HORIZON PHARMA, INC.
Form 10-Q
August 09, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(MARK ONE)

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

For the quarterly period ended June 30, 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)

Delaware **(State or other jurisdiction of incorporation or organization)**	**27-2179987** **(I.R.S. Employer Identification No.)**
520 Lake Cook Road, Suite 520 **Deerfield, Illinois** **(Address of principal executive offices)**	**60015** **(Zip Code)**

(224) 383-3000

(Registrant s telephone number, including area code)

Not applicable

(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) 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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act:

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 in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Number of shares of registrant s common stock, par value $0.0001, outstanding as of August 6, 2013: 64,492,748.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

HORIZON PHARMA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share data)

	June 30, 2013	December 31, 2012
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 69,340	$ 104,087
Restricted cash	800	800
Accounts receivable, net	7,340	3,463
Inventories, net	5,787	5,245
Prepaid expenses and other current assets	3,367	3,323
Total current assets	86,634	116,918
Property and equipment, net	3,500	3,725
Developed technology, net	64,544	68,892
Other assets	3,839	4,449
TOTAL ASSETS	$ 158,517	$ 193,984
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,624	$ 5,986
Accrued expenses	20,516	16,784
Deferred revenues current portion	1,498	2,230
Notes payable current portion	15,913	11,935
Total current liabilities	43,551	36,935
LONG-TERM LIABILITIES:		
Notes payable, net of current	31,938	36,866
Deferred revenues, net of current	9,363	9,554
Deferred tax liabilities, net	3,148	4,408
Other long term liabilities	203	243
Total long-term liabilities	44,652	51,071
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 63,310,334 and 61,722,247 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively	6	6

Additional paid-in capital		422,798		417,455
Accumulated other comprehensive loss		(3,767)		(3,372)
Accumulated deficit		(348,723)		(308,111)
Total stockholders equity		70,314		105,978
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$	158,517	$	193,984

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

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HORIZON PHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

(In thousands, except share and per share data)

	Three Months Ended June 30, 2013	Three Months Ended June 30, 2012	Six Months Ended June 30, 2013	Six Months Ended June 30, 2012
REVENUES:				
Sale of goods	$ 17,490	$ 4,556	$ 28,120	$ 7,411
Contract revenue	147	52	215	105
Gross sales	17,637	4,608	28,335	7,516
Sales discounts and allowances	(5,383)	(767)	(6,910)	(1,152)
Net sales	12,254	3,841	21,425	6,364
Cost of goods	3,517	2,855	7,764	4,922
Gross profit	8,737	986	13,661	1,442
OPERATING EXPENSES:				
Research and development	2,833	4,233	5,031	8,302
Sales and marketing	16,526	10,543	32,854	21,515
General and administrative	5,182	4,555	10,124	9,758
Total operating expenses	24,541	19,331	48,009	39,575
Operating loss	(15,804)	(18,345)	(34,348)	(38,133)
OTHER (EXPENSE) INCOME, NET:				
Interest expense, net	(3,442)	(3,191)	(7,045)	(7,742)
Foreign exchange gain (loss)	454	(1,401)	(451)	(900)
Other, net		(4)		(56)
Total other expense, net	(2,988)	(4,596)	(7,496)	(8,698)
Loss before benefit for income taxes	(18,792)	(22,941)	(41,844)	(46,831)
BENEFIT FOR INCOME TAXES	(351)	(159)	(1,232)	(323)
NET LOSS	$ (18,441)	$ (22,782)	$ (40,612)	$ (46,508)
NET LOSS PER COMMON SHARE - Basic and diluted	$ (0.29)	$ (0.68)	$ (0.65)	$ (1.61)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING - Basic and diluted	62,872,173	33,715,703	62,339,285	28,909,080
OTHER COMPREHENSIVE INCOME (LOSS), NET OF TAX				
Foreign currency translation adjustments	402	(832)	(395)	261
Other comprehensive income (loss)	402	(832)	(395)	261
COMPREHENSIVE LOSS	$ (18,039)	$ (23,614)	$ (41,007)	$ (46,247)

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

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HORIZON PHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)

	Six Months Ended June 30, 2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (40,612)	$ (46,508)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	3,855	2,140
Stock-based compensation	2,100	2,490
Non-cash interest expense	1,829	1,169
Paid in kind interest expense	1,525	1,079
Foreign exchange loss	451	900
Loss on disposal of assets		68
Changes in operating assets and liabilities:		
Accounts receivable	(3,880)	1,751
Inventories	(559)	(2,001)
Prepaid expenses and other current assets	(58)	(1,631)
Accounts payable	(348)	(255)
Accrued expenses	3,795	1,527
Deferred revenues	(774)	2,973
Deferred tax liabilities	(1,203)	(349)
Other non-current assets and liabilities	211	
Net cash used in operating activities	(33,668)	(36,647)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(345)	(1,043)
Net cash used in investing activities	(345)	(1,043)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the sale of common stock under an ATM agreement, net of issuance costs	3,039	
Proceeds from the issuance of common stock through ESPP programs	204	147
Proceeds from the issuance of notes payable, net of issuance costs		55,578
Proceeds from private equity offerings, net of issuance costs		47,475
Repayment of notes payable	(3,978)	(19,814)
Net cash (used in) provided by financing activities	(735)	83,386
Effect of foreign exchange rate changes on cash	1	(202)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(34,747)	45,494
CASH AND CASH EQUIVALENTS, beginning of the year	104,087	17,966
CASH AND CASH EQUIVALENTS, end of the year	$ 69,340	$ 63,460
Supplemental cash flow information:		
Cash paid for interest	$ 3,734	$ 3,932

Cash paid for income taxes	26	28
Commitment fee paid on notes payable		600

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

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HORIZON PHARMA, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(In thousands, except share and per share data)

NOTE 1 BASIS OF PRESENTATION

The unaudited condensed consolidated financial statements presented herein have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, all adjustments, including normal recurring adjustments, considered necessary for a fair statement of the financial statements have been included. Operating results for the three and six months ended June 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. The December 31, 2012 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by GAAP.

The unaudited condensed consolidated financial statements presented herein include the accounts of Horizon Pharma, Inc. (the Company) and its wholly-owned subsidiaries. All inter-company transactions and balances have been eliminated. Additionally, certain reclassifications have been made to prior period financial statements to conform to the current period presentation, including the reclassification of $258 from general and administrative expenses to selling and marketing expenses in the June 30, 2013 year to date results.

Business Overview

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

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

On April 23, 2011, the U.S. Food and Drug Administration (FDA) approved DUEXIS, 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 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 recently further expanded its sales force to approximately 170 representatives following the termination of its co-promotion agreement with Mallinckrodt LLC (Mallinckrodt), in June 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, the Company does not expect a material level of sales from DUEXIS in European markets.

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

Limited (Mundipharma).

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

The accompanying unaudited condensed consolidated 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 June 30, 2013, the Company had cash and cash equivalents totaling $69,340. The Company believes that it has sufficient liquidity and capital resources to operate into the third quarter of 2014 and potentially beyond 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 in the U.S. market, where it was fully launched in January 2012, and the commercial success of RAYOS in the U.S. market, which was fully launched in January 2013. The Company has incurred net operating losses and negative cash flows from operations since its inception. In order to continue its operations, the Company must generate sufficient revenue to meet the trailing twelve month net revenue covenants of its $60,000 senior secured loan facility with a group of institutional lenders (the Senior Secured Loan) and achieve profitable operations or it may be required to obtain additional debt or equity financing. There can be no assurance, however, that such financing will be available or on terms acceptable to the Company. While the Company did meet the trailing twelve month net revenue covenants of its Senior Secured Loan as of the quarter ended June 30, 2013, should the Company not meet these quarterly minimum trailing twelve month net revenue covenants in the future, in addition to an increase in the interest rate payable under the loan facility, the lenders would have the right to demand repayment of the obligations under the loan. The Company also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if the Company was unable to meet the minimum quarterly trailing twelve month net revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on the Company s financial position and results of operations. These uncertainties and lack of commercial operating history raise substantial doubt about the Company s ability to continue as a going concern.

NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Foreign Currency Translation and Transactions

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

The U.S. dollar is the functional currency for the Company s U.S. based businesses and the Euro is the functional currency for its subsidiaries in Switzerland and Germany. Foreign currency-denominated assets and liabilities of these subsidiaries are translated into U.S. dollars based on exchange rates prevailing at the end of the period, revenues and expenses are translated at average exchange rates prevailing during the corresponding period, and stockholders equity accounts are translated at historical exchange rates as of the date of any equity transaction. The effects of foreign exchange gains and losses arising from the translation of assets and liabilities of those entities where the functional currency is not the U.S. dollar are included as a component of accumulated other comprehensive gain (loss).

Gains and losses resulting from foreign currency translations are reflected within the Company s results of operations and have generally not had a material impact on the Company s operating results. During the three months ended June 30, 2013, the Company recorded a gain from foreign currency translations of $454 compared to a loss from foreign currency translation during the three months ended June 30, 2012 of $1,401. During the six months ended June 30, 2013 and 2012, the Company recorded a loss from foreign currency translation of $451 and $900, respectively. The Company does not currently utilize and has not in the past utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

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Revenue Recognition

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

Revenue from up-front license fees

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

Revenue from milestone receipts

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

Revenue from product deliveries

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

The Company anticipates revenues will continue to result from distribution, marketing, manufacturing and supply agreements with third parties in Europe and certain Asian, Latin American and other countries with respect to LODOTRA. The Company also recognizes revenues related to up-front license fees, milestone receipts and product deliveries.

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

Under the manufacturing and supply agreements with Mundipharma Medical Company (Mundipharma Medical), Mundipharma Medical agreed to purchase LODOTRA exclusively from the Company at a price based on a specified percentage of the average net selling price (ANSP) for sales in a given country, subject to a minimum price. Mundipharma Medical has a nine-month period from purchase date to request an ANSP adjustment. If the ANSP is lower than the actual purchase price, then Mundipharma Medical would receive a price adjustment. Beginning in 2011, products sold to Mundipharma Medical have been recognized upon delivery at the minimum price, as no contractual right of return exists. The difference between the actual selling price and the minimum price is recorded as deferred revenue until such time as adjustments for product returns, rebates and discounts can be reliably estimated or the nine-month ANSP adjustment period passes, at which time any previously deferred revenue would be recognized as revenue. As of June 30, 2013 and December 31, 2012, deferred revenues related to the sale of LODOTRA were $887 and $1,939, respectively. Additionally, as of June 30, 2013 and December 31, 2012, deferred revenues related to milestone and upfront payments received under existing agreements were $8,324 and $8,175, respectively.

In December 2011, the Company began recognizing revenues from the sale of DUEXIS following its commercial launch in the U.S. DUEXIS is currently sold to wholesale pharmaceutical distributors and to several national and regional retail chains. Until the Company could reliably estimate returns, the Company determined that shipment of products to wholesale pharmaceutical distributors and regional retail chains did not meet the criteria for revenue recognition at the time of shipment. The Company therefore deferred DUEXIS revenue recognition until the right

of return no longer existed, which was the earlier of DUEXIS being dispensed through patient prescriptions or the expiration of the right of return (twelve months after the expiration date of the product).

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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 recognizes revenue on the sale of DUEXIS and RAYOS at the point of sale to the wholesaler.

DUEXIS/RAYOS Product Sales Discounts and Allowances

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

Prompt Pay Discounts

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

Product Launch Discounts

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

Patient Discount Programs

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

Chargebacks

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

Rebates

The Company participates in certain federal government rebate programs, such as Medicare and Medicaid, as well as commercial rebate programs. Under these rebate programs, the Company pays a rebate to the federal government, 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 expense as a reduction of revenue.

Cost of Goods Sold

As a result of the commercial launch of DUEXIS in the U.S. in December 2011, and RAYOS in December 2012, the Company also began to recognize cost of goods sold in connection with its sale of DUEXIS and RAYOS. The Company accrues fees based on the contractually defined terms with each wholesaler for distribution and inventory management services and records the expense as cost of goods sold. Cost of goods sold of DUEXIS includes all costs directly related to the acquisition of product from the Company s third party manufacturers, including freight charges as well as costs of distribution. Also included in cost of goods sold are distribution service fees paid to wholesalers.

Cost of goods sold of RAYOS includes all costs directly related to the manufacture and delivery of product, including raw material costs, costs associated with third parties who manufacture RAYOS for the Company, supply chain costs, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes. Until the Company began recognizing revenue at the point of sale of DUEXIS to the wholesaler in the fourth quarter of 2012, it also deferred the related DUEXIS cost of goods sold and recorded such amounts as other current assets until revenue was recognized.

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Cost of goods sold of LODOTRA includes raw material costs, costs associated with third parties who manufacture LODOTRA for the Company, supply chain costs, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

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 June 30, 2013 and December 31, 2012, the Company had inventories of $5,787 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 June 30, 2013 and December 31, 2012, the Company had product sample inventory of $753 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 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.

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 Senior Secured Loan was determined using Level 2 inputs and was based on the notional amounts of the outstanding debt instrument and borrowing rates of recent debt transactions. At June 30, 2013, the fair value of the Senior Secured Loan approximated its carrying value.

Cash and Cash Equivalents

Cash and cash equivalents primarily consist of cash balances and money market funds. Cash and cash equivalents were $69,340 and $104,087 as of June 30, 2013 and December 31, 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 June 30, 2013 and December 31, 2012, the Company had restricted cash in the amount of $800.

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.

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

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

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

Intangible Assets

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

Research and Development Expenses

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

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 U.S. 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 in late January 2013, these medical affairs expenses were classified as part of 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 various banks in the U.S., Switzerland and Germany that management believes are creditworthy. At times, deposits in these banks may exceed the amount of insurance provided on such deposits. To date, the Company has not experienced any losses on its deposits of cash and cash equivalents.

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

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

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

The Company is required to maintain compliance with applicable Swiss laws with respect to its Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. The Company reviews on a regular basis whether its Swiss subsidiary is overindebted. As of June 30, 2013 and December 31, 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

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overindebtedness, until such time as its Swiss subsidiary generates positive income at a statutory level, which could require the Company to have cash at its Swiss subsidiary in excess of its near term operating needs and could affect the Company s ability to have sufficient cash at its U.S. subsidiary to meet its near term operating needs.

Historically, the Company s accounts receivable balances have been highly concentrated with a select number of customers, consisting primarily of large wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. The Company s top three customers, Mundipharma, McKesson Corporation and Cardinal Health, Inc., accounted for approximately 78% and 83% of total consolidated gross sales during the six months ended June 30, 2013 and for the year ended December 31, 2012, respectively. In addition, three customers, Cardinal Health, Inc., Walgreen Company and McKesson Corporation, accounted for approximately 83% and 77% of the Company s total outstanding accounts receivable balances as of June 30, 2013 and December 31, 2012, respectively. 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 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 other comprehensive income on the respective line items in net income if the amount being reclassified is required under GAAP to be reclassified in its entirety to net income. For other amounts that are not required under GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under GAAP that provide additional detail about those amounts. As of June 30, 2013 and December 31, 2012, accumulated other comprehensive loss was $3,767 and $3,372, respectively.

NOTE 3 EARNINGS PER SHARE

The following table presents basic and diluted earnings per share for the three and six months ended June 30, 2013 and 2012:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Basic and diluted earnings per share calculation:				
Net loss	$ (18,441)	$ (22,782)	$ (40,612)	$ (46,508)
Weighted average of common shares outstanding	62,872,173	33,715,703	62,339,285	28,909,080
Basic and diluted net loss per share	$ (0.29)	$ (0.68)	$ (0.65)	$ (1.61)

The following dilutive securities were excluded from the computation of diluted earnings per share for the three and six months ended June 30, 2013 and 2012 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 4,093,024 and 2,545,797 shares of common stock at June 30, 2013 and 2012, respectively, and outstanding and unsettled restricted stock units covering an aggregate of 855,854 and 820,549 shares of common stock at June 30, 2013 and 2012, respectively.

Outstanding warrants to purchase an aggregate of 17,480,243 and 7,120,887 shares of common stock at June 30, 2013 and 2012, respectively.

NOTE 4 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.

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The components of inventories as of June 30, 2013 and December 31, 2012, are summarized as follows:

	June 30, 2013	December 31, 2012
Raw materials	$ 341	$ 40
Work-in-process	450	824
Finished goods	4,996	4,381
Net inventories	$ 5,787	$ 5,245

NOTE 5 PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets as of June 30, 2013 and December 31, 2012, consisted of the following:

	June 30, 2013	December 31, 2012
Product samples inventory	$ 753	$ 875
Prepaid software license fees	804	518
Prepaid clinical trial studies	651	661
Prepaid marketing expenses	518	607
Prepaid insurance	237	265
Prepaid FDA product and manufacturing fees	25	139
Other prepaid expenses	379	227
Other current assets		31
Total prepaid and other current assets	$ 3,367	$ 3,323

NOTE 6 PROPERTY AND EQUIPMENT

Property and equipment as of June 30, 2013 and December 31, 2012, consisted of the following:

	June 30, 2013	December 31, 2012
Machinery and equipment	$ 2,320	$ 2,248
Furniture and fixtures	112	116
Computer equipment	1,376	1,211
Software	694	646
Trade show equipment	228	228
Leasehold improvement	783	783
	5,513	5,232
Less-accumulated depreciation	(2,013)	(1,507)
Total property and equipment	$ 3,500	$ 3,725

Depreciation expense was $300 and $208 for the three months ended June 30, 2013 and 2012, respectively, and was $558 and $392 for the six months ended June 30, 2013 and 2012, respectively.

NOTE 7 INTANGIBLE ASSETS

The Company s intangible assets consist of developed technology related to its approved and marketed products: LODOTRA outside the U.S. and RAYOS in the U.S. Developed technology is amortized on a straight-line basis over its estimated useful life of twelve years for both RAYOS and LODOTRA.

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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 second quarter of 2013, the Company did not identify any events or circumstances that would require a review of its intangible assets. As of June 30, 2013 and December 31, 2012, intangible assets consisted of the following:

	June 30, 2013			December 31, 2012		
	Cost Basis	Accumulated Amortization	Net Book Value	Cost Basis	Accumulated Amortization	Net Book Value
Developed technology(1)	$ 78,700	$ (14,156)	$ 64,544	$ 79,940	$ (11,048)	$ 68,892

(1) The Company s developed technology relates to intangible assets of its Horizon Pharma AG subsidiary, whose functional currency is the Euro. The cost basis and accumulated amortization as of June 30, 2013 and December 31, 2012 include the effects of currency translation adjustments associated with the translation into U.S. dollars of these assets based on the exchange rates prevailing at the end of each period.

Amortization expense was $1,641 and $856 for the three months ended June 30, 2013 and 2012, respectively, and was $3,297 and $1,748 for the six months ended June 30, 2013 and 2012, respectively. As of June 30, 2013, estimated future amortization expense was as follows:

2013	$ 3,310
2014	6,619
2015	6,619
2016	6,619
2017 and thereafter	41,377
Total	$ 64,544

NOTE 8 ACCRUED LIABILITIES

Accrued liabilities as of June 30, 2013 and December 31, 2012, consisted of the following:

	June 30, 2013	December 31, 2012
Payroll related expenses	$ 6,774	$ 6,290
Accrued rebates and royalties	6,904	2,704
Interest expense	2,525	2,538
Co-promotion agreement	1,131	226
Sales and marketing expenses	1,089	1,265
Deferred rent	801	876
Consulting and professional services	365	627
Clinical and regulatory expenses	268	652
Contract manufacturing expenses	120	1,094
Accrued other	539	512
Total accrued liabilities	$ 20,516	$ 16,784

NOTE 9 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 as issued by FASB ASC Topic 820 Fair Value Measurements (ASC 820). Assets and liabilities are measured at fair value and 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.

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

Assets measured at fair value on a recurring basis subject to the disclosure requirements of ASC 820 at June 30, 2013 and December 31, 2012, were as follows:

	As of June 30, 2013			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 60,849	$	$	$ 60,849
Total assets at fair value	$ 60,849	$	$	$ 60,849

	As of December 31, 2012			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 97,670		$	$ 97,670
Total assets at fair value	$ 97,670	$	$	$ 97,670

NOTE 10 COMMITMENTS AND CONTINGENCIES

Lease Obligations

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

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

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 June 30, 2013, the minimum remaining purchase commitment based on tablet pricing in effect under the agreement was $3,378. 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 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. Pursuant to the agreement, sanofi-aventis U.S. is obligated to manufacture and supply DUEXIS to the Company in final, packaged form, and the Company is obligated to purchase DUEXIS exclusively from sanofi-aventis U.S. for the commercial requirements of DUEXIS in North America, South America and certain countries and territories in Europe, including the European Union member states and Scandinavia. At June 30, 2013, the Company had a

$9,700 blanket purchase commitment to sanofi-aventis U.S. for DUEXIS to be delivered through December 2013, of which $3,260 represented a binding purchase order issued from the Company to sanofi-aventis U.S. for DUEXIS to be delivered in the third quarter of 2013.

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Royalty Agreement

In connection with the August 2004 development and license agreement with SkyePharma AG (SkyePharma) and Jagotec, a wholly-owned subsidiary of SkyePharma, regarding certain proprietary technology and know-how owned by SkyePharma, Jagotec is entitled to receive a single digit percentage royalty on net sales of RAYOS/LODOTRA and on any sub-licensing income, which includes any payments not calculated based on the net sales of LODOTRA, such as license fees, and lump sum and milestone payments. Royalty expense recognized in cost of goods sold for the three months ended June 30, 2013 and 2012 was $161 and $98, respectively, and for the six months ended June 30, 2013 and 2012 was $330 and $259, respectively.

Contingencies

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

Indemnification

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

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

NOTE 11 LEGAL PROCEEDINGS

On February 15, 2012, the Company received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. (Par) advising that Par had filed an Abbreviated New Drug Application (ANDA) with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par has not advised the Company as to the timing or status of the FDA s review of its filing, or whether it has complied with FDA requirements for proving bioequivalence. In March 2012, the Company filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par s ANDA and/or preventing Par from selling a generic version of DUEXIS. In January 2013, the Company filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par s ANDA and/or preventing Par from selling a generic version of DUEXIS. A patent claim construction hearing is scheduled for August 21, 2013, and a trial date is currently set for the second quarter of 2014. All of the Company s issued U.S. patents covering DUEXIS are listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Under the FDA s rules and regulations, because the Company initiated a patent infringement suit to defend a patent identified in the Paragraph IV notice within 45 days after the FDA s receipt of the notice, the FDA is prevented from approving the ANDA until the earlier of 30 months from the date of the first suit or a decision in the infringement case that the patent is not infringed or invalid.

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 (WLF), advising that WLF had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. WLF has not advised the Company as to the timing or status of the FDA s review of its filing. The Company is evaluating the Paragraph IV Patent Certifications and intends to vigorously enforce its intellectual property

rights relating to RAYOS. All of the issued U.S. patents covering RAYOS are listed in the FDA s Orange Book. Under the FDA s rules and regulations, if the Company initiates a patent infringement suit to defend the patents identified in a Paragraph IV notice within 45 days after the FDA s receipt of a proper notice under 21 U.S.C. 355(j)(2)(B), the FDA would be prevented from approving the ANDA until the earlier of 30 months from the date of the suit or a decision in the infringement case that each of the patents is not infringed or invalid.

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NOTE 12 DEBT AGREEMENTS

The Company s outstanding debt balances as of June 30, 2013 and December 31, 2012, consisted of the following:

	June 30, 2013	December 31, 2012
Senior Secured Loan	$ 59,420	$ 61,843
Current debt maturities	(15,913)	(11,935)
Debt discount	(11,569)	(13,042)
Long-term debt, net of current maturities	$ 31,938	$ 36,866

In February 2012, the Company entered into the $60,000 Senior Secured Loan with a group of institutional lenders. Under the terms of the Senior Secured Loan, the outstanding principal accrues interest until maturity in January 2017 at a rate of 17% per annum, payable quarterly unless repaid earlier. The Senior Secured Loan allows the Company to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt (i.e., payment in kind borrowings). Beginning in April 2013, and each quarter thereafter, the lenders have the option to require the Company to repay $3,978 of the loan principal. The Company may also prepay the loan at any time, subject to certain prepayment premiums. In March 2013, two of the lenders notified the Company of their election to request a partial repayment of the loan principal, effective on the April 1, 2013 interest payment date and each quarter thereafter. 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.

In connection with the Senior Secured Loan, the Company also issued warrants to the lenders to purchase up to an aggregate of 3,277,191 shares of common stock at an exercise price of $0.01 per share. The warrants became exercisable 180 days after issuance and will remain exercisable until the maturity date of the Loan on January 22, 2017, subject to limited exceptions. The Senior Secured Loan is secured by a lien on substantially all of the Company s assets including intellectual property, and the Company pledged all of its equity interests in Horizon Pharma USA, Inc. and 65% of its equity interests in Horizon Pharma AG.

The Senior Secured Loan restricts the Company s ability to incur additional indebtedness, incur liens, pay dividends and engage in significant business transactions, such as a change of control, so long as the Company owes any amounts to the lenders under the related loan agreements. If the Company defaults under its Senior Secured Loan, its lenders may accelerate all of its repayment obligations and take control of the pledged assets. The Company s lenders could declare the Company in default under its debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect upon it as defined under the loan agreements, thereby requiring the Company to repay the loan immediately or to attempt to reverse the lenders declaration through negotiation or litigation. Among other loan covenant requirements, the Senior Secured Loan also requires the Company to maintain a minimum level of liquidity of at least $10,000 at all times during the term of the loan unless its quarterly consolidated EBITDA is at least $6,000 and to meet specified minimum net revenues during a trailing twelve-month period, which commenced on June 30, 2012. The negative covenants include, among other things, restrictions on transferring or licensing the Company s assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on the Company s assets, in each case subject to customary exceptions. During 2012, the Company elected to pay the 12% interest in cash, and the remaining 5% interest due of $1,842 was added to the principal loan balance as a payment in kind borrowing. During the first and second quarter of 2013, the Company elected to pay the 12% interest in cash, and the remaining 5% interest due of $782 and $774, respectively, was added to the principal loan balance as a payment in kind borrowing.

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

In lieu of paying a cash fee in consideration for entering into the Senior Secured Loan Amendment, the Company agreed to issue an aggregate of 1,250,000 shares of the Company s common stock to the lenders. The fair value of the common stock issued in connection with the Senior Secured Loan Amendment was $5,075 and was classified as debt discount in the Company s consolidated balance sheets and is being amortized to interest expense over the remaining life of the Senior Secured Loan. At June 30, 2013, the outstanding balance on the Senior Secured Loan was $59,420 and the Company was in compliance with all applicable financial loan covenants.

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NOTE 13 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. During the second quarter of 2013, Cowen sold 1,266,161 shares of the Company s common stock for gross proceeds of $3,177 and net proceeds of $3,039, after deducting $138 in commissions and other issuance costs. As of June 30, 2013, $24,213 worth of the Company s common stock was available for future issuance under the ATM sales agreement, after giving effect to the limited amount of securities registered under the Company s shelf registration statement associated with the ATM sales agreement.

NOTE 14 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 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 15 RELATED PARTY TRANSACTIONS

The Company has entered into a consulting agreement with a former director of Horizon Pharma USA, Inc. and Horizon Pharma AG has entered into a consulting agreement with a former owner and majority shareholder of Nitec. Consulting fees paid to related parties during the three months ended June 30, 2013 and 2012 were $196 and $179, respectively, and were $393 and $367 for the six months ended June 30, 2013 and 2012, respectively.

NOTE 16 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 following table presents the benefit for income taxes for the three and six months ended June 30, 2013 and 2012, as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Net loss before benefit for income taxes	$ (18,792)	$ (22,941)	$ (41,844)	$ (46,831)
Benefit for income taxes	(351)	(159)	(1,232)	(323)
Net loss	$ (18,441)	$ (22,782)	$ (40,612)	$ (46,508)

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At June 30, 2013, the Company had a net deferred tax liability of $3,148 primarily related to temporary differences associated with its intangible assets. The increase in income tax benefit recorded during the three months ended June 30, 2013 was primarily associated with a reduction in the Company s deferred tax liability resulting from higher intangible amortization expense in the current period. The increase in amortization expense was associated with the FDA approval of RAYOS in July 2012, which required the Company to begin amortization, and the balance sheet reclassification of an indefinite-lived intangible asset to a definite-lived intangible asset. During the six months ended June 30, 2013, the increase in income tax benefit was primarily due to a reduction in the Company s deferred tax valuation allowance resulting from a determination during the first quarter of 2013 that a portion of deferred tax assets associated with the Company s deferred revenues from milestone payments would be realized in future years.

NOTE 17 EQUITY INCENTIVE PLANS

Employee Stock Purchase Plan

In July 2010, the Company s Board of Directors adopted an Employee Stock Purchase Plan (ESPP) and in June 2011, the Company s stockholders approved the 2011 Purchase Plan (the 2011 Purchase Plan), and it became effective upon the signing of the underwriting agreement related to the Company s initial public offering in July 2011. The Company reserved a total of 463,352 shares of common stock for issuance under the 2011 Purchase Plan. The 2011 Purchase Plan provides that an additional number of shares will automatically be added to the shares authorized for issuance under the 2011 Purchase Plan 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 Purchase Plan. Employees purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of the six-month offering period.

On December 15, 2011, pursuant to the terms of the 2011 Purchase Plan, the Company s Board of Directors approved for issuance 100,000 shares under the ESPP, effective January 1, 2012. On December 6, 2012, the Company s Board of Directors approved for issuance 200,000 shares under the ESPP, effective January 1, 2013. As of June 30, 2013, 201,381 shares have been issued and an aggregate of 544,199 shares of common stock were authorized and available for issuance under the ESPP.

Stock-Based Compensation Plans

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

In July 2010, the Company s Board of Directors adopted the 2011 Plan and in June 2011, the Company s stockholders approved the 2011 Plan, and it became effective upon the signing of the underwriting agreement related to the Company s initial public offering on July 28, 2011. The 2011 Plan 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 Plan s effective date and 1,600,673 new shares of common stock reserved. The 2011 Plan provides that an additional number of shares will automatically be added 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). On December 6, 2012, pursuant to the terms of the 2011 Plan, the Company s board of directors approved an increase in the number of shares available for issuance under the 2011 Plan of 1,474,304 shares, effective January 1, 2013. As of June 30, 2013, there were 256,912 shares available for future grants under the 2011 Plan.

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

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Stock Option Plans

The following table summarizes stock option activity during the six months ended June 30, 2013 as follows:

	Options	Weighted Average Exercise Price
Outstanding as of December 31, 2012	2,746,918	$ 8.85
Granted	1,631,825	$ 2.38
Forfeited	(285,719)	$ 4.07
Outstanding as of June 30, 2013	4,093,024	$ 6.61
Exercisable as of June 30, 2013	1,675,477	$ 10.78

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 six months ended June 30, 2013 and 2012, and assumptions used to value stock options, are as follows:

	Six Months Ended June 30,	
	2013	2012
Dividend yield		
Risk-free interest rate	1.0%	1.0%
Weighted average volatility	88.1%	89.7%
Expected life (in years)	6.0	5.95
Weighted average grant date fair value per share of options granted	$ 1.73	$ 3.12

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.

During the six months ended June 30, 2013 and 2012, the Company utilized a forfeiture rate of 5% for estimating the forfeitures of stock options granted.

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Restricted Stock Units

The following table summarizes restricted stock unit activity during the six months ended June 30, 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	698,000	$ 1.77
Vested	(2,500)	$ 0.00
Forfeited	(71,804)	$ 2.36
Outstanding as of June 30, 2013	855,854	$ 2.57

The following table summarizes share-based compensation expense included in the Company s condensed consolidated statements of operations for the six months ended June 30, 2013 and 2012 as follows:

	Six Months Ended June 30, 2013	2012
Stock-based compensation expense:		
Research and development	$ 474	$ 608
Sales and marketing	660	523
General and administrative	966	1,359
Net effect of stock-based compensation expense on net loss	$ 2,100	$ 2,490

The Company estimates that, as of June 30, 2013, pre-tax compensation expense was $7,966 for all unvested share-based awards, including both stock options and restricted stock units that will be recognized through the third quarter of 2016. The Company expects to satisfy the exercise of stock options and future distribution of shares of restricted stock by issuing new shares of its common stock which have been reserved under the 2011 Plan.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and the related notes that appear elsewhere in this report. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties which are subject to safe harbors under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements include, but are not limited to, statements concerning our strategy and other aspects of our future operations, future financial position, future revenues, projected costs, expectations regarding demand and acceptance for our products, growth opportunities and trends in the market in which we operate, prospects and plans and objectives of management. The words anticipates , believes , estimates , expects , intends , may , plans , projects , will , would and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, Risk Factors in this report and in our other filings with the Securities and Exchange Commission. We do not assume any obligation to update any forward-looking statements.

(Dollars are presented in thousands except share data or unless otherwise stated)

OUR BUSINESS

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

On April 23, 2011, the U.S. Food and Drug Administration, or FDA, approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis, or RA, and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. Between July and November 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 recently further expanded our sales force to approximately 170 representatives following the termination of our co-promotion agreement with Mallinckrodt LLC, or Mallinckrodt, in June 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, we do not expect a material level of sales from DUEXIS in European markets.

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

RESULTS OF OPERATIONS

Comparison of Three Months Ended June 30, 2013 and 2012

The summary of selected financial data table below should be referenced in connection with a review of the following discussion of our results of operations for the three months ended June 30, 2013, compared to the three months ended June 30, 2012.

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	Three Months Ended June 30, 2013	2012	Increase / (Decrease)
Gross sales	$ 17,637	$ 4,608	$ 13,029
Sales discounts and allowances	(5,383)	(767)	4,616
Net sales	12,254	3,841	8,413
Cost of good sold	3,517	2,855	662
Gross profit	8,737	986	7,751
Operating expenses			
Research and development	2,833	4,233	(1,400)
Sales and marketing	16,526	10,543	5,983
General and administrative	5,182	4,555	627
Total operating expenses	24,541	19,331	5,210
Operating loss	(15,804)	(18,345)	(2,541)
Other (expense) income			
Interest expense, net	(3,442)	(3,191)	251
Foreign exchange gain (loss)	454	(1,401)	(1,855)
Other expense		(4)	(4)
Total other expense, net	(2,988)	(4,596)	(1,608)
Loss before benefit for income taxes	(18,792)	(22,941)	(4,149)
Benefit for income taxes	(351)	(159)	192
Net loss	$ (18,441)	$ (22,782)	$ (4,341)

Sales. During the three months ended June 30, 2013, gross and net sales were $17,637 and $12,254, respectively, compared to $4,608 and $3,841 in gross and net sales, respectively, during the three months ended June 30, 2012. DUEXIS gross and net sales during the second quarter of 2013 were $15,767 and $10,547, respectively, after deducting trade discounts, sales returns and allowances of $3,636 and co-pay assistance costs of $1,584, and represented 89% of gross sales and 86% of net sales during the quarter, compared to gross and net sales of $2,073 and $1,564, respectively, during the second quarter of 2012. The increase in DUEXIS sales during the second quarter of 2013 was primarily the result of our expanded sales force in addition to a product price increase implemented at the end of the first quarter of 2013. LODOTRA gross and net sales during the second quarter of 2013 were $1,175 and $1,156, respectively, after deducting trade allowances of $19, compared to gross and net sales of $2,535 and $2,277, respectively, during the second quarter of 2012. The decrease in LODOTRA sales during the three months ended June 30, 2013 compared to the same period in the prior year was the result of lower product shipments to our European distribution partner, Mundipharma. LODOTRA sales to Mundipharma occur at the time we ship product to Mundipharma based on its estimated requirements. Accordingly, our LODOTRA sales are not linear or tied to Mundipharma sales to the market and can therefore fluctuate from quarter to quarter. RAYOS gross and net sales were $695 and $551, respectively, during the second quarter of 2013 after deducting trade discounts and allowances of $86 and co-pay costs of $58 compared to no RAYOS sales during the second quarter of 2012 as the product was launched in late 2012.

Cost of Goods Sold. Cost of goods sold increased $662, from $2,855 during the three months ended June 30, 2012, to $3,517 during the three months ended June 30, 2013. The increase in cost of goods sold was primarily due to an increase in DUEXIS product shipments and higher intangible amortization expense in the second quarter of 2013, offset by lower cost of goods sold associated with LODOTRA as we primarily recognized LODOTRA deferred revenues in the second quarter of 2013, which has negligible cost of goods sold associated with it, versus revenue and cost of goods associated with LODOTRA product deliveries in the second quarter of 2012. The increase in intangible amortization expense was primarily the result of the FDA approval of RAYOS in July 2012, which required us to begin amortization and the balance sheet reclassification of an indefinite-lived intangible asset to a definite-lived intangible asset. For the three months ended June 30, 2013, intangible amortization expense accounted for 47% of total cost of goods sold.

Research and Development Expenses. Research and development expenses decreased $1,400, from $4,233 during the three months ended June 30, 2012, to $2,833 during the three months ended June 30, 2013. The decrease in research and development expenses during the second quarter of 2013 was primarily associated with the classification of $1,223 in medical affairs expenses to sales and marketing expenses and a $266 reduction in regulatory submission fees, which was partially offset

by a $93 increase in equipment 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 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, these medical affairs expenses were classified as part of research and development expenses.

Sales and Marketing Expenses. Sales and marketing expenses increased $5,983, from $10,543 during the three months ended June 30, 2012, to $16,526 during the three months ended June 30, 2013. The increase was primarily attributable to an increase of $4,547 in salaries and benefits expenses due to the increase in staffing of our field sales force, the new classification of $1,223 of medical affairs expenses to sales and marketing expenses and a $248 increase in marketing and commercialization expenses.

General and Administrative Expenses. General and administrative expenses increased $627, from $4,555 during the three months ended June 30, 2012, to $5,182 during the three months ended June 30, 2013. The increase was primarily attributable to a $682 increase in salaries and benefits expense associated with new employees and $186 in higher facilities costs, which were partially offset by a reduction in consulting expenses of $231.

Interest Expense, Net. Interest expense, net increased $251, from $3,191 during the three months ended June 30, 2012, to $3,442 during the three months ended June 30, 2013. The increase in interest expense was primarily attributable to higher debt discount expenses associated with the September 2012 amendment of our $60,000 senior secured loan facility with a group of institutional investors, or Senior Secured Loan, entered into in February 2012.

Foreign Exchange Gain/(Loss). During the three months ended June 30, 2013, we reported a foreign exchange gain of $454 compared to a foreign exchange loss of $1,401 during the three months ended June 30, 2012. The foreign exchange gain in the second quarter of 2013 was primarily due to a reduction in U.S. dollar denominated transactions for our Swiss subsidiary, Horizon Pharma AG, whose functional currency is the Euro, in addition to a strengthening of the Euro against the U.S. dollar during the three months ended June 30, 2013.

Income Tax Benefit. Income tax benefit increased $192, from $159 during the three months ended June 30, 2012, to $351 during the three months ended June 30, 2013. The increase in income tax benefit during the second quarter of 2013 was primarily due to a reduction in our deferred tax liability resulting from higher intangible amortization expense in the current period. The increase in amortization expense was associated with the FDA approval of RAYOS in July 2012, which required us to begin amortization and the balance sheet reclassification of an indefinite-lived intangible asset to a definite-lived intangible asset.

Net Loss. Net loss decreased from $22,782 during the three months ended June 30, 2012, to $18,441 during the three months ended June 30, 2013, primarily as a result of the increase in sales and related gross margins, partially offset by an increase in expenses as described above.

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Comparison of Six Months Ended June 30, 2013 and 2012

The summary of selected financial data table below should be referenced in connection with a review of the following discussion of our results of operations for the six months ended June 30, 2013, compared to the six months ended June 30, 2012.

	Six Months Ended June 30,		Increase /
	2013	2012	(Decrease)
Gross sales	$ 28,335	$ 7,516	$ 20,819
Sales discounts and allowances	(6,910)	(1,152)	5,758
Net sales	21,425	6,364	15,061
Cost of good sold	7,764	4,922	2,842
Gross profit	13,661	1,442	12,219
Operating expenses			
Research and development	5,031	8,302	(3,271)
Sales and marketing	32,854	21,515	11,339
General and administrative	10,124	9,758	366
Total operating expenses	48,009	39,575	8,434
Operating loss	(34,348)	(38,133)	(3,785)
Other (expense) income			
Interest expense, net	(7,045)	(7,742)	(697)
Foreign exchange loss	(451)	(900)	(449)
Other expense		(56)	(56)
Total other expense, net	(7,496)	(8,698)	(1,202)
Loss before benefit for income taxes	(41,844)	(46,831)	(4,987)
Benefit for income taxes	(1,232)	(323)	909
Net loss	$ (40,612)	$ (46,508)	$ (5,896)

Sales. During the six months ended June 30, 2013, gross and net sales were $28,335 and $21,425, respectively, compared to $7,516 and $6,364 in gross and net sales, respectively, during the six months ended June 30, 2012. DUEXIS gross and net sales during the six months ended June 30, 2013 were $22,493 and $15,891, respectively, after deducting trade discounts and allowances of $4,185 and co-pay assistance costs of $2,417, and represented 79% of gross sales and 74% of net sales, compared to gross and net sales of $3,211 and $2,502, respectively, during the six months ended June 30, 2012. The increase in DUEXIS sales during the first six months of 2013 was primarily the result of our expanded sales force in addition to a product price increase implemented at the end of the first quarter of 2013. LODOTRA gross and net sales during the six months ended June 30, 2013 were $4,729 and $4,608, respectively, after deducting trade discounts and allowances of $121, compared to gross and net sales of $4,305 and $3,862, respectively, during the six months ended June 30, 2012. The increase in LODOTRA sales during the six months ended June 30, 2013 compared to the same period in the prior year was primarily the result of an increase in the recognition of deferred revenues in the current year offset by lower product shipments to our European distribution partner, Mundipharma. LODOTRA sales to Mundipharma occur at the time we ship product to Mundipharma based on its estimated requirements. Accordingly, our LODOTRA sales are not linear or tied to Mundipharma sales to the market and can therefore fluctuate from year to year. RAYOS gross sales were $1,113 and, after deducting trade discounts and allowances of $129 and co-pay costs of $58, net sales were $926 during the six months ended June 30, 2013, compared to no sales during the six months ended June 30, 2012 as the product was launched in late 2012.

Cost of Goods Sold. Cost of goods sold increased $2,842, from $4,922 during the six months ended June 30, 2012, to $7,764 during the six months ended June 30, 2013. The increase in cost of goods sold was primarily due to an increase in DUEXIS product shipments and higher intangible amortization expense during the six months ended June 30, 2013, offset by lower cost of goods sold associated with LODOTRA during the six months ended June 30, 2013, as we recognized more LODOTRA deferred revenues, which has a negligible cost of goods associated with it, than we did during the six months ended June 30, 2012. The increase in intangible amortization expense was primarily the result of the FDA approval of RAYOS in July

2012, which required us to begin amortization and the balance sheet reclassification of an indefinite-lived intangible asset to a definite-lived intangible asset. For the six months ended June 30, 2013, intangible amortization expense accounted for 42% of total cost of goods sold.

Research and Development Expenses. Research and development expenses decreased $3,271, from $8,302 during the six months ended June 30, 2012, to $5,031 during the six months ended June 30, 2013. The decrease in research and development expenses during the six months ended June 30, 2013 was primarily associated with the classification of $2,598 in medical affairs expenses to sales and marketing expenses, a $491 reduction in expenses associated with DUEXIS clinical studies and a $452 decrease in consulting expenses, which was partially offset by a $187 increase in equipment expenses and $96 in additional salaries and benefits costs. During the first quarter of 2013, in connection with the full commercial launch of RAYOS, we began to classify our medical affairs expenses, which 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, these medical affairs expenses were classified as part of research and development expenses.

Sales and Marketing Expenses. Sales and marketing expenses increased $11,339, from $21,515 during the six months ended June 30, 2012, to $32,854 during the six months ended June 30, 2013. The increase was primarily attributable to an increase of $8,775 in salaries and benefits expenses due to the expansion of our field sales force and the classification of $2,598 of medical affairs expenses to sales and marketing expenses during the six months ended June 30, 2013.

General and Administrative Expenses. General and administrative expenses increased $366, from $9,758 during the six months ended June 30, 2012, to $10,124 during the six months ended June 30, 2013. The increases was primarily due to $535 in higher salaries and benefits expenses associated with new employees, $404 increase in facilities costs and $208 in higher legal fees associated with intellectual property related matters, which was primarily offset by a $740 reduction in professional fees compared to the prior year.

Interest Expense, Net. Interest expense, net decreased $697, from $7,742 during the six months ended June 30, 2012, to $7,045 during the six months ended June 30, 2013. The decrease in interest expense was primarily attributable to the absence of debt extinguishment costs in 2013, partially offset by higher debt discount expenses. During the six months ended June 30, 2012, we incurred approximately $2,500 in pre-payment and end of loan payments associated with the extinguishment of our prior debt facilities.

Foreign Exchange Loss. During the six months ended June 30, 2013 and 2012, we a reported foreign exchange loss of $451 and $900, respectively. The decrease in the foreign exchange loss during the six months ended June 30, 2013 was primarily due to a reduction in U.S. dollar denominated transactions for our Swiss subsidiary, Horizon Pharma AG, whose functional currency is the Euro, in addition to a strengthening of the Euro against the U.S. dollar in 2013.

Income Tax Benefit. Income tax benefit increased $909, from $323 during the six months ended June 30, 2012, to $1,232 during the six months ended June 30, 2013. The increase in income tax benefit during the six months ended June 30, 2013 was primarily due to a reduction in our deferred tax valuation allowance resulting from a determination that a greater portion of deferred tax assets associated with deferred revenues from milestone payments would be realized in future years. Accordingly, we recorded an additional income tax benefit of $831 during the six months ended June 30, 2013 to properly account for the realization of our deferred tax asset positions.

Net Loss. Net loss decreased from $46,508 during the six months ended June 30, 2012, to $40,612 during the six months ended June 30, 2013, primarily as a result of the increase in sales and related gross margins, partially offset by an increase in expenses as described above.

SUMMARY OF CRITICAL ACCOUNTING POLICIES

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

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

Revenue Recognition

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

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Revenue from product deliveries

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

Revenue from up-front license fees

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

Revenue from milestone receipts

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

Cost of Goods Sold

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

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

Cost of goods sold for LODOTRA includes all costs directly related to the manufacture and delivery of product and out-licensing of distribution and marketing rights to third parties. The costs in connection with product delivery to our distribution partners consist of raw material costs, costs associated with third parties who manufacture LODOTRA for us, supply chain costs, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

Inventories

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

Provision for Income Taxes

We account for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are recognized for deductible temporary differences, and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in the opinion of

management, it is more likely than not that some portion or

all of the deferred tax assets will not be realized. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the year that the change is enacted. We also account for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return.

Stock-Based Compensation

We account for employee stock-based compensation by measuring and recognizing compensation expense for all stock-based payments based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee s requisite service period, which is generally 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.

LIQUIDITY, FINANCIAL POSITION AND CAPITAL RESOURCES

We have incurred losses since our inception in June 2005 and, as of June 30, 2013, we had an accumulated deficit of $348,723. We anticipate that we will continue to incur net losses for at least the next few years. We expect that our sales and marketing expenses will continue to increase moderately as a result of our commercialization of DUEXIS and RAYOS/LODOTRA. As a result, we will need to generate significant net product sales, and royalty and other revenues to achieve profitability.

We have financed our operations to date through equity financings, debt financings and the issuance of convertible notes. As of June 30, 2013, we had $69,340 in cash and cash equivalents. In February 2012, we entered into the $60,000 Senior Secured Loan. Under the terms of the Senior Secured Loan, the outstanding principal accrues interest until maturity in January 2017 at a rate of 17% per annum, payable quarterly unless repaid earlier. The Senior Secured Loan allows us to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt. We may prepay the loan at any time, subject to certain prepayment premiums. In connection with the Senior Secured Loan, we also issued warrants to the lenders to purchase up to an aggregate of approximately 3,277,191 shares of our common stock at an exercise price of $0.01 per share. The warrants became exercisable 180 days after issuance and will remain exercisable until the maturity date of the Senior Secured Loan on January 22, 2017, subject to limited exceptions. The Senior Secured Loan is secured by a lien covering substantially all of our assets including intellectual property in addition to a pledge of all of our equity interests in Horizon Pharma USA, Inc. and 65% of our equity interests in Horizon Pharma AG.

The Senior Secured Loan restricts our ability to incur additional indebtedness, incur liens, pay dividends and engage in significant business transactions, such as a change of control, so long as we owe any amounts to the lenders under the related loan agreements. If we default under our Senior Secured Loan, our lenders may accelerate all of our repayment obligations and take control of our pledged assets. Our lenders could declare us in default under our debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect upon us as defined under the loan agreements, thereby requiring us to repay the loans immediately or to attempt to reverse the lenders declaration through negotiation or litigation. Among other loan covenant requirements, the Senior Secured Loan requires us to maintain a minimum level of liquidity of at least $10,000 at all times during the term of the loan unless our quarterly consolidated EBITDA is at least $6,000 and to meet specified minimum net revenues during a trailing 12 month period commencing on June 30, 2012. The negative covenants include, among other things, restrictions on transferring or licensing our assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions and creating other liens on our assets, in each case subject to customary exceptions. During 2012, we paid 12% interest in cash and elected to add the remaining 5% interest due of $1,842 to the principal loan balance as payment in kind borrowings. During the six months ended June 30, 2013, we again paid 12% interest in cash and elected to add the remaining 5% interest due of $1,556 to the principal loan balance as payment in kind borrowings.

In September 2012, we and the lenders entered into an amendment of the Senior Secured Loan, or the Senior Secured Loan Amendment, whereby affirmative covenants under the Senior Secured Loan with respect to minimum levels of liquidity and net revenue were modified. Under the Senior Secured Loan Amendment, we were required to have a minimum liquidity of $30,000 as of December 31, 2012, rather than the $10,000 required at all other times, and we were no longer required to achieve minimum net revenue levels for the trailing 12 month periods at the end of the third and fourth quarters of 2012, and the minimum trailing 12 month net revenues as of the end of each quarter of 2013 and the first quarter of 2014 were reduced. In lieu of paying a cash fee in consideration for entering into the Senior Secured Loan Amendment, we

agreed to issue an aggregate of 1,250,000 shares of our common stock to the lenders.

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At June 30, 2013, the outstanding balance on the Senior Secured Loan was $59,420 and we were in compliance with all applicable financial covenants under the Senior Secured Loan as amended. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations. These uncertainties and lack of commercial operating history raise substantial doubt about our ability to continue as a going concern. Additionally, our ability to comply with the operating and financial covenants under the Senior Secured Loan in future periods will be dependent on several factors including: the continued growth of the arthritis, pain and inflammation markets; acceptance of our products by patients, primary care specialists and other key specialists, including rheumatologists, orthopedic surgeons and pain specialists; the level of sales discounts and allowances we maintain for our products; and potential or perceived advantages or disadvantages of our products over alternative treatments, including cost of treatment and relative convenience and ease of administration. Changes in key markets or our inability to execute our operating plan could result in non-compliance with our operating and financial covenants which may adversely affect our cost of financing or cause an acceleration of our debt obligations.

Beginning in April 2013, and for each quarter thereafter, the lenders have the option to require us to repay $3,978 of the loan principal. In March 2013, two of the lenders notified us of their 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 is provided to us. Accordingly, on April 1, 2013, we made a payment of $5,836, which consisted of $3,978 in principal and $1,858 in interest. To the extent that we are required to make on-going quarterly prepayments of principal under the Senior Secured Loan, we may be required to seek additional funding earlier than we otherwise would in order to sustain our operations as well as maintain compliance with our minimum liquidity requirements under the Senior Secured Loan.

In 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 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. During the second quarter of 2013, Cowen sold 1,266,161 shares of our common stock for gross proceeds of $3,177 and net proceeds of $3,039, after deducting $138 in commissions and other issuance costs. As of August 6, 2013, Cowen had sold a cumulative total of 2,448,575 shares of our common stock with gross proceeds to us of $6,238 and we had $21,152 of common stock available for future issuance under the ATM sales agreement, after giving effect to the limited amount of securities registered under our shelf registration statement associated with the ATM sales agreement.

We are required to maintain compliance with applicable Swiss laws with respect to our Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. We review on a regular basis whether our Swiss subsidiary is overindebted. As of June 30, 2013 and December 31, 2012, our Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. We will continue to monitor and review steps to address any overindebtedness until such time as our Swiss subsidiary may generate positive income at a statutory level, which could require us to have cash at our Swiss subsidiary in excess of its near term operating needs and could affect our ability to have sufficient cash at our U.S. subsidiary to meet its near term operating needs.

The following table provides a summary of our cash flows for the six months ended June 30, 2013 and 2012, as follows:

	Six Months Ended June 30,	
	2013	2012
Cash and cash equivalents	$ 69,340	$ 63,460
Cash (used in) provided by :		
Operating activities	(33,668)	(36,647)
Investing activities	(345)	(1,043)
Financing activities	(735)	83,386

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Sources and Uses of Cash

Operating Cash Flows

During the six months ended June 30, 2013 and 2012, net cash used in operating activities was $33,668 and $36,647, respectively. The decrease in net cash used in operating activities was primarily attributable to a reduction in our operating losses during the six months ended June 30, 2013, which was partially offset by additional cash used in operating activities related to increases in our working capital requirements.

Investing Cash Flows

During the six months ended June 30, 2013 and 2012, net cash flows used in investing activities was $345 and $1,043, respectively. During 2012, we had capital expenditures related to computer and equipment expenses associated with the initial expansion of our field sales force.

Financing Cash Flows

During the six months ended June 30, 2013, net cash used in financing activities was $735, compared to net cash provided by financing activities of $83,386 during the six months ended June 30, 2012. During the six months ended June 30, 2013, we sold 1,266,161 shares of our common stock through ATM offerings for gross proceeds of $3,177 and net proceeds of $3,039, after deducting $138 in commissions and other issuance costs. Additionally, we repaid $3,978 in principal during the six months ended June 30, 2013 under our Senior Secured Loan. In February 2012, we entered into our $60,000 Senior Secured Loan, net of issuance costs of $4,422. As part of the closing of the Senior Secured Loan, we repaid outstanding principal under our prior outstanding debt facilities totaling $19,730. In March 2012, we received gross proceeds of $50,820 and net proceeds of $47,581, after deducting $3,239 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.

Contractual Obligations

During the three months ended June 30, 2013, there were no material changes outside of the ordinary course of business to our contractual obligations.

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 10, Commitments and Contingencies in the notes to our condensed consolidated financial statements included in this report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

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

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

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

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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. Our top three customers, Mundipharma, McKesson Corporation and Cardinal Health, Inc., accounted for approximately 78% and 83% of total consolidated gross sales during the six months ended June 30, 2013 and for the year ended December 31, 2012, respectively. In addition, three customers, Cardinal Health, Inc., Walgreen Company and McKesson Corporation, accounted for approximately 83% and 77% of our total outstanding accounts receivable balances as of June 30, 2013 and December 31, 2012, respectively. Historically, we have not experienced any losses related to our accounts receivable balances.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. As required by paragraph (b) of Rules 13a-15 and 15d-15 promulgated under the Exchange Act, our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report of the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rule 13a-15(e) and 15d-15(e). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2013, the end of the period covered by this report.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting during the period covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc., or Par, advising that Par had filed an Abbreviated New Drug Application, or ANDA, with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par has not advised us as to the timing or status of the FDA s review of its filing, or whether it has complied with FDA requirements for proving bioequivalence. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par s ANDA and/or preventing Par from selling a generic version of DUEXIS. In January 2013, we filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par s ANDA and/or preventing Par from selling a generic version of DUEXIS. A patent claim construction hearing is scheduled for August 21, 2013, and a trial date is currently set for the second quarter of 2014. All of our issued U.S. patents covering DUEXIS are listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Under the FDA s rules and regulations, because we initiated a patent infringement suit to defend a patent identified in the Paragraph IV notice within 45 days after the FDA s receipt of the notice, the FDA is prevented from approving the ANDA until the earlier of 30 months from the date of the first suit or a decision in the infringement case that the patent is not infringed or invalid.

On March 13, 2013, we received 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 WLF, advising that WLF had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. WLF has not advised us as to the timing or status of the FDA s review of its filing. We are evaluating the Paragraph IV Patent Certifications and intend to vigorously enforce our intellectual property rights relating to RAYOS. All of the issued U.S. patents covering RAYOS are listed in the FDA s Orange Book. Under the FDA s rules and regulations, if we initiate a patent infringement suit to defend the patents identified in a Paragraph IV notice within 45 days after the FDA s receipt of a proper notice under 21 U.S.C. 355(j)(2)(B), the FDA would be prevented from approving the ANDA until the earlier of 30 months from the date of the suit or a decision in the infringement case that each of the patents is not infringed or invalid.

Item 1A: Risk Factors

You should consider carefully the risks described below, together with all of the other information included in this report, and in our other filings with the Securities and Exchange Commission, or SEC, before deciding whether to invest in or continue to hold our common stock. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually occurs, our

business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

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The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing changes, including any material changes, from the risk factors previously disclosed in Item 1A of our annual report on Form 10-K for the year ended December 31, 2012, as filed with the SEC.

Risks Related to Our Business and Industry

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

DUEXIS® and RAYOS®/LODOTRA®, and other product candidates that we may develop, acquire, in-license or co-promote, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. In the U.S. market, we began selling DUEXIS in December 2011 and announced in October 2012 that we had completed the expansion of our sales force. We began commercial sales of RAYOS, which was approved by the 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 U.S., LODOTRA has been sold in a limited number of countries. Sales of DUEXIS and LODOTRA have been limited to date outside the U.S. and sales may not grow to expected levels, in part because, with respect to LODOTRA, we depend on our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for commercialization outside the U.S. With respect to DUEXIS, we have only received marketing approval in the United Kingdom, or UK, thus far, and even if it is approved in other European countries, we do not expect the opportunity in Europe to be material to our business given the current state of the market in Europe for pain products and the revenue being generated by existing branded non-steroidal anti-inflammatory drugs, or NSAIDs, in Europe. We believe that the degree of market acceptance and our ability to generate revenues from our products will depend on a number of factors, including:

- timing of market introduction of our products as well as competitive drugs;
- efficacy and safety of our products;
- continued projected growth of the arthritis, pain and inflammation markets;
- prevalence and severity of any side effects;
- acceptance by patients, primary care specialists and key specialists, including rheumatologists, orthopedic surgeons and pain specialists;
- the performance of our distribution and co-promotion partners, over which we have limited control;
- potential or perceived advantages or disadvantages of our products over alternative treatments, including cost of treatment and relative convenience and ease of administration;
- strength of sales, marketing and distribution support;
- the price of our products, both in absolute terms and relative to alternative treatments;

- impact of past and future product price increases;
- 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, 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 will be limited. Some physicians may also be reluctant to prescribe DUEXIS due to the inability to vary the dose of ibuprofen or if they believe treatment with NSAIDs or GI protective agents other than ibuprofen and famotidine, including those of our competitors, would be more effective for their patients. With respect to both DUEXIS and RAYOS/LODOTRA, their higher cost compared to the

generic forms of their active ingredients alone may limit adoption by physicians, patients and healthcare payers. If DUEXIS, RAYOS/LODOTRA or any other product candidates that we may seek approval for, acquire, in-license or co-promote fail to attain market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

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

Our strategy is to build a fully-integrated U.S.-focused biopharmaceutical company to successfully execute the commercial launches of DUEXIS and RAYOS in the U.S. market. We may not be able to successfully commercialize either DUEXIS or RAYOS in the U.S. Prior to our commercial launch of DUEXIS in the U.S. in December 2011, we did not have any experience commercializing pharmaceutical products on our own. LODOTRA was commercially launched in Europe by our exclusive distribution partners Merck Serono and Mundipharma. In order to commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Although we recently expanded our sales force to approximately 170 sales representatives in connection with the termination of the Mallinckrodt co-promotion agreement in June 2013, we currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market these products and any additional products we may acquire, in-license or co-promote will be expensive and time-consuming and could delay any product launch. Nor can we be certain that we will be able to continue to successfully develop this capability. As a result of the evolving role of various constituents in the prescription decision making process, we adjusted the profile of the sales representatives we hire from those with traditional pharmaceutical sales experience to those with successful business to business experience. For example, we have faced challenges due to pharmacists increasingly switching a patient s intended prescription from DUEXIS to a generic or over the counter brand. We expect that we will face similar challenges for RAYOS. While we believe the new profile of our representatives is better suited for this evolving environment, we cannot be certain that our representatives will be able to successfully protect DUEXIS and RAYOS prescriptions or that we will be able to continue attracting and retaining sales representatives with our desired profile and skills. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain commercial personnel. To the extent we rely on additional third parties to commercialize any approved products, we may receive less revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of any third parties involved in our commercialization efforts. In the event we are unable to successfully develop and maintain our own commercial organization or collaborate with a third-party sales and marketing organization or enter into co-promotion agreements, we would not be able to commercialize our product candidates and execute on our business plan. If we are unable to successfully implement our commercial plans and drive adoption by patients and physicians of any approved products through our sales, marketing and commercialization efforts, or if our partners fail to successfully commercialize our products, then we will not be able to generate sustainable revenues from product sales which will have a material adverse effect on our business and prospects.

*We are highly dependent on the success of DUEXIS and RAYOS/LODOTRA, and we may not be able to successfully commercialize these products. Failure to do so may adversely impact our existing debt facility and/or access to capital.**

To date, we have expended significant time, resources and effort on the development of DUEXIS and RAYOS, and a substantial majority of our resources are now focused on the commercialization of DUEXIS in the U.S. and seeking additional marketing approvals for DUEXIS. Our ability to generate significant product revenues and to achieve commercial success in the near term will initially depend almost entirely on our ability to successfully commercialize DUEXIS and RAYOS in the U.S. DUEXIS has been approved for marketing in the UK but is not yet approved in any other countries in Europe and therefore, unless we obtain regulatory approval in other countries, DUEXIS may not be commercialized to any significant extent outside of the U.S. Even if DUEXIS is approved in other European countries, we do not expect the opportunity in Europe to be material to our business given the current state of the market in Europe for pain products and the revenue being generated by existing branded NSAIDs in Europe. Our initial strategy for RAYOS is to solely focus on the rheumatology indications approved for RAYOS where our Phase 3 clinical trial data supports our commercial plans. We initially launched RAYOS in the United States to a subset of rheumatologists in the fourth quarter of 2012, and the full launch to the majority of U.S. rheumatologists and key primary care physicians occurred in late January 2013. Although LODOTRA is approved for marketing in 30 countries outside the U.S., 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 U.S. and from similar foreign regulatory agencies in other jurisdictions) and in some jurisdictions, reimbursement authorization. There are no guarantees that we or our commercialization partners will obtain any additional regulatory approvals for our products. Even if we or our commercialization partners obtain additional regulatory approvals, we may never generate significant revenues from any commercial sales of our products. If we fail to successfully commercialize DUEXIS or RAYOS, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be adversely affected.

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Our $60.0 million senior secured loan that we entered into in February 2012 with a group of institutional lenders, or Senior Secured Loan, includes certain performance covenants, including minimum trailing twelve month revenue covenants at specified quarter ends beginning on June 30, 2012. Should we not meet these quarterly minimum trailing twelve month revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. There can be no assurance that we will be able to satisfy the operating and financial covenants under the Senior Secured Loan for future periods. We also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if we were unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations.

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

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

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

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

To market any drugs outside of the U.S., we and current or future collaborators must comply with numerous and varying regulatory and compliance related requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Applications for regulatory approval, including a marketing authorization application, or MAA, for marketing new drugs in Europe, must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. Regulatory authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem a product candidate to be adequately safe and effective;

may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;

may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we do;

may not approve the manufacturing processes or facilities associated with our product candidates;

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

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

We have two products approved in the U.S., one product with broad approval for commercial sale in Europe, and another product approved only for commercial sale in the UK thus far. RAYOS/LODOTRA has been approved in the U.S. and 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 U.S. on April 23, 2011, and in March 2013 we announced we were granted marketing authorization for DUEXIS in the UK, and we have generated limited revenues for DUEXIS to date. We only recently began the commercial sale of RAYOS in the U.S. in the fourth quarter of 2012. We face considerable risks and difficulties as a company with limited commercial operating history, particularly as a consolidated entity with operating subsidiaries that also have limited operating histories. If we do not successfully address these risks, our business, prospects, operating results and financial condition will be materially and adversely harmed. Our limited commercial operating history makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. For example, our Senior Secured Loan includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end. Should we not meet these quarterly minimum revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. There can be no assurance that we will be able to satisfy the operating and financial covenants under the Senior Secured Loan, as amended for future periods. We also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if we were unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations.

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

The facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities. We do not control the manufacturing processes of third-party manufacturers and are currently completely dependent on our third-party manufacturing partners sanofi-aventis U.S. LLC, or sanofi-aventis U.S., operating through Valeant Pharmaceuticals International, Inc., or Valeant, its manufacturing partner located in Laval, Canada for production of DUEXIS, and Jagotec AG, a wholly-owned subsidiary of SkyePharma PLC, located in Lyon, France, for production of LODOTRA. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to Aenova France SAS, or Aenova. As such, Aenova is now a subcontractor for Jagotec for the manufacture of RAYOS/LODOTRA, with our consent. 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 Laboratories in India, and the primary active ingredient for RAYOS/LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and Sanofi Chimie in France. If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to supply our primary active ingredients or manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products.

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

Although we have entered into supply agreements for the manufacture of our products, our manufacturers may not perform as agreed or may terminate their agreements with us. Under our manufacturing and supply agreement with sanofi-aventis U.S., operating through Valeant, either we or sanofi-aventis U.S. may terminate the agreement upon an uncured breach by the other party or without cause upon two years prior written notice, so long as such notice is given after the third anniversary of the first commercial sale of DUEXIS. Under our manufacturing and supply agreement with Jagotec, either we or Jagotec may terminate the agreement in the event of an insolvency, liquidation or bankruptcy of the other party or upon an uncured breach by the other party. While we have the right to receive a continuing supply of RAYOS/LODOTRA from Jagotec for a period of 24 months after termination, we would need to move our manufacturing to our alternate supplier of RAYOS/LODOTRA, Bayer 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, 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 U.S., as well as any additional countries as may be agreed to by the parties. We intend to sell drug product finished and packaged by either Temmler 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 U.S. as well as any additional countries as may be agreed to by the parties.

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

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.

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

As of December 31, 2010, we employed 41 full-time employees as a consolidated entity. In anticipation of the commercial launch of DUEXIS, we hired 80 sales representatives during the period from September 2011 through October 2011. As of December 31, 2012 and June 30, 2013, we employed 247 and 280 full-time employees, respectively, as a consolidated entity. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired in connection with the commercial launch of DUEXIS and RAYOS, requiring us to hire and train new sales representatives. Our management, personnel, systems and facilities currently in place may not be adequate to support this recent growth, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses.

As our commercialization plans and strategies develop, we will need to continue recruiting and training sales and marketing personnel and expect to need to expand the size of our employee base for managerial, operational, financial and other resources. We may also need to expand these capabilities, along with our field sales force size and capabilities if we develop, acquire, in-license or co-promote additional products. Our ability to manage any future growth effectively may require us to do, among other things, the following:

- continue to manage and expand the sales and marketing efforts for DUEXIS and RAYOS;
- enhance our operational, financial and management controls, reporting systems and procedures;
- expand our international resources;
- manage the MAA review process for DUEXIS to ensure additional approvals in Europe beyond the UK;
- successfully identify, recruit, hire, train, maintain, motivate and integrate additional employees;
- establish and increase our access to commercial supplies of our products and product candidates;
- expand our facilities and equipment; and
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators, distributors and other third parties.

Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities and towards managing these growth activities. Our future financial performance and our ability to execute on our business plan will depend, in part, on our ability to effectively manage any future growth and our failure to effectively manage growth could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

As DUEXIS and RAYOS were not fully commercially launched until January 2012 and January 2013, respectively, the members of our sales force have limited experience promoting DUEXIS and almost no experience promoting RAYOS. As a result, we are required to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense DUEXIS and RAYOS. In addition, we must train our sales force to ensure that a consistent and appropriate message about DUEXIS and RAYOS is being delivered to our potential customers. Our sales representatives may also experience challenges promoting two products

when they call on physicians and their office staff, and our representatives may also be distracted from selling DUEXIS with the recent launch of RAYOS as all of our representatives were previously focused solely on selling DUEXIS. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired in connection with the commercial launch of DUEXIS and RAYOS, requiring us to train new sales representatives. As a result of the managed care environment and pharmacies switching patient s prescriptions to a generic or over the counter brand, we have had to adjust the profile of the sales representatives we hire from the traditional pharmaceutical representative to a representative with business to business experience that is focused on the total office call in order to protect the prescription the physician has written and ensure the patient receives what their doctor ordered. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of DUEXIS and RAYOS and their proper administration and label indication, our efforts to successfully commercialize DUEXIS and RAYOS could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.

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

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the U.S. and international markets, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors and we will have to find new ways to compete and may have to potentially merge with or acquire

other businesses to stay competitive. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or in-licensing on an exclusive basis, products that are more effective and/or less costly than DUEXIS and RAYOS/LODOTRA or any product candidates that we may develop.

DUEXIS faces competition from Celebrex®, marketed by Pfizer Inc., Vimovo®, marketed by AstraZeneca AB, Arthrotec®, marketed by Pfizer, and several other branded NSAIDs. DUEXIS also faces significant competition from the separate use of NSAIDs for pain relief and GI protective medications to reduce the risk of NSAID-induced upper GI ulcers. Both NSAIDs and GI protective medications are available in generic form and may be less expensive to use separately than DUEXIS. Legislation enacted in most states in the U.S. allows or, in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded product, in the absence of specific instructions from the prescribing physician. Because pharmacists often have economic and other incentives to prescribe lower-cost generics, if physicians prescribe DUEXIS, those prescriptions may not result in sales. If we are unsuccessful in convincing physicians to provide prescribing instructions prohibiting the substitution of generic ibuprofen and famotidine separately as a substitution for DUEXIS, sales of DUEXIS may suffer despite any success we may have in promoting DUEXIS to physicians. In addition, other product candidates that contain ibuprofen and famotidine in combination, while not currently known to us, may be developed and compete with DUEXIS in the future.

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc., or Par, advising that Par had filed an Abbreviated New Drug Application, or ANDA, with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par has not advised us as to the timing or status of the FDA s review of its filing, or whether it has complied with FDA requirements for proving bioequivalence. In March 2012, we filed a patent infringement lawsuit against Par and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS. In January 2013, we filed a second suit against Par claiming patent infringement of additional patents that have been issued for DUEXIS. A trial date is currently set for the second quarter of 2014. All of our issued U.S. patents covering DUEXIS are listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Under the FDA s rules and regulations, because we initiated a patent infringement suit to defend a patent identified in the Paragraph IV notice within 45 days after the FDA s receipt of the notice, the FDA is prevented from approving the ANDA until the earlier of 30 months from the date of the first suit or a decision in the infringement case that the patent is not infringed or invalid. However, if we are unsuccessful on the patent litigation, we will likely face generic competition and our sales of DUEXIS will be substantially harmed.

RAYOS/LODOTRA competes with a number of pharmaceuticals on the market to treat rheumatoid arthritis, or RA, including corticosteriods, such as prednisone, disease modifying antirheumatic drugs, or DMARDs, such as methotrexate, and biologic agents such as HUMIRA®, marketed by Abbott, and Enbrel®, marketed by Amgen Inc. and Pfizer. It is typical for an RA patient to take a combination of a DMARD, an oral glucocorticoid, an NSAID and/or a biologic agent. Therefore, we believe that RAYOS/LODOTRA s principal competition is prednisone, the active pharmaceutical ingredient in RAYOS/LODOTRA, or other oral corticosteriods, which, while they may be suboptimal, are less expensive than RAYOS/LODOTRA. In addition, other product candidates that contain prednisone or other oral corticosteriods in alternative delayed release forms, while not currently known to us, may be developed and compete with LODOTRA in the future.

On March 13, 2013, we received 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 WLF, advising that WLF had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. WLF has not advised us as to the timing or status of the FDA s review of its filing. We are evaluating the Paragraph IV Patent Certifications and intend to vigorously enforce our intellectual property rights relating to RAYOS. All of the issued U.S. patents covering RAYOS are listed in the FDA s Orange Book. Under the FDA s rules and regulations, if we initiate a patent infringement suit to defend the patents identified in a Paragraph IV notice within 45 days after the FDA s receipt of a proper notice under 21 U.S.C. 355(j)(2)(B), the FDA would be prevented from approving the ANDA until the earlier of 30 months from the date of the suit or a decision in the infringement case that each of the patents is not infringed or invalid. If we are unsuccessful in enforcing our intellectual property rights relating to RAYOS or if Alvogen s or WLF s ANDA is otherwise approved, we will likely face generic competition and our sales of RAYOS will be substantially harmed.

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

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

- develop, acquire, in-license or co-promote medicines that are superior to other products in the market;
- attract qualified clinical, regulatory, and sales and marketing personnel;
- obtain patent and/or other proprietary protection for our products and technologies;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new product candidates.

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

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 U.S., and Mundipharma is in the process of obtaining pricing and reimbursement approval for, and preparing to market, LODOTRA in other European countries, as well as in certain Asian and Latin American countries. Also, Grünenthal S.A. is in the registration process for the commercialization of DUEXIS in Latin America. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for our products;
- compliance with Swiss laws with respect to our Horizon Pharma AG subsidiary, including laws requiring maintenance of cash in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities;
- difficulties in staffing and managing foreign operations;
- in certain circumstances, including with respect to the commercialization of LODOTRA in Europe and certain Asian and Latin American countries, and commercialization of DUEXIS in Latin America, increased dependence on the commercialization efforts and regulatory compliance of our distributors or strategic partners;

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

foreign government taxes, regulations and permit requirements;

U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;

economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;

fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;

compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;

workforce uncertainty in countries where labor unrest is more common than in the U.S.;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;

changes in diplomatic and trade relationships; and

- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.

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

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

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

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

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

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

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

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

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, sales and marketing and scientific and medical personnel, including our Chairman, President and Chief Executive Officer, Timothy P. Walbert, our Executive Vice President and Chief Financial Officer, Robert J. De Vaere, our Executive Vice President, Development, Regulatory Affairs, Manufacturing and Chief Medical Officer, Jeffrey W. Sherman, M.D., and our Executive Vice President and Chief Commercial Officer, Todd Smith. In order to retain valuable

employees at our company, in addition to salary and cash incentives, we provide incentive stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

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Despite our efforts to retain valuable employees, members of our management, sales and marketing, regulatory, clinical affairs, medical affairs and development teams may terminate their employment with us on short notice. Although we have written employment arrangements with all of our employees, these employment arrangements generally provide for at-will employment, which means that our employees can leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. We do not maintain key man insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior sales and marketing and scientific and medical personnel.

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, Warning Letters or holds on clinical trials;

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

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- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions, the imposition of civil or criminal penalties, or exclusions.

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

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

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

Outside of the U.S., 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 30 countries outside the U.S., and reimbursement for LODOTRA has been obtained in Germany, Italy and Switzerland. Mundipharma is seeking coverage for LODOTRA in a number of countries 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 DUEXIS, RAYOS/LODOTRA or any other product candidates that we may develop.

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

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

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any payment or transfer of value made or distributed to teaching hospitals, prescribers and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection to be required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services to be required by March 31, 2014 and by the 90th day of each subsequent calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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

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

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

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

The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines up to $25,000 per violation and imprisonment for not more than five years, or both, and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

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

The federal False Claims Act prohibits persons from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to a federal healthcare program or knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes any request or demand for money or property presented to the U.S. government. Suits filed under the False Claims Act, known as qui tam actions, can be brought by any individual on behalf of the government and such individuals, commonly known as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of pharmaceutical, medical device and other healthcare companies to have to defend False Claims Act actions. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of $5,500 to $11,000 for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

Several states now require pharmaceutical companies to report expenses relating to marketing and promotional activities of pharmaceutical products and report gifts or other transfers of value to individual physicians in the states. Other states prohibit pharmaceutical companies from providing gifts or meals to healthcare providers or require companies to post information relating to clinical studies, pharmaceutical product pricing and aggregate marketing and advertising spending. In addition, some states specifically require pharmaceutical companies to establish marketing compliance programs. For example, California has enacted a statute requiring pharmaceutical companies to adopt a comprehensive compliance program that is in accordance with the Office of Inspector General of the Department of Health and Human Services Compliance Program Guidance for Pharmaceutical Manufacturers. This compliance program must include policies for compliance with the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, as well as a specific annual dollar limit on gifts or other items given to individual healthcare professionals in California, and further requires us to post an annual declaration of compliance.

Currently, several additional states are considering similar proposals. Compliance with these laws, including the development of a comprehensive compliance program, is difficult, costly and time consuming and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of applicable safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

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

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

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

In addition, if we or others identify undesirable side effects caused by DUEXIS, RAYOS/LODOTRA 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 DUEXIS or RAYOS/LODOTRA, our ability to generate significant revenues from the sale of these products would be significantly harmed.

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

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

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

Switching or adding additional CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can

materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition or prospects.

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

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. 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.

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

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

To the extent that we are required to conduct additional clinical development of DUEXIS or RAYOS/LODOTRA or we conduct clinical development of earlier stage product candidates or for additional indications for RAYOS/LODOTRA, we may experience delays in these clinical trials. A ten patient investigator-initiated Phase 2 study was recently completed to investigate LODOTRA as a potential treatment for PMR and a manuscript has been prepared by the investigator. Pursuant to a March 2011 letter agreement, Mundipharma has agreed to conduct a separate Phase 3 clinical trial for LODOTRA in this indication. While we are currently not focusing any resources on internal development of new product candidates, we do not know whether any additional clinical trials will be initiated in the future, begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

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

- clinical sites dropping out of a trial;
- adding new sites; or
- manufacturing sufficient quantities of product candidates for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians and patients perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our future clinical trials and while we intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our collaborators, the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical

protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or if we terminate, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. While we carry insurance for certain of these events 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 located in Laval, Quebec, Canada and Lyon, France, and possibly elsewhere to produce our products. We also rely on a packaging provider located in Munich, Germany. Our ability to obtain commercial supplies of our products could be disrupted and our results of operations and financial condition could be materially and adversely affected if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The ultimate impact of such events on us, our significant suppliers and our general infrastructure is unknown.

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

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

an event of default under our $60.0 million Senior Secured Loan;

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- the inability to commercialize our products or product candidates; and
- a decline in our stock price.

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

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

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to Our Financial Position and Capital Requirements

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

We have a limited operating history. We have financed our operations primarily through equity and debt financings and have incurred significant operating losses since our inception. We had a net loss of $40.6 million during the six months ended June 30, 2013 and net losses of $87.8 million, $113.3 million and $27.1 million for the years ended December 31, 2012, 2011 and 2010, respectively. As of June 30, 2013, we had an accumulated deficit of $348.7 million. We do not know whether or when we will become profitable. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders deficit and working capital. Our losses have resulted principally from costs incurred in our development activities for our products and product candidates. We anticipate that we will continue to incur operating losses in 2013 and into 2014 as we execute our plan to expand our development and commercialization activities of

DUEXIS and RAYOS/LODOTRA, and seek other products or product candidates to develop, acquire, in-license or co-promote.

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

Our $60.0 million Senior Secured Loan is secured by a lien covering substantially all of our U.S. based assets, including intellectual property. We also pledged as collateral all of our equity interests in Horizon Pharma USA, Inc. and 65% of our equity interests in Horizon Pharma AG.

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

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

Our ability to become profitable depends upon our ability to generate revenues from sales of our products. DUEXIS was approved by the FDA on April 23, 2011, and we began generating revenues from sales of DUEXIS in late 2011 following the commercial launch in the U.S. LODOTRA is approved for marketing in 30 countries outside the U.S., and to date we have generated only limited revenues from sales of LODOTRA. RAYOS was approved by the FDA on July 26, 2012, and we began marketing it in the U.S through our full field sales force in late January 2013. We may never be able to successfully commercialize DUEXIS or RAYOS or develop or commercialize other products in the U.S., which we believe represents our most significant commercial opportunity, or sell DUEXIS in Europe, where we do not consider it to be material to our business. Our ability to generate future revenues depends heavily on our success in:

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

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

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

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

- launch and commercialize DUEXIS and RAYOS in the U.S.;
- complete the regulatory approval process, and any future required clinical development related thereto, for DUEXIS and RAYOS/LODOTRA;
- conduct clinical trials with respect to RAYOS/LODOTRA to generate clinical data in diseases beyond RA, such as PMR, or support our partner, Mundipharma, who is conducting such trials; and
- potentially acquire, in-license and/or co-promote complementary products or products which augment our current therapeutic areas of focus.

We believe that our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations into the third quarter of 2014 and potentially beyond based on our current expectations of continued revenue growth. We may need to raise additional funds sooner if we choose to expand our commercialization or development efforts more rapidly than we presently anticipate, if we develop, acquire, in-license and/or co-promote additional products, or 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 June 30, 2013 and December 31, 2012, our Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. We will continue to monitor and review steps to address any overindebtedness, until such time as our Swiss subsidiary generates positive income at a statutory level, which could require us to have cash at our Swiss subsidiary in excess of its near term operating needs and could affect our ability to have sufficient cash at our U.S. subsidiary to meet its near term operating needs.

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

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

We may seek additional capital through a combination of private and public equity offerings, debt financings, receivables or royalty financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other

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

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. As of June 30, 2013, $24.2 million worth of our common stock was available under the ATM sales agreement for future issuance. 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 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.

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

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. In September 2012, the sale of our common stock and warrants to purchase shares of our common stock in a public equity offering triggered an ownership change limitation and, as a result, we will be subject to annual limits on our ability to utilize net operating loss carryforwards. We estimate that these annual limits will be $27.9 million, $22.0 million and $22.0 million for the years 2013, 2014 and 2015, respectively, and will be cumulative such that any use of the carryforwards below the limitation in one year will result in a corresponding increase in the limitation for the subsequent tax year. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including potentially as a result of our debt and equity financings. Any limitation on our ability to use our net operating loss carryforwards will likely increase the taxes we would otherwise pay in future years if we were not subject to such limitations.

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

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

At June 30, 2013, we had $69.3 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 June 30, 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 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.

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Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the U.S. or in other foreign countries. If this were to occur, early generic competition could be expected against DUEXIS, RAYOS/LODOTRA and other product candidates in development. There is no assurance that the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in DUEXIS and RAYOS/LODOTRA have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications.

Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. On February 15, 2012, we received a Paragraph IV Patent Certification from Par advising that Par had filed an ANDA with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par has not advised us as to the timing or status of the FDA s review of its filing, or whether it has complied with FDA requirements for proving bioequivalence. In March 2012, we filed a patent infringement lawsuit against Par and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS. In January 2013, we filed a second suit against Par claiming patent infringement of additional patents that have been issued for DUEXIS. A patent claim construction hearing is scheduled for August 21, 2013, and a trial date is currently set for the second quarter of 2014. All of our issued U.S. patents covering DUEXIS are listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Under the FDA s rules and regulations, because we initiated a patent infringement suit to defend a patent identified in Par s Paragraph IV notice within 45 days after the FDA s receipt of the notice, the FDA is prevented from approving Par s ANDA until the earlier of 30 months from the date of the first suit or a decision in the infringement case that the patent is not infringed or invalid.

In addition, on March 13, 2013, we received 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 WLF advising that WLF had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. WLF has not advised us as to the timing or status of the FDA s review of its filing. Under the FDA s rules and regulations, if we initiate a patent infringement suit to defend the patents identified in a Paragraph IV notice within 45 days after the FDA s receipt of a proper notice under 21 U.S.C. 355(j)(2)(B), the FDA would be prevented from approving the ANDA until the earlier of 30 months from the date of the suit or a decision in the infringement case is made.

We intend to vigorously defend our intellectual property rights relating to DUEXIS and RAYOS, but we cannot predict the outcome of the Par, Alvogen or WLF matters. Any adverse outcome in these matters could result in one or more generic versions of DUEXIS and/or RAYOS being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of DUEXIS and/or RAYOS and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

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

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 U.S. 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 U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to 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 U.S. and Canada. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. 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 U.S. 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 U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the U.S. PTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

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

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

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

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

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

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

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

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

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.

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

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

Risks Related to Ownership of our Common Stock

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

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

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

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

- our failure to successfully execute our commercialization strategy with respect to our approved products, particularly our commercial launches of DUEXIS and RAYOS in the U.S.;
- disputes or other developments relating to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products and product candidates;
- unanticipated serious safety concerns related to the use of DUEXIS, RAYOS/LODOTRA or any of our other product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our products or product candidates, including but not limited to clinical trial requirements for approvals;
- inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;
- developments concerning our commercial partners, including but not limited to those with our sources of manufacturing supply;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

adverse results or delays in clinical trials;

our failure to successfully develop, acquire, in-license and/or co-promote additional product candidates;

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

our inability to effectively manage our growth;

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

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

actual or anticipated variations in quarterly operating results;

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

- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- our inability to successfully enter new markets;
- the termination of a collaboration or the inability to establish additional collaborations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our inability to maintain an adequate rate of growth;
- ineffectiveness of our internal controls;
- additions or departures of key management, commercial or regulatory personnel;
- issuances of debt or equity securities;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- effects of natural or man-made catastrophic events or other business interruptions; and
- other events or factors, many of which are beyond our control.

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

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

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

to stockholders will therefore be limited to the increase, if any, of our stock price.

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

Our officers, directors and funds affiliated with our directors held in the aggregate approximately 22% and 18% of our outstanding voting stock as of December 31, 2012 and June 30, 2013, respectively. Therefore, these stockholders have the ability to influence us through this ownership position, including through matters requiring stockholder approval. For example, these stockholders may be able to influence the elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

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

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In particular, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the NASDAQ Stock Market, Inc., or NASDAQ, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. These rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time-consuming and costly. If these requirements divert the attention of our

management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will continue to decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain and maintain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. If we fail to comply with the continued listing requirements of NASDAQ, our common stock could be delisted from The NASDAQ Global Market, which would adversely affect the liquidity of our common stock and our ability to obtain future financing.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform annual system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our independent registered public accounting firm is also required to deliver a report on the effectiveness of our internal control over financial reporting. Our testing, or the testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management efforts, particularly because of our holding company structure and international operations. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, as well as retain and work with consultants with such knowledge. Moreover, if we are not able to comply with the requirements of Section 404 or if we or our independent registered public accounting firm identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our common stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

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

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans are or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

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

We expect that additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in subsequent transactions, our existing stockholders may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of our common stock.

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 August 6, 2013, Cowen had sold a cumulative total of 2,448,575 shares of our common stock with gross proceeds to us of $6,238, and we had $21,152 of common stock available for future issuance under the ATM sales agreement, after giving effect to the limited amount of securities registered under our shelf registration statement associated with the ATM sales agreement.

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

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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 14, 2012, pursuant to the terms of our 2011 EIP and 2011 ESPP, our board of directors approved increases in the number of shares available for issuance under the 2011 EIP and the 2011 ESPP of 1,474,304 shares and 200,000 shares, respectively, effective January 1, 2013.

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

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

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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.

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Item 6. Exhibits

The exhibits listed on the Index to Exhibits following the signature page are filed as part of this Quarterly Report on Form 10-Q.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HORIZON PHARMA, INC.

Date: August 9, 2013

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

(Principal Executive Officer)

Date: August 9, 2013

By: /s/ Robert J. De Vaere
Robert J. De Vaere
Executive Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

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INDEX TO EXHIBITS

Exhibit Number	Description of Document
3.1(2)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated Bylaws.
4.1(1)	Form of Common Stock Certificate.
4.2(1)	Form of Warrant issued by Horizon Pharma, Inc. to bridge financing investors.
4.3(1)	Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Comerica Bank.
4.4(1)	Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Hercules Technology Growth Capital, Inc.
4.5(1)	Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Comerica Bank.
4.6(1)	Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Hercules Technology Growth Capital, Inc.
4.7(1)	Warrant issued by Horizon Pharma, Inc. on April 1, 2010 to Silicon Valley Bank.
4.8(1)	Investors Rights Agreement, dated April 1, 2010, by and among Horizon Pharma, Inc. and certain of its stockholders.
4.9(1)	Form of Warrant issued by Horizon Pharma, Inc. on June 2, 2011 to Oxford Finance LLC.
4.10(1)	Warrant issued by Horizon Pharma, Inc. on June 2, 2011 to Silicon Valley Bank.
4.11(1)	Conversion and Amendment Agreement, dated June 16, 2011, by and among Horizon Pharma, Inc. and certain of its stockholders.
4.12(3)	Form of Warrant issued by Horizon Pharma, Inc. pursuant to the Loan and Security Agreement, dated February 22, 2012, by and among Horizon Pharma USA, Inc., Horizon Pharma, Inc., Cortland Capital Market Services, LLC, as administrative agent, and the Lenders listed therein.
4.13(3)	Form of Warrant issued by Horizon Pharma, Inc. pursuant to the Securities Purchase Agreement, dated February 28, 2012, by and among Horizon Pharma, Inc. and the Purchasers and Warrant Holders listed therein.
4.14(3)	Amendment to Investors Rights Agreement, dated February 22, 2012.
4.15(4)	Form of Warrant issued in Public Offering of Units.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document

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

* Confidential treatment has been requested 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 Current Report on Form 8-K, filed on March 1, 2012.

(4) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on September 20, 2012.