determined by the compensation committee to be at the 25<sup>th</sup> percentile of the long-term incentive compensation levels provided by our peers, and were made at this level in order to conserve the number of shares available for grant under the share reserve of our equity incentive plan.

In January 2014, based on the recommendation of the compensation committee, the board of directors granted restricted stock units and stock options to our named executive officers as part of their overall compensation package. The restricted stock unit grants were as follows: 198,000 restricted stock units for Mr. Walbert and 62,000 restricted stock units for each of Messrs. De Vaere and Smith and Dr. Sherman. The stock option grants were as follows: 223,000 stock options for Mr. Walbert and 70,000 stock options for each of Messrs. De Vaere and Smith and Dr. Sherman. These equity award levels were determined by the compensation committee to approximate the 75<sup>th</sup> percentile of the long-term incentive compensation levels provided by our peers, and were made at a level exceeding the 50<sup>th</sup> percentile of our peers in order to reward the executives for our above target performance in 2013 as well as compensate for the lower level of equity awards previously granted to the named executive officers in January 2013 due to the limited number of shares available for grant under the equity incentive plan at that time. Subject to continued services, the restricted stock units vest in four equal annual installments, and the options vest in 48 equal monthly installments, in each case commencing January 2, 2014.

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

**Table of Contents**

In January 2014, our compensation committee reviewed severance and change of control benefits of the peer group companies and based on that review, recommended, and the board approved changes to certain of the terms of the severance and change of control benefits for our executive officers. Mr. Walbert, Mr. De Vaere, Dr. Sherman and Mr. Smith each have severance benefit protection under the terms of their employment agreements which provide for up to 12 months' base salary and COBRA health insurance premiums in the event of an involuntary or constructive termination. Mr. Walbert also receives his target annual bonus amount for the preceding year in the event of his involuntary termination. In the event of an involuntary or constructive termination in connection with a change in control, Mr. Walbert has severance benefit protection under the terms of his employment agreements which provide for up to 24 months' base salary, two years of target bonus and 12 months COBRA health insurance premiums, and Mr. De Vaere, Dr. Sherman, and Mr. Smith have severance benefit protection under the terms of their employment agreements which provide for up to 12 months' base salary, one year of target bonus and 12 months COBRA health insurance premiums. In addition, stock option and other equity awards are subject to acceleration under the terms of their employment agreements in the event of a qualifying termination within 90 days prior to or within 18 months following a change in control. Each of Mr. Walbert, Mr. De Vaere, Dr. Sherman and Mr. Smith must enter into a non-competition agreement that is to be effective during the period that the severance benefits are payable.

Our Severance Benefit Plan provides severance benefit protection for executives employed by Horizon Pharma, Inc. and its affiliates that do not have executive employment agreements, for a period of at least three months for vice president level and above. Mr. Adatto was eligible to receive severance benefits under the Severance Benefit Plan, which provided for six months' base salary and COBRA health insurance premiums. In addition, stock option and other equity awards are subject to acceleration in the event of a qualifying termination within 90 days prior to or within 18 months following a change in control.

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

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

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

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

**Table of Contents**

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

**Summary Compensation Table**

The following table provides information regarding the compensation earned during the years ended December 31, 2013, 2012 and 2011 by our Chairman, President and Chief Executive Officer; Executive Vice President and Chief Financial Officer; Executive Vice President, Development, Manufacturing and Regulatory Affairs and Chief Medical Officer; Executive Vice President and Chief Commercial Officer; and former Senior Vice President, Managed Care and Commercial Development, whom we collectively refer to as our named executive officers.

Name and Principal Position	Year	Salary	Bonus	Option Awards <sup>(1)</sup>	Stock Awards <sup>(2)</sup>	Non Equity Incentive Plan	All Other Compensation <sup>(9)</sup>	Total
Timothy P. Walbert Chairman, President and Chief Executive Officer	2013	\$ 589,160	\$ 0	\$ 257,250	\$ 606,282	\$ 441,870 <sup>(3)</sup>	\$ 600	\$ 1,895,162
	2012	\$ 572,000	\$ 0	\$ 0	\$ 588,000	\$ 275,000 <sup>(3)</sup>	\$ 1,218	\$ 1,436,218
	2011	\$ 550,000	\$ 0	\$ 797,744	\$ 658,883	\$ 363,000 <sup>(3)</sup>	\$ 1,218	\$ 2,370,845
Robert J. De Vaere Executive Vice President and Chief Financial Officer	2013	374,920	\$ 0	\$ 89,250	\$ 256,667	\$ 187,460 <sup>(4)</sup>	\$ 600	\$ 908,897
	2012	\$ 364,000	\$ 0	\$ 0	\$ 462,000	\$ 120,000 <sup>(4)</sup>	\$ 1,156	\$ 947,156
	2011	\$ 350,000	\$ 0	\$ 197,170	\$ 162,843	\$ 162,800 <sup>(4)</sup>	\$ 1,156	\$ 873,969
Jeffrey W. Sherman Executive Vice President, Development, Manufacturing, and Regulatory Affairs, and Chief Medical Officer	2013	\$ 396,340	\$ 0	\$ 89,250	\$ 231,914	\$ 198,172 <sup>(5)</sup>	\$ 600	\$ 916,276
	2012	\$ 384,800	\$ 0	\$ 0	\$ 462,000	\$ 142,000 <sup>(5)</sup>	\$ 1,070	\$ 989,870
	2011	\$ 370,000	\$ 0	\$ 197,170	\$ 162,843	\$ 162,800 <sup>(5)</sup>	\$ 1,070	\$ 893,883
Todd Smith Executive Vice President and Chief Commercial Officer	2013	\$ 375,950	\$ 0	\$ 106,750	\$ 255,914	\$ 187,975 <sup>(6)</sup>	\$ 600	\$ 927,189
	2012	\$ 332,583	\$ 0	\$ 0	\$ 315,000	\$ 106,000 <sup>(6)</sup>	\$ 824	\$ 754,407
	2011	\$ 274,275	\$ 0	\$ 80,455	\$ 66,448	\$ 96,250 <sup>(6)</sup>	\$ 824	\$ 518,252
Michael Adatto <sup>(8)</sup> Former Senior Vice President, Managed Care and Commercial Development	2013	\$ 139,719	\$ 0	\$ 38,063	\$ 47,520	\$ 0	\$ 300	\$ 225,602
	2012	\$ 300,000	\$ 0	\$ 0	\$ 315,000	\$ 37,000 <sup>(7)</sup>	\$ 1,331	\$ 653,331
	2011	\$ 274,275	\$ 0	\$ 80,455	\$ 66,448	\$ 96,250 <sup>(7)</sup>	\$ 1,331	\$ 518,759

- (1) Amounts shown in this column do not reflect actual compensation received by our named executive officers. The amounts reflect the grant date fair value of stock option awards and are calculated in accordance with the provisions of FASB Accounting Standards Codification Topic 718 *Compensation - Stock Compensation*, or ASC Topic 718, and assume no forfeiture rate derived in the calculation of the grant date fair value of these awards. Assumptions used in the calculation of these awards are included in Note 17 *Equity Incentive Plans* in the notes to our consolidated financial statements included in this Annual Report on Form 10-K. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

**Table of Contents**

- (2) Amounts shown in this column do not reflect actual compensation received by our named executive officers. The amounts reflect the grant date fair value of restricted stock units issued in accordance with the provisions of ASC Topic 718 and are based on the closing stock price of our common stock on the date of grant and assume no forfeiture rate derived in the calculation of the grant date fair value of these awards. Stock awards granted to our named executive officers during 2013 and 2011 consisted of restricted stock units that vest equally in four annual installments commencing on the anniversary date of the grant. Stock awards granted to our named executive officers during 2013 also included a fully vested deferred issuance of restricted stock units provided as a one-time bonus payment in connection with the completion of our acquisition of the U.S rights to VIMOVO. Stock awards granted to our named executive officers during 2012 consisted of performance-based restricted stock units and vested only upon the achievement of certain performance objectives during 2012. See Note 17 Equity Incentive Plans in the notes to our consolidated financial statements included in this Annual Report on Form 10-K for further information on our restricted stock units.
- (3) In December 2011, our board approved Mr. Walbert's 2011 bonus in the amount of \$363,000, but deferred payment until completion of a debt financing, which occurred in February 2012. Mr. Walbert's target bonus amount for 2012 was \$343,200. In December 2012, our board approved Mr. Walbert's bonus in the amount of \$275,000, which was paid in January 2013. Mr. Walbert's target bonus amount for 2013 was \$353,496, or 60% of base salary. In December 2013, our board approved Mr. Walbert's bonus in the amount of \$441,870, which was paid in January 2014.
- (4) In December 2011, our board approved Mr. De Vaere's 2011 bonus in the amount of \$162,800, but deferred payment until the completion of the debt financing, which occurred in February 2012. Mr. De Vaere's target bonus amount for 2012 was \$145,600. In December 2012, our board approved Mr. De Vaere's bonus in the amount of \$120,000, which was paid in January 2013. Mr. De Vaere's target bonus amount for 2013 was \$149,968, or 40% of base salary. In December 2013, our board approved Mr. De Vaere's bonus in the amount of \$187,460, which was paid in January 2014.
- (5) In December 2011, our board approved Dr. Sherman's 2011 bonus in the amount of \$162,800, but deferred payment until the completion of the debt financing, which occurred in February 2012. Dr. Sherman's target bonus amount for 2012 was \$153,920. In December 2012, our board approved Dr. Sherman's bonus in the amount of \$142,000, which was paid in January 2013. Dr. Sherman's target bonus amount for 2013 was \$158,536, or 40% of base salary. In December 2013, our board approved Dr. Sherman's bonus in the amount of \$198,172, which was paid in January 2014.
- (6) In December 2011, our board approved Mr. Smith's 2011 bonus in the amount of \$96,250, but deferred payment until the completion of the debt financing, which occurred in February 2012. Mr. Smith's target bonus for 2012 was \$146,000. In December 2012, our board approved Mr. Smith's bonus in the amount of \$106,000, which was paid in January 2013. Mr. Smith's target bonus amount for 2013 was \$150,380, or 40% of base salary. In December 2013, our board approved Mr. Smith's bonus in the amount of \$187,975, which was paid in January 2014.
- (7) In December 2011, our board approved Mr. Adatto's 2011 bonus in the amount of \$96,250, but deferred payment until the completion of the debt financing, which occurred in February 2012. Mr. Adatto's target bonus amount for 2012 was \$105,000. In December 2012, our board approved Mr. Adatto's bonus in the amount of \$37,000, which was paid in January 2013.
- (8) On March 14, 2013, our board of directors determined that Mr. Adatto, our Senior Vice President, Managed Care and Commercial Development, would increasingly focus his efforts on managed care activities and, as a result, would no longer retain his prior policy making functions. Accordingly, his status as an executive officer at Horizon ended as of that date. On June 17, 2013, Mr. Adatto terminated his employment with us. Upon termination of his employment, Mr. Adatto was eligible to receive severance benefits under the Severance Benefit Plan, which provided for six months' base salary and COBRA health insurance premiums. On June 16, 2013, we entered into a three month consulting agreement with Mr. Adatto effective upon his termination of employment.
- (9) Amounts shown in this column include imputed income on life insurance benefits.

---

**Table of Contents**

*Payments Made Upon Termination.* In January 2014, we entered into an amendment to the amended and restated employment agreement with Mr. Walbert, our president and Chief Executive Officer, that provides if we terminate Mr. Walbert without cause or if Mr. Walbert resigns for good reason, he will be entitled to (1) be compensated at his then annual base salary for 12 months from his date of termination, (2) receive his target bonus in effect at the time of termination or, if none, his last target bonus, and (3) receive COBRA health insurance premiums for up to 12 months from the date of his termination. In addition, if Mr. Walbert is terminated without cause or if Mr. Walbert resigns for good reason within 90 days prior to or within 18 months following a change in control, 100% of the shares subject to options and restricted stock awards granted to Mr. Walbert will fully vest as of the termination date, and Mr. Walbert will be entitled to (1) be compensated at his then annual base salary for two years from his date of termination, (2) receive two times his target bonus in effect at the time of termination or, if none, two times his last target bonus, and (3) receive COBRA health insurance premiums for up to 12 months from the date of his termination. Cause is defined as gross negligence or willful failure to substantially perform duties and responsibilities to us or willful and deliberate violation of any of our policies; conviction of a felony involving commission of any act of fraud, embezzlement or dishonesty against us or involving moral turpitude; the unauthorized use or disclosure of any of our proprietary information or trade secrets and willful and deliberate breach of the executive's obligations under the employment agreement that cause material injury to us. Resignation for good reason is defined as a material reduction in duties, authority or responsibilities; the relocation of the place of employment by more than 50 miles; or a material reduction of salary or annual target bonus opportunity. In the event of termination due to Mr. Walbert's death or complete disability, he and/or his heirs shall be eligible to receive a pro-rated bonus for the year in which such termination occurs, as determined by our board or compensation committee based on actual performance.

In January 2014, we entered into an amendment to the amended and restated employment agreement with Mr. De Vaere, our executive vice president and Chief Financial Officer, that provides if we terminate Mr. De Vaere without cause or if Mr. De Vaere resigns for good reason, he will be entitled to be compensated at his then annual base salary for 12 months from his date of termination and will also be entitled to receive COBRA health insurance premiums for up to 12 months from the date of his termination. In addition, if Mr. De Vaere is terminated without cause or resigns for good reason within 90 days prior to or within 18 months following a change in control, 100% of the shares subject to options and restricted stock awards granted to Mr. De Vaere will fully vest as of the termination date, and Mr. De Vaere will be entitled to (1) be compensated at his then annual base salary for 12 months from his date of termination, (2) receive his target bonus in effect at the time of termination or, if none, his last target bonus, and (3) receive COBRA health insurance premiums for up to 12 months from the date of his termination. Cause is defined as gross negligence or willful failure to substantially perform duties and responsibilities to us or willful and deliberate violation of any of our policies; conviction of a felony or the commission of any act of fraud, embezzlement or dishonesty against us or involving moral turpitude; the unauthorized use or disclosure of any of our proprietary information or trade secrets; and willful and deliberate breach of the executive's obligations under the employment agreement that cause material injury to us. Resignation for good reason is defined as a material reduction in duties, authority or responsibilities; the relocation of the place of employment by more than 50 miles; or a material reduction of salary or annual target bonus opportunity. In the event of termination due to Mr. De Vaere's death or complete disability, he and/or his heirs shall be eligible to receive a pro-rated bonus for the year in which such termination occurs, as determined by our board or compensation committee based on actual performance.

In January 2014, we entered into an amendment to the amended and restated employment agreement with Dr. Sherman, our executive vice president of development, manufacturing and regulatory affairs and chief medical officer, that provides if we terminate Dr. Sherman without cause or if Dr. Sherman resigns for good reason, he will be entitled to be compensated at his then annual base salary for 12 months from his date of termination and will also be entitled to receive COBRA health insurance premiums for up to 12 months from the date of his termination. In addition, if Dr. Sherman is terminated without cause or resigns for good reason within 90 days prior to or within 18 months following a change in control, 100% of the shares subject to options and restricted stock awards granted to Dr. Sherman will fully vest as of the termination date, and Dr. Sherman will be entitled to (1) be compensated at his then annual base salary for 12 months from his date of termination,

**Table of Contents**

(2) receive his target bonus in effect at the time of termination or, if none, his last target bonus, and (3) receive COBRA health insurance premiums for up to 12 months from the date of his termination. Cause is defined as gross negligence or failure to substantially perform duties and responsibilities to us or willful violation of any of our policies; conviction of a felony or the commission of any act of fraud, embezzlement or dishonesty against us or involving moral turpitude; the unauthorized use or disclosure of any of our proprietary information or trade secrets; and breach of the executive's obligations under the employment agreement that causes injury to us. Resignation for good reason is defined as the relocation of the place of employment by more than 50 miles, or a material reduction of salary or annual target bonus opportunity. In the event of termination due to Dr. Sherman's death or complete disability, he and/or his heirs shall be eligible to receive a pro-rated bonus for the year in which such termination occurs, as determined by our board or compensation committee based on actual performance.

In January 2014, we entered into an amendment to the employment agreement with Mr. Smith, our executive vice president and chief commercial officer, that provides if we terminate Mr. Smith without cause or if Mr. Smith resigns for good reason, he will be entitled to be compensated at his then annual base salary for 12 months from his date of termination and will also be entitled to receive COBRA health insurance premiums for up to 12 months from the date of his termination. In addition, if Mr. Smith is terminated without cause or resigns for good reason within 90 days prior to or within 18 months following a change in control, 100% of the shares subject to options and restricted stock awards granted to Mr. Smith will fully vest as of the termination date, and Mr. Smith will be entitled to (1) be compensated at his then annual base salary for 12 months from his date of termination, (2) receive his target bonus in effect at the time of termination or, if none, his last target bonus, and (3) receive COBRA health insurance premiums for up to 12 months from the date of his termination. Cause is defined as gross negligence or willful failure to substantially perform duties and responsibilities to us or willful violation of any of our policies; conviction of a felony or the commission of any act of fraud, embezzlement or dishonesty against us or involving moral turpitude; the unauthorized use or disclosure of any of our proprietary information or trade secrets; and willful and deliberate breach of the executive's obligations under the employment agreement that causes injury to us. Resignation for good reason is defined as material reduction in executive duties, authority or responsibilities; the relocation of the place of employment by more than 50 miles; or a material reduction of salary or annual target bonus opportunity. In the event of termination due to Mr. Smith's death or complete disability, he and/or his heirs shall be eligible to receive a pro-rated bonus for the year in which such termination occurs, as determined by our board or compensation committee based on actual performance.

On June 17, 2013, Mr. Adatto terminated his employment with us. Upon termination of his employment, Mr. Adatto was eligible to receive severance benefits under the Severance Benefit Plan, which provided for six months' base salary and COBRA health insurance premiums. On June 16, 2013, we entered into a three month consulting agreement with Mr. Adatto effective upon termination of his employment.

*Change in Control.* A change in control under our employment agreements with Mr. Walbert, Mr. De Vaere, Dr. Sherman and Mr. Smith is defined generally as (1) the sale of all or substantially all of our assets; (2) a merger or consolidation in which we are not the surviving entity and in which the holders of our outstanding voting stock immediately prior to such transaction own less than 50% of the voting power of the entity surviving the transaction or, where the surviving entity is a wholly-owned subsidiary of another entity, the surviving entity's parent; (3) a reverse merger in which we are the surviving entity but the shares of common stock outstanding prior to the merger are converted into other property and in which the holders of our voting stock immediately prior to such transaction own less than 50% of the voting power of our stock, or where we are a wholly-owned subsidiary of another entity, of our parent; or (4) an acquisition by any person, entity or group of beneficial ownership of at least 75% of the combined voting power entitled to vote in an election of our directors.

*Releases.* All termination-based payments (other than due to death or complete disability) to Mr. Walbert, Mr. De Vaere, Dr. Sherman and Mr. Smith pursuant to their employment agreements are contingent upon (1) the executive's execution of a standard release of claims in our favor and (2) the executive's entering into a

**Table of Contents**

non-competition agreement to be effective during the period during which the executive receives severance benefits.

*Sections 280G and 4999.* Any payment or benefit provided under our named executive officers' employment agreements or otherwise in connection with a change in control may be subject to an excise tax under Section 4999 of the IRC. These payments also may not be eligible for a company tax deduction pursuant to Section 280G of the IRC. If any of these payments or benefits are subject to the excise tax, they may be reduced to provide the individual with the best after-tax result. Specifically, the individual will receive either a reduced amount so that the excise tax is not triggered, or the individual will receive the full amount of the payments and benefits and then be liable for any excise tax.

The following table sets forth potential payments payable to our named executive officers upon a termination of employment without cause or resignation for good reason or termination of employment without cause or resignation for good reason following a change in control. The table below reflects amounts payable to our named executive officers assuming their employment was terminated on December 31, 2013 and, if applicable, a change in control also occurred on such date:

Name	Upon Termination Without Cause or Resignation for Good Reason - No Change of Control					Upon Termination Without Cause or Resignation for Good Reason - Change of Control <sup>(1)</sup>				
	Cash Severance	Medical Benefits	Bonus	Accelerated Vesting <sup>(2)</sup>	Total	Cash Severance	Medical Benefits	Bonus	Accelerated Vesting <sup>(2)</sup>	Total
Timothy P. Walbert	\$ 644,100	\$ 19,192	\$ 386,460	\$ 0	\$ 1,049,752	\$ 1,288,200	\$ 19,192	\$ 772,920	\$ 1,816,692	\$ 3,897,004
Robert J. De Vaere	\$ 386,168	\$ 19,252	\$ 0	\$ 0	\$ 405,420	\$ 386,168	\$ 19,252	\$ 154,467	\$ 632,887	\$ 1,192,774
Jeffrey W. Sherman	\$ 408,234	\$ 19,252	\$ 0	\$ 0	\$ 427,486	\$ 408,234	\$ 19,252	\$ 163,294	\$ 605,432	\$ 1,196,212
Todd N. Smith	\$ 387,229	\$ 19,252	\$ 0	\$ 0	\$ 406,481	\$ 387,229	\$ 19,252	\$ 154,892	\$ 607,581	\$ 1,168,954
Michael Adatto <sup>(3)</sup>					\$ 0					\$ 0

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

(2) The value of accelerated vesting is equal to the closing stock price of \$7.62 per share on December 31, 2013, multiplied by the number of shares subject to accelerated vesting, less the stock option exercise price, if applicable.

(3) Mr. Adatto terminated employment with us on June 17, 2013.

**Table of Contents****Grants of Plan-Based Awards**

The following table sets forth certain information regarding grants of non-equity incentive plan and equity incentive plan-based awards to our named executive officers for 2013

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards Target	All Other Stock Awards: Number of Shares of Stock or Units (#)	Grant Date Fair Value of Stock and Options Awards (\$) <sup>(7)</sup>
Timothy P. Walbert	N/A	\$ 441,870 <sup>(1)</sup>		
	1/2/2013		128,700 <sup>(5)</sup>	\$ 308,880
	12/5/2013		43,290 <sup>(6)</sup>	\$ 297,402
Robert J. De Vaere	N/A	\$ 187,460 <sup>(2)</sup>		
	1/2/2013		45,000 <sup>(5)</sup>	\$ 108,000
	12/5/2013		21,640 <sup>(6)</sup>	\$ 148,667
Jeffrey W. Sherman	N/A	\$ 198,172 <sup>(3)</sup>		
	1/2/2013		45,000 <sup>(5)</sup>	\$ 108,000
	12/5/2013		18,037 <sup>(6)</sup>	\$ 123,914
Todd Smith	N/A	\$ 187,975 <sup>(4)</sup>		
	1/2/2013		55,000 <sup>(5)</sup>	\$ 132,000
	12/5/2013		18,037 <sup>(6)</sup>	\$ 123,914
Michael Adatto	1/2/2013		19,800 <sup>(5)</sup>	\$ 47,520

- (1) Mr. Walbert's target bonus for 2013 was \$353,496 or 60% of his base salary. In December 2013, our compensation committee approved Mr. Walbert's bonus in the amount of \$441,870, or 125% of his target bonus, which was paid in January 2014.
- (2) Mr. De Vaere's target bonus for 2013 was \$149,968 or 40% of his base salary. In December 2013, our compensation committee approved Mr. De Vaere's bonus in the amount of \$187,460, or 125% of his target bonus, which was paid in January 2014.
- (3) Dr. Sherman's target bonus for 2013 was \$158,536 or 40% of his base salary. In December 2013, our compensation committee approved Dr. Sherman's bonus in the amount of \$198,172, or 125% of his target bonus, which was paid in January 2014.
- (4) Mr. Smith's target bonus for 2013 was \$150,380 or 40% of his base salary. In December 2013, our compensation committee approved Mr. Smith's bonus in the amount of \$187,975, or 125% of his target bonus, which was paid in January 2014.
- (5) On January 2, 2013, our named executive officers were granted restricted stock units vesting in four equal annual installments beginning on the first anniversary of the grant date.
- (6) On December 5, 2013, our named executive officers were granted a fully vested deferred issuance of restricted stock units provided as a one-time bonus payment in connection with the completion of our acquisition of the U.S rights to VIMOVO.
- (7) Amounts shown in this column do not reflect dollar amounts actually received by our named executive officers. Instead, these amounts reflect the grant date fair value of such awards and are calculated in accordance with the provisions of ASC Topic 718 and assume no forfeiture rate derived in the calculation of the grant date fair value of these awards. Assumptions used in the calculation of these amounts and further information on our restricted stock units are included in Note 17 "Equity Incentive Plans" in the notes to our consolidated financial statements included in this Annual Report on Form 10-K.

**Table of Contents****Outstanding Equity Awards at December 31, 2013**

The following table sets forth certain information regarding outstanding stock options and restricted stock units held by our named executive officers on December 31, 2013.

Name	Award Grant Date	Option Awards					Stock Awards		Equity Incentive Plan
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested <sup>(5)</sup>	Market Value of Stock that Has Not Vested <sup>(7)</sup>	Equity Awards: Incentive Plan or Awards: Number of Unearned Shares, Units or Other Rights that Have Not Vested <sup>(8)</sup>
Timothy P. Walbert	7/16/2008	121,701 <sup>(1)(2)</sup>			\$ 10.43	7/15/2018			
	2/3/2010	123,564 <sup>(3)</sup>	5,373 <sup>(3)</sup>		\$ 5.20	2/2/2020			
	6/16/2010	98,688 <sup>(3)</sup>	14,099 <sup>(3)</sup>		\$ 12.94	6/15/2020			
	12/8/2011	108,477 <sup>(4)</sup>	108,478 <sup>(4)</sup>		\$ 4.96	12/7/2021	66,421	\$ 506,128	
	1/2/2013	33,687 <sup>(4)</sup>	113,313 <sup>(4)</sup>		\$ 2.40	1/1/2023	128,700	980,694	
	12/5/2013				\$ 6.87	12/4/2023	43,290 <sup>(6)</sup>	329,870	
			486,117	241,263			238,411	\$ 1,816,692	\$
Robert J. De Vaere	10/6/2008	46,335 <sup>(1)(2)</sup>			\$ 10.43	10/5/2018			
	2/3/2010	45,668 <sup>(3)</sup>	1,986 <sup>(3)</sup>		\$ 5.20	2/2/2020			
	6/16/2010	37,008 <sup>(3)</sup>	5,287 <sup>(3)</sup>		\$ 12.94	6/5/2020			
	12/8/2011	26,810 <sup>(4)</sup>	26,811 <sup>(4)</sup>		\$ 4.96	12/7/2021	16,416	\$ 125,090	
	1/2/2013	11,687 <sup>(4)</sup>	39,313 <sup>(4)</sup>		\$ 2.40	1/1/2023	45,000	342,900	
	12/5/2013				\$ 6.87	12/4/2023	21,640 <sup>(6)</sup>	164,897	
		167,508	73,397			83,056	\$ 632,887	\$	
Jeffrey W. Sherman	6/23/2009	46,335 <sup>(1)(2)</sup>			\$ 13.47	6/22/2019			
	2/3/2010	45,668 <sup>(3)</sup>	1,986 <sup>(3)</sup>		\$ 5.20	2/2/2020			
	6/16/2010	37,008 <sup>(3)</sup>	5,287 <sup>(3)</sup>		\$ 12.94	6/15/2020			
	12/8/2011	26,810 <sup>(4)</sup>	26,811 <sup>(4)</sup>		\$ 4.96	12/7/2021	16,416	\$ 125,090	
	1/2/2013	11,687 <sup>(4)</sup>	39,313 <sup>(4)</sup>		\$ 2.40	1/1/2023	45,000	342,900	
	12/5/2013				\$ 6.87	12/4/2023	18,037 <sup>(6)</sup>	137,442	
		167,508	73,397			79,453	\$ 605,432	\$	
Todd Smith	12/2/2010	15,005 <sup>(2)</sup>	3,950 <sup>(2)</sup>		\$ 20.78	12/1/2020			
	12/8/2011	10,940 <sup>(4)</sup>	10,940 <sup>(4)</sup>		\$ 4.96	12/7/2021	6,698	\$ 51,039	
	1/2/2013	13,979 <sup>(4)</sup>	47,021 <sup>(4)</sup>		\$ 2.40	1/1/2023	55,000	419,100	
	12/5/2013				\$ 6.87	12/4/2023	18,037 <sup>(6)</sup>	137,442	
		39,924	61,911			79,735	\$ 607,581		
Michael Adatto <sup>(8)</sup>									

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

## Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

- (2) 1/4<sup>th</sup> of the shares vest one year after the vesting commencement date and 1/48<sup>th</sup> of the shares vest monthly thereafter over the next three years. The options reflected in the table have the following vesting commencement dates: Mr. Walbert June 30, 2008, Mr. De Vaere October 6, 2008, Dr. Sherman June 29, 2009 and Mr. Smith October 1, 2010.
- (3) 1/4<sup>th</sup> of the shares vest one year after the vesting commencement date, which is the same date as the grant date, and 1/48<sup>th</sup> of the shares vest monthly thereafter over the next three years.
- (4) 1/48<sup>th</sup> of the shares vest in equal monthly installments over the four years following the vesting commencement date, which is the grant date.
- (5) Stock awards represent restricted stock units granted and vest in four equal annual installments commencing on the anniversary of the grant date.
- (6) Represents restricted stock units that are fully vested but are subject to delayed issuance. As of December 31, 2013, the underlying shares had not yet been issued.
- (7) The market value of stock awards that have not vested is based on the closing stock price of our common stock of \$7.62 per share on December 31, 2013.
- (8) Mr. Adatto terminated employment with us on June 17, 2013.

**Table of Contents***Option Exercises and Stock Vested*

The following table sets forth certain information regarding option exercises and stock vested for our named executive officers for the fiscal year ended December 31, 2013. Mr. Walbert and Mr. Smith each sold shares of our common stock pursuant to a trading plan established under Rule 10b5-1 to satisfy certain withholding tax obligations.

Name	Option Awards		Stock Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting (\$)
Timothy P. Walbert			43,290 <sup>(1)</sup>	\$ 297,402
			33,210 <sup>(2)</sup>	\$ 224,832
Robert J. De Vaere			21,640 <sup>(1)</sup>	\$ 148,667
			8,208 <sup>(2)</sup>	\$ 55,568
Jeffrey W. Sherman			18,037 <sup>(1)</sup>	\$ 123,914
			8,208 <sup>(2)</sup>	\$ 55,568
Todd Smith			18,037 <sup>(1)</sup>	\$ 123,914
			3,350 <sup>(2)</sup>	\$ 22,680
Michael Adatto <sup>(3)</sup>				

(1) Represents a fully vested deferred issuance of restricted stock units granted on December 5, 2013 to our named executive officers which was provided as a one-time bonus payment in connection with the completion of our acquisition of the U.S rights to VIMOVO.

(2) Represents restricted stock units granted on December 8, 2011, vesting over 4 annual installments.

(3) Mr. Adatto terminated employment with us on June 17, 2013.

*Option Repricings*

We did not engage in any repricings or other modifications to any of our named executive officers' outstanding equity awards during the year ended December 31, 2013.

*Pension Benefits*

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

*Nonqualified Deferred Compensation*

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

*Other Benefits*

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

**Table of Contents****Non-Employee Director Compensation**

Our board of directors adopted a compensation policy for our non-employee directors who are not affiliated with any holder of more than 5% of our common stock, which became effective upon our initial public offering in July 2011.

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

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

The following table sets forth compensation information for our non-employee directors who earned or received compensation under our non-employee director compensation policy in 2013:

<b>Name</b>	<b>Fees Earned or Paid in Cash</b>	<b>Stock Awards<sup>(1)</sup></b>	<b>Total</b>
Ronald Pauli	\$ 65,000	\$ 117,296	\$ 182,296
Michael Grey	\$ 65,000	\$ 117,296	\$ 182,296
Gino Santini	\$ 57,500	\$ 117,296	\$ 174,796
Jeffrey Bird	\$ 32,813	\$ 117,296	\$ 150,109

- (1) The amounts shown in this column reflect the grant date fair value of option awards issued to our non-employee directors during 2013, calculated in accordance with the provisions of ASC Topic 718 and assumes no forfeiture rate. See the assumptions used in the Black-Scholes model in the notes to our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2013.

**Limitation of Liability and Indemnification**

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

breach of their duty of loyalty to the corporation or its stockholders;

act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or

## Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

transaction from which the directors derived an improper personal benefit.

Our amended and restated certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, which remain available under Delaware law. These limitations also do not affect a director's responsibilities under any

## **Table of Contents**

other laws, such as the federal securities laws or other state or federal laws. Our amended and restated bylaws provide that we will indemnify our directors and officers, and may indemnify employees and other agents, to the extent not prohibited by law. Our amended and restated bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding and also permit us to secure insurance on behalf of any officer, director, employee or other agent required or permitted to be indemnified by our amended and restated bylaws. We have obtained a policy of directors' and officers' liability insurance.

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

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

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

### **Compensation Committee Interlocks and Insider Participation**

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

### **Compensation Committee Report**

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

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

This report of the compensation committee is not soliciting material, shall not be deemed filed with the SEC and shall not be incorporated by reference by any general statement incorporating by reference this Annual Report on Form 10-K into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing, except to the extent that we specifically incorporate this information by reference, and shall not otherwise be deemed filed under such acts.

**Table of Contents**

The foregoing report has been furnished by the compensation committee.

Respectively submitted,

The Compensation Committee of the Board of Directors

Jeff Himawan, Ph.D., Chairman

Michael Grey

Ronald Pauli

127

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

The following table provides information as of December 31, 2013, with respect to shares of our common stock that may be issued under our existing equity compensation plans:

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrant, and rights	(b) Weighted-average exercise price of outstanding options, warrant, and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by stockholders:			
2005 Stock Plan	1,197,259 <sup>(1)</sup>	\$ 13.85	
2011 Equity Incentive Plan	3,721,222 <sup>(1)</sup>	\$ 2.74	78,795
2011 Employee Stock Purchase Plan		\$ 0.00	412,805
Equity compensation plans not approved by stockholders:			
2011 Equity Incentive Plan	325,600 <sup>(2)</sup>	\$ 5.36	674,400

(1) All shares issuable upon exercise of options.

(2) All shares issuable upon exercise of options. On November 7, 2013 and November 16, 2013, our board of directors amended the 2011 Equity Incentive Plan to reserve an additional 200,000 and 800,000 shares, respectively, of our common stock to be issued exclusively as employment inducements pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules.

**2005 Stock Plan.** Our board of directors adopted and our stockholders approved our 2005 stock plan, or the 2005 plan, in October 2005 for eligible employees, directors and consultants. The 2005 plan provided for the grant of up to 1,771,289 shares of our common stock as stock awards. The terms of the stock option agreements, including vesting requirements, were determined by our compensation committee, subject to the provisions of the 2005 plan. Options granted under the 2005 plan generally vest over four years and are exercisable after they have been granted and up to ten years from the date of grant. The exercise price of the incentive stock options must equal at least the fair market value of the stock on the date of grant. Following the signing of the underwriting agreement for our initial public offering and stockholder approval of the 2011 equity incentive plan, or 2011 EIP, all future equity awards will be granted under our 2011 EIP. However, all stock options granted under the 2005 plan prior to the initial public offering will continue to be governed by the terms of the 2005 plan.

**2011 Equity Incentive Plan.** The 2011 EIP provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of equity compensation, or collectively, stock awards. In addition, the 2011 EIP provides for the grant of performance cash awards. Incentive stock options may be granted only to employees, subject to certain limitations. All other awards may be granted to employees, including officers, as well as directors and consultants. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2011 EIP was 3,366,228 shares, which number is the sum of (1) the number of shares reserved for future issuance under the 2005 plan at the time the 2011 EIP became effective, (2) an additional number of shares, up to 1,317,534, that are subject to outstanding stock awards granted under the 2005 plan that expire or terminate for any reason prior to their exercise or settlement and would otherwise return to the 2005 Plan reserve and (3) an additional 1,600,673 of new shares. Then, the number of shares of our common stock reserved for issuance under the 2011 EIP will automatically increase on January 1 of each year through January 1, 2021, by the least of (a) 5% of the total number of shares of our common stock outstanding on

---

## **Table of Contents**

December 31 of the preceding calendar year, (b) 1,474,304 shares, or (c) such lesser number of shares of common stock as determined by our board of directors. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2011 EIP is 2,106,149 shares plus the number of shares that are added to the 2011 EIP share reserve pursuant to annual evergreen increases or pursuant to outstanding 2005 plan awards that expire or terminate prior to exercise or settlement. The exercise price for an incentive stock option or a non-qualified stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted typically vest over a four-year period and the term can be up to ten years. As of December 31, 2013, there were 78,795 shares available for future grants under the 2011 EIP. On December 5, 2013, pursuant to the terms of our 2011 EIP, our board of directors approved an increase in the number of shares available for issuance under the 2011 EIP of 1,474,304 shares, effective January 1, 2014.

In addition, (i) on November 7, 2013, November 16, 2013 and March 3, 2014, our board of directors approved amendments to our 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, or Rule 5635(c)(4) 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. As of December 31, 2013, there were 674,400 shares available for future grants under the 2011 EIP pursuant to Rule 5635(c)(4).

*Employee Stock Purchase Plan.* Our board of directors adopted our 2011 employee stock purchase plan, or the 2011 ESPP, in July 2010 and our stockholders approved the 2011 ESPP in June 2011. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the 2011 ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the 2011 ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the 2011 ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering or (b) 85% of the fair market value of a share of our common stock on the date of purchase. Initially, the 2011 ESPP authorized the issuance of 463,352 shares of our common stock pursuant to purchase rights granted to our employees or to employees of our subsidiaries. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year through January 1, 2021, by the least of (a) 4% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year, (b) 1,053,074 shares, or (c) a number determined by our board of directors that is less than (a) or (b). As of December 31, 2013, there were 412,805 shares available for future grants under the 2011 ESPP. On December 5, 2013, pursuant to the terms of our 2011 ESPP, our board of directors approved an increase in the number of shares available for issuance under the 2011 ESPP of 1,053,074 shares, effective January 1, 2014.

## **Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth information regarding the beneficial ownership of our common stock as of March 6, 2014 for:

each of our Named Executive Officers as defined in Part III Item 11, Executive Compensation of this report;

each of our directors;

each person known by us to beneficially own more than 5% of our common stock; and

all of our Named Executive Officers and directors as a group.

**Table of Contents**

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting and investment power with respect to the securities. Except as indicated by footnote, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. The number of shares of common stock used to calculate the percentage ownership of each listed person includes the shares of common stock underlying options, warrants or other rights held by such persons that are exercisable as of May 5, 2014, which is 60 days after March 6, 2014.

Percentage of beneficial ownership is based on 67,733,417 shares of common stock outstanding as of March 6, 2014. Unless otherwise indicated, the address for the following stockholders is c/o Horizon Pharma, Inc., 520 Lake Cook Road, Suite 520, Deerfield, IL 60015.

Name and Address of Beneficial Owner or Identity of Group	Number and Percentage of Shares Beneficially Owned	
	Shares	Percentage
<b>5% or greater stockholders:</b>		
Fidelity and its affiliates <sup>(1)</sup> 82 Devonshire St. Boston, Massachusetts 02109	6,698,856	9.5%
Essex Woodlands Health Ventures Fund VII, L.P. <sup>(2)</sup> 335 Bryant St., 3rd Floor Palo Alto, CA 94301	5,815,940	8.5%
Deerfield Management, L.P. <sup>(3)</sup> 780 Third Avenue, 37th Floor New York, NY 10017	4,638,888	6.8%
Broadfin Capital, LLC <sup>(4)</sup> 237 Park Avenue, Suite 900 New York, NY 10017	4,257,469	6.3%
Discovery Group <sup>(5)</sup> 191 N. Wacker Dr., Suite 1685 Chicago, IL 60606	4,174,909	6.2%
Quaker Bioventures Capital II, LLC <sup>(6)</sup> 2929 Arch St., 3rd Floor, the Cira Centre Philadelphia, PA 19104-2857	4,206,378	6.1%
CD-Venture and its affiliates <sup>(7)</sup> Bergheimer St. 89/1 69115 Heidelberg, Germany	4,157,575	6.1%
Atlas Venture Fund VI, L.P. and its affiliates <sup>(8)</sup> 25 First Street, Suite 303 Cambridge, MA 02141	3,895,404	5.7%
<b>Directors and named executive officers:</b>		
Jeff Himawan, Ph.D. <sup>(9)</sup>	5,815,940	8.5%
Jean-François Formela, M .D. <sup>(10)</sup>	3,895,404	5.7%
Jeffrey W. Bird, M .D., Ph.D. <sup>(11)</sup>	2,710,390	4.0%
Michael Grey <sup>(12)</sup>	32,665	*
Ronald Pauli <sup>(13)</sup>	32,665	*
Gino Santini <sup>(14)</sup>	30,910	*
Timothy P. Walbert <sup>(15)</sup>	733,537	1.1%
Robert J. De Vaere <sup>(16)</sup>	290,126	*
Jeffrey W. Sherman, M .D., FACP <sup>(17)</sup>	291,228	*
Todd N. Smith <sup>(18)</sup>	110,620	*
All executive officers and directors as a group (10 persons) <sup>(19)</sup>	13,943,485	19.8%

**Table of Contents**

\* Represents beneficial ownership of less than one percent.

- (1) Includes (a) 3,915,400 shares and (b) 2,783,456 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on January 10, 2014 by FMR LLC, which reflects beneficial ownership as of December 31, 2013. FMR LLC reported that it had beneficial ownership of, and sole dispositive power with respect to, 3,915,400 shares of our common stock, including 2,783,456 shares issuable upon exercise of warrants. The Schedule 13G includes shares beneficially owned by Edward C. Johnson, III and family members, Fidelity Management & Research Company, or Fidelity, Fidelity SelectCo, LLC, or SelectCo, and Strategic Advisers, Inc., or Strategic Advisers. Fidelity, SelectCo and Strategic Advisers are all wholly-owned subsidiaries of FMR LLC and are beneficial owners as a result of acting as investment advisers to various registered investment companies, or Fidelity funds. Mr. Johnson is Chairman of FMR LLC. The Schedule 13G states that Mr. Johnson and various family members, through their ownership of FMR LLC common stock and the execution of a stockholders' voting agreement, may be deemed a controlling group with respect to FMR LLC. The Schedule 13G also states that neither FMR LLC nor Mr. Johnson has the sole power to vote or direct the voting of the shares owned directly by the Fidelity funds, which power resides with the Fidelity funds' boards of trustees pursuant to established guidelines.
- (2) Includes (a) 5,064,731 shares and (b) 751,209 shares issuable upon exercise of warrants. James L. Currie, Jeff Himawan, Martin Sutter, Immanuel Thangaraj and Petri Vainio share voting and investment power over the shares held by Essex Woodlands Health Ventures Fund VII, L.P. and each disclaim beneficial ownership of such shares except to the extent of any pecuniary interest therein.
- (3) Includes (a) 4,488,888 shares and (b) 150,000 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on February 14, 2014. The shares are beneficially owned by Deerfield Partners, L.P., Deerfield International Master Fund, L.P., Deerfield Special Situations Fund, L.P. and Deerfield Special Situations International Master Fund, L.P., of which Deerfield Management, L.P. is the general partner.
- (4) Includes 4,257,469 shares beneficially owned by Broadfin Capital, LLC, Broadfin Healthcare Master Fund, Ltd. and Kevin Kotler. This information is based on the Schedule 13G filed on February 14, 2014 with the SEC.
- (5) Includes 4,174,909 shares held by Discovery Group. This information is based on the Schedule 13D filed with the SEC on March 3, 2014. Discovery Group is the sole general partner of Discovery Equity Partners and has sole discretionary investment authority with respect to Discovery Equity Partners' investment in the common stock. Messrs. Donoghue and Murphy are the sole managing members of Discovery Group. As a consequence, Discovery Group and Messrs. Donoghue and Murphy may be deemed to share beneficial ownership of all of the shares of common stock owned by both Discovery Group and Discovery Equity Partners, while Discovery Equity Partners shares beneficial ownership with Discovery Group and Messrs. Donoghue and Murphy of only the shares of common stock owned by it.
- (6) Includes (a) 3,516,009 shares and (b) 690,369 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on February 14, 2013. Quaker BioVentures Capital II, L.P., the general partner of Quaker BioVentures II, L.P., and Quaker BioVentures Capital II, LLC, the general partner of Quaker BioVentures Capital II, L.P., may be deemed to share voting and investment power with respect to such shares with Quaker BioVentures II, L.P.
- (7) Includes (a) 3,595,714 shares and (b) 561,861 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on February 14, 2014 by Christoph F. Boehringer and CD-Venture GmbH. Mr. Boehringer is the beneficial owner of 4,157,575 shares of our common stock, including 2,357,575 shares of our common stock beneficially owned by CD-Venture.
- (8) Includes (a) 3,516,377 shares held by Atlas Venture Fund VI, L.P., or Atlas VI, (b) 64,385 shares held by Atlas Venture Fund VI GmbH & Co. KG, or Atlas GmbH, (c) 107,532 shares held by Atlas Venture Entrepreneurs' Fund VI, L.P., or Atlas EVC, and (d) 197,456, 3,616, and 6,038 shares issuable upon exercise of warrants held by Atlas VI, Atlas GmbH and Atlas EVC, respectively. These shares are held directly by Atlas VI, Atlas EVC and Atlas GmbH. Atlas Venture Associates VI, L.P., or AVA VI L.P. is the sole general partner of Atlas VI and Atlas EVC and the managing limited partner of Atlas GmbH. Atlas Venture Associates VI, Inc., or AVA VI Inc., is the sole general partner of AVA VI L.P. Jean-Francois Formela, M.D., Jeffrey Fagnan and Kristen Laguerre are each directors of AVA VI Inc. As a result,

**Table of Contents**

each of Dr. Formela, Mr. Fagnan and Ms. Laguerre may be deemed to have beneficial ownership with respect to all shares held by AVA VI Inc. Each of the foregoing disclaims beneficial ownership of these shares except to the extent of their pecuniary interest therein.

- (9) Includes the shares referred to in footnote (2) above. Dr. Himawan disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
- (10) Includes the shares referred to in footnote (8) above. Dr. Formela disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
- (11) Includes (a) 99,912 shares held by the Jeffrey W. Bird and Christina R. Bird Trust dated October 31, 2000, or the Bird Trust, of which Dr. Bird is a trustee, (b) 21,685 shares issuable upon exercise of warrants held by the Bird Trust, (c) 2,096,558 shares held by Sutter Hill Ventures, a California Limited Partnership, or SHV, (d) 458,902 shares issuable upon exercise of warrants held by SHV, (e) 5,000 shares held by Dr. Bird in a Roth IRA account, (f) 1,250 shares issuable upon the exercise of warrants held by Dr. Bird in a Roth IRA account, (g) 7,000 shares held by NestEgg Holdings, a Limited Partnership, (h) 1,750 shares issuable upon exercise of warrants held by NestEgg Holdings and (i) 18,333 shares that Dr. Bird has the right to acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options. Dr. Bird disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
- (12) Includes 32,665 shares that Mr. Grey has the right to acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options.
- (13) Includes 32,665 shares that Mr. Pauli has the right to acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options.
- (14) Includes 30,910 shares that Mr. Santini has the right to acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options.
- (15) Includes (a) 105,207 shares, (b) 75,465 restricted stock units that are fully vested but are subject to a delayed issuance stock award such that the underlying shares have not yet been issued and (c) 552,865 shares that Mr. Walbert has the right to acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options.
- (16) Includes (a) 68,604 shares, (b) 32,890 restricted stock units that are fully vested but are subject to a delayed issuance stock award such that the underlying shares have not yet been issued and (c) 188,632 shares that Mr. De Vaere has the right to acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options.
- (17) Includes (a) 73,309 shares, (b) 29,287 restricted stock units that are fully vested but are subject to a delayed issuance stock award such that the underlying shares have not yet been issued and (c) 188,632 shares that Dr. Sherman has the right to acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options.
- (18) Includes (a) 22,924 shares, (b) 31,787 restricted stock units that are fully vested but are subject to a delayed issuance stock award such that the underlying shares have not yet been issued and (c) 55,909 shares that Mr. Smith has the right to acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options.
- (19) Includes the following held by our executives and directors, in the aggregate: (a) 11,231,539 shares, (b) 169,429 restricted stock units that are fully vested but are subject to a delayed issuance stock award such that the underlying shares have not yet been issued, (c) 1,100,611 shares that can be acquired within 60 days of March 6, 2014 pursuant to the exercise of stock options and (d) 1,441,906 shares issuable upon the exercise of warrants.

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

We describe below transactions and any series of similar transactions, since the beginning of fiscal year 2013, with respect to which we were a party, will be a party, or otherwise benefited, in which:

the amounts involved exceeded or will exceed \$120,000; and

a director, executive officer, holder of more than 5% of our common stock or any member of their immediate family had or will have a direct or indirect material interest.

---

## **Table of Contents**

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

### **Employment Agreements and Change of Control Arrangements**

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

### **Stock Options and Stock Awards Granted to Executive Officers and Directors**

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

### **Indemnification of Officers and Directors**

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

### **Policies and Procedures for Transactions with Related Persons**

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

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

the risks, costs and benefits to us;

the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;

**Table of Contents**

the terms of the transaction;

the availability of other sources for comparable services or products; and

the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

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

**Director Independence**

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

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

Director	Principal Stockholder
Jean-François Formela, M.D.	Atlas Venture Fund VI, L.P.
Jeff Himawan, Ph.D.	Essex Woodlands Health Ventures Fund VII, L.P.

**Item 14. Principal Accounting Fees and Services****Audit and All Other Fees**

The following table presents fees for services rendered by PricewaterhouseCoopers LLP, our independent registered public accounting firm, for 2013 and 2012 in the following categories:

	2013	2012
Audit fees <sup>(1)</sup>	\$ 1,326,000	\$ 1,021,000
Tax fees <sup>(2)</sup>		13,000
<b>Total</b>	<b>\$ 1,326,000</b>	<b>\$ 1,034,000</b>

- Audit fees consist of fees for professional services performed by PricewaterhouseCoopers LLP for the audit of our annual financial statements, review of our quarterly financial statements, review of our registration statements, including our registration statement on Form S-1 for our equity finance offering, and related services that are normally provided in connection with statutory and regulatory filings or engagements.
- Tax fees consist of fees for professional services performed by PricewaterhouseCoopers LLP with respect to tax compliance, tax advice and tax planning.

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



**Table of Contents**

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

The audit committee has established a policy that all audit and permissible non-audit services provided by our independent registered public accounting firm will be pre-approved by the audit committee, and all such services were pre-approved in accordance with this policy during the fiscal years ended December 31, 2013 and 2012. These services may include audit services, audit-related services, tax services and other services. The audit committee considers whether the provision of each non-audit service is compatible with maintaining the independence of our independent registered public accounting firm. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. Our independent registered public accounting firm and management are required to periodically report to the audit committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

**(a) Documents filed as part of this report.**

**1. Financial Statements**

The financial statements listed on the Index to Financial Statements F-3 to F-43 are filed as part of this Annual Report on Form 10-K.

**2. Financial Statement Schedules**

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

**3. Exhibits**

The exhibits listed on the Index to Exhibits are filed as part of this Annual Report on Form 10-K.

**Table of Contents****SIGNATURES**

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

HORIZON PHARMA, INC.

Dated: March 13, 2014

By: /s/ Timothy P. Walbert  
Timothy P. Walbert

President, Chief Executive Officer and

Chairman of the Board

**KNOW ALL PERSONS BY THESE PRESENTS**, that each person whose signature appears below constitutes and appoints Timothy P. Walbert and Robert J. De Vaere, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Timothy P. Walbert Timothy P. Walbert	Chairman, President and Chief Executive Officer ( <i>Principal Executive Officer</i> )	March 13, 2014
/s/ Robert J. De Vaere Robert J. De Vaere	Executive Vice President and Chief Financial Officer ( <i>Principal Financial and Accounting Officer</i> )	March 13, 2014
/s/ Jeffrey Bird, M.D., Ph.D. Jeffrey Bird, M.D., Ph.D.	Director	March 13, 2014
/s/ Jean-Francois Formela, M.D. Jean-François Formela, M.D.	Director	March 13, 2014
/s/ Michael Grey Michael Grey	Director	March 13, 2014
/s/ Jeff Himawan, Ph.D. Jeff Himawan, Ph.D.	Director	March 13, 2014

Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

/s/ Ronald Pauli

Director

March 13, 2014

Ronald Pauli

/s/ Gino Santini

Director

March 13, 2014

Gino Santini

136

**Table of Contents**

**HORIZON PHARMA, INC.**

**Index to Financial Statements**

	<b>Page</b>
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2013 and 2012	F-3
Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2013, 2012 and 2011	F-4
Consolidated Statements of Stockholders' Equity (Deficit) for the Years Ended December 31, 2013, 2012 and 2011	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2013, 2012 and 2011	F-6
Notes to Consolidated Financial Statements	F-7

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of comprehensive loss, stockholders equity (deficit) and cash flows present fairly, in all material respects, the financial position of Horizon Pharma, Inc. and its subsidiaries at December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control - Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting incorporated by reference under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits (which were integrated audits in 2012 and 2013). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. Given the Company's commercial operating history, as discussed in Note 1 to the financial statements, and the fact that the Company also has convertible debt which may be required to be settled in cash up to the principal amount upon certain circumstances outside the control of the Company, prior to obtaining stockholder approval to issue enough shares to cover the conversion option, there are circumstances which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

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

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

/s/ PricewaterhouseCoopers LLP

Chicago, Illinois

March 13, 2014

**Table of Contents**

**HORIZON PHARMA, INC.**  
**CONSOLIDATED BALANCE SHEETS**

(In thousands, except share data)

	As of December 31,	
	2013	2012
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 80,480	\$ 104,087
Restricted cash	738	800
Accounts receivable, net	15,958	3,463
Inventories, net	8,701	5,245
Prepaid expenses and other current assets	4,888	3,323
Total current assets	110,765	116,918
Property and equipment, net	3,780	3,725
Intangible assets, net	131,094	68,892
Other assets	6,957	4,449
<b>TOTAL ASSETS</b>	<b>\$ 252,596</b>	<b>\$ 193,984</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 9,921	\$ 5,986
Accrued expenses	24,049	16,784
Accrued royalties	8,010	
Deferred revenues - current portion	1,330	2,230
Notes payable - current portion		11,935
Total current liabilities	43,310	36,935
<b>LONG-TERM LIABILITIES:</b>		
Convertible debt, net	110,762	
Derivative liability	109,410	
Accrued royalties	24,982	
Notes payable, net of current		36,866
Deferred revenues, net of current	9,686	9,554
Deferred tax liabilities, net	3,362	4,408
Other long term liabilities	166	243
Total long-term liabilities	258,368	51,071
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS EQUITY:</b>		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 66,097,417 and 61,722,247 shares issued and outstanding at December 31, 2013 and 2012, respectively	7	6
Additional paid-in capital	410,430	417,455
Accumulated other comprehensive loss	(2,403)	(3,372)
Accumulated deficit	(457,116)	(308,111)

Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

Total stockholders (deficit) equity	(49,082)	105,978
<b>TOTAL LIABILITIES AND STOCKHOLDERS EQUITY</b>	<b>\$ 252,596</b>	<b>\$ 193,984</b>

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

F-3

**Table of Contents****HORIZON PHARMA, INC.****CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

(In thousands, except share data)

	For the Years Ended December 31,		
	2013	2012	2011
<b>REVENUES:</b>			
Gross sales	\$ 102,995	\$ 22,978	\$ 6,939
Sales discounts and allowances	(28,979)	(4,134)	(12)
Net sales	74,016	18,844	6,927
Cost of goods sold	14,625	11,875	7,267
Gross profit (loss)	59,391	6,969	(340)
<b>OPERATING EXPENSES:</b>			
Research and development	10,084	16,837	15,358
Sales and marketing	68,595	49,561	20,314
General and administrative	23,566	19,444	15,008
Intangible impairment charge			69,621
Total operating expenses	102,245	85,842	120,301
Operating loss	(42,854)	(78,873)	(120,641)
<b>OTHER (EXPENSE) INCOME, NET:</b>			
Interest expense, net	(39,178)	(14,525)	(6,284)
Foreign exchange gain (loss)	1,206	489	(1,023)
Loss on derivative fair value	(69,300)		
Other, net		(56)	
Total other expense, net	(107,272)	(14,092)	(7,307)
Loss before benefit for income taxes	(150,126)	(92,965)	(127,948)
<b>BENEFIT FOR INCOME TAXES</b>	(1,121)	(5,171)	(14,683)
<b>NET LOSS</b>	\$ (149,005)	\$ (87,794)	\$ (113,265)
<b>NET LOSS PER COMMON SHARE - Basic and diluted</b>	\$ (2.34)	\$ (2.26)	\$ (12.56)
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING - Basic and diluted</b>	63,657,924	38,871,422	9,014,968
<b>OTHER COMPREHENSIVE INCOME (LOSS), NET OF TAX</b>			
Foreign currency translation adjustments	969	416	(1,559)
Other comprehensive income (loss)	969	416	(1,559)
<b>COMPREHENSIVE LOSS</b>	\$ (148,036)	\$ (87,378)	\$ (114,824)

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



**Table of Contents****HORIZON PHARMA, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)**

(In thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Accumulated Deficit		Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount		Loss	Deficit	
<b>Balances at December 31, 2010</b>	24,961,340	\$ 2	1,490,551	\$	\$ 206,336	\$ (2,230)	\$ (107,052)	\$ 97,056
Common stock issuance in public offering, net of underwriting fees and issuance costs			5,500,000	1	41,744			41,745
Issuance of common stock in conjunction with the conversion of bridge notes payable			2,017,242		18,156			18,156
Conversion of convertible preferred stock to common stock	(24,961,340)	(2)	10,514,431	1	1			
Issuance of common stock in conjunction with option exercises and ESPP purchases			24,172		124			124
Stock-based compensation					2,530			2,530
Issuance of common stock in conjunction with warrant exercises			81,348					
Issuance of warrants in connection with notes payable amendment					1,124			1,124
Currency translation adjustment						(1,558)		(1,558)
Net loss							(113,265)	(113,265)
<b>Balances at December 31, 2011</b>	\$	\$	\$ 19,627,744	\$ 2	\$ 270,015	\$ (3,788)	\$ (220,317)	\$ 45,912
Issuance of common stock in conjunction with equity financing offerings, net of underwriting fees and issuance costs.			38,672,579	4	128,075			128,079
Issuance of common stock in conjunction with vesting of restricted stock units			74,050					
Issuance of common stock in conjunction with ESPP purchases			106,955		287			287
Stock-based compensation					4,661			4,661
Issuance of common stock in conjunction with warrant exercises			1,990,919		154			154
Issuance of warrants in connection with notes payable					9,188			9,188
Issuance of common stock in connection with notes payable amendment			1,250,000		5,075			5,075
Currency translation adjustment						416		416
Net loss							(87,794)	(87,794)
<b>Balances at December 31, 2012</b>	\$	\$	\$ 61,722,247	\$ 6	\$ 417,455	\$ (3,372)	\$ (308,111)	\$ 105,978
Issuance of common stock in conjunction with ATM equity financing offerings, net of issuance costs			2,448,575	1	5,997			5,998
Issuance of common stock in conjunction with vesting of restricted stock units and stock option exercises			340,029		161			161
Issuance of common stock in conjunction with ESPP purchases			225,820		478			478
Stock-based compensation					5,014			5,014
Issuance of common stock in conjunction with warrant exercises			1,360,746					
Purchase of capped calls					(18,675)			(18,675)
Currency translation adjustment						969		969

Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

Net loss							(149,005)	(149,005)
<b>Balances at December 31, 2013</b>	\$	\$	\$ 66,097,417	\$ 7	\$ 410,430	\$ (2,403)	\$ (457,116)	\$ (49,082)

F-5

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

**Table of Contents****HORIZON PHARMA, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(In thousands)**

	<b>For the Years Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (149,005)	\$ (87,794)	\$ (113,265)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation and amortization expense	9,310	5,538	4,199
Stock-based compensation	5,014	4,661	2,530
Loss on derivative revaluation	69,300		
Intangible impairment charge			69,621
Paid in kind interest expense	2,225	2,607	
Amortization of debt discount, deferred financing costs and debt extinguishment	17,245	2,740	2,708
Foreign exchange (gain) loss	(1,206)	(489)	1,023
Loss on disposal of assets		76	
Changes in operating assets and liabilities:			
Accounts receivable	(12,491)	(1,087)	(1,817)
Inventories	(3,426)	(4,022)	(923)
Prepaid expenses and other current assets	(1,240)	(543)	(1,897)
Accounts payable	3,908	(2,209)	5,643
Accrued expenses	7,942	7,052	3,215
Deferred revenues	(1,145)	2,616	3,237
Deferred tax liabilities	(1,186)	(5,206)	(15,778)
Other non-current assets and liabilities	468	(581)	(36)
Net cash used in operating activities	(54,287)	(76,641)	(41,540)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of property and equipment	(1,198)	(1,336)	(1,604)
Change in restricted cash	63	(50)	(550)
VIMOVO asset acquisition	(35,000)		
Net cash used in investing activities	(36,135)	(1,386)	(2,154)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from the issuance of convertible debt, net of issuance costs	143,598		
Purchase of capped calls	(18,675)		
Proceeds from the issuance of common stock under an ATM agreement, net of issuance costs	5,998		
Proceeds from issuance of common stock in initial public offering, net of underwriting fees and issuance costs			44,678
Proceeds from issuance of bridge notes payable to related parties			6,766
Proceeds from equity finance offerings, net of offering costs		128,077	
Proceeds from the issuance of notes payable		55,578	16,651
Proceeds from the issuance of common stock	639	441	124
Repayment of notes payable	(64,844)	(19,788)	(13,067)
Net cash provided by financing activities	66,716	164,308	55,152
Effect of foreign exchange rate changes on cash	99	(160)	1,124
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(23,607)</b>	<b>86,121</b>	<b>12,582</b>
<b>CASH AND CASH EQUIVALENTS, beginning of the year</b>	<b>104,087</b>	<b>17,966</b>	<b>5,384</b>
<b>CASH AND CASH EQUIVALENTS, end of the year</b>	<b>\$ 80,480</b>	<b>\$ 104,087</b>	<b>\$ 17,966</b>

Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

**Supplemental cash flow information:**

Cash paid for interest	\$ 8,573	\$ 7,554	\$ 2,757
Cash paid for income taxes	44	57	
Cash paid for debt extinguishment interest and penalties	\$ 12,152	\$ 2,124	\$ 440

**Significant non-cash investing activities:**

Contingent liabilities assumed in acquisition	\$ 32,992		
Intangible assets acquired in acquisition	\$ 67,705		

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

F-6

**Table of Contents**

**HORIZON PHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2013, 2012 and 2011**

**(in thousands, except share and per share data)**

**NOTE 1 THE COMPANY**

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

The Company is a specialty pharmaceutical company commercializing DUEXIS, VIMOVO and RAYOS/LODOTRA, each of which targets unmet therapeutic needs in arthritis, pain and inflammatory diseases. The Company developed DUEXIS and RAYOS/LODOTRA, and it acquired the U.S. rights to VIMOVO from AstraZeneca AB ("AstraZeneca") in November 2013. The Company's strategy is to develop, acquire or in-license additional innovative medicines or acquire companies where the Company can execute a targeted commercial approach among specific target physicians, such as primary care physicians, orthopedic surgeons and rheumatologists, while taking advantage of its commercial strengths and the infrastructure that has been put in place.

On April 23, 2011, the U.S. Food and Drug Administration ("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 ("RA"), osteoarthritis ("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, the Company hired its initial commercial organization, including approximately 80 sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In June 2012, the Company licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products. In the third quarter of 2012, the Company expanded its sales force to approximately 150 representatives and has subsequently further expanded its sales force to approximately 290 representatives, most recently by adding approximately 115 representatives in connection with the Company's acquisition of the U.S. rights to VIMOVO in November 2013. In March 2013, the Company announced that the United Kingdom ("UK") Medicines and Healthcare Products Regulatory Agency granted a National Marketing Authorization for DUEXIS in the UK. The Company will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded non-steroidal anti-inflammatory drugs ("NSAIDs"), the Company does not expect a material level of sales from DUEXIS in European markets.

The Company's 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 rheumatica ("PMR"), psoriatic arthritis, ankylosing spondylitis ("AS"), asthma and chronic obstructive pulmonary disease and a number of other conditions. The Company is focusing its promotion of RAYOS in the United States on rheumatology indications, including RA and PMR. The Company began detailing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of U.S. rheumatologists and key primary care physicians. LODOTRA is currently marketed outside the United States by the Company's distribution partner, Mundipharma International Corporation Limited ("Mundipharma").

**Table of Contents**

On November 18, 2013, the Company entered into agreements with AstraZeneca pursuant to which the Company 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. ( 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, the Company acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the investigational new drug application ( IND ) and new drug application ( 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 the Company 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. For accounting purposes, the acquisition of the U.S. rights to VIMOVO was treated as a business combination. Collectively, these transactions are referred to as the VIMOVO Acquisition.

In December 2013, as a result of its acquisition of the U.S. rights to VIMOVO, the Company began the expansion of its sales force to approximately 250 primary care representatives and 40 rheumatology sales specialists and recognized revenues under the transition agreement with AstraZeneca. The Company announced the availability of Horizon-labeled VIMOVO on January 2, 2014. The Company completed the hiring and training of its expanded sales force in January 2014 and began selling VIMOVO in early February 2014. The Company's 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 will promote VIMOVO in a second position among these target physicians. The Company's 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. The Company's 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. The Company has also expanded its rheumatology specialty sales force from 25 sales specialists to approximately 40 sales specialists, with these specialist representatives promoting RAYOS and VIMOVO to rheumatologists. The Company has also included VIMOVO in its *Prescriptions-Made-Easy* specialty pharmacy program, along with DUEXIS and RAYOS, and offers co-pay assistance for all of its marketed products to ensure patients receive them at a reasonable out-of-pocket cost.

**Revision of Prior Period Financial Statements**

In the course of preparing the Company's Consolidated Statements of Comprehensive Loss for this Annual Report on Form 10-K, the Company determined that there had been a misclassification of certain fees in its 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 the Company's annual financial statements for the year ended December 31, 2012 (collectively, the Affected Financial Statements ).

The Affected Financial Statements classified wholesaler service fees as cost of goods sold. The Company determined that these fees should be classified as sales discounts and allowances, which was a reduction in

**Table of Contents**

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 the Company's reported gross profit, net loss or cash flows.

In evaluating whether the Company's previously issued consolidated financial statements were materially misstated, the Company considered the guidance in Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( 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*. The Company 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.

**Table of Contents**

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

	As Reported	Adjustment (in thousands)	As Revised
<b><u>Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2012</u></b>			
Sales discounts and allowances	(384)	(38)	(422)
Net Sales	2,523	(38)	2,485
Cost of goods sold	2,067	(38)	2,029
<b><u>Consolidated Statements of Comprehensive Loss for the Three Months Ended June 30, 2012</u></b>			
Sales discounts and allowances	(767)	(160)	(927)
Net Sales	3,841	(160)	3,681
Cost of goods sold	2,855	(160)	2,695
<b><u>Consolidated Statements of Comprehensive Loss for the Three Months Ended September 30, 2012</u></b>			
Sales discounts and allowances	(790)	(202)	(992)
Net Sales	6,521	(202)	6,319
Cost of goods sold	3,810	(202)	3,608
<b><u>Consolidated Statements of Comprehensive Loss for the Three Months Ended December 31, 2012</u></b>			
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
<b><u>Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2013</u></b>			
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
<b><u>Consolidated Statements of Comprehensive Loss for the Three Months Ended June 30, 2013</u></b>			
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
<b><u>Consolidated Statements of Comprehensive Loss for the Six Months Ended June 30, 2013</u></b>			
Sales discounts and allowances	(6,910)	(1,601)	(8,511)
Net Sales	21,425	(1,601)	19,824
Cost of goods sold	7,764	(1,601)	6,163
<b><u>Consolidated Statements of Comprehensive Loss for the Three Months Ended September 30, 2013</u></b>			
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

**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

F-10

---

## **Table of Contents**

The financial statements are prepared on a going concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business. As of December 31, 2013, the Company had cash and cash equivalents totaling \$80,480. The Company believes that it has sufficient liquidity and capital resources to reach cash flow positive operations based on the Company's current expectations of continued revenue growth. However, the Company is highly dependent in the near term on the commercial success of DUEXIS, VIMOVO and RAYOS in the U.S. market. Additionally, the Company has convertible debt which may be required to be settled in cash up to the principal amount upon certain circumstances outside the control of the Company, prior to obtaining stockholder approval to issue enough shares to cover the conversion option in shares of its common stock.

The Company has incurred net operating losses and negative cash flows from operations since its inception. In order to continue its operations, the Company must generate sufficient revenue and achieve profitable operations. If that does not occur, the Company's plan is to obtain additional debt or equity financing. There can be no assurance, however, that such financing will be available or on terms acceptable to the Company. These uncertainties and lack of commercial operating history raise substantial doubt about the Company's ability to continue as a going concern.

### **NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

#### *Basis of Presentation*

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

#### *Principles of Consolidation*

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

#### *Segment Information*

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

#### *Use of Estimates*

The preparation of the accompanying consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### *Foreign Currency Translation and Transactions*

The reporting currency of the Company and its subsidiaries is the U.S. dollar.

The U.S. dollar is the functional currency for the Company's U.S. based businesses and the Euro is the functional currency for its subsidiaries in Switzerland and Germany. Foreign currency-denominated assets and liabilities of these subsidiaries are translated into U.S. dollars based on exchange rates prevailing at the end of the

## **Table of Contents**

period, revenues and expenses are translated at average exchange rates prevailing during the corresponding period, and stockholders' equity (deficit) accounts are translated at historical exchange rates as of the date of any equity transaction. The effects of foreign exchange gains and losses arising from the translation of assets and liabilities of those entities where the functional currency is not the U.S. dollar are included as a component of accumulated other comprehensive income (loss).

Gains and losses resulting from foreign currency translations are reflected within the Company's results of operations. During the years ended December 31, 2013 and 2012, the Company recorded gains from foreign currency translations of \$1,206 and \$489, respectively, compared to a loss from foreign currency translations during the year ended December 31, 2011 of \$1,023. The Company does not currently utilize and has not in the past utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

### *Revenue Recognition*

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

#### *Revenue from upfront license fees*

The Company recognizes 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 the Company's part, revenues are recognized on the earlier of when payments are received or collection is reasonably assured. Where continuing involvement by the Company is required in the form of technology transfer, product manufacturing or technical support, revenues are deferred and recognized over the term of the agreement.

#### *Revenue from milestone receipts*

Milestone payments are recognized as revenue based on achievement of the associated milestones, as defined in the relevant agreements. Revenue from a milestone achievement is recognized when earned, as evidenced by acknowledgment from the Company's partner, provided that (1) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (2) the milestone represents the culmination of an earnings process and (3) the milestone payment is non-refundable. If all of these criteria are not met, revenue from the milestone achievement is recognized over the remaining minimum period of the Company's performance obligations under the agreement.

#### *Revenue from product deliveries*

The Company recognizes revenue from the delivery of its products when delivery has occurred, title has transferred, the selling price is fixed or determinable, collectability is reasonably assured and the Company has no further performance obligations. In addition, revenue is only recognized when the right of return no longer exists (which is the earlier of the product being dispensed through patient prescriptions or the expiration of the right of return) or when product returns can be reasonably estimated. Prior to October 2012, revenue from products sold to the Company's wholesale distributors and retail chains was recognized based on the amount of product sold through to the end consumer. Since October 2012, due to the Company's ability to reasonably estimate and determine allowances for product returns, rebates and discounts, the Company has been recognizing DUEXIS and RAYOS revenue at the point of sale to wholesale pharmaceutical distributors and retail chains. The Company has been recognizing VIMOVO revenue at the point of sale, consistent with its revenue recognition of DUEXIS and RAYOS, given the availability of prior VIMOVO product return data.

---

## **Table of Contents**

The Company anticipates revenues will continue to result from distribution, marketing, manufacturing and supply agreements with third parties in Europe and certain Asian, Latin American and other countries with respect to LODOTRA.

Under the manufacturing and supply agreements with Mundipharma Medical Company ( Mundipharma Medical ), Mundipharma Medical agreed to purchase LODOTRA exclusively from the Company at a price based on a specified percentage of the average net selling price ( ANSP ) for sales in a given country, subject to a minimum price. Mundipharma Medical has a nine-month period from purchase date to request an ANSP adjustment. If the ANSP is lower than the actual purchase price, then Mundipharma Medical would receive a price adjustment. Products sold to Mundipharma Medical are recognized upon delivery at the minimum price, as no contractual right of return exists. The difference between the actual selling price and the minimum price is recorded as deferred revenue until such time as adjustments for product returns, rebates and discounts can be reliably estimated or the nine-month ANSP adjustment period passes, at which time any previously deferred revenue would be recognized as revenue. As of December 31, 2013 and 2012, deferred revenues related to the sale of LODOTRA were \$615 and \$1,939, respectively. Additionally, as of December 31, 2013 and 2012, deferred revenues related to milestone and upfront payments received under existing agreements were \$8,682 and \$8,175, respectively.

In December 2011, the Company began recognizing revenues from the sale of DUEXIS following its commercial launch in the United States. DUEXIS is currently sold to wholesale pharmaceutical distributors and to several national and regional retail chains. Until the Company could reliably estimate returns, the Company determined that shipment of products to wholesale pharmaceutical distributors and regional retail chains did not meet the criteria for revenue recognition at the time of shipment. The Company therefore deferred DUEXIS revenue recognition until the right of return no longer existed, which was the earlier of DUEXIS being dispensed through patient prescriptions or the expiration of the right of return (twelve months after the expiration date of the product).

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

### *Product Sales Discounts and Allowances*

Prior to the fourth quarter of 2012, the Company recorded DUEXIS sales to wholesale pharmaceutical distributors and retail chains as deferred revenue. Allowances for product returns, rebates and discounts were also deferred at the time of sale to wholesale pharmaceutical distributors and national and regional retail chains. These deferred expenses were recognized to arrive at net product sales at the time the related revenue was recognized. In the fourth quarter of 2012, the Company began recognizing revenue at the point of sale to its wholesale pharmaceutical distributors and retail chains, at which point the associated allowances for product returns, rebates and allowances were also recognized. The Company is required to make significant judgments and estimates in determining some of these allowances. If actual results differ from its estimates, the Company will be required to make adjustments to these allowances in the future. In connection with its marketing of VIMOVO in the United States, the Company has been recognizing VIMOVO revenue at the point of sale to its wholesale pharmaceutical distributors and retail chains.

### *Customer Discounts and Rebates*

#### *Product Launch Discounts*

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

## **Table of Contents**

### *Customer Rebates*

The Company participates in certain commercial rebate programs. Under these rebate programs, the Company pays a rebate to the commercial entity or third-party administrator of the program. The Company accrues estimated rebates based on contract prices, estimated percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel and records the rebate as a reduction of revenue.

### *Distribution Service Fees*

The Company includes distribution service fees paid to its 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*

The Company participates in certain federal government rebate programs, such as Medicare and Medicaid. The Company accrues estimated rebates based on 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 records the rebate as a reduction of revenue.

#### *Government Chargebacks*

The Company provides discounts to federal government qualified entities with whom the Company has contracted. These federal entities purchase products from the wholesale pharmaceutical distributors at a discounted price, and the wholesale pharmaceutical distributors then charge back to the Company the difference between the current retail price and the contracted price that the federal entities paid for the products. The Company accrues estimated chargebacks based on contract prices and sell-through sales data obtained from third party information and records the chargeback as a reduction of revenue.

#### *Co-Pay Assistance*

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

#### *Returns and Prompt Pay Allowances*

##### *Sales Returns*

Consistent with industry practice, the Company maintains 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 product returns result from product dating, which falls within the range set by the Company's policy, and are settled through the issuance of a credit to the customer. The estimate of the provision for returns is based upon the Company's historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which the customer may return product. This period is known to the Company based on the shelf life of products at the time of shipment. The Company records sales returns as an allowance against accounts receivable and a reduction of revenue.

## **Table of Contents**

### *Prompt Pay Discounts*

As an incentive for prompt payment, the Company offers a 2% cash discount to customers. The Company expects that all customers will comply with the contractual terms to earn the discount. The Company records the discount as an allowance against accounts receivable and a reduction of revenue.

### *Bad Debt Expense*

The Company's products are sold to wholesale distributors and retail chains through manufacturing and supply agreements. For the years ended December 31, 2013, 2012 and 2011, the Company did not experience a bad debt expense related to its accounts receivable balances. Accordingly, the Company has not established a reserve for bad debt expense. The Company will continue to monitor its accounts receivable balances to determine the impact, if any, of such factors as changes in customer concentration, credit risk and the realizability of its accounts receivable would require a bad debt reserve allowance in subsequent periods.

### *Cost of Goods Sold*

The Company recognizes cost of goods sold in connection with its sale of DUEXIS and RAYOS.

Cost of goods sold of DUEXIS includes all costs directly related to the acquisition of product from the Company's third party manufacturers, including freight charges and costs of distribution.

Cost of goods sold of RAYOS includes all costs directly related to the acquisition of product from the Company's third party manufacturers, including freight charges, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

Until the Company began recognizing revenue at the point of sale of DUEXIS to the wholesaler in the fourth quarter of 2012, it also deferred the related DUEXIS cost of goods sold and recorded such amounts as other current assets until revenue was recognized.

Cost of goods sold of LODOTRA includes raw material costs, costs associated with third parties who manufacture LODOTRA for the Company, supply chain costs, 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 the Company's 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. The Company has entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. The Company's inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs. As of December 31, 2013 and December 31, 2012, the Company had inventories of \$8,701 and \$5,245, respectively.

Inventories exclude product sample inventory, which is included in other current assets and is expensed as a component of sales and marketing expense when provided to physicians or healthcare providers. As of December 31, 2013 and 2012, the Company had product sample inventory of \$1,323 and \$875, respectively.

### *Preclinical Studies and Clinical Trial Accruals*

The Company's preclinical studies and clinical trials have historically been conducted by third-party contract research organizations and other vendors. Preclinical study and clinical trial expenses are based on the



## **Table of Contents**

services received from these contract research organizations and vendors. Payments depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients and site initiation. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts the accrual accordingly. To date, the Company has had no significant adjustments to accrued clinical expenses.

### *Net Loss Per Share*

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

### *Cash and Cash Equivalents*

Cash and cash equivalents primarily consist of cash balances and money market funds. Cash and cash equivalents were \$80,480 and \$104,087 as of December 31, 2013 and 2012, respectively. The Company's policy is to invest excess cash in money market funds, which are generally of a short-term duration based upon operating requirements.

### *Restricted Cash*

Restricted cash consists of balances included in interest-bearing money market accounts required by a vendor for the Company's sponsored employee credit card program and by the lessor for the Company's corporate office. As of December 31, 2013 and 2012, the Company had restricted cash in the amount of \$738 and \$800, respectively.

### *Fair Value of Financial Instruments*

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities. The estimated fair value of the Company's derivative liability related to the convertible portion of its 5.00% Convertible Senior Notes due 2018 (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 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, the Company concluded that these inputs were Level 3 inputs. The Company will continue to derive the fair value of the derivative liability using the binomial lattice approach and these assumptions in all future reporting periods.

### *Business Combinations*

The Company accounts for business combinations in accordance with the pronouncement guidance in ASC 805, *Business Combinations*, in which acquired assets and liabilities are measured at their respective estimated fair values as of the acquisition date. The Company may be required, as in the case of intangible assets, contingent royalties or derivatives, to determine the fair value associated with these amounts by estimating the fair value using an income approach under the discounted cash flow method, which may include revenue projections and other assumptions made by the Company to determine the fair value.

**Table of Contents***Property and Equipment, Net*

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

Leasehold improvements are amortized on a straight-line basis over the term of the applicable lease, or the useful life of the assets, whichever is shorter.

Depreciation and amortization periods for the Company's property and equipment are as follows:

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

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

*Intangible Assets*

The Company's intangible assets consist of developed technology related to three of its approved products: LODOTRA outside the United States, RAYOS in the United States and intellectual property rights related to the Company's acquisition of the U.S. rights to VIMOVO. The Company amortizes the LODOTRA and RAYOS intangible assets over twelve years, which is the estimated useful life of the underlying patents, and amortizes the U.S. intellectual property rights of the VIMOVO intangible asset over an estimated useful life of 61.5 months. The Company reviews its intangible assets when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. The Company measures fair value based on the estimated future discounted cash flows associated with these assets in addition to other assumptions and projections that the Company deems to be reasonable and supportable.

*Research and Development Expenses*

Research and development expenses include, but are not limited to, payroll and other personnel expenses, consultant expenses, expenses incurred under agreements with contract research organizations to conduct clinical trials and expenses incurred to manufacture clinical trial materials.

*Sales and Marketing Expenses*

Sales and marketing expenses consist principally of payroll of sales representatives and marketing and support staff, travel and other personnel-related expenses, marketing materials and distributed sample inventories. With the full commercial launch of RAYOS in the United States in late January 2013, the Company determined that costs related to medical affairs, which consist of expenses related to scientific publications, health outcomes, biostatistics, medical education and information, and medical communications, should be charged to sales and marketing expenses as incurred in accordance with GAAP. Prior to the full commercial launch of RAYOS, these medical affairs expenses were classified as research and development expenses.

*Concentration of Credit Risk and Other Risks and Uncertainties*

Financial instruments that may potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents. The Company's cash and cash equivalents are invested in deposits with



**Table of Contents**

various banks in the United States, Switzerland and Germany that management believes are creditworthy. At times, deposits in these banks may exceed the amount of insurance provided on such deposits. To date, the Company has not experienced any losses on its deposits of cash and cash equivalents.

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

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

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

The Company is required to maintain compliance with applicable Swiss laws with respect to its Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. The Company reviews on a regular basis whether its Swiss subsidiary is overindebted. As of December 31, 2013 and 2012, the Company's Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. The Company will continue to monitor and review steps to address any overindebtedness until such time as its Swiss subsidiary may generate positive income at a statutory level, which could require the Company to have cash at its Swiss subsidiary in excess of its near term operating needs and could affect the Company's ability to have sufficient cash at its U.S. subsidiary to meet its near term operating needs. As of December 31, 2013 and 2012, Horizon Pharma AG had cash and cash equivalents of \$3,476 and \$4,708, respectively. Based upon the cash and cash equivalents held by Horizon Pharma AG as of December 31, 2013 and 2012 and Horizon Pharma AG's level of overindebtedness at such time, the Company does not expect that its financial position or results of operations will be materially affected by any need to address overindebtedness at its Swiss subsidiary. To date, the overindebtedness of the Company's Swiss subsidiary has not resulted in the need to divert material cash resources from its U.S. subsidiary.

Historically, the Company's accounts receivable balances have been highly concentrated with a select number of customers, consisting primarily of large wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. For the year ended December 31, 2013, the Company's top five customers, AmerisourceBergen, McKesson Corporation, Cardinal Health, Inc., Mundipharma and Rochester Drug Company, accounted for approximately 89% of total consolidated gross sales. For the year ended December 31, 2012, the Company's top three customers, Mundipharma, McKesson Corporation and Cardinal Health, Inc., accounted for approximately 83% of total consolidated gross sales. In addition, four customers, McKesson Corporation, AmerisourceBergen, Rochester Drug Company and Cardinal Health, Inc., accounted for approximately 85% of the Company's total outstanding accounts receivable balances at December 31, 2013. As of December 31, 2012, three customers, Cardinal Health, Inc., Walgreen Company and McKesson Corporation, accounted for approximately 77% of the Company's total outstanding accounts receivable balances. Historically, the Company has not experienced any losses related to its accounts receivable balances.

*Comprehensive Income (Loss)*

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss) (OCI). OCI includes certain changes in stockholders' equity that are excluded from net income (loss), which consist of foreign currency translation adjustments. In February 2013, the Company adopted on a prospective

**Table of Contents**

basis FASB Accounting Standards Update 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* ( ASU 2013-02 ). ASU 2013-02 requires an entity to report the effect of significant reclassifications out of accumulated OCI on the respective line items in net income if the amount being reclassified is required under GAAP to be reclassified in its entirety to net income. For other amounts that are not required under GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under GAAP that provide additional detail about those amounts. As of December 31, 2013 and 2012, accumulated other comprehensive loss was \$2,403 and \$3,372, respectively.

**NOTE 3 BUSINESS ACQUISITION**

On November 18, 2013, the Company entered into agreements with AstraZeneca pursuant to which the Company 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), 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, was approved by the FDA in 2010 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.

Pursuant to the transactions contemplated by the asset purchase agreement, the Company 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. The Company will also be entitled to the benefit of a covenant not to sue granted by Merck Sharp & Dohme Corp. and certain of its affiliates (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, AstraZeneca assigned to the Company 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 (the Pozen license agreement ) are described below.

In November 2013, in connection with the closing of the transactions contemplated by the asset purchase agreement, the Company 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. The Company also executed a transition agreement with AstraZeneca pursuant to which AstraZeneca transitioned to the Company 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 the Company the net profits recognized on sales of VIMOVO in the United States. Beginning January 1, 2014, the Company commenced commercialization of VIMOVO in the United States on its own behalf and under new pricing for VIMOVO. In consideration for the U.S. rights to VIMOVO, the Company paid to AstraZeneca a one-time upfront cash payment of \$35,000.

The Company is responsible for and controls 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 the Company purchased under the asset purchase agreement and the patents the Company licensed from Pozen under the Pozen license agreement. AstraZeneca will be responsible for and will retain control of VIMOVO outside the United States.

## **Table of Contents**

Additionally, in connection with the closing of the transactions contemplated by the asset purchase agreement, the Company entered into a license agreement with AstraZeneca (the AstraZeneca license agreement), pursuant to which AstraZeneca granted the Company 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 the Company 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 the Company 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, the Company granted AstraZeneca a non-exclusive sublicense under such licensed intellectual property and a non-exclusive right of reference under certain regulatory documentation controlled by the Company 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, the Company and its affiliates are subject to certain limitations and restrictions on its 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 the Company may commercialize VIMOVO or any such other products, restrictions on the Company's ability to develop or seek regulatory approval with respect to such other products that contain esomeprazole, restrictions on the Company's ability to develop or seek regulatory approval for VIMOVO for any indications other than the indications for which NSAIDs are indicated, and restrictions on the Company's marketing activities with respect to VIMOVO and any such other products.

Under the Pozen license agreement, Pozen granted to the Company 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 the Company 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, the Company is required to pay Pozen a flat 10% royalty on net sales of VIMOVO and such other products sold by the Company, its 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. The Company's 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, the Company is obligated to reimburse Pozen for costs, including attorneys' fees, incurred by Pozen in connection with VIMOVO patent litigation moving forward, subject to agreed caps.

The Company is responsible for and is required to use diligent and reasonable efforts to commercialize VIMOVO or another qualified product in the United States. The Company also owns and maintains all regulatory filings and marketing approvals in the United States for any such products, including all INDs and NDAs for VIMOVO. Pozen has 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.

**Table of Contents**

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 any uncured material breach by the other party or upon the bankruptcy or similar proceeding of the other party. The Company also has 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, the Company, AstraZeneca and Pozen entered into a letter agreement in which Pozen consented to AstraZeneca's assignment of the Pozen license agreement to the Company 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 (the "Pozen-AstraZeneca license agreement"). Under the letter agreement, the Company and AstraZeneca agreed to pay Pozen milestone payments upon the achievement by the Company and AstraZeneca, collectively, of certain annual aggregate global sales thresholds ranging from \$550.0 million to \$1.25 billion with respect to products licensed by Pozen to the Company 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 the Company, collectively, under the letter agreement is \$260.0 million, with the amount payable by each of the Company and AstraZeneca with respect to each milestone to be based upon the proportional sales achieved by each of the Company and AstraZeneca, respectively, in the applicable year.

The letter agreement will terminate with respect to Pozen and the Company 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.

In November 2013, in connection with the asset purchase agreement, the Company entered into a supply agreement with AstraZeneca pursuant to which AstraZeneca agreed to supply VIMOVO to the Company for commercialization in the United States through December 31, 2014. Under the supply agreement, AstraZeneca will supply the quantity of VIMOVO that the Company orders, both for the Company's own use and for use by the Company's sublicensees, on a transitional basis through December 31, 2014. The Company agreed to pay a set transfer price agreed to by the Company 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, the Company has 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.

Pursuant to ASC Topic 805, *Business Combinations*, the Company accounted for the acquisition of the U.S. rights to VIMOVO under the acquisition method of accounting, in which the Company recognized and accounted for the acquisition of the U.S. rights to VIMOVO as a business combination. Net tangible and intangible assets acquired and contingent royalty liabilities, based upon their respective estimated fair values as of the acquisition date (November 22, 2013). The following table shows the fair values assigned to the assets acquired and liabilities assumed by the Company as part of the asset purchase agreement:

	<b>Allocation</b>
Samples inventory	\$ 287
VIMOVO intellectual property	67,705
Contingent royalty liabilities	(32,992)
 Total cash consideration paid	 \$ 35,000

**Table of Contents**

The valuation of the intellectual property acquired, an identifiable intangible asset, was based on management's estimates, information and reasonable and supportable assumptions. The allocation was generally based on the Company's estimated fair value of the rights to payments with respect to U.S. revenue associated with VIMOVO which were acquired in the transaction. This estimated fair value was determined using the income approach under the discounted cash flow method. Significant assumptions used in valuing the intellectual property intangible asset included revenue projections through 2030 based on assumptions relating to pricing and reimbursement rates and market size and market penetration rates, cost of goods sold based on current manufacturing experience, general and administrative expenses, sales and marketing expenses, and research and development expenses for clinical and regulatory support. The calculated value of the VIMOVO intellectual property intangible asset is amortized using the straight-line method over an estimated useful life of 61.5 months.

Additionally, the Company assigned a fair value to its liability for contingent royalties. The contingent royalty liability was based on anticipated revenue streams utilizing the income approach under the discounted cash flow method. As a result, the Company recorded \$33,000 of fair value royalty payments due to Pozen, of which \$24,500 was guaranteed during the years 2014 through 2018 and \$8,500 was contingent on meeting certain revenue targets.

*Pro Forma Financial Information*

The following table represents the consolidated financial information for the Company on a pro forma basis, assuming that the acquisition of the U.S. rights to VIMOVO occurred as of January 1, 2012. The historical financial information has been adjusted to give effect to pro forma items that are directly attributable to the acquisition and are expected to have a continuing impact on the consolidated results. These items include, among others, adjustments to record the amortization of acquired VIMOVO intellectual property and interest expense, debt discount and deferred financing costs associated with the convertible debt issued in connection with the acquisition. Additionally, the following table sets forth unaudited financial information and has been compiled from historical financial statements and other information, but is not necessarily indicative of the results that actually would have been achieved had the transactions occurred on the dates indicated or that may be achieved in the future.

	For the Years Ended December 31,					
	As reported	2013 Pro-forma adjustments (Unaudited)	Pro-forma (Unaudited)	As reported	2012 Pro-forma adjustments (Unaudited)	Pro-forma (Unaudited)
Net revenues	\$ 74,016	\$ 20,379	\$ 94,395	\$ 18,844	\$ 25,195	\$ 44,039
Net income (loss)	(149,005)	14,464	(134,541)	(87,794)	(38,793)	(126,587)
Loss per share: Basic and diluted	\$ (2.34)	\$ 0.23	\$ (2.11)	\$ (2.26)	\$ (1.00)	\$ (3.26)

**NOTE 4 EARNINGS PER SHARE**

The following table presents basic and diluted earnings (loss) per share for the years ended December 31, 2013, 2012 and 2011 as follows:

	For the Years Ended December 31,		
	2013	2012	2011
<b>Basic and diluted earnings per share calculation:</b>			
Net loss	\$ (149,005)	\$ (87,794)	\$ (113,265)
Weighted average of common shares outstanding	63,657,924	38,871,422	9,014,968
Basic and diluted net loss per share	\$ (2.34)	\$ (2.26)	\$ (12.56)

**Table of Contents**

The following securities were excluded from the computation of diluted earnings per share for the years ended December 31, 2013, 2012 and 2011 due to the anti-dilutive effects resulting from the Company's net loss for the periods presented:

Outstanding stock options to purchase an aggregate of 4,411,080, 2,746,918 and 2,532,262 shares of common stock at December 31, 2013, 2012 and 2011, respectively; outstanding and unvested restricted stock units covering an aggregate of 833,001, 232,158 and 304,890 shares of common stock at December 31, 2013, 2012 and 2011, respectively; and 101,004 and 225,000 vested restricted stock units outstanding at December 31, 2013 and 2012, respectively.

Outstanding common stock warrants to purchase an aggregate of 16,114,746 and 17,480,243 shares of common stock at December 31, 2013, and 2012, respectively.

The conversion of approximately 13,164,951 shares of the Company's common stock associated with the conversion feature of the Convertible Senior Notes as the conversion of the Convertible Senior Notes is subject to receiving stockholder approval to issue enough authorized and unissued shares to cover the conversion option and satisfy the NASDAQ share cap rule.

**NOTE 5 INVENTORIES**

Inventories are stated at the lower of cost or market value. Inventories consist of raw materials, work-in-process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. The Company's inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs. Inventories exclude product sample inventory, which are included in other current assets and are expensed as a component of sales and marketing expense when provided to physicians or healthcare providers.

The components of inventories as of December 31, 2013 and 2012 consisted of the following:

	<b>As of December 31,</b>	
	<b>2013</b>	<b>2012</b>
Raw materials	\$ 91	\$ 40
Work-in-process	522	824
Finished goods	8,088	4,381
Net inventories	\$ 8,701	\$ 5,245

**NOTE 6 PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses and other current assets as of December 31, 2013 and 2012 consisted of the following:

	<b>As of December 31,</b>	
	<b>2013</b>	<b>2012</b>
Product samples inventory	\$ 1,323	\$ 875
Prepaid software license fees	855	
Prepaid clinical trial studies	688	661
Prepaid co-pay expenses	621	
Prepaid marketing expenses	381	607
Prepaid insurance	379	265
Prepaid FDA product and manufacturing fees	312	139
Other prepaid expenses	329	745
Other current assets		31

Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

Total prepaid and other current assets	\$ 4,888	\$ 3,323
--	----------	----------

F-23

**Table of Contents****NOTE 7 PROPERTY AND EQUIPMENT**

Property and equipment as of December 31, 2013 and 2012 consisted of the following:

	As of December 31,	
	2013	2012
Machinery and equipment	\$ 2,367	\$ 2,248
Furniture and fixtures	113	116
Computer equipment	2,160	1,211
Software	775	646
Trade show equipment	228	228
Leasehold improvement	783	783
	6,426	5,232
Less-accumulated depreciation	(2,646)	(1,507)
<b>Total property and equipment</b>	<b>\$ 3,780</b>	<b>\$ 3,725</b>

Depreciation expense for the years ended December 31, 2013, 2012 and 2011 was \$1,173, \$806 and \$446, respectively.

**NOTE 8 INTANGIBLE ASSETS**

The Company's intangible assets consist of developed technology related to the Company's approved products: LODOTRA in Europe, RAYOS in the United States, and VIMOVO intellectual property rights in the United States.

On July 26, 2012, the FDA approved RAYOS for the treatment of a broad range of indications, which resulted in the Company reclassifying the entire asset balance of \$35,456 from its indefinite-lived in-process research and development (IPR&D) asset to a finite-lived developed technology asset and commenced amortization. At December 31, 2012, the Company had no remaining IPR&D intangible assets.

On November 18, 2013, the Company entered into an asset purchase agreement with AstraZeneca, pursuant to which the Company acquired from AstraZeneca and its affiliates certain intellectual property with respect to VIMOVO and obtained the 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.

The Company tests its intangible assets for impairment when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. During the fourth quarter of 2011, the Company performed its annual test of its indefinite-lived intangible assets for impairment. The Company utilized a fair value approach by calculating its business enterprise value, which equated to the market value of the Company's common stock as of December 31, 2011, and included an appropriate control risk premium. The result of this analysis indicated that the carrying value of its IPR&D asset was impaired. Additionally, the Company calculated the business enterprise value, which included its IPR&D asset, using a discounted cash flow approach. The fair value of the IPR&D utilizing this method was estimated to be \$36,638 as of December 31, 2011. Accordingly, the Company recorded an intangible impairment charge related to its IPR&D asset of \$69,621 during the fourth quarter of 2011. The Company does not believe there have been any circumstances or indicators that carrying value of any of its intangible assets has been impaired as of December 31, 2013.

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

**Table of Contents**

As of December 31, 2013 and 2012, intangible assets consisted of the following:

	December 31, 2013				December 31, 2012			
	Cost Basis	Accumulated Amortization	Currency Translation	Net Book Value	Cost Basis	Accumulated Amortization	Currency Translation	Net Book Value
Developed technology	\$ 84,779	\$ (17,823)	\$ (2,136)	\$ 64,820	\$ 84,779	\$ (11,118)	\$ (4,769)	\$ 68,892
VIMOVO intellectual property	67,705	(1,431)		66,274				
<b>Total intangible assets</b>	<b>\$ 152,484</b>	<b>\$ (19,254)</b>	<b>\$ (2,136)</b>	<b>\$ 131,094</b>	<b>\$ 84,779</b>	<b>\$ (11,118)</b>	<b>\$ (4,769)</b>	<b>\$ 68,892</b>

Amortization expense of the Company's developed technology for the years ended December 31, 2013, 2012 and 2011 was \$8,137, \$4,732 and \$3,753, respectively. As of December 31, 2013, estimated future amortization expense was as follows:

2014	\$ 19,906
2015	19,906
2016	19,906
2017	19,906
2018 and thereafter	51,471
<b>Total</b>	<b>\$ 131,094</b>

**NOTE 9 OTHER ASSETS**

Other assets as of December 31, 2013 and 2012, consisted of the following:

	As of December 31,	
	2013	2012
Deferred financing costs	\$ 6,268	\$ 3,195
Long-term clinical study deposits	114	661
Long-term inventory deposits	479	505
Other	96	88
<b>Total other assets</b>	<b>\$ 6,957</b>	<b>\$ 4,449</b>

**NOTE 10 ACCRUED LIABILITIES**

Accrued liabilities as of December 31, 2013 and 2012, consisted of the following:

	As of December 31,	
	2013	2012
Payroll related expenses	\$ 9,491	\$ 6,290
Accrued trade discounts and rebates	8,463	2,704
Sales and marketing expenses	1,761	1,265
Accrued interest	810	2,538
Deferred rent	755	876
Clinical and regulatory expenses	488	652
Professional services	350	399

Edgar Filing: HORIZON PHARMA, INC. - Form 10-K

Contract manufacturing expenses	301	1,094
Consulting services	283	228
Accrued other	1,347	738
<b>Total accrued liabilities</b>	<b>\$ 24,049</b>	<b>\$ 16,784</b>

F-25

**Table of Contents****NOTE 11 FAIR VALUE MEASUREMENTS**

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

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

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

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

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

**Assets and liabilities measured at fair value on a recurring basis**

The following table sets forth the Company's financial assets and liabilities at fair value on a recurring basis as of December 31, 2013 and 2012:

	2013			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 66,817	\$	\$	\$ 66,817
<b>Total assets at fair value</b>	<b>\$ 66,817</b>	<b>\$</b>	<b>\$</b>	<b>\$ 66,817</b>
<b>Liabilities:</b>				
Derivative liability	\$	\$	\$ 109,410	\$ 109,410
<b>Total liabilities at fair value</b>	<b>\$</b>	<b>\$</b>	<b>\$ 109,410</b>	<b>\$ 109,410</b>
	<b>2012</b>			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 97,670	\$	\$	\$ 97,670
<b>Total assets at fair value</b>	<b>\$ 97,670</b>	<b>\$</b>	<b>\$</b>	<b>\$ 97,670</b>

In accordance with the pronouncement guidance in ASC 815 *Derivatives and Hedging*, the conversion option included within the Convertible Senior Notes was deemed to include an embedded derivative, which required the Company to bifurcate and separately account for the embedded derivative as a separate liability on its consolidated balance sheets. The estimated fair value 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 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, the Company concluded that these inputs were Level 3 inputs.



**Table of Contents**

The following table presents the assumptions used by the Company to determine the initial fair value and the fair value as of December 31, 2013 of the conversion option embedded in the Convertible Senior Notes:

	November 18, 2013	December 31, 2013
Stock price	\$ 4.47	\$ 7.62
Risk free rate	1.33%	1.69%
Borrowing cost	5.0% and 3.5%	5.0% and 3.5%
Weights	Equal weight	Equal weight
Credit spread (in basis points)	1,030 and 1,170	930 and 1,170
Volatility	40.00%	40.00%
Initial conversion price	\$ 5.36	\$ 5.36
Remaining time to maturity (in years)	5.0	4.9

As part of the Company's accounting entries to record the Convertible Senior Notes, the Company recorded a \$40,110 derivative liability. At December 31, 2013, the Company conducted a fair value assessment to properly reflect the market value adjustments for the embedded derivative due to changes in the Company's common stock value. To properly reflect the fair value of the embedded derivative of \$109,410 as of December 31, 2013, the Company recorded a \$69,300 expense in its results of operations for the three and twelve months ended December 31, 2013.

**NOTE 12 COMMITMENTS AND CONTINGENCIES***Lease Obligations*

In September 2011, the Company entered into an office lease agreement for 21,182 square feet of office space in Deerfield, Illinois, which was effective August 31, 2011. The initial term of the lease commenced on December 1, 2011, and expires on June 30, 2018. The minimum net rent was initially approximately \$30 per month during the first year and increases each year during the initial term, up to approximately \$35 per month after the sixth year. The Company has the option to extend the lease for an additional five-year term, which would commence upon the expiration of the initial term. In August 2012, the Company entered into an amendment to the lease agreement to expand the office space available to it by an additional 4,926 square feet in the same Deerfield, Illinois facility as its existing office space. The initial rent on the additional lease is \$7 per month and will increase up to a maximum of \$8 per month after the sixth year. In December 2013, the Company entered into a second amendment to the lease agreement to expand the office space available to it by an additional 8,352 square feet. The two amendments to the lease term coincide with the original lease and run through June 30, 2018. The initial rent on the second amendment is \$12 per month and will increase up to a maximum of \$14 per month after the fifth year.

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

The Company recognizes rent expense on a monthly basis over the lease term based on a straight-line method. Rent expense was \$463, \$458 and \$507 for the years ended December 31, 2013, 2012 and 2011, respectively.

*Annual Purchase Commitments*

In August 2007, the Company entered into a manufacturing and supply agreement with Jagotec AG (Jagotec). Under the agreement, Jagotec or its affiliates are required to manufacture and supply RAYOS/LODOTRA exclusively to the Company in bulk. The Company committed to a minimum purchase of RAYOS/LODOTRA tablets from Jagotec for five years from the date of first launch of RAYOS/LODOTRA in a major country, as defined in the agreement, which was in April 2009. At December 31, 2013, the minimum remaining

## **Table of Contents**

purchase commitment based on tablet pricing in effect under the agreement was \$3,351. The agreement automatically renews on a yearly basis until either party provides two years advance written notice of termination. In April 2013, the agreement automatically renewed, and, therefore, the earliest the current agreement can expire according to this advance notice procedure is April 15, 2016.

In May 2011, the Company entered into a manufacturing and supply agreement with sanofi-aventis U.S., and recently amended the agreement effective as of September 25, 2013. Pursuant to the agreement, as amended, sanofi-aventis U.S. is obligated to manufacture and supply DUEXIS to the Company in final, packaged form, and the Company is obligated to purchase DUEXIS exclusively from sanofi-aventis U.S. for the commercial requirements of DUEXIS in North America, South America and certain countries and territories in Europe, including the European Union member states and Scandinavia. At December 31, 2013, the Company had a binding purchase commitment to sanofi-aventis U.S. for DUEXIS of \$10,286, of which \$3,672 of such amount was delivered in the fourth quarter of 2013 and \$6,614 is to be delivered in the first quarter of 2014.

In November 2013, the Company and AstraZeneca entered in a supply agreement pursuant to which AstraZeneca agreed to supply VIMOVO to the Company for commercialization in the United States through December 31, 2014. As of December 5, 2013, the Company has been providing AstraZeneca with a forecast of its supply requirements, including any forecasts for its sublicensees. The first four months of each forecast is a binding purchase commitment and may not be changed without AstraZeneca's written consent. As of December 31, 2013, the minimum binding purchase commitment to AstraZeneca was \$4,402 and is to be delivered through the third quarter of 2014.

### *Royalty Agreements*

In connection with the August 2004 development and license agreement with SkyePharma AG ( SkyePharma ) and Jagotec, a wholly-owned subsidiary of SkyePharma, regarding certain proprietary technology and know-how owned by SkyePharma, Jagotec is entitled to receive a single digit percentage royalty on net sales of RAYOS/LODOTRA and on any sub-licensing income, which includes any payments not calculated based on the net sales of RAYOS/LODOTRA, such as license fees, lump sum and milestone payments. Royalty expense recognized in cost of goods sold for the years ended December 31, 2013, 2012 and 2011 was \$901, \$539 and \$455, respectively.

Under the Pozen license agreement, the Company is required to pay Pozen a flat 10% royalty on net sales of VIMOVO and such other products sold by the Company, its 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. The Company's 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.

### *Contingencies*

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

### *Indemnification*

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have

**Table of Contents**

not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

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

**NOTE 13 LEGAL PROCEEDINGS**

On February 15, 2012, the Company received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an Abbreviated New Drug Application (ANDA) with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, the Company 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. (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, the Company filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par's ANDA and/or prevent Par from selling a generic version of DUEXIS.

On August 21, 2013, the Company entered into a settlement agreement (Par settlement agreement), and license agreement (Par license agreement) with Par relating to its patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both the Company 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, the Company 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 (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.

---

**Table of Contents**

Under the Par license agreement, the Company also agreed not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by the Company 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 the Company or if Par commits a material breach of the agreement that is not cured or curable within 30 days after the Company provides notice of the breach. The Company 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.

On March 13, 2013, the Company received purported Notice Letters that a Paragraph IV Patent Certification had been filed by Alvogen Pine Brook, Inc. (Alvogen) advising that Alvogen had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. 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, the Company received a Paragraph IV Patent Certification from Watson Laboratories, Inc. Florida (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 the Company as to the timing or status of the FDA's review of its filing. On August 26, 2013, the Company, 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., (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, the Company 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, the Company 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. On October 22, 2013, the Company, 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, the Company was 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, the Company 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, 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. (Dr. Reddy's); Lupin Pharmaceuticals Inc. (Lupin); Anchen Pharmaceuticals Inc. (Anchen) (collectively, the DRL cases); (ii) Mylan Laboratories Limited (collectively the Mylan cases); and (iii) Watson Pharma, Inc. (collectively, the Watson cases). The Company understands that Dr. Reddy's has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium

**Table of Contents**

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 the Company's acquisition of the U.S. rights to VIMOVO, the Company has taken over and is responsible for the patent litigations that include the Pozen patents licensed to the Company 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. The Company understands 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. The Company understands 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. The Company understands 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. The Company understands 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. The Company understands 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.

**NOTE 14 DEBT AGREEMENTS**

The Company's outstanding debt balances as of December 31, 2013 and 2012, consisted of the following:

	As of December 31,	
	2013	2012
Convertible Senior Notes	\$ 150,000	\$
Senior Secured Loan		61,843
Current debt maturities		(11,935)
Debt discount	(39,238)	(13,042)
Long-term debt, net of current maturities	\$ 110,762	\$ 36,866

**Senior Secured Loan**

In February 2012, the Company entered into a \$60,000 senior secured loan facility with a group of institutional lenders (the Senior Secured Loan). Under the terms of the Senior Secured Loan, the outstanding principal was to accrue interest until maturity in January 2017 at a rate of 17% per annum, payable quarterly unless repaid earlier. The Senior Secured Loan allowed the Company to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt (i.e., payment in kind borrowings). During 2012, the Company elected to pay the 12% interest in cash, and the remaining 5% interest due of \$1,842 was added to the principal loan balance as a payment in kind borrowing. During 2013, the Company again elected to pay the 12% interest in cash, and the remaining 5% interest due of \$3,001 was added to the principal loan balance as a payment in kind borrowing.

---

**Table of Contents**

On September 7, 2012, the Company and the lenders entered into an amendment to the Senior Secured Loan (the Senior Secured Loan Amendment ), whereby certain affirmative covenants under the Senior Secured Loan relating to minimum levels of liquidity and net revenue were modified.

In lieu of paying a cash fee in consideration for entering into the Senior Secured Loan Amendment, the Company agreed to issue an aggregate of 1,250,000 shares of the Company s common stock to the lenders. The fair value of the common stock issued in connection with the Senior Secured Loan Amendment was \$5,075 and was classified as debt discount in the Company s consolidated balance sheet.

Beginning in April 2013, and each quarter thereafter, the lenders had the option to require the Company to repay \$3,978 of the loan principal. The Company could also prepay the loan at any time, subject to certain prepayment premiums. In March 2013, one of the lenders notified the Company of its election to request a partial repayment of the loan principal, effective on the April 1, 2013 interest payment date and each quarter thereafter. In March 2013 and June 2013, a second lender notified the Company of its election to request a partial repayment of the loan principal, effective on the April 1, 2013 and July 1, 2013 interest payment dates, respectively. Accordingly, on April 1, 2013, the Company made a payment of \$5,836, which consisted of \$3,978 in principal and \$1,858 in interest. Additionally, on July 1, 2013, the Company made a payment of \$5,761, which consisted of \$3,978 in principal and \$1,783 in interest. In September 2013, the Company was notified by the first lender mentioned above of its election to rescind its on-going request of a partial repayment of the loan principal, effective starting with the fourth quarter of 2013.

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

On November 22, 2013, the Company used \$70,409 of the proceeds from the Convertible Senior Notes to repay the Senior Secured Loan. As a result of the extinguishment of the Senior Secured Loan, the Company incurred a \$26,404 loss on debt extinguishment from the write-off of the remaining debt discount and deferred financing costs, pre-payment penalty, interest and end of loan fees. The loss on the extinguishment of debt is included in interest expense in the consolidated statement of comprehensive loss for the year ended December 31, 2013.

***Convertible Senior Notes***

On November 18, 2013, the Company entered into note purchase agreements with investors to issue \$150,000 aggregate principal amount of Convertible Senior Notes. The note purchase agreements contain customary representations, warranties, covenants and closing conditions. The Convertible Senior Notes were issued on November 22, 2013. The Company received net proceeds of \$143,598 from the sale of the Convertible Senior Notes, after deducting fees and expenses of \$6,402. The Convertible Senior Notes are governed by an Indenture, dated as of November 22, 2013, between the Company and U.S. Bank National Association, as trustee. The Convertible Senior Notes bear interest at a rate of 5.00% per year, payable in arrears on May 15 and November 15 of each year, beginning on May 15, 2014. The Convertible Senior Notes will mature on November 15, 2018, unless earlier repurchased or converted.

The Company used a portion of the proceeds from the Convertible Senior Notes to purchase \$18,675 related to a capped call transaction. The capped call transaction is comprised of a net settled purchased call option and a net settled written call option. The Company purchased the call option with an initial strike price of \$5.364, which was equal to the initial conversion price, and sold a call option with a strike price of \$6.705, which is equal to the cap price. The number of options underlying the capped call is 150,000 or the equivalent to the number of \$1,000 Convertible Senior Notes initially issued by the Company.

**Table of Contents**

The Convertible Senior Notes were sold at a price equal to 100% of the principal amount thereof and 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. Prior to August 15, 2018, the Convertible Senior Notes will be convertible, at the option of the holders thereof, only under the following circumstances:

1. *Conversion upon Satisfaction of Sale Price Condition:* During any fiscal quarter beginning after June 30, 2014, if the closing price of the Company's common stock for at least 20 trading days during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day.
  
2. *Conversion upon Satisfaction of Trading Price Condition:* The Convertible Senior Notes can be surrendered for conversion during the five business day period after any five consecutive trading day period in which the trading price per \$1,000 principal amount of Convertible Senior Notes was less than 98% of the product of the last reported sale price of the Company's common stock and the applicable conversion rate on such date.
  
3. *Conversion upon Specified Distributions:* If the Company elects to:
  - i. issue to all or substantially all holders of the Company's common stock any rights, options or warrants (other than in connection with a stockholder rights plan) entitling them, for a period of not more than 45 calendar days after the declaration date for such issuance, to subscribe for or purchase shares of the Company's common stock at a price per share that is less than the average of the last reported sale prices of the Company's common stock for the 10 consecutive trading day period ending on, and including, the trading day immediately preceding the declaration date for such issuance; or
  
  - ii. distribute to all or substantially all holders of the Company's common stock our assets, securities or rights to purchase our securities, which distribution has a per share value, as reasonably determined by the Company's board of directors or a committee thereof, exceeding 10% of the last reported sale price of the Company's common stock on the trading day preceding the date of announcement for such distribution.
  
4. *Conversion upon Specified Corporate Events:* If (i) a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs or (ii) the Company is party to a consolidation, merger, binding share exchange, or transfer or lease of all or substantially all of its consolidated assets pursuant to which the Company's common stock would be converted into cash, securities or other assets.

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, the Company may settle conversions of the Convertible Senior Notes by paying or delivering, as the case may be, cash, shares of common stock or a combination of cash and shares of the Company's common stock, at the Company's election. If the Company undergoes a fundamental change prior to the maturity date of the Convertible Senior Notes, the holders may require the Company to repurchase for cash all or any portion of their Convertible Senior Notes at a price equal to 100% of the principal amount of the Convertible Senior Notes to be repurchased, plus accrued and unpaid interest.

The conversion rate for the Convertible Senior Notes will initially be 186.4280 shares of common stock per \$1,000 principal amount of Convertible Senior Notes (equivalent to an initial conversion price of approximately \$5.36 per share of common stock); provided that unless and until the Company obtains stockholder approval to issue more than 13,164,951 shares of its common stock, which is 19.99% of the Company's common stock outstanding on November 18, 2013, upon conversion of the Convertible Senior Notes in accordance with the



**Table of Contents**

listing standards of The NASDAQ Global Market, the number of shares of common stock deliverable upon conversion will be subject to a conversion share cap. Unless and until such stockholder approval is obtained, the Company is required to settle conversions of the Convertible Senior Notes in cash up to their principal amount, shares for any conversion spread, and, if the number of shares deliverable for the conversion spread exceeds the conversion share cap, cash in lieu of shares that would otherwise be deliverable. The conversion rate of the Convertible Senior Notes, and the corresponding conversion price, is subject to adjustment for certain events, but will not be adjusted for accrued and unpaid interest.

As of December 31, 2013, the carrying value of the Convertible Senior Notes approximated their fair value due to the recent issuance of such Convertible Senior Notes. Additionally, pursuant to a number of factors outlined in ASC Topic 815, *Derivative and Hedging*, the conversion option in the Convertible Senior Notes were deemed an embedded derivative that required bifurcation and separate accounting. As such, the Company ascertained the value of the conversion option as if separate from the convertible issuance and appropriately recorded that value as a derivative liability. Accordingly, a derivative liability and a corresponding debt discount in the amount of \$40,110 were recorded at November 22, 2013. The debt discount will be charged to interest expense ratably over the life of the convertible debt. The effective interest rate computed on the Convertible Senior Notes was 11.22%.

The derivative liability will be subject to revaluation on a quarterly basis to reflect the market value change of the embedded conversion option. At December 31, 2013, the Company conducted a fair value assessment to ascertain the market value of the embedded derivative. Due primarily to changes in the Company's common stock value, the Company recorded a \$69,300 expense in its results of operations for the three and twelve months ended December 31, 2013 to properly reflect the fair value of the embedded derivative at \$109,410 as of December 31, 2013. Upon receiving shareholder approval, the derivative liability will be re-measured on such date of approval to determine the fair value. Any gains or losses as a result of the re-measurement of the derivative liability will be recorded in the Company's results of operations during that period and the entire fair value of the derivative liability will be recorded to the Company's additional paid-in capital upon conversion.

**NOTE 15 STOCKHOLDERS EQUITY**

In August 2012, the Company entered into a sales agreement with Cowen and Company, LLC ( Cowen ) pursuant to which the Company may sell its common stock through Cowen in at-the-market ( ATM ) offerings. Subject to the terms 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 the Company's common stock or to or through a market maker. On March 25, 2013, the Company requested Cowen to begin making sales under the sales agreement and provided Cowen both daily volume and minimum price restrictions under which Cowen could sell the Company's common stock. Cowen has not sold shares under the ATM since July 2013. As of December 31, 2013, Cowen had sold a cumulative total of 2,448,575 shares of the Company's common stock with gross proceeds to the Company of \$6,238.

In September 2013, warrants to purchase an aggregate of 1,365,497 shares of the Company's common stock were exercised in cashless exercises, resulting in the issuance of 1,360,746 shares of common stock.

**NOTE 16 CO-PROMOTION AGREEMENT**

In June 2012, the Company entered into a co-promotion agreement with Mallinckrodt (the Mallinckrodt Agreement ), pursuant to which the Company 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 the Company agreed not to grant to any third party the right to co-promote DUEXIS to those targeted physicians in the agreed

---

**Table of Contents**

upon territory during the term, other than an existing third party agreement that has since been terminated. Under the terms of the Mallinckrodt Agreement, the Company was 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. On June 1, 2013, the Company provided written notice to Mallinckrodt of 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.

**NOTE 17 EQUITY INCENTIVE PLANS**

**Employee Stock Purchase Plan**

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

On December 5, 2013, pursuant to the terms of the 2011 ESPP, the Company's board of directors approved an increase in the number of shares available for issuance under the 2011 ESPP of 1,053,074 shares, effective January 1, 2014. As of December 31, 2013, 350,547 shares have been issued and an aggregate of 412,805 shares of common stock were authorized and available for future grants under the 2011 ESPP.

**Stock-Based Compensation Plans**

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

In July 2010, the Company's board of directors adopted the 2011 EIP. In June 2011, the Company's stockholders approved the 2011 EIP, and it became effective upon the signing of the underwriting agreement related to the Company's initial public offering on July 28, 2011. The 2011 EIP had an initial reserve of 3,366,228 shares of common stock, including 460,842 shares of common stock previously reserved for future issuance under the 2005 Plan, 1,304,713 shares of common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan as of the 2011 EIP's effective date and 1,600,673 new shares of common stock reserved. The 2011 EIP provides that an additional number of shares will automatically be added

**Table of Contents**

to the shares authorized for issuance each year on January 1, until 2021. The number of shares added each year will be equal to the least of: (a) 5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (b) 1,474,304 shares of common stock; or (c) a number of shares of common stock that may be determined each year by the Company's board of directors that is less than (a) and (b). As of December 31, 2013, there were 78,795 shares available for future grants under the 2011 EIP. On December 5, 2013, pursuant to the terms of the Company's 2011 EIP, the Company's board of directors approved an increase in the number of shares available for issuance under the 2011 EIP of 1,474,304 shares, effective January 1, 2014.

On November 7, 2013, November 16, 2013 and March 3, 2014, the Company's board of directors approved amendments to the Company's 2011 EIP to reserve an additional 200,000 shares, 800,000 shares and 730,000 shares of the Company's common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company (or following a bona fide period of non-employment with the Company), as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules (Rule 5635(c)(4)). On January 10, 2014, the Company's 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 (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. As of December 31, 2013, there were 674,400 shares available for future grants under the 2011 EIP pursuant to Rule 5635(c)(4).

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

The following table summarizes stock options activity under the 2011 EIP for the year ended December 31, 2013 as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2012	2,746,918	\$ 8.85		
Granted	2,158,950	\$ 2.84		
Exercised	(41,820)	\$ 3.88		
Forfeited	(452,968)	\$ 3.88		
Outstanding as of December 31, 2013	4,411,080	\$ 6.47	7.9 years	\$ 13,283
Exercisable as of December 31, 2013	2,079,728	\$ 9.57	6.8 years	\$ 3,860

The following table summarizes the Company's outstanding stock options at December 31, 2013:

Exercise Price Ranges	Options Outstanding			Options Exercisable	
	Number of options outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Number Exercisable	Weighted Average Exercise Price
\$1.36 - \$3.97	2,079,203	\$ 2.63	9.1 years	432,699	\$ 2.65
\$4.10 - \$5.20	1,039,318	4.98	7.5 years	651,196	5.02
\$7.48 - \$12.94	935,627	10.04	7.0 years	645,136	11.01
\$13.47 - \$17.22	106,568	13.91	5.6 years	104,547	13.85
\$20.78 - \$28.83	250,364	28.05	651 years	246,150	28.18
	4,411,080	\$ 6.47	7.9 years	2,079,728	\$ 9.57



**Table of Contents**

During the years ended December 31, 2013, 2012 and 2011, the Company granted stock options to purchase an aggregate of 2,158,950, 516,325 and 1,256,339 shares of common stock, respectively, with a weighted average grant date fair value of \$2.23, \$3.44 and \$5.77, respectively.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The determination of the fair value of each stock option is affected by the Company's stock price on the date of grant, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company's expected stock price volatility over the expected life of the awards and actual and projected stock option exercise behavior. The weighted average fair value per share of stock option awards granted during the years ended December 31, 2013, 2012 and 2011, and assumptions used to value stock options, are as follows:

	For the Years Ended December 31,		
	2013	2012	2011
Dividend yield			
Risk-free interest rate	1.2%	1.0%	1.2%
Weighted average volatility	86.7%	89.0%	89.3%
Expected life (in years)	5.98	5.96	6.00
Weighted average grant date fair value per share of options granted	\$ 2.8	\$ 2.5	\$ 4.2

*Dividend yields*

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

*Risk-Free Interest Rate*

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

*Volatility*

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

*Expected Term*

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

*Forfeitures*

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

**Table of Contents****Restricted Stock Units**

The following table summarizes restricted stock unit activity for the year ended December 31, 2013 as follows:

	Number of Units	Weighted Average Grant-Date Fair Value Per Units
Outstanding as of December 31, 2012	232,158	\$ 4.92
Granted	831,004	\$ 2.95
Vested	(174,213)	\$ 6.05
Forfeited	(55,948)	\$ 2.86
<b>Outstanding as of December 31, 2013</b>	<b>833,001</b>	<b>\$ 2.86</b>

During the years ended December 31, 2013, 2012 and 2011, the Company granted 730,000, 520,000 and 304,890, respectively, restricted stock units to acquire shares of the Company's common stock to its employees. The restricted stock units vest over a four-year period on each anniversary of the vesting commencement date. In addition, in December 2013, the Company granted 101,004 fully vested deferred issuance restricted stock units to the Company's named executive officers in connection with a one-time bonus payment associated with the completion of the Company's acquisition of the U.S. rights to VIMOVO.

The following table summarizes share-based compensation expense included in the Company's consolidated statements of operations for the years ended December 31, 2013, 2012 and 2011:

	For the Years Ended December 31,		
	2013	2012	2011
<b>Share-based compensation expense:</b>			
Research and development	\$ 1,054	\$ 1,186	\$ 760
Sales and marketing	1,465	1,090	451
General and administrative	2,495	2,385	1,319
<b>Net effect of share-based compensation expense on net loss</b>	<b>\$ 5,014</b>	<b>\$ 4,661</b>	<b>\$ 2,530</b>

No income tax benefit has been recognized relating to stock-based compensation expense and no tax benefits have been realized from exercised stock options, due to the Company's net loss position. As of December 31, 2013, the Company estimates that pre-tax unrecognized compensation expense of \$7,459 for all unvested share-based awards, including both stock options and restricted stock units, will be recognized through the fourth quarter of 2016, with \$5,792 in pre-tax compensation expense estimated to be recognized during the year ended December 31, 2014. The Company expects to satisfy the exercise of stock options and future distribution of shares of restricted stock by issuing new shares of its common stock which have been reserved under the 2011 EIP.

**NOTE 18 RELATED PARTY TRANSACTIONS**

The Company has entered into consulting agreements with three stockholders, two of whom previously served as directors of Horizon Pharma USA. Two of the consulting agreements terminated as of December 31, 2011, while one remains in effect. In addition, the Company's wholly-owned subsidiary, Horizon Pharma AG, has entered into a consulting agreement with a former owner and majority shareholder of Nitec. For the years ended December 31, 2013, 2012 and 2011, the Company paid \$691, \$716 and \$678, respectively, in consulting fees to the related parties.

**Table of Contents****NOTE 19 INCOME TAXES**

The Company accounts for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the year that the change is enacted.

The components of the benefit for income taxes were as follows for the years ended December 31, 2013, 2012 and 2011:

	<b>For the Years Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
<b>Current provision</b>			
Federal	\$	\$	\$
State	4	4	3
Foreign	43	35	28
<b>Total current provision</b>	<b>47</b>	<b>39</b>	<b>31</b>
<b>Deferred benefit</b>			
Federal			
State			
Foreign	(1,168)	(5,210)	(14,714)
<b>Total deferred benefit</b>	<b>(1,168)</b>	<b>(5,210)</b>	<b>(14,714)</b>
<b>Total benefit for income taxes</b>	<b>\$ (1,121)</b>	<b>\$ (5,171)</b>	<b>\$ (14,683)</b>

Total benefit for income taxes was \$1,121, \$5,171 and \$14,683 for the years ended December 31, 2013, 2012 and 2011, respectively. The \$4,050 decrease in the income tax benefit during the year ended December 31, 2013 was primarily attributable to the absence of one-time tax benefits in 2013 that were recorded during 2012. On July 26, 2012, the FDA approved RAYOS, which resulted in the reclassification of \$35,456, from an indefinite-lived intangible asset to a finite-lived intangible asset. The reclassification required the Company to amortize this asset over the estimated useful life of the asset, which resulted in a corresponding reduction to the Company's net deferred tax liabilities and the recognition of a one-time net income tax benefit of \$4,258 that was recorded as an additional income tax benefit during the third quarter of 2012.

During the year ended December 31, 2011, total benefit for income taxes was \$14,683. The increase in income tax benefit during this period compared to the year ended December 31, 2010 was associated with a reduction in the Company's deferred income tax liabilities and a corresponding income tax benefit recorded as a result of intangible asset impairment charge. During the fourth quarter of 2011, the Company performed its annual impairment test related to its indefinite-lived intangible asset and determined that the carrying value of its indefinite-lived in process research and development (IPR&D) asset was greater than the fair value of this asset. Accordingly, the Company recorded an intangible asset impairment charge of \$69,621 associated with the Company's IPR&D asset during 2011, which reduced the Company's deferred income tax liability and increased the income tax benefit for the period.

**Table of Contents**

The Company's loss before benefit for income taxes by jurisdiction for the years ended December 31, 2013, 2012 and 2011 is as follows:

	For the Years Ended December 31,		
	2013	2012	2011
United States	\$ (139,347)	\$ 56,038	\$ (43,148)
International	(10,779)	(149,003)	(84,800)
<b>Loss before benefit for income taxes</b>	<b>\$ (150,126)</b>	<b>\$ (92,965)</b>	<b>\$ (127,948)</b>

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

	For the Years Ended December 31,		
	2013	2012	2011
U.S. federal income taxes at statutory tax rate	\$ (52,543)	\$ (32,538)	\$ (44,781)
Stock based compensation	1,107	1,063	658
Foreign tax rate differential	2,019	4,376	14,994
Deferred taxes not benefited	23,921	21,715	14,499
Derivative liability	24,255		
Research and development credit	120	(5)	(79)
Other		218	26
<b>Effective income taxes</b>	<b>\$ (1,121)</b>	<b>\$ (5,171)</b>	<b>\$ (14,683)</b>

The tax effects of the temporary differences and net operating losses that give rise to significant portions of deferred tax assets and liabilities are as follows:

	As of December 31,		
	2013	2012	2011
<b>Deferred tax assets:</b>			
Net operating loss carryforwards	\$ 121,001	\$ 97,724	\$ 68,689
Derivative liability	14,799		
Accruals and reserves	7,073	5,144	1,906
Original issuance discount related to capped call	6,740		
Contingent royalties	3,122		
Research and development credits	2,571	2,445	2,447
Foreign intangible assets	63	76	90
<b>Total deferred tax assets</b>	<b>155,369</b>	<b>105,389</b>	<b>73,132</b>
Valuation allowance	(128,422)	(95,970)	(68,194)
<b>Deferred tax assets, net of valuation allowance</b>	<b>26,947</b>	<b>9,419</b>	<b>4,938</b>
<b>Deferred tax liabilities:</b>			
Debt discount	\$ 14,477	\$	\$
In-process research and development			7,354
Developed technology	13,009	13,827	7,145
Intangible assets	2,823		
<b>Total deferred tax liabilities</b>	<b>30,309</b>	<b>13,827</b>	<b>14,499</b>

Net deferred income tax liability	\$ 3,362	\$ 4,408	\$ 9,561
-----------------------------------	----------	----------	----------

F-40

**Table of Contents**

The increase in the deferred tax valuation allowance was \$32,452, \$27,776 and \$14,213 for the years ended December 31, 2013, 2012 and 2011, respectively. The increase in the deferred tax valuation allowance in 2013 was primarily the result of higher federal and state net operating losses, which were fully reserved for due to the uncertainty surrounding the realization of these assets. A reconciliation of the beginning and ending amounts of the valuation allowance for the years ended December 31, 2013, 2012 and 2011 were as follows:

Valuation allowance at December 31, 2010	\$ (53,981)
Increase for current year activity	(14,213)
Valuation allowance at December 31, 2011	\$ (68,194)
Increase for current year activity	(32,034)
Release in valuation allowance (1)	4,258
Valuation allowance at December 31, 2012	\$ (95,970)
Increase for current year activity	(32,452)
Valuation allowance at December 31, 2013	\$ (128,422)

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

As of December 31, 2013, the Company had net operating loss carryforwards of approximately \$275,430, \$123,257 and \$91,804 available to reduce future taxable income, if any, for federal, state, and foreign income tax purposes, respectively. Net operating loss carryforwards for state and federal income tax purposes will begin to expire in 2015 and 2025, respectively. Utilization of the net operating loss carryforwards may be subject to annual limitations as prescribed by federal and state statutory provisions. The annual limitation may result in the expiration of net operating loss carryforwards prior to its utilization. The Company's net operating loss of \$995, when realized, will be recorded through stockholders' equity.

As of December 31, 2013, the Company had research and development credit carryforwards for federal and state income tax purposes of approximately \$2,745 and \$394, respectively, available to reduce future taxable income. The federal research and development credits will expire beginning in 2026 if not utilized while the state research and development credits have an unlimited carryforward period.

The Company has provided a full valuation allowance for its deferred tax assets at December 31, 2013 due to the uncertainty surrounding the future realization of these assets. During the year ended December 31, 2013, \$6,740 of the valuation allowance related to the deferred tax asset, which was created as a result of the original debt discount associated with the capped call transaction, was recorded to stockholders' equity. As this deferred tax asset which was recorded through stockholders' equity is removed, the related valuation allowance will also be removed through stockholders' equity.

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

**Table of Contents**

annual limits will be a cumulative carryforward of \$49,893 in 2014, and at a minimum, \$22,001 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.

The Company accounts for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return. The changes in the Company's uncertain income tax positions for the years ended December 31, 2013, 2012 and 2011 consisted of the following:

	For the Years Ended December 31,		
	2013	2012	2011
Beginning balance	\$ 442	\$ 442	\$ 424
Tax positions related to current year:			
Additions	51	2	34
Reductions			
	51	2	34
Tax positions related to prior years:			
Additions			
Reductions	(2)	(2)	(16)
Settlements			
Lapses in statutes of limitations			
Additions from current year acquisitions			
	(2)	(2)	(16)
Ending balance	\$ 491	\$ 442	\$ 442

The Company has assessed that its liability for unrecognized income tax benefits will not significantly change within the next twelve months. If these unrecognized tax benefits are recognized, the impact on the Company's effective tax rate would be immaterial. Additionally, there was no interest or penalties accrued at December 31, 2013 and 2012, respectively, due to the Company's net operating loss position.

The Company files income tax returns in the U.S. federal and in various state and foreign jurisdictions. At December 31, 2013, all open tax years in the federal and some state jurisdictions date back to 2005 due to the taxing authorities' ability to adjust operating loss carryforwards. No changes in settled tax years have occurred through December 31, 2013 and the Company does not anticipate there will be a material change in the total amount of unrecognized tax benefits within the next 12 months.

**NOTE 20 EMPLOYEE BENEFIT PLANS**

The Company sponsors a defined contribution 401(k) retirement savings plan covering all of its U.S. employees, whereby an eligible employee may elect to contribute a portion of his or her salary on a pre-tax basis, subject to applicable federal limitations. Under the terms of the plan, the Company is not required to make any discretionary matching of employee contributions. For the years ended December 31, 2013, 2012 and 2011, the Company did not record any expense under the plan.

The Company's wholly-owned subsidiary, Horizon Pharma AG, sponsors a defined benefit savings plan covering all of its employees in Switzerland and a defined contribution plan for its employees in Germany. For the years ended December 31, 2013, 2012 and 2011, the Company recognized expenses of \$52, \$52 and \$55, respectively, under these plans.

**Table of Contents****NOTE 21 SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**

The following table provides a summary of selected financial results of operations by quarter for the years ended December 31, 2013 and 2012 as follows:

<b>2013</b>	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
Net sales (1)	\$ 8,693	\$ 11,131	\$ 24,112	\$ 30,080
Gross profit	4,924	8,737	20,905	24,825
Loss from operations	(18,544)	(15,804)	(2,744)	(5,762)
Net loss	(22,171)	(18,441)	(5,492)	(102,901)
Net loss per common share-basic and diluted	\$ (0.36)	\$ (0.29)	\$ (0.08)	\$ (1.56)
<b>2012</b>	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
Net sales (1)	\$ 2,485	\$ 3,681	\$ 6,319	\$ 6,359
Gross profit	456	986	2,711	2,816
Loss from operations	(19,788)	(18,345)	(18,714)	(22,026)
Net loss	(23,726)	(22,782)	(16,953)	(24,333)
Net loss per common share-basic and diluted	\$ (0.98)	\$ (0.68)	\$ (0.47)	\$ (0.40)

- (1) The net sales amounts listed above for the First, Second and Third quarters of 2013 have been revised from \$9,171, \$12,254 and \$26,218, respectively, and the net sales amounts listed above for the First, Second, Third and Fourth quarters of 2012 have been revised from \$2,523, \$3,842, \$6,520 and \$6,747, respectively, reflecting the reclassification of wholesaler service fees from cost of goods sold to sales discounts and allowances. See Note 1 The Company in the notes to the Company's consolidated financial statements included in this Annual Report on Form 10-K.

---

**Table of Contents**

**INDEX TO EXHIBITS**

**Description of Document**

Certificate of Incorporation.

Bylaws.

Stock Certificate.

Agreement by Horizon Pharma, Inc. to bridge financing investors.

Agreement by Horizon Pharma, Inc. on December 18, 2007 to Comerica Bank.

Agreement by Horizon Pharma, Inc. on December 18, 2007 to Hercules Technology Growth Capital, Inc.

Agreement by Horizon Pharma, Inc. on November 21, 2008 to Comerica Bank.

Agreement by Horizon Pharma, Inc. on November 21, 2008 to Hercules Technology Growth Capital, Inc.

Agreement by Horizon Pharma, Inc. on April 1, 2010 to Silicon Valley Bank.

Agreement, dated April 1, 2010, by and among Horizon Pharma, Inc. and certain of its stockholders.

Agreement by Horizon Pharma, Inc. on June 2, 2011 to Oxford Finance LLC.

Agreement by Horizon Pharma, Inc. on June 2, 2011 to Silicon Valley Bank.

Agreement, dated June 16, 2011, by and among Horizon Pharma, Inc. and certain of its stockholders.

Agreement by Horizon Pharma, Inc. pursuant to the Securities Purchase Agreement, dated February 28, 2012, by and among Horizon Pharma, Inc. and the Purchasers and Warrant Holders.

Warrant Holders' Rights Agreement, dated February 22, 2012.

Agreement in Public Offering of Units.

Agreement, dated November 22, 2013, by and between Horizon Pharma, Inc. and U.S. Bank National Association.

Agreement for Convertible Senior Note due 2018.

Agreement.

Form of Stock Option Agreement thereunder.

Agreement, as amended, and Form of Option Agreement and Form of Stock Option Grant Notice thereunder.

Purchase Plan and Form of Offering Document thereunder.

Agreement, dated August 20, 2004, by and among Horizon Pharma AG, Jagotec AG and SkyePharma AG.

Agreement and License Agreement, dated August 3, 2007, by and among Horizon Pharma AG, Jagotec AG and SkyePharma AG.

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>
10.7*(1)	Manufacturing and Supply Agreement, dated August 3, 2007, by and between Horizon Pharma AG and Jagotec AG.
10.8*(1)	Technology Transfer Agreement, dated August 2, 2004, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck KgaA.
10.9*(1)	Transfer, License and Supply Agreement, dated December 21, 2006, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH (which was subsequently assigned to Mundipharma Laboratories GmbH in April 2011).
10.10*(1)	Amendment to Transfer, License and Supply Agreement, dated December 17, 2008, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH (which was subsequently assigned to Mundipharma Laboratories GmbH in April 2011).
10.11*(1)	Transfer, License and Supply Agreement, dated March 26, 2009, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck GesmbH.
10.12+(1)	Form of Employee Proprietary Information and Inventions Agreement.
10.13*(1)	Manufacturing and Supply Agreement, dated March 24, 2009, by and between Horizon Pharma AG and Mundipharma Medical Company.
10.14*(1)	Exclusive Distribution Agreement, dated March 24, 2009, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.
10.15(1)	Amendment to Exclusive Distribution Agreement, dated July 7, 2009, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.
10.16+(1)	Amended and Restated Executive Employment Agreement, dated July 27, 2010, by and between Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Timothy P. Walbert.
10.17+(1)	Amended and Restated Executive Employment Agreement, dated July 27, 2010, by and between Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Robert J. De Vaere.
10.18+(1)	Amended and Restated Executive Employment Agreement, dated July 27, 2010, by and between Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D. FACP.
10.19*(1)	Amendment to Manufacturing and Supply Agreement, dated March 4, 2011, by and between Horizon Pharma AG and Jagotec AG.
10.20*(1)	Manufacturing and Supply Agreement, dated May 25, 2011, by and between Horizon Pharma USA, Inc. and sanofi-aventis U.S. LLC.
10.21+(17)	Non-Employee Director Compensation Policy.
10.22*(1)	Sales Contract, dated July 1, 2010, by and between Horizon Pharma USA, Inc. and BASF Corporation.
10.23*(1)	Manufacturing and Supply Agreement, dated November 4, 2010 by and between Horizon Pharma AG and Mundipharma Medical Company.
10.24*(1)	Exclusive Distribution Agreement, dated November 4, 2010 by and between Horizon Pharma AG and Mundipharma International Corporation Limited.
10.25*(1)	Letter Agreement, dated March 2, 2011, by and among Horizon Pharma AG, Horizon Pharma GmbH, Mundipharma International Corporation Limited and Mundipharma Medical Company.
10.26*(13)	Amendment to Manufacturing and Supply Agreement, effective as of September 25, 2013, by and between Horizon Pharma USA, Inc. and sanofi-aventis U.S. LLC.
10.27*(3)	Standard Office Lease, effective August 31, 2011, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>
10.28(12)	Letter Agreement, dated October 17, 2012, by and among Horizon Pharma AG, Mundipharma International Corporation Limited and Mundipharma Medical Company.
10.29*(12)	Letter Agreement, dated March 21, 2013, by and among Horizon Pharma AG, Mundipharma International Corporation Limited and Mundipharma Medical Company.
10.30*(5)	Amendment No. 1 to Exclusive Distribution Agreement, dated March 5, 2012, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.
10.31(5)	Amendment No. 1 to Manufacturing and Supply Agreement, dated March 5, 2012, by and between Horizon Pharma AG and Mundipharma Medical Company.
10.32+(6)	Form of Restricted Stock Unit Purchase Agreement.
10.33+(6)	Amended and Restated Severance Benefit Plan Dated March 1, 2012.
10.34+(7)	Executive Employment Agreement, dated June 1, 2012, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Todd N. Smith.
10.35*(9)	First Amendment to Lease, dated July 31, 2012, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.
10.36*	Second Amendment to Lease, dated December 10, 2013, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.
10.37(10)	Sales Agreement, dated August 14, 2012, between Horizon Pharma, Inc. and Cowen and Company, LLC.
10.38*(11)	Second Letter Agreement, dated October 6, 2011, by and among Horizon Pharma AG, Mundipharma International Corporation Limited and Mundipharma Medical Company.
10.39*	Amendment No. 2 to Exclusive Distribution Agreement, dated October 25, 2013, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.
10.40	Amendment No. 2 to Manufacturing and Supply Agreement, dated October 25, 2013, by and between Horizon Pharma AG and Mundipharma Medical Company.
10.41*(13)	Settlement Agreement, dated August 21, 2013, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.
10.42*(13)	License Agreement, dated August 21, 2013, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.
10.43*	Asset Purchase Agreement, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and AstraZeneca AB.
10.44*	License Agreement, dated November 22, 2013, by and between Horizon Pharma USA, Inc. and AstraZeneca AB.
10.45*	Supply Agreement, dated November 22, 2013, by and between Horizon Pharma USA, Inc. and AstraZeneca AB.
10.46*	Amended and Restated Collaboration and License Agreement for the United States, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and POZEN Inc.
10.47*	Amendment No. 1 to Amended and Restated Collaboration and License Agreement for the United States, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and POZEN Inc.
10.48*	Letter Agreement, dated November 18, 2013, by and among Horizon Pharma USA, Inc., AstraZeneca AB and POZEN Inc.
10.49*	Master Manufacturing Services Agreement, dated October 31, 2013, by and between Horizon Pharma, Inc. and Patheon Pharmaceuticals, Inc.

**Table of Contents**

Exhibit Number	Description of Document
10.50(15)	Capped Call Confirmation, dated November 19, 2013, by and between Horizon Pharma, Inc. and Deutsche Bank AG, London Branch.
10.51(15)	Capped Call Confirmation, dated November 19, 2013, by and between Horizon Pharma, Inc. and Société Générale.
10.52+(16)	First Amendment to Amended and Restated Executive Employment Agreement, dated January 16, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Timothy P. Walbert.
10.53+(16)	First Amendment to Amended and Restated Executive Employment Agreement, dated January 16, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Robert J. De Vaere.
10.54+(16)	First Amendment to Amended and Restated Executive Employment Agreement, dated January 16, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D., FACP.
10.55+(16)	First Amendment to Executive Employment Agreement, dated January 16, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Todd N. Smith.
10.56+	Executive Employment Agreement, dated March 5, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Robert F. Carey.
21.1	Subsidiaries of Horizon Pharma, Inc.
23.1	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
99.1	Unaudited pro forma condensed combined statements of income/(loss) for the year ended December 31, 2013.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

\* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(1) Incorporated by reference to Horizon Pharma, Inc. s Registration Statement on Form S-1 (No. 333-168504), as amended.

(2) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on August 2, 2011.

(3) Incorporated by reference to Horizon Pharma, Inc. s Quarterly Report on Form 10-Q, filed on November 14, 2011.

**Table of Contents**

- (4) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on March 1, 2012.
- (5) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on March 8, 2012.
- (6) Incorporated by reference to Horizon Pharma, Inc. s Annual Report on Form 10-K, filed on March 23, 2012.
- (7) Incorporated by reference to Horizon Pharma, Inc. s Quarterly Report on Form 10-Q, filed on August 10, 2012.
- (8) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on September 20, 2012.
- (9) Incorporated by reference to Horizon Pharma, Inc. s Quarterly Report on Form 10-Q, filed on November 13, 2012.
- (10) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on August 14, 2012.
- (11) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on September 7, 2012.
- (12) Incorporated by reference to Horizon Pharma, Inc. s Quarterly Report on Form 10-Q, filed on May 10, 2013.
- (13) Incorporated by reference to Horizon Pharma, Inc. s Quarterly Report on Form 10-Q, filed on November 8, 2013.
- (14) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on March 4, 2014.
- (15) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on November 25, 2013.
- (16) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on January 16, 2014.
- (17) Incorporated by reference to Horizon Pharma, Inc. s Annual Report on Form 10-K, filed on March 18, 2013.