HORIZON PHARMA, INC.
Form 10-Q
November 13, 2012
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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 September 30, 2012

OR

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

For the transition period from to

Commission File Number 001-35238

HORIZON PHARMA, INC.

(Exact name of registrant as specified in its charter)

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

(224) 383-3000

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant is a shell company (as defined 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 November 9, 2012: 61,584,365.

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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)

	As of September 30, 2012	As of December 31, 2011
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 121,326	$ 17,966
Restricted cash	800	750
Accounts receivable, net	5,979	2,372
Inventories, net	3,666	1,195
Prepaid expenses and other current assets	4,334	2,763
Total current assets	136,105	25,046
Property and equipment, net	3,620	3,245
Developed technology, net	68,647	35,602
In-process research and development		36,638
Other assets	3,971	547
TOTAL ASSETS	$ 212,343	$ 101,078
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 6,854	$ 8,170
Accrued expenses	12,613	8,926
Deferred revenues-current portion	3,584	3,281
Notes payable-current portion	7,957	3,604
Total current liabilities	31,008	23,981
Notes payable, net of debt discount	39,366	15,834
Deferred revenues, net of current	8,814	5,666
Deferred tax liabilities, net	4,615	9,561
Other long term liabilities	123	124
TOTAL LIABILITIES	83,926	55,166
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY:		
	6	2

Common stock, $0.0001 par value; 200,000,000 shares authorized; 61,038,167 and 19,627,744 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively		
Additional paid-in capital	416,325	270,015
Accumulated other comprehensive loss	(4,136)	(3,788)
Accumulated deficit	(283,778)	(220,317)
Total stockholders equity	128,417	45,912
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 212,343	$ 101,078

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 September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
REVENUES:				
Sale of goods	$ 7,260	$ 233	$ 14,671	$ 3,290
Contract revenue	51	40	156	111
Gross sales	7,311	273	14,827	3,401
Sales discounts and allowances	(790)		(1,942)	
Net sales	6,521	273	12,885	3,401
Cost of goods sold	3,810	1,249	8,732	5,191
Gross profit (loss)	2,711	(976)	4,153	(1,790)
OPERATING EXPENSES:				
Research and development	3,796	5,346	12,098	11,536
Sales and marketing	12,951	5,141	34,466	7,426
General and administrative	4,678	4,192	14,436	10,640
Total operating expenses	21,425	14,679	61,000	29,602
Operating loss	(18,714)	(15,655)	(56,847)	(31,392)
OTHER (EXPENSE) INCOME, NET:				
Interest expense, net	(3,339)	(995)	(11,081)	(5,465)
Foreign exchange gain (loss)	588	(758)	(312)	(226)
Other expense			(56)	
Total other expense, net	(2,751)	(1,753)	(11,449)	(5,691)
Loss before benefit for income taxes	(21,465)	(17,408)	(68,296)	(37,083)
BENEFIT FOR INCOME TAXES	(4,512)	(177)	(4,835)	(545)
NET LOSS	$ (16,953)	$ (17,231)	$ (63,461)	$ (36,538)
NET LOSS PER COMMON SHARE - Basic and diluted	$ (0.47)	$ (1.30)	$ (2.03)	$ (6.69)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING - Basic and diluted	35,972,657	13,256,189	31,227,336	5,458,561
OTHER COMPREHENSIVE INCOME (LOSS), NET OF TAX				
Foreign currency translation adjustments	483	(5,977)	(348)	3,194
Other comprehensive income (loss)	483	(5,977)	(348)	3,194

COMPREHENSIVE LOSS	$ (16,470)	$ (23,208)	$ (63,809)	$ (33,344)

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)

	Nine Months Ended September 30,	
	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (63,461)	$ (36,538)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	3,648	3,071
Stock-based compensation	3,662	1,827
Non-cash interest expense	1,827	2,499
Paid in kind interest expense	1,860	
Foreign exchange loss	312	226
Loss on disposal of assets	76	
Changes in operating assets and liabilities:		
Accounts receivable	(3,600)	342
Inventories	(2,475)	(838)
Prepaid expenses and other current assets	(1,577)	(706)
Accounts payable	(1,314)	1,180
Accrued expenses	2,937	656
Deferred revenues	3,498	1,909
Deferred tax liabilities	(4,866)	(567)
Net cash used in operating activities	(59,473)	(26,939)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(1,012)	(449)
Increase in restricted cash	(50)	(250)
Net cash used in investing activities	(1,062)	(699)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of notes payable, net of issuance costs	55,578	16,651
Proceeds from equity finance offerings, net of issuance costs	128,092	
Proceeds from the issuance of common stock in initial public offering, net of underwriting fees and issuance costs		46,035
Repayment of notes payable	(19,780)	(12,747)
Proceeds from the issuance of common stock	296	
Proceeds from the issuance of bridge notes payable to related parties		6,766
Deferred financing expenses		(1,637)
Proceeds from stock option exercises		45
Net cash provided by financing activities	164,186	55,113
Effect of foreign exchange rate changes on cash and cash equivalents	(291)	138
NET INCREASE IN CASH AND CASH EQUIVALENTS	103,360	27,613
CASH AND CASH EQUIVALENTS, beginning of the period	17,966	5,384

CASH AND CASH EQUIVALENTS, end of the period	$	121,326	$	32,997
Supplemental cash flow information:				
Cash paid for interest	$	5,762	$	2,032
Cash paid for income taxes		44		31
Commitment fee paid on notes payable		600		
Supplemental non-cash flow information:				
Common stock issued in connection with debt amendment	$	5,075	$	
Payment in kind incremental borrowings		1,096		

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 nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. The December 31, 2011 consolidated balance sheets were derived from audited financial statements, but do 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.

Condensed Consolidated Statements of Comprehensive Loss Revision

During the second quarter of 2012, the Company identified an inconsistency in its presentation of gross sales and sales discounts and allowances between its Horizon Pharma USA, Inc. and Horizon Pharma AG subsidiaries for the three months ended March 31, 2012. As a result, gross sales of the Company s Horizon Pharma AG subsidiary were presented net of sales discounts and allowances within its condensed consolidated statements of comprehensive loss. An adjustment to conform the presentation of gross sales between the Company s Horizon Pharma USA, Inc. and Horizon Pharma AG subsidiaries resulted in an increase in consolidated gross revenue for the three months ended March 31, 2012 of $185 and a corresponding increase of $185 in consolidated deductions for sales discounts and allowances, which is reflected in the results for the nine months ended September 30, 2012. There was no impact to consolidated net sales, net loss, or net loss per common share as a result of this adjustment. The adjustment was not considered material to the previously issued statements of comprehensive loss. The following table summarizes the presentation adjustments as described above:

	Three Months Ended March 31, 2012	
	As Presented	As Adjusted
Gross sales	$ 2,669	$ 2,854
Add: Contract revenue	53	53
Less: Sales discounts and allowances	(199)	(384)
Net sales	$ 2,523	$ 2,523
Net loss	$ (23,726)	$ (23,726)

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 biopharmaceutical company that is developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases. On April 23, 2011, the U.S. Food and Drug Administration (FDA) approved DUEXIS®, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis (RA) and osteoarthritis 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,

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the Company hired its initial commercial organization of approximately 80 field sales representatives and completed sales force training. The Company began detailing DUEXIS to physicians in December 2011 and held its launch meeting for DUEXIS in the U.S. in January 2012. In June 2012, the Company began expanding its commercial organization and in early October 2012, announced the completed expansion to approximately 150 field sales representatives. Also in June 2012, the Company engaged Mallinckrodt LLC, the pharmaceutical business of Covidien plc, on a non-exclusive basis to co-promote DUEXIS in the U.S. As of October 1, 2012, as a result of the Company s sales force expansion and the Mallinckrodt co-promotion agreement, the called-on physician targets for DUEXIS increased five-fold, to fifty thousand, compared to the ten thousand physician targets the Company s original 80 sales representatives were able to cover. Also in June 2012, the Company entered into an exclusive collaboration, license and supply agreement with Grünenthal S.A. for the potential commercialization of DUEXIS in Latin America. In October 2010, the Company submitted a Marketing Authorization Application (MAA) for DUEXIS in the United Kingdom (UK), the Reference Member State, through the Decentralized Procedure. In February 2012, the Company announced that it withdrew and updated the DUEXIS MAA submission to include the recently approved manufacturing site in Laval, Quebec through the National Procedure in the UK. The Company anticipates a decision on the MAA in the fourth quarter of 2012, but does not consider the DUEXIS opportunity in Europe to be material to its business given the pricing of and the revenue being generated by existing branded NSAIDS in Europe.

The Company s second product, RAYOS®, known as LODOTRA® outside the U.S., is a proprietary delayed release formulation of low-dose prednisone that was approved in the U.S. on July 26, 2012 and is currently marketed in Europe by the Company s distribution partner, Mundipharma International Corporation Limited (Mundipharma), for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. In addition, the Company has granted to Mundipharma commercialization rights to LODOTRA in Asia and Latin America. On July 26, 2012, the FDA approved RAYOS for the treatment of a broad range of diseases, including RA, polymyalgia rheumatica, psoriatic arthritis, ankylosing spondylitis, asthma and chronic obstructive pulmonary disease. The Company s initial strategy for RAYOS is to solely focus on the rheumatology indications approved for RAYOS where the Company s Phase 3 clinical trial data supports its commercial plans. The Company anticipates initially launching RAYOS in the United States to a subset of high-value rheumatologists in the fourth quarter of 2012, with a full launch to the majority of U.S. rheumatologists and primary care physicians occurring in late January of 2013. The Company s strategy is to commercialize its products in the U.S. and to enter into licensing or additional distribution agreements for commercialization of its products outside the U.S.

On August 2, 2011, the Company closed its initial public offering of 5,500,000 shares of common stock at an offering price of $9.00 per share. In connection with the closing of the initial public offering, all of the Company s convertible preferred stock was converted to common stock.

In February 2012, the Company entered into a $60,000 loan facility with a group of institutional investors (the Senior Secured Loan), which includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end, beginning in the second quarter of 2012. In September 2012, the Company entered into an amendment of the Senior Secured Loan (the Senior Secured Loan Amendment), which modified affirmative covenants under the Senior Secured Loan with respect to minimum levels of liquidity and net revenue. Under the Senior Secured Loan Amendment, the Company is required to have a minimum liquidity of $30,000 as of December 31, 2012. The Company is no longer required to achieve minimum net revenue levels for the trailing 12 month periods at the end of the third and fourth quarters of 2012, and the minimum trailing 12 month net revenues as of the end of each quarter of 2013 and the first quarter of 2014 have been reduced. No other terms of the Senior Secured Loan were modified. As of September 30, 2012, the Company was in compliance with all financial loan covenants pursuant to the Senior Secured Loan. Should the Company not meet these quarterly minimum revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. The Company also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if the Company was unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on the Company s financial position and results of operations. These uncertainties and lack of commercial operating history raise substantial doubt about the Company s ability to continue as a going concern.

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

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

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

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 September 30, 2012, the Company had cash and cash equivalents totaling $121,326. The Company believes that it has sufficient liquidity and capital resources to operate through 2013. However, the Company is highly dependent in the near term on the commercial success of DUEXIS in the U.S. market, where it was fully launched in January 2012, and the commercial success of RAYOS in the U.S. market, which will be initially launched during the fourth quarter of 2012 to a subset of high-value rheumatologists and fully launched in late January 2013 to the majority of U.S. rheumatologists and primary care physicians, and has insufficient commercial operating history to accurately predict its future performance.

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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 unaudited 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 transactions are reflected within the Company s results of operations and have generally not had a material impact on the Company s operating results. During the three months ended September 30, 2012, the Company recorded a gain from foreign currency transactions of $588 compared to a loss of $758 during the three months ended September 30, 2011. The Company does not currently utilize and has not in the past utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

Revenue Recognition

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

Revenue from up-front license fees

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

In June 2012, the Company received a non-refundable and non-creditable upfront payment associated with its entry into a collaboration, license and supply agreement with Grünenthal S.A. for the potential commercialization of DUEXIS in Latin America. The upfront payment was deferred and recorded on the balance sheet as long-term deferred revenue. As of September 30, 2012, deferred revenues under the collaboration, license and supply agreement was $1,650.

Revenue from milestone receipts

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

from the milestone achievement is recognized over the remaining minimum period of the Company s performance obligations under the agreement.

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Revenue from product deliveries

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

As a result of the acquisition of Nitec in April 2010, the Company began recognizing revenues from the sale of LODOTRA. The Company anticipates revenues will continue to result from distribution, marketing, manufacturing and supply agreements with third parties in Europe and certain Asian, Latin American and other countries 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 September 30, 2012 and December 31, 2011, deferred revenues related to the sale of LODOTRA were $2,023 and $1,554, 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 can reliably estimate returns, the Company has determined that shipment of products to wholesale distributors and retail chains do not meet the criteria for revenue recognition at the time of shipment. The Company is currently deferring DUEXIS revenue recognition until the right of return no longer exists, which is the earlier of DUEXIS being dispensed through patient prescriptions or the expiration of the right of return (twelve months after the expiration date of the product). As of September 30, 2012, and December 31, 2011, the Company had $1,353 and $1,517, respectively, in deferred revenue on its balance sheet related to DUEXIS shipments.

The Company also defers the related cost of goods sold and records such amounts as other current assets until revenue is recognized. As of September 30, 2012 and December 31, 2011, the Company had a deferred cost of goods sold balance of $260 and $1,067, respectively.

DUEXIS Product Sales Discounts and Allowances

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

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

Product Launch Discounts. The Company offers additional discounts to wholesale distributors for product purchased. The Company records the discount as an allowance against accounts receivable and a reduction of deferred revenue based on orders placed.

Patient Discount Programs. The Company offers discount card programs to patients under which the patient receives a discount on his or her prescription. The Company reimburses pharmacies for this discount through a third-party vendor. The Company records the total amount of

discounts issued in the period as a reduction of deferred revenue.

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Distribution Service Fees. The Company pays distribution services fees to each wholesaler for distribution and inventory management services. The Company accrues for the fees based on contractually defined terms with each wholesaler and records the expense as deferred cost of goods sold.

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

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

Cost of Goods Sold

As a result of the acquisition of Nitec in April 2010, the Company began to recognize cost of goods sold in connection with its sale of LODOTRA. Cost of goods sold of LODOTRA includes raw material costs, costs associated with third parties who manufacture LODOTRA for the Company, supply chain costs, royalty payments to third parties for the use of certain licensed patents and applicable taxes. Cost of goods sold also includes amortization of developed technology related to the acquisition of Nitec.

As a result of the commercial launch of DUEXIS in the U.S. in December 2011, the Company also began to recognize cost of goods sold in connection with its sale of DUEXIS. 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. The Company also defers the related DUEXIS cost of goods sold and records such amounts as other current assets until revenue is recognized.

Inventories

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

Inventories exclude product sample inventory, which is included in other current assets and is expensed as a component of sales and marketing expense when provided to physicians or healthcare providers. As of September 30, 2012 and December 31, 2011, the Company had product sample inventory of $1,194 and $629, respectively.

Preclinical Studies and Clinical Trial Accruals

The Company s preclinical studies and clinical trials have been conducted by third-party contract research organizations and other vendors. Preclinical study and clinical trial expenses are based on the services received from these contract research organizations and vendors. Payments depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients and site initiation. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts the accrual accordingly. To date, the Company has had no significant adjustments to accrued clinical expenses.

Fair Value of Financial Instruments

The carrying amounts of the Company s financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities. The estimated fair value of the Company s Senior Secured Loan was determined using Level 2 inputs and was based on the notional amounts of the outstanding debt instrument and borrowing rates of recent debt transactions. At September 30, 2012, the fair value of the Senior Secured Loan approximated its carrying value.

Cash and Cash Equivalents

Cash and cash equivalents primarily consist of cash balances and money market funds. Cash and cash equivalents were $121,326 and $17,966 as of September 30, 2012, and December 31, 2011, respectively. The Company s policy is to invest excess cash in money market funds, which are

generally of a short-term duration based upon operating requirements.

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Restricted Cash

Restricted cash consists of balances included in interest-bearing money market accounts required by a vendor for the Company s sponsored employee credit card program and by the lessor for the Company s corporate office. As of September 30, 2012, and December 31, 2011, the Company had restricted cash in the amounts of $800 and $750, respectively.

Property and Equipment, Net

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

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

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

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

Intangible Assets

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

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

Research and Development Expenses

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

Sales and Marketing Expenses

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

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that may potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents. The Company s cash and cash equivalents are invested in deposits with various banks in the U.S., Switzerland and Germany that management believes are creditworthy. At times, deposits in these banks may exceed the amount of insurance provided on such deposits. To date, the

Company has not experienced any losses on its deposits of cash and cash equivalents.

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

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

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

The Company is required to maintain compliance with applicable Swiss laws with respect to its Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. The Company reviews on a regular basis whether its Swiss subsidiary is overindebted. As of December 31, 2011, and September 30, 2012, the Company s Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. The Company will continue to monitor and review steps to address any overindebtedness,

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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.

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss) (OCI). OCI includes certain changes in stockholders equity (deficit) that are excluded from net income (loss), which consist of foreign currency translation adjustments. As of September 30, 2012, and December 31, 2011, accumulated other comprehensive loss was $4,136 and $3,788, respectively.

Net Loss Per Share

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

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

NOTE 3 EARNINGS PER SHARE

The following table presents basic and diluted earnings per share for the three and nine months ended September 30, 2012 and 2011 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Basic and diluted earnings per share calculation:				
Net loss	$ (16,953)	$ (17,231)	$ (63,461)	$ (36,538)
Weighted average of common shares outstanding	35,972,657	13,256,189	31,227,336	5,458,561
Basic and diluted net loss per share	$ (0.47)	$ (1.30)	$ (2.03)	$ (6.69)

The following dilutive securities were excluded from the computation of diluted earnings per share for the three and nine months ended September 30, 2012 and 2011 due to the anti-dilutive effects resulting from the Company s net loss for the periods presented:

Outstanding stock options to purchase an aggregate of 2,463,777 and 1,679,761 shares of common stock at September 30, 2012 and 2011, respectively, and outstanding and unvested restricted stock units covering an aggregate of 816,208 shares of common stock at September 30, 2012.

Outstanding warrants to purchase an aggregate of 18,026,441 and 459,003 shares of common stock at September 30, 2012, and 2011, 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 September 30, 2012, and December 31, 2011, are summarized as follows:

	September 30, 2012	December 31, 2011
Raw materials	$ 92	$ 75
Work-in-process	265	488
Finished goods	3,309	632
Net inventories	$ 3,666	$ 1,195

NOTE 5 PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets as of September 30, 2012, and December 31, 2011, consisted of the following:

	September 30, 2012	December 31, 2011
Deferred cost of goods sold	$ 260	$ 1,067
Product samples inventory	1,194	629
Prepaid clinical trial studies	772	
Prepaid marketing expenses	663	509
Prepaid insurance	269	230
Prepaid FDA product and manufacturing fees	339	139
Other prepaid expenses	837	115
Other current assets		74
Total prepaid and other current assets	$ 4,334	$ 2,763

NOTE 6 PROPERTY AND EQUIPMENT

Property and equipment as of September 30, 2012, and December 31, 2011, consisted of the following:

	September 30, 2012	December 31, 2011
Machinery and equipment	$ 1,836	$ 1,797
Furniture and fixtures	108	158
Computer equipment	1,192	677
Software	437	286
Trade show equipment	228	228
Leasehold improvement	712	705
Construction in progress	407	165
	4,920	4,016
Less-accumulated depreciation	(1,300)	(771)
Total property and equipment	$ 3,620	$ 3,245

Depreciation expense was $167 and $98 for the three months ended September 30, 2012, and 2011, respectively. Depreciation expense was $559 and $308 for the nine months ended September 30, 2012, and 2011, respectively.

NOTE 7 INTANGIBLE ASSETS

The Company s intangible assets consist of developed technology related to the Company s approved and/or marketed products: LODOTRA in Europe and RAYOS in the U.S. On July 26, 2012, the FDA approved RAYOS for the treatment of a broad range of indications, which resulted in the Company reclassifying the entire asset balance of $35,456, from its indefinite-lived IPR&D asset to a finite-lived developed technology asset. At September 30, 2012, the Company had no remaining IPR&D intangible assets.

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

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

As of September 30, 2012, and December 31, 2011, intangible assets subject to amortization consisted of the following:

	As of September 30, 2012			As of December 31, 2011		
	Cost Basis	Accumulated Amortization	Net Book Value	Cost Basis	Accumulated Amortization	Net Book Value
Developed technology	$ 77,775	$ (9,128)	$ 68,647	$ 41,680	$ (6,078)	$ 35,602

Amortization expense of the Company s developed technology was $1,341 and $950 for the three months ended September 30, 2012, and 2011, respectively, and was $3,089 and $2,849 for the nine months ended September 30, 2012, and 2011, respectively. As of September 30, 2012, estimated future amortization expense was as follows:

2012	$ 1,616
2013	6,463
2014	6,463
2015	6,463
2016 and thereafter	47,641
Total	$ 68,647

NOTE 8 OTHER ASSETS

Other assets as of September 30, 2012, and December 31, 2011, consisted of the following:

	September 30, 2012	December 31, 2011
Deferred financing costs	$ 3,371	$
Long-term inventory deposits	505	505
Long-term rent deposits	41	42
Other	54	
Total other assets	$ 3,971	$ 547

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NOTE 9 ACCRUED LIABILITIES

Accrued liabilities as of September 30, 2012, and December 31, 2011, consisted of the following:

	September 30, 2012	December 31, 2011
Payroll related expenses	$ 4,380	$ 4,237
Sales and marketing expenses	1,134	1,199
Deferred rent	878	811
Accrued rebates and royalties	2,101	694
Clinical and regulatory expenses	257	439
Professional services	359	394
Contract manufacturing expenses	78	220
Taxes and licenses	449	196
Interest expense	2,597	163
Consulting services	185	150
Accrued other	195	423
Total accrued liabilities	$ 12,613	$ 8,926

NOTE 10 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 under 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.

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.

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Assets measured at fair value on a recurring basis subject to the disclosure requirements ASC 820 at September 30, 2012, and December 31, 2011, were as follows:

	As of September 30, 2012			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 117,121	$	$	$ 117,121
Total assets at fair value	$ 117,121	$	$	$ 117,121

	As of December 31, 2011			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 15,448		$	$ 15,448
Total assets at fair value	$ 15,448	$	$	$ 15,448

NOTE 11 COMMITMENTS AND CONTINGENCIES

Lease Obligations

In September 2011, the Company entered into an office lease agreement for approximately 22,000 square feet of office space in Deerfield, Illinois, which was effective August 31, 2011. The initial term of the lease commenced on December 1, 2011, and expires on June 30, 2018. The minimum net rent is initially approximately $30 per month during the first year and will increase each year during the initial term, up to approximately $35 per month after the sixth year. The Company has the option to extend the lease for an additional five-year term, which would commence upon the expiration of the initial term. In August 2012, the Company entered into an additional lease agreement to expand the office space available to it by an additional 4,900 square feet in the same Deerfield, Illinois facility as its existing office space. The lease term coincides with its original lease in this facility and runs through June 30, 2018. The initial rent on the additional lease will be $7 per month and will increase up to a maximum of $8 per month after the sixth year.

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

Purchase Commitments

In August 2007, the Company entered into a manufacturing and supply agreement with Jagotec AG. 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 September 30, 2012, the minimum remaining purchase commitment based on tablet pricing in effect under the agreement was $3,130. The purchase agreement automatically renews on a yearly basis until either party provides a written two year advanced notice of termination. The earliest the agreement can expire according to this advance notice procedure is April 15, 2015.

In May 2011, the Company entered into a manufacturing and supply agreement with sanofi-aventis U.S. Pursuant to the agreement, sanofi-aventis U.S. is obligated to manufacture and supply DUEXIS to the Company in final, packaged form, and the Company is obligated to purchase DUEXIS exclusively from sanofi-aventis U.S. for our commercial requirements of DUEXIS in North America and certain countries and territories in Europe, including the European Union member states and Scandinavia, and South America. At September 30, 2012, the Company had a $9,700 blanket purchase commitment to sanofi-aventis for DUEXIS to be delivered through December 2013, of which $140 represented a binding purchase order issued from the Company to sanofi-aventis U.S. for DUEXIS to be delivered in the first quarter of 2013.

Royalty Agreement

In connection with the August 2004 development and license agreement with SkyePharma AG (SkyePharma) and Jagotec AG, 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 during the three months ended September 30, 2012 and 2011 was $136 and $101, respectively, and $395 and $356 for the nine months ended September 30, 2012 and 2011, respectively.

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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 12 LEGAL PROCEEDINGS

On February 15, 2012, the Company received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. (Par Pharmaceutical) advising that Par Pharmaceutical 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 Pharmaceutical 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 against Par Pharmaceutical and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS. A trial date is currently set for the first 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 or a decision in the infringement case that the patent is not infringed or invalid.

NOTE 13 DEBT AGREEMENTS

The Company s outstanding debt balances as of September 30, 2012, and December 31, 2011, consisted of the following:

	September 30, 2012	December 31, 2011
Senior Secured Loan	$ 61,096	$
Oxford Facility		16,598
Kreos Facility		2,840
	61,096	19,438
Current debt maturities	(7,957)	(3,604)
Debt discount	(13,773)	
Long-term debt, net of current maturities	$ 39,366	$ 15,834

On April 1, 2010, in connection with the acquisition of Nitec, Horizon Pharma AG renegotiated the payment terms of an existing 7,500 Euro debt facility (the Kreos Facility) with Kreos Capital III (UK) Limited (Kreos). In June 2011, in connection with the debt facility with Oxford Finance LLC (Oxford) and Silicon Valley Bank (SVB) described below (the Oxford Facility), the Company paid Kreos $1,450 (1,000 Euros) in exchange for Kreos consent to a partial assignment of the Kreos Facility

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to Horizon Pharma, Inc. As a result, Horizon Pharma, Inc. became a co-lender with Kreos to Horizon Pharma AG. The Company also issued a warrant to Kreos to purchase an aggregate of 100,000 shares of its Series B convertible preferred stock with an exercise price of $0.01 per share, which became a warrant to purchase an aggregate of 42,122 shares of common stock upon the completion of the Company s initial public offering. In March 2012, Kreos exercised this warrant (see Note 14). Refer to Note 9 to the Company s consolidated financial statements in the Company s annual report on Form 10-K for the year ended December 31, 2011 for further discussion of the Kreos Facility and Oxford Facility.

In February 2012, the Company entered into a $60,000 Senior Secured Loan with a group of institutional investors. The Company used $22,381 of the Senior Secured Loan proceeds to repay the Oxford Facility and the Kreos Facility. As a result of the extinguishment of the Oxford Facility and Kreos Facility, the Company incurred a $2,973 loss on debt extinguishment from the write-off of the remaining debt discount, pre-payment penalty, interest and end of loan fees. The loss on the extinguishment of debt is included in interest expense in the condensed consolidated statement of comprehensive income for the three and nine months ended September 30, 2012.

Under the terms of the Senior Secured Loan, the outstanding principal accrues interest until maturity in January 2017 at a rate of 17% per annum, payable quarterly unless repaid earlier. The Senior Secured Loan allows the Company to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt (payment in kind borrowings). Beginning in April 2013, and each quarter thereafter, the lenders may require the Company to repay $3,978 of the loan principal. The Company may also prepay the loan at any time, subject to certain prepayment premiums. In connection with the Senior Secured Loan, the Company also issued warrants to the lenders to purchase up to an aggregate of 3,277,191 shares of common stock at an exercise price of $0.01 per share. The warrants became exercisable 180 days after issuance and will remain exercisable until the maturity date of the Loan on January 22, 2017, subject to limited exceptions. The Senior Secured Loan is secured by a lien on substantially all of the Company s assets including intellectual property, and the Company pledged all of its equity interests in Horizon Pharma USA, Inc. and 65% of its equity interests in Horizon Pharma AG.

The Senior Secured Loan restricts the Company s ability to incur additional indebtedness, incur liens, pay dividends and engage in significant business transactions, such as a change of control, so long as the Company owes any amounts to the lenders under the related loan agreements. If the Company defaults under its Senior Secured Loan, its lenders may accelerate all of its repayment obligations and take control of the pledged assets. The Company s lenders could declare the Company in default under its debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect upon it as defined under the loan agreements, thereby requiring the Company to repay the loan immediately or to attempt to reverse the lenders declaration through negotiation or litigation. Among other loan covenant requirements, the Senior Secured Loan also requires the Company to maintain a minimum level of liquidity of at least $10,000 at all times during the term of the loan unless its quarterly consolidated EBITDA is at least $6,000 and to meet specified minimum net revenues during a trailing twelve-month period, which commenced on June 30, 2012. The negative covenants include, among other things, restrictions on transferring or licensing the Company s assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on the Company s assets, in each case subject to customary exceptions. In April 2012, the Company elected to pay the 12% interest in cash and the remaining 5% interest due of $333 was added to the principal loan balance as a payment in kind borrowing. Additionally, in July 2012, the Company elected to pay the 12% interest in cash and the remaining 5% interest due of $763 was added to the principal loan balance as a payment in kind borrowing.

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

In lieu of paying a cash fee in consideration for entering into the Senior Secured Loan Amendment, the Company agreed to issue an aggregate of 1,250,000 shares of the Company s common stock to the lenders. The fair value of the common stock issued in connection with the Senior Secured Loan Amendment was $5,075 and was classified as debt discount in the Company s consolidated balance sheets and will be amortized to interest expense over the remaining life of the Senior Secured Loan. At September 30, 2012, the outstanding balance on the Senior Secured Loan was $61,096 and the Company was in compliance with all applicable financial loan covenants.

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NOTE 14 STOCKHOLDERS EQUITY

In February 2012, in connection with the $60,000 Senior Secured Loan, the Company issued warrants to purchase an aggregate of 3,277,191 shares of the Company s common stock at an exercise price of $0.01 per share. The warrants expire on January 22, 2017.

In March 2012, the Company received gross proceeds of $50,820 from the sale of 14,033,829 shares of common stock and warrants to purchase an aggregate of 3,508,448 shares of common stock with an exercise price of $4.308 per share to certain institutional and accredited investors in a private equity placement. For each share of common stock purchased, the investors received a warrant to purchase 0.25 of a share of common stock. The warrants expire on March 2, 2017.

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

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

In August 2012, warrants to purchase an aggregate of 34,518 shares of the Company s common stock were exercised in a cash exercise resulting in the issuance of 34,518 shares of common stock.

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

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

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

NOTE 15 RELATED PARTY TRANSACTIONS

The Company has entered into consulting agreements with three stockholders, two of whom previously served as directors of Horizon Pharma USA. Two of the consulting agreements terminated as of December 31, 2011, while one remains in effect as of September 30, 2012. In addition, the Company s wholly-owned subsidiary, Horizon Pharma AG, has entered into a consulting agreement with a former owner and majority shareholder of Nitec. Consulting fees paid to related parties during the three months ended September 30, 2012 and 2011 were $176 and $173, respectively, and $543 and $573 for the nine months ended September 30, 2012 and 2011, 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.

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The following table presents the benefit for income taxes for the three and nine months ended September 30, 2012, and 2011, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Loss before benefit for income taxes	$ (21,465)	$ (17,408)	$ (68,296)	$ (37,083)
Benefit for income taxes	(4,512)	(177)	(4,835)	(545)
Net loss	$ (16,953)	$ (17,231)	$ (63,461)	$ (36,538)

In connection with the FDA approval of RAYOS on July 26, 2012, the Company reclassified its indefinite-lived IPR&D intangible asset to a finite-lived developed technology intangible asset and began amortizing the asset to cost of goods during the third quarter of 2012. The reclassification to developed technology required the Company to reassess its deferred tax positions, which indicated that it was more likely than not that a greater portion of the Company s deferred tax assets would be realized as a result of the reclassification of its intangible asset from indefinite-lived to finite-lived. As a result of this assessment, the Company reduced its deferred tax asset valuation allowances, which resulted in a corresponding reduction to the Company s net deferred tax liabilities and the recognition of a one-time net income tax benefit of $4,258 that was recorded as an additional benefit for income taxes during the three months ended September 30, 2012.

NOTE 17 EQUITY INCENTIVE PLANS

Employee Stock Purchase Plan

In July 2010, the Company s Board of Directors adopted the Employee Stock Purchase Plan (the 2011 Purchase Plan) and in June 2011, the Company s stockholders approved the 2011 Purchase Plan, and it became effective upon the signing of the underwriting agreement related to the Company s initial public offering in July 2011. The Company reserved a total of 463,352 shares of common stock for issuance under the 2011 Purchase Plan. The 2011 Purchase Plan provides that an additional number of shares will automatically be added annually to the shares authorized for issuance under the 2011 Purchase Plan on January 1, from 2012 until 2021. The number of shares added each year will be equal to the least of: (a) 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (b) 1,053,074 shares of common stock; or (c) a number of shares of common stock that may be determined each year by the 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, the Company s board of directors approved an additional 100,000 shares to be available for issuance under the 2011 Purchase Plan, effective as of January 1, 2012. As of September 30, 2012, 60,895 shares had been issued and an aggregate of 502,457 shares of common stock were authorized and available for issuance under the 2011 Purchase Plan.

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, consultants and advisors of the Company. Options granted under the 2005 Plan may be either incentive stock options (ISO) or nonqualified stock options (NSO). 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 annually to the shares authorized for issuance on January 1, from 2012 until 2021. The number of shares added each year will be equal to the least of: (a) 5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (b) 1,474,304 shares of common stock; or (c) a number of shares of common stock that may be determined each year

by the board of directors that is less than (a) and (b). On December 15, 2011, pursuant to the terms of the 2011 Plan, the Company s board of directors approved additional shares available for issuance under the 2011 Plan of 672,500 shares, effective as of January 1, 2012. As of September 30, 2012, 758,070 shares of common stock were reserved for issuance under the 2011 Plan.

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

Stock Option Plans

The following table summarizes stock option activity during the nine months ended September 30, 2012 as follows:

	Options	Weighted Average Exercise Price
Outstanding as of December 31, 2011	2,532,262	$ 9.93
Granted	177,030	$ 3.98
Forfeited	(245,515)	$ 7.88
Outstanding as of September 30, 2012	2,463,777	$ 9.70
Exercisable as of September 30, 2012	1,180,322	$ 13.20

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 nine months ended September 30, 2012, and 2011, and assumptions used to value stock options, are as follows:

	Nine Months Ended September 30, 2012	2011
Dividend yield		
Risk-free interest rate	1.0%	1.2%
Weighted average volatility	89.6%	86.0%
Expected life (in years)	5.94	6.02
Weighted average grant date fair value per share of options granted	$ 2.92	$ 5.3

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.

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During the nine months ended September 30, 2012 and 2011, the Company utilized a forfeiture rate of 5% for estimating the forfeitures of stock options granted.

Restricted Stock Units

The following table summarizes restricted stock unit activity during the nine months ended September 30, 2012 as follows:

	Number of Units	Weighted Average Grant-Date Fair Value Per Units
Outstanding as of December 31, 2011	304,890	$ 4.96
Granted	520,000	$ 4.20
Vested	(180,000)	$ 4.20
Forfeited	(8,682)	$ 4.96
Unvested shares outstanding as of September 30, 2012	636,208	$ 4.55

In January 2012, the Compensation Committee of the Board of Directors of the Company granted 510,000 restricted stock units to senior management of the Company. The restricted stock units are performance based and require the achievement of certain Company defined milestones, with awards being granted in the form of common stock on the earlier of termination of service or December 31, 2012. In March 2012, certain performance goals related to financing activities were met, which resulted in the vesting of 72,000 restricted stock units and a corresponding acceleration of stock-based compensation expense related to these units. In July 2012, performance goals related to RAYOS FDA approval were met, which resulted in the vesting of 108,000 restricted stock units and a corresponding acceleration of stock-based compensation expense related to these units.

The following table summarizes share-based compensation expense included in the Company s condensed consolidated statements of operations for the nine months September 30, 2012, and 2011, as follows:

	Nine Months Ended September 30, 2012	2011
Stock-based compensation expense:		
Research and development	$ 929	$ 582
Sales and marketing	773	238
General and administrative	1,960	1,007
Net effect of stock-based compensation expense on net loss	$ 3,662	$ 1,827

As of September 30, 2012, the Company estimates that pre-tax compensation expense of $7,204 for all unvested share-based awards, including both stock options and restricted stock units will be recognized through the third quarter of 2015. The Company expects to satisfy the exercise of stock options and future distribution of shares of restricted stock by issuing new shares of its common stock which have been reserved under the 2011 Plan.

NOTE 18 RECENT ACCOUNTING PRONOUNCEMENTS

The following is a listing of recent accounting standards issued by the Financial Accounting Standards Board (FASB) and their effect on the Company.

In December 2011, FASB issued ASU No. 2011-12*, Comprehensive Income (ASC Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassification of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05,* which defers only those changes in ASC 220 that relate to the presentation of reclassification adjustments. The Company does not believe that

this pronouncement will have a material effect on the Company s results of operations.

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NOTE 19 DISTRIBUTION, MANUFACTURING AND SUPPLY AGREEMENTS

On March 5, 2012, the Company amended its November 2010 Exclusive Distribution Agreement with Mundipharma and its November 2010 Manufacturing and Supply Agreement with Mundipharma Medical. The amendments added the following additional territories to each of the underlying agreements: Mexico, Brazil, Argentina, Colombia, Venezuela, Peru, Chile, Ecuador, Dominican Republic, Guatemala, Costa Rica, Uruguay, Bolivia, Panama, Nicaragua, El Salvador and Honduras. The amendment to the Company s Exclusive Distribution Agreement requires Mundipharma to meet specified minimum sales targets, which range from thousands to millions of tablets of product in bulk or finished form on a country by country basis, over specified periods of time. If Mundipharma does not meet the minimum sales volumes, the marketing rights granted will become nonexclusive with respect to the applicable country unless Mundipharma pays the Company the shortfall. Further, under the amendment to the Exclusive Distribution Agreement, the Company may receive aggregate up-front and milestone payments of up to $2,000.

On June 14, 2012, the Company entered into a co-promotion agreement with Mallinckrodt LLC (Mallinckrodt), the pharmaceutical business of Covidien plc (the Mallinckrodt Agreement), pursuant to which the Company engaged Mallinckrodt on a non-exclusive basis to promote DUEXIS in the United States, excluding any territories or possessions and excluding Puerto Rico. Under the terms of the Mallinckrodt Agreement, Mallinckrodt has agreed to use commercially reasonable efforts to promote DUEXIS to an agreed list of physician promotion targets. Mallinckrodt is required to achieve minimum levels of prescriptions from targeted physicians on a quarterly basis during the term of the Mallinckrodt Agreement, and 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. Under the terms of the Mallinckrodt Agreement, the Company is responsible for the manufacture, supply and distribution of DUEXIS.

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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, or the Securities Act, 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, or SEC. 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 biopharmaceutical company that is developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases. On April 23, 2011, the U.S. Food and Drug Administration, or FDA, approved DUEXIS®, 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. In the second half of 2011, we hired our initial commercial organization of approximately 80 field sales representatives and completed sales force training. We began detailing DUEXIS to physicians in December 2011 and held our launch meeting for DUEXIS in the U.S. in January 2012. In June 2012, we began expanding our commercial organization and in early October 2012, we announced that we had completed the expansion to approximately 150 field sales representatives. Also in June 2012, we engaged Mallinckrodt LLC, the pharmaceutical business of Covidien plc, on a non-exclusive basis to co-promote DUEXIS in the U.S. As of October 1, 2012, as a result of the our sales force expansion and the Mallinckrodt co-promotion agreement, the called-on physician targets for DUEXIS increased five-fold, to fifty thousand, compared to the ten thousand physician targets that our original 80 sales representatives were able to cover. Also in June 2012, we entered into an exclusive collaboration, license and supply agreement with Grünenthal S.A. for the potential commercialization of DUEXIS in Latin America. In October 2010, we submitted a Marketing Authorization Application, or MAA, for DUEXIS in the United Kingdom, or the UK, the Reference Member State, through the Decentralized Procedure. In February 2012, we announced that we withdrew and updated the DUEXIS MAA submission to include the recently approved manufacturing site in Laval, Quebec through the National Procedure in the UK. We anticipate a decision on the MAA in the fourth quarter of 2012, but do not consider the DUEXIS opportunity in Europe to be material to our business given the pricing of and the revenue being generated by existing branded NSAIDS in Europe.

Our second product, RAYOS®, known as LODOTRA® outside the U.S., is a proprietary delayed release formulation of low-dose prednisone that was approved in the U.S. on July 26, 2012 and is currently marketed in Europe by our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. In addition, we have granted to Mundipharma commercialization rights to LODOTRA in Asia and Latin America. On July 26, 2012, the FDA approved RAYOS for the treatment of a broad range of diseases, including RA, polymyalgia rheumatica, or PMR, psoriatic arthritis, ankylosing spondylitis, asthma and chronic obstructive pulmonary disease. 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 anticipate the initial launch of RAYOS in the United States to a subset of high-value rheumatologists in the fourth quarter of 2012, with a full launch to the majority of U.S. rheumatologists and primary care physicians occurring in late January of 2013. Our strategy is to commercialize our products in the U.S. and to enter into licensing or additional distribution agreements for commercialization of our products outside the U.S.

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RESULTS OF OPERATIONS

Comparison of Three Months Ended September 30, 2012 and 2011

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 September 30, 2012, compared to the three months ended September 30, 2011.

	Three Months Ended September 30, 2012	2011	Increase / (Decrease)
Gross sales	$ 7,311	$ 273	$ 7,038
Sales discounts and allowances	(790)		(790)
Net sales	6,521	273	6,248
Cost of good sold	3,810	1,249	2,561
Gross profit (loss)	2,711	(976)	3,687
Operating expenses			
Research and development	3,796	5,346	(1,550)
Sales and marketing	12,951	5,141	7,810
General and administrative	4,678	4,192	486
Total operating expenses	21,425	14,679	6,746
Operating loss	(18,714)	(15,655)	(3,059)
Other income (expense)			
Interest expense, net	(3,339)	(995)	(2,344)
Foreign exchange gain (loss)	588	(758)	1,346
Total other expense, net	(2,751)	(1,753)	(998)
Net loss before benefit for income taxes	(21,465)	(17,408)	(4,057)
Benefit for income taxes	(4,512)	(177)	(4,335)
Net loss	$ (16,953)	$ (17,231)	$ 278

Sales. During the three months ended September 30, 2012, gross sales and net sales were $7,311 and $6,521, respectively, compared to $273 in gross and net sales during the three months ended September 30, 2011. DUEXIS gross and net sales during the quarter were $2,966 and $2,572, respectively, after deducting trade discounts and allowances of $68 and co-pay assistance costs of $326, and represented 41% of gross sales and 39% of net sales during the quarter ended September 30, 2012. LODOTRA gross and net sales during the quarter were $4,345 and $3,949, respectively, after deducting trade discounts and allowances of $396 during the quarter ended September 30, 2012. The $4,072 increase in LODOTRA sales during the three months ended September 30, 2012 compared to the same period in the prior year was the result of higher product shipments and the recognition of deferred revenues to our European distribution partner, Mundipharma.

We have determined that the shipment of DUEXIS to wholesale distributors and retail chains does not currently meet the criteria for revenue recognition at the time of shipment which requires a reliable estimate of returns based on history. Therefore, we continue to defer DUEXIS revenue recognition until the right of return no longer exists, which is the earlier of DUEXIS being dispensed through patient prescriptions or the expiration of the right of return (twelve months after the expiration date of the product). As of September 30, 2012, we had $1,353 in deferred revenue on our balance sheet related to DUEXIS shipments.

Cost of Goods Sold. Cost of goods sold increased $2,561, from $1,249 during the three months ended September 30, 2011, to $3,810 during the three months ended September 30, 2012. The increase in cost of goods sold during the 2012 period was primarily the result of higher product sales of LODOTRA, cost of goods sold related to DUEXIS sales, which began in 2012, and a $392 increase in intangible amortization expense.

The increase in intangible amortization expense was primarily the result of the FDA approval of RAYOS in July 2012, which resulted in the reclassification and subsequent amortization of an indefinite-lived intangible asset to a definite-lived intangible asset. For the three months ended September 30, 2012, intangible amortization expense accounted for 35% of total cost of goods sold.

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Research and Development Expenses. Research and development expenses decreased $1,550, from $5,346 during the three months ended September 30, 2011, to $3,796 during the three months ended September 30, 2012. The decrease in research and development expenses during the 2012 period was primarily associated with a $1,900 reduction in regulatory submission fees and clinical trial expenses and a $300 reduction in consulting fees, which was partially offset by a $700 increase in salaries and benefits expense as a result of an additional staffing and personnel expenses, which was primarily related to staffing our medical affairs group which supports scientific publications, health outcomes medical education and information and medical communications.

Sales and Marketing Expenses. Sales and marketing expenses increased $7,810, from $5,141 during the three months ended September 30, 2011, to $12,951 during the three months ended September 30, 2012. The increase in expenses was primarily attributable to ongoing sales and promotional efforts related to our DUEXIS product launch and pre-launch activities related to RAYOS, which included a $4,800 increase in salaries and benefits expense associated with additional staffing of our sales and marketing functions, a $2,100 increase in market research and marketing programs and a $900 increase in consulting and outside service costs.

General and Administrative Expenses. General and administrative expenses increased $486, from $4,192 during the three months ended September 30, 2011, to $4,678 during the three months ended September 30, 2012. The increase in general and administrative expenses was primarily due to a $400 increase in salaries, benefits and stock compensation expense associated with additional finance and administrative personnel as we built out our corporate infrastructure, a $300 increase in legal costs associated with intellectual property related matters and a $200 increase in facility costs associated with higher rent and insurance costs, partially offset by a $400 reduction in consulting expenses during the third quarter of 2012.

Interest Expense, Net. Interest expense, net increased $2,344, from $995 during the three months ended September 30, 2011, to $3,339 during the three months ended September 30, 2012. The increase in interest expense during the three months ended September 30, 2012 was primarily the result of incremental interest expense associated with higher borrowing balances under our $60,000 senior secured loan with a group of institutional investors, or Senior Secured Loan, compared to outstanding notes payable balances of $19,853 in the prior year.

Foreign Exchange Gain (Loss), Net. During the three months ended September 30, 2012, we reported a foreign exchange gain of $588, compared to a foreign exchange loss of $758 during the three months ended September 30, 2011. The foreign exchange gain during the third quarter of 2012 was associated with an increase in the value of the Euro against the U.S. dollar during the three months ended September 30, 2012, which resulted in a favorable currency impact on re-measuring intercompany borrowings at Horizon Pharma AG subsidiary.

Income Tax Benefit. Income tax benefit increased $4,335, from $177 during the three months ended September 30, 2011, to $4,512 during the three months ended September 30, 2012. The increase in income tax benefit was due to a one-time income tax benefit of $4,258 recorded during the third quarter of 2012. In connection with the FDA approval of RAYOS on July 26, 2012, we reclassified our indefinite-lived in-process research & development, or IPR&D, intangible asset to a finite-lived developed technology intangible asset and began amortizing the asset to cost of goods sold during the third quarter of 2012. The reclassification to developed technology required us to reassess our deferred tax positions, which indicated that it was more likely than not that a greater portion of our deferred tax assets would be realized as a result of the reclassification of our intangible asset from indefinite-lived to finite-lived. As a result of this assessment, we reduced our deferred tax asset valuation allowances, which resulted in a corresponding reduction to our net deferred tax liabilities and the recognition of a one-time net income tax benefit of $4,258 that was recorded as an additional benefit for income taxes during the three months ended September 30, 2012.

Net Loss. Net loss decreased from $17,231 during the three months ended September 30, 2011, to $16,953 during the three months ended September 30, 2012, primarily as a result of higher sales and gross profit and the recognition of a one-time income tax benefit, partially offset by the increase in expenses described above.

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Comparison of Nine Months Ended September 30, 2012 and 2011

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 nine months ended September 30, 2012, compared to the nine months ended September 30, 2011.

	Nine Months Ended September 30, 2012	2011	Increase / (Decrease)
Gross sales	$ 14,827	$ 3,401	$ 11,426
Sales discounts and allowances	(1,942)		(1,942)
Net sales	12,885	3,401	9,484
Cost of goods sold	8,732	5,191	3,541
Gross profit (loss)	4,153	(1,790)	5,943
Operating expenses			
Research and development	12,098	11,536	562
Sales and marketing	34,466	7,426	27,040
General and administrative	14,436	10,640	3,796
Total operating expenses	61,000	29,602	31,398
Operating loss	(56,847)	(31,392)	(25,455)
Other income (expense)			
Interest expense, net	(11,081)	(5,465)	(5,616)
Foreign exchange loss	(312)	(226)	(86)
Other expense	(56)		(56)
Total other expense, net	(11,449)	(5,691)	(5,758)
Net loss before benefit for income taxes	(68,296)	(37,083)	(31,213)
Benefit for income taxes	(4,835)	(545)	(4,290)
Net loss	$ (63,461)	$ (36,538)	$ (26,923)

Sales. During the nine months ended September 30, 2012, gross sales and net sales were $14,827 and $12,885, respectively, compared to $3,401 in gross and net sales during the nine months ended September 30, 2011. DUEXIS gross and net sales during the nine months ended September 30, 2012 were $6,177 and $5,074, respectively, after deducting trade discounts and allowances of $375 and co-pay assistance costs of $728, and represented 42% of gross sales and 39% of net sales during the nine months ended September 30, 2012. LODOTRA gross and net sales during the nine month period were $8,650 and $7,811, respectively, after deducting trade discounts and allowances of $839 during the nine months ended September 30, 2012. The $5,250 increase in LODOTRA sales during the nine months ended September 30, 2012 compared to the same period in the prior year was the result of higher product shipments and the recognition of deferred revenues to the Company s distribution partner, Mundipharma.

Cost of Goods Sold. Cost of goods sold increased $3,541, from $5,191 during the nine months ended September 30, 2011, to $8,732 during the nine months ended September 30, 2012. The increase in cost of goods sold was primarily the result of a $1,770 increase in product costs associated with higher LODOTRA product shipments in the current year and $1,532 in product costs related to DUEXIS, which began shipment in 2012. For the nine months ended September 30, 2012, intangible amortization expense accounted for 35% of total cost of goods sold.

Research and Development Expenses. Research and development expenses increased $562, from $11,536 during the nine months ended September 30, 2011, to $12,098 during the nine months ended September 30, 2012. The increase in research and development expenses was primarily associated with a $2,300 increase in salaries and benefits expense and $800 in medical education and related grants, which was offset by a $2,100 reduction in regulatory submission fees and clinical studies expenses and $400 in lower consulting fees.

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Sales and Marketing Expenses. Sales and marketing expenses increased $27,040, from $7,426 during the nine months ended September 30, 2011, to $34,466 during the nine months ended September 30, 2012. The increase was primarily attributable to the staffing of our field sales organization and marketing functions, which resulted in $15,300 in higher salaries and benefits expenses. In addition, sales and promotional efforts in support of our DUEXIS product launch and pre-launch activities related to RAYOS during the nine months ended September 30, 2012 were higher as a result of an increase of $6,600 in advertising and promotional expenses, a $2,600 increase in samples expenses, $1,600 in higher consulting fees and a $1,000 increase in market research expenses.

General and Administrative Expenses. General and administrative expenses increased $3,796, from $10,640 during the nine months ended September 30, 2011, to $14,436 during the nine months ended September 30, 2012. The increase in general and administrative expenses was due to a $1,900 increase in salaries and benefits expense as a result of additional finance and administrative personnel as we built out our corporate infrastructure, $1,100 in higher legal and consulting costs associated with intellectual property related matters and an $800 increase in facility costs associated with higher rent and insurance expense.

Interest Expense, Net. Interest expense, net increased $5,616, from $5,465 during the nine months ended September 30, 2011, to $11,081 during the nine months ended September 30, 2012. The increase in interest expense was primarily attributable to higher borrowing balances under our Senior Secured Loan compared to the prior year and higher debt extinguishment costs. During the nine months ended September 30, 2011, there was a $1,900 charge related to the loss on extinguishment of our prior debt facility with Kreos Capital III (UK) Limited and Silicon Valley Bank, compared to a $2,500 charge related to extinguishment of our debt facility with Oxford Finance LLC and Silicon Valley Bank and our debt facility with Kreos Capital III (UK) Limited during the nine months ended September 30, 2012.

Foreign Exchange Loss, Net. During the nine months ended September 30, 2012, we had a foreign exchange loss of $312 compared to a foreign exchange loss of $226 during the nine months ended September 30, 2011. The foreign exchange loss during both periods was associated with a decline in the value of the Euro against the U.S. dollar, which resulted in an unfavorable currency impact for our Horizon Pharma AG subsidiary.

Other Expense. Other expense was $56 during the nine months ended September 30, 2012 and primarily represented a loss on disposal of office furniture.

Income Tax Benefit. Income tax benefit increased $4,290, from $545 during the nine months ended September 30, 2011, to $4,835 during the nine months ended September 30, 2012. The increase in income tax benefit was due to a one-time income tax benefit of $4,258 recorded during the third quarter of 2012. In connection with the FDA approval of RAYOS on July 26, 2012, we reclassified our indefinite-lived IPR&D intangible asset to a finite-lived developed technology intangible asset and began amortizing the asset to cost of goods sold during the third quarter of 2012. The reclassification to developed technology required us to reassess our deferred tax positions, which indicated that it was more likely than not that a greater portion of our deferred tax assets would be realized as a result of the reclassification of our intangible asset from indefinite-lived to finite-lived. As a result of this assessment, we reduced our deferred tax asset valuation allowances, which resulted in a corresponding reduction to our net deferred tax liabilities and the recognition of a one-time net income tax benefit of $4,258 that was recorded as an additional benefit for income taxes during the three months ended September 30, 2012.

Net Loss. Net loss increased from $36,538 during the nine months ended September 30, 2011 to $63,461 during the nine months ended September 30, 2012, primarily as a result of the increase in expenses described above, partially offset by higher sales and gross profit.

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 to the partner, distributor or retail chain, 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. Products sold to our wholesale distributors and retail chains are recognized based on the amount of product sold through to the end user consumer until such time as a reasonable estimate of allowances for product returns, rebates and discounts can be made.

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

Cost of goods sold for DUEXIS includes all costs directly related to the acquisition of product from our manufacturer, including freight charges and manufacturing overhead costs. We defer the DUEXIS related cost of goods sold and record such amounts as other current assets until related revenue is recognized.

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.

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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 the equity awards granted to non-employees is 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.

Recent Accounting Pronouncements

The following is a listing of recent accounting standards issued by the FASB and their effect on us.

In December 2011, FASB issued ASU No. 2011-12*, Comprehensive Income (ASC Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassification of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05,* which defers only those changes in ASC 220 that relate to the presentation of reclassification adjustments. We believe that the pronouncement will not have a material effect on our results of operations.

LIQUIDITY, FINANCIAL POSITION AND CAPITAL RESOURCES

We have incurred losses since our inception in June 2005 and, as of September 30, 2012, we had an accumulated deficit of $283,778. We anticipate that we will continue to incur net losses for at least the next few years. We expect that our sales and marketing expenses will continue to increase as a result of our commercialization of DUEXIS and RAYOS/LODOTRA. As a result, we will need to generate significant net product sales, and royalty and other revenues to achieve profitability.

We have financed our operations to date through equity financings, debt financings and the issuance of convertible notes. As of September 30, 2012, we had $121,326 in cash and cash equivalents. In February 2012, we entered into the $60,000 Senior Secured Loan. We used $22,381 of the loan proceeds to repay the remaining obligations under the Oxford facility and the Kreos facility. Under the terms of the Senior Secured Loan, the outstanding principal accrues interest until maturity in January 2017 at a rate of 17% per annum, payable quarterly unless repaid earlier. The Senior Secured Loan allows us to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt. Beginning in April 2013, and for each quarter thereafter, the lenders may require us to repay $4,000 of the loan principal. We may prepay the loan at any time, subject to certain prepayment premiums. In connection with the Senior Secured Loan, we also issued warrants to the lenders to purchase up to an aggregate of approximately 3,277,191 shares of our common stock at an exercise price of $0.01 per share. The warrants became exercisable 180 days after issuance and will remain exercisable until the maturity date of the Loan on January 22, 2017, subject to limited exceptions. The Senior Secured Loan is secured by a lien covering substantially all of our assets including intellectual property in addition to pledging all of our equity interests in Horizon Pharma USA, Inc. and 65% of our equity interests in Horizon Pharma AG.

The Senior Secured Loan restricts our ability to incur additional indebtedness, incur liens, pay dividends and engage in significant business transactions, such as a change of control, so long as we owe any amounts to the lenders under the related loan agreements. If we default under our Senior Secured Loan, our lenders may accelerate all of our repayment obligations and take control of our pledged assets. Our lenders could declare us in default under our debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect upon us as defined under the loan agreements, thereby requiring us to repay the loans immediately or to attempt to reverse the lenders declaration through negotiation or litigation. Among other loan covenant requirements, the Senior Secured Loan also requires us to maintain a minimum level of liquidity of at least $10,000 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 twelve-month period commencing on June 30, 2012. The negative covenants include, among other things, restrictions on transferring or licensing our assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions and creating other liens on our assets, in each case subject to customary exceptions. In April 2012, we elected to pay the 12% interest in cash and the remaining 5% interest of $333 was added to the principal loan balance as incremental debt. Additionally, in July 2012, we elected to pay the 12% interest in cash and the remaining 5% interest due of $763 was added to the principal loan balance as a payment in kind borrowing.

On September 7, 2012, we and the lenders entered into an amendment of the Senior Secured Loan, or the Senior Secured Loan Amendment, whereby affirmative covenants under the Senior Secured Loan with respect to minimum levels of liquidity and net revenue were modified. Under the Senior Secured Loan Amendment, we are required to have a minimum liquidity of $30,000 as of December 31, 2012 and we are no longer required to achieve minimum net revenue levels for the trailing 12 month periods at the end of the third and fourth quarters of 2012, and the minimum trailing 12 month net revenues as of the end of each quarter of 2013 and the first quarter of 2014 have been reduced. In lieu of paying a cash fee in consideration for entering into the Senior Secured Loan Amendment, we agreed to issue an aggregate of 1,250,000 shares of our common stock to the lenders. At September 30, 2012, the outstanding balance on the Senior Secured Loan was $61,096.

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As of September 30, 2012, we were in compliance with all applicable financial covenants under the Senior Secured Loan. 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; whether we are able to obtain marketing approvals for DUEXIS in Europe; acceptance of our products by patients, primary care specialists and other key specialists, including rheumatologists, orthopedic surgeons and pain specialists; and potential or perceived advantages or disadvantages of our products over alternative treatments, including cost of treatment and relative convenience and ease of administration. Changes in key markets or our inability to execute our operating plan could result in non-compliance with our operating and financial covenants which may adversely affect our cost of financing or cause an acceleration of our debt obligations.

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

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

We are required to maintain compliance with applicable Swiss laws with respect to our Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. We review on a regular basis whether our Swiss subsidiary is overindebted. As of December 31, 2011, and September 30, 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. The following table provides a summary of our cash flows for the nine months ended September 30, 2012 and 2011, as follows:

	Nine Months Ended September 30,	
	2012	2011
Cash provided by (used in):		
Operating activities	$ (59,473)	$ (26,939)
Investing activities	$ (1,062)	$ (699)
Financing activities	$ 164,186	$ 55,113

Sources and Uses of Cash

Operating Cash Flows

During the nine months ended September 30, 2012 and 2011, net cash used in operating activities was $59,473 and $26,939, respectively. The increase in net cash used in operating activities during the nine months ended September 30, 2012 was primarily attributable to our ongoing product launch efforts for DUEXIS, which resulted in higher personnel costs associated with staffing our sales and administrative functions, higher marketing and promotional expenses in addition to working capital outflows to build our product and sample inventories.

Investing Cash Flows

During the nine months ended September 30, 2012 and 2011, net cash flows used in investing activities was $1,062 and $699, respectively. The increase in the current period represented capital expenditures related to purchases associated with laptop computers for new employees and other computer hardware.

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Financing Cash Flows

During the nine months ended September 30, 2012 and 2011, net cash provided by financing activities was $164,186 and $55,113, respectively. The increase in net cash provided by financing activities was primarily the result of our debt refinancing and equity offerings completed during the current year. In February 2012, we entered into our $60,000 Senior Secured Loan with a group of institutional lenders. As part of the closing of the Senior Secured Loan, we repaid outstanding principal under the Oxford and Kreos debt facilities totaling $19,730. In March 2012, we received gross proceeds of $50,820 and net proceeds of $47,475, after deducting $3,345 in issuance costs, from the sale of 14,033,829 shares of our common stock and warrants to purchase an aggregate of 3,508,448 shares of our common stock to certain institutional and accredited investors in a private equity placement. In September 2012, we received gross proceeds of $86,236 and net proceeds of $80,961 after deducting $5,275 in issuance costs from the sale of 24,638,750 shares of common stock and warrants to purchase an aggregate of 12,319,375 shares of common stock to certain institutional and accredited investors in a public offering. During the nine months ended September 30, 2011, we received $46,035 in net proceeds from the completion of our initial public offering, $16,651 in proceeds from the issuance of notes payable and $6,766 in proceeds from the issuance of bridge notes to related parties. Additionally, net cash provided by financing activities was reduced by $19,780 from the repayment of notes payable during the nine months ended September 30, 2012, compared to repayment of notes payable of $12,747 during the nine months ended September 30, 2011.

Contractual Obligations

During the three months ended September 30, 2012, there were no material changes outside the ordinary course of business to our contractual obligations as previously disclosed in Part I, Item 2 of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.

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

Foreign Currency Risk. Our sales contracts relating to LODOTRA are principally denominated in Euros and therefore, until we derive material revenues from sales of DUEXIS and RAYOS, which was approved on July 26, 2012, in the U.S., our revenues will be subject to significant foreign currency risk. We also incur certain operating expenses in currencies other than the U.S. dollar in relation to Horizon Pharma AG; therefore, we are subject to volatility in cash flows due to fluctuations in foreign currency exchange rates, particularly changes in the Euro. To date, we have not entered into any hedging contracts since exchange rate fluctuations have had minimal impact on our results of operations and cash flows.

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

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 September 30, 2012, the end of the period covered by this report.

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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 Pharmaceutical, advising that Par Pharmaceutical 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 Pharmaceutical 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 Pharmaceutical and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS. A trial date is currently set for the first 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 or a decision in the infringement case that the patent 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 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.

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, 2011, as filed with the SEC.

Risks Related to Our Business and Industry

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

DUEXIS and RAYOS/LODOTRA and our other product candidates, if approved, 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 we announced in October 2012 that we had completed the expansion of our sales force. We have not yet begun commercial sales of RAYOS, which was recently approved by the FDA in July 2012. We expect we will begin the initial commercial sales of RAYOS in the fourth quarter of 2012 and the full launch of RAYOS in late January 2013. Outside the U.S., LODOTRA has been sold in a limited number of European countries. Sales of DUEXIS and LODOTRA have been limited to date 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. We believe that the degree of market acceptance and our ability to generate revenues from any products for which we obtain marketing approval will depend on a number of factors, including:

- timing of market introduction of our products as well as competitive drugs;
- efficacy and safety of our products;

continued projected growth of the arthritis, pain and inflammation markets;

prevalence and severity of any side effects;

acceptance by patients, primary care specialists and key specialists, including rheumatologists, orthopedic surgeons and pain specialists;

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;

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the effect of current and future healthcare laws;

availability of coverage and adequate reimbursement and pricing from government and other third-party payers; and

product labeling or product insert requirements of the Food and Drug Administration, or FDA, or other regulatory authorities.

With respect to DUEXIS, studies indicate that physicians do not commonly co-prescribe GI protective agents to high-risk patients taking NSAIDs. We believe this is due in part to a lack of awareness among physicians prescribing NSAIDs of the risk of NSAID-induced upper GI ulcers, in addition to the inconvenience of prescribing two separate medications and patient compliance issues associated with multiple prescriptions. If physicians remain unaware of, or do not otherwise believe in, the benefits of combining GI protective agents with NSAIDs, our market opportunity for DUEXIS will be limited. Some physicians may also be reluctant to prescribe DUEXIS due to the inability to vary the dose of ibuprofen or if they believe treatment with NSAIDs or GI protective agents other than ibuprofen and famotidine, including those of our competitors, would be more 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, which was approved on July 26, 2012, in the U.S. market. We may not be able to successfully commercialize either DUEXIS or RAYOS in the U.S. Prior to initial detailing in December 2011 and our commercial launch of DUEXIS in the U.S. in December 2011, we did not have any experience commercializing pharmaceutical products on our own. LODOTRA was commercially launched in Europe by our exclusive distribution partners Merck Serono and Mundipharma. In order to commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Although we announced in October 2012 the completion of our sales force expansion to approximately 150 sales representatives, we currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market these products and any additional products we may acquire, in-license or co-promote will be expensive and time-consuming and could delay any product launch. Nor can we be certain that we will be able to continue to successfully develop this capability. As a result of the evolving role of various constituents in the prescription decision making process, we adjusted the profile of the sales representatives we hire from those with traditional pharmaceutical sales experience to those with successful business to business experience. For example, we have faced challenges due to pharmacists increasingly switching a patient s intended prescription from DUEXIS to a generic or over the counter brand. 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 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 or successfully obtain additional marketing approvals for DUEXIS in Europe.**

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 is not approved for marketing in any jurisdiction outside of the U.S. and therefore, unless it obtains regulatory approval in other countries it may never be commercialized outside of the U.S. Even if DUEXIS is approved in Europe, 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 anticipate initially launching RAYOS in the United States to a subset of high-value rheumatologists in the fourth quarter of 2012 with the full launch to the majority of U.S. rheumatologists and primary care physicians occurring in late January of 2013. Although LODOTRA is approved for marketing in 19 countries outside the U.S., to date it has only been marketed in a limited number of European countries. While we anticipate that LODOTRA will be marketed in additional European countries as our distribution partner, Mundipharma, formulates its reimbursement strategy, the ability to market LODOTRA in additional

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European countries will depend on Mundipharma s ability to obtain reimbursement approvals in these countries. Even if we obtain additional marketing and reimbursement approvals, our product revenues in Europe are entirely dependent upon the marketing efforts of our exclusive distribution partner, over which we have no control. Before we can market and sell these products in a particular jurisdiction, we need to obtain necessary regulatory approvals (from the FDA in the U.S. and from similar foreign regulatory agencies in other jurisdictions) and in some jurisdictions, reimbursement authorization. There are no guarantees that we or our commercialization partners will obtain any additional regulatory approvals for our products. Even if we or our commercialization partners obtain additional regulatory approvals, we may never generate significant revenues from any commercial sales of our products. If we fail to successfully commercialize DUEXIS or RAYOS, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be adversely affected.

Our $60.0 million Senior Secured Loan includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end beginning on March 31, 2013. Should we not meet these quarterly minimum trailing twelve month revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. There can be no assurance that we will be able to satisfy the operating and financial covenants under the Senior Secured Loan for future periods. We also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if we were unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations.

*The success of our efforts to commercialize DUEXIS in the United States will be partially dependent on our co-promotion agreement with Mallinckrodt.**

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

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

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

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

We are 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

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

*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;
- 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.

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

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Even if we believe that data collected from our preclinical studies, CMC studies and clinical trials of our product candidates are promising and that our information and procedures regarding CMC are sufficient, our data may not be sufficient to support marketing approval by regulatory authorities, or regulatory interpretation of these data and procedures may be unfavorable. Even if approved, product candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed, restricted distribution methods or other limitations. Our business and reputation may be harmed by any failure or significant delay in obtaining regulatory approval for the sale of any of our product candidates. We cannot predict when or whether regulatory approval will be obtained for any product candidate we develop.

While we anticipate that LODOTRA will be marketed in additional European Union countries as Mundipharma formulates its reimbursement strategy, the ability to market LODOTRA in additional European Union countries will depend on Mundipharma s ability to obtain regulatory and reimbursement approvals in these countries. Similarly, our ability to market DUEXIS outside of the U.S. will depend on obtaining regulatory and reimbursement approval in each country where we expect DUEXIS to be marketed. However, certain countries have a very difficult reimbursement environment and we may not obtain reimbursement approval in all countries where we expect DUEXIS to be marketed, or we may obtain reimbursement approval at a level that would make marketing DUEXIS in certain countries not viable.

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

We were incorporated as Horizon Pharma, Inc. on March 23, 2010. On April 1, 2010, we effected a recapitalization and acquisition pursuant to which we became a holding company that operates through our two wholly-owned subsidiaries, Horizon Pharma USA, Inc. (formerly known as Horizon Therapeutics, Inc.) and Horizon Pharma AG (formerly known as Nitec Pharma AG, or Nitec). Horizon Pharma USA began its operations in 2005 and Nitec began its operations in 2004. We face considerable risks and difficulties as a holding company with limited operating history, particularly as a consolidated entity with operating subsidiaries that also have limited operating histories. If we do not successfully address these risks, our business, prospects, operating results and financial condition will be materially and adversely harmed. Our limited operating history makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. For example, our Senior Secured Loan includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end beginning in the first quarter of 2013. Should we not meet these quarterly minimum revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. There can be no assurance that we will be able to satisfy the operating and financial covenants under the Senior Secured Loan, as amended for future periods. We also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if we were unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations. Moreover, we have two products approved in the U.S. and one approved in Europe for commercial sale. RAYOS/LODOTRA has only been approved in the U.S., select countries within Europe, Australia and Israel, and we have a limited history of marketing LODOTRA through our distribution partners. DUEXIS was approved in the U.S. on April 23, 2011 and we have only recently increased our commercialization activities to enable us to market DUEXIS, and we have generated limited revenues for DUEXIS to date. We expect the commercial sale of RAYOS in the U.S. to begin in the fourth quarter of 2012. This limited history of commercial sales also makes evaluating our business and future prospects difficult, and may increase the risk of any investment in our common stock. We have limited experience as a consolidated operating entity, particularly with commercialization activities, and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical or biotechnology areas.

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

The facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities. We do not control the manufacturing processes of third-party manufacturers and are currently completely dependent on our third-party manufacturing partners sanofi-aventis U.S. LLC, or sanofi-aventis U.S., operating through Valeant Pharmaceuticals International, Inc., or Valeant, its manufacturing partner located in Laval, Canada for production of DUEXIS, and Jagotec AG, a wholly-owned subsidiary of SkyePharma PLC, located in Lyon, France, for production of LODOTRA. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to the Aenova France SAS, or Aenova. As such, Aenova is now a subcontractor for Jagotec for the manufacture of RAYOS/LODOTRA, with our consent. Bayer Schering Pharma AG in Germany has been qualified as a backup manufacturer. In December 2011, Valeant acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. We purchase the primary active ingredients for DUEXIS from BASF Corporation in Bishop, Texas and Dr. Reddy s Laboratories in India, and the

primary active ingredient for RAYOS/LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and Sanofi-Aventis SA in France. If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to supply our primary active ingredients or manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products.

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

Although we have entered into supply agreements for the manufacture of our products, our manufacturers may not perform as agreed or may terminate their agreements with us. Under our manufacturing and supply agreement with sanofi-aventis U.S., 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 cannot assure you that we would be able to establish another commercial supply of RAYOS/LODOTRA in that time-frame, or qualify any new supplier with the applicable regulatory authorities on a timely basis or at all.

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

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Though we believe we have resolved any stability issues with respect to the commercial formulation of DUEXIS, we cannot assure you that any other stability or other issues relating to the manufacture of any of our products will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to 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.

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

As of December 31, 2010, we employed 41 full-time employees as a consolidated entity. In anticipation of the commercial launch of DUEXIS, we hired 80 sales representatives during the period from September 2011 through October 2011. As of December 31, 2011, and September 30, 2012, we employed 164 and 239 full-time employees, respectively, as a consolidated entity. We also recently announced in October 2012 that we had completed the expansion of our field sales force to approximately 150 sales representatives. We have also experienced, and may continue to experience, turnover on the sales representatives that we hired in connection with the commercial launch of DUEXIS, 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.

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

- build an appropriate commercial organization and manage 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;
- 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 was not fully commercially launched until January 2012, and as we do not expect to begin commercial sales of RAYOS until the fourth quarter of 2012 to a subset of high-value rheumatologists and primary care physicians with the full launch to the majority of U.S. rheumatologists occurring in late January of 2013, the members of our sales force have limited experience promoting DUEXIS and no experience promoting RAYOS as yet. 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 when we launch RAYOS broadly through our sales organization in late January 2013 as all of our representatives will have previously been focused solely on selling DUEXIS up to that point. We have also experienced, and may continue to experience, turnover on the sales representatives that we hired in connection with the commercial launch of DUEXIS and the expected launch of 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. 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 are currently developing or that we may develop.

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

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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 advising that Par Pharmaceutical 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 Pharmaceutical 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 Pharmaceutical and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS. A trial date is currently set for the first 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 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.

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

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

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

- In-license or develop 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 European countries, and Mundipharma is in the process of obtaining pricing and reimbursement approval for, and preparing to market, LODOTRA in other European countries. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

compliance with differing or unexpected regulatory requirements for our products;

compliance with Swiss laws with respect to our Horizon Pharma AG subsidiary, including laws requiring maintenance of cash in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities;

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- difficulties in staffing and managing foreign operations;
- in certain circumstances, including with respect to the commercialization of LODOTRA in Europe, increased dependence on the commercialization efforts 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 are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.**

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

lucrative offers from other companies.

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

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, Warning Letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions, the imposition of civil or criminal penalties, or exclusions.

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

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

*profitably.**

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 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 health care. 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

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third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the U.S. and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

In Europe, the success of our products, including LODOTRA and, if approved, DUEXIS, will depend largely on obtaining and maintaining government coverage, because in many European countries patients are unlikely to use prescription drugs that are not covered by their government health care programs. To date, LODOTRA is approved in 19 countries outside the U.S., and reimbursement for LODOTRA has been obtained in Germany, Italy and Switzerland. Mundipharma is seeking coverage for LODOTRA in a number of countries in Europe and Israel and currently sells LODOTRA without coverage in a limited number of European countries. Negotiating coverage and reimbursement with governmental authorities can delay commercialization by 12 months or more. Coverage and reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and we expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceutical products, which we believe has impacted the reimbursement rates and timing to launch for LODOTRA to date, and we expect these discounts to continue as countries attempt to manage healthcare expenditures, especially in light of current economic conditions. For example, legislation was recently enacted in Germany that will increase the rebate on prescription pharmaceuticals and likely lower the revenues from the sale of LODOTRA in Germany that we would otherwise receive. As a result of these pricing practices, it may become difficult to achieve profitability or expected rates of growth in revenue or results of operations. Any shortfalls in revenue could adversely affect our business, financial condition and results of operations.

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

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

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;

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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 no earlier than January 1, 2013 and reporting to be required at a later date;

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

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

a licensure framework for follow-on biologic products; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In June 2012, the United States Supreme Court heard a constitutional challenge to PPACA and upheld the constitutionality of PPACA, except that the Court held unconstitutional a provision of PPACA authorizing the Secretary of the Department of Health and Human Services to withdraw all of a state s Medicaid funding if the state declines to participate in PPACA s expansion of Medicaid eligibility. PPACA and/or certain of PPACA s provisions may be modified or eliminated by future legislation or litigation. 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 adequate coverage and reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and expected revenue and profitability which would have a material adverse effect on our business, results of operations, financial condition and prospects. We may also experience pressure from payers concerning certain promotional approaches that we may implement such as co-pay programs whereby we assist patients to achieve an acceptable co-pay for our product, which may be contrary to payers financial interests. If we are unsuccessful with our co-pay initiatives, we would be at a competitive disadvantage in terms of pricing versus preferred branded and generic competitors.

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

DUEXIS and RAYOS, and any of our other products or product candidates that are approved by the FDA and commercialized in the U.S. may subject us directly, or indirectly through our customers, to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and 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, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

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

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

Several states now require pharmaceutical companies to report expenses relating to marketing and promotional activities of pharmaceutical products and report gifts to individual physicians in the states. Other states prohibit pharmaceutical companies from providing gifts or meals to healthcare providers or require companies to post information relating to clinical studies. In addition, California requires pharmaceutical companies that engage in marketing to implement a comprehensive compliance program that includes a limit on expenditures for, or payments to, individual prescribers. Currently, several additional states are considering similar proposals. Compliance with these laws, including the development of a comprehensive compliance program, is difficult, costly and time consuming and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of applicable safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

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

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

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

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

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

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.

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

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

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

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

In addition, pursuant to a March 2011 letter agreement and in connection with our waiver of certain milestone payments, Mundipharma 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 RAYOS/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, or PREA, to conduct an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients. Although we are committed to carrying out these commitments, there are challenges in conducting studies in pediatric patients including availability of patients and obtaining parental informed consent.

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

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

To the extent that we are required to conduct additional clinical development of DUEXIS or RAYOS/LODOTRA or we conduct clinical development of earlier stage product candidates or 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 is currently being prepared by the investigator. Pursuant to a March 2011 letter agreement, Mundipharma has agreed to conduct a

separate Phase 3 clinical trial for RAYOS/LODOTRA in this indication. Additionally, we have several earlier stage product candidates to treat pain-related diseases including TRUNOC (tarenflurbil) for the treatment of pain-related diseases and HZN-602, a single pill combination of naproxen and famotidine, for reducing the risk of

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NSAID-induced upper GI ulcers in patients with mild to moderate pain and arthritis who require the use of naproxen. While we are currently not focusing any resources on these potential product candidates, we do not know whether any additional clinical trials will be initiated in the future, begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

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

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

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

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

A key element of our strategy is to develop, 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 that otherwise fit into our development 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.

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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 these lead product candidates, and our business and prospects would therefore be harmed.

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

From time to time, we may seek to engage in strategic transactions with third parties, such as acquisitions of companies or divisions of companies, asset purchases, or in-licensing 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 research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential. There is no assurance that, following the consummation of a strategic transaction, we will achieve the anticipated revenues or net income that justifies such transaction. Any failures or delays in entering into strategic transactions could also delay or negatively impact the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. In addition, any failures or delays in entering into strategic transactions anticipated by analysts or the investment community could result in a decline in our stock price.

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

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

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

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

- decreased demand for our products or product candidates that we may develop;
- injury to our reputation;

withdrawal of clinical trial participants;

initiation of investigations by regulators;

costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

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

loss of revenue;

exhaustion of any available insurance and our capital resources;

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

the inability to commercialize our products or product candidates; and

a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies and commercial product sales in the amount of $10 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of DUEXIS and/or the commercial launch of RAYOS/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 $63.5 million during the nine months ended September 30, 2012 and net losses of $113.3 million, $27.1 million and $20.5 million for the years ended December 31, 2011, 2010 and 2009, respectively. As of September 30, 2012, we had an accumulated deficit of $283.8 million. We do not know whether or when we will

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become profitable. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders deficit and working capital. Our losses have resulted principally from costs incurred in our development activities for our products and product candidates. We anticipate that our operating losses will substantially increase over the next several years as we execute our plan to expand our development and commercialization activities of DUEXIS and RAYOS/LODOTRA.

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

Our ability to become profitable depends upon our ability to generate revenues from sales of our products. DUEXIS was approved by the FDA on April 23, 2011, and we began generating limited revenues from sales of DUEXIS in late 2011 following the commercial launch in the U.S. LODOTRA is approved for marketing in 19 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 expect to begin marketing it in the U.S in the fourth quarter of 2012. 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 its 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 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.

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

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

The loan agreements governing the Senior Secured Loan contain customary affirmative and negative covenants and events of default. Among the affirmative covenants are covenants requiring us to maintain a minimum level of at least $10.0 million in liquidity at all times during the term of the loan unless our quarterly consolidated EBITDA is at least $6.0 million, and to achieve minimum net revenues during specified trailing 12 month periods beginning with the 12 month period ended March 31, 2013. Should we not meet these quarterly minimum revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. There can be no assurance that we will be able to satisfy the operating and financial covenants under the Senior Secured Loan for future periods. We also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if we were unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations. The negative covenants include, among other things, restrictions on transferring or licensing our assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on our assets, in each case subject to customary exceptions. Further, our lenders may require us to make prepayments of loan principal if we receive net cash proceeds from certain transfers or licenses of our assets or as a result of the loss or destruction of our assets, or if we undergo a change in control. Beginning with our second fiscal quarter of 2013 and in any fiscal quarter thereafter, our lenders may require that we prepay up to an aggregate of approximately $4.0 million for each quarter for which we receive a prepayment request. In 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.

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

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

- launch and commercialize DUEXIS and RAYOS in the U.S., including expanding our own sales force in the U.S.;
- complete the regulatory approval process, and any future required clinical development related thereto, for DUEXIS and RAYOS/LODOTRA; and
- continue our research and development programs to advance our product pipeline in the future, including future clinical trials with respect to RAYOS/LODOTRA to generate clinical data in multiple diseases beyond RA.

We believe that our existing cash and cash equivalents, including net proceeds from our recently completed debt and equity financings, together with interest thereon, will be sufficient to fund our operations through 2013. We may need to raise additional funds sooner if we choose to expand our commercialization or development efforts more rapidly than we presently anticipate or our revenues do not meet expectations.

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

- seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Even if we obtain additional financing, our Horizon Pharma AG subsidiary is subject to Swiss laws regarding overindebtedness that require Horizon Pharma AG to maintain assets in excess of its liabilities. As of December 31, 2011, and September 30, 2012, our Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. We will continue to monitor and review steps to address any overindebtedness, until such time as our Swiss subsidiary generates positive income at a statutory level, which could require us to have cash at our Swiss subsidiary in excess of its near term operating needs and could affect our ability to have sufficient cash at our U.S. subsidiary to meet its near term operating needs.

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

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

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

favorable to us.

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

Our management has broad discretion in the application of our cash, and investors will be relying on the judgment of our management regarding the use of our cash. Our management may not apply our cash in ways 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 our other product candidates and for working capital, capital expenditures and general corporate purposes. We may also invest our cash in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause the price of our common stock to decline.

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

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

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

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

At September 30, 2012, we had $121.3 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 September 30, 2012, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities owned by us.

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

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

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent 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 all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in DUEXIS and 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

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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 Pharmaceutical advising that Par Pharmaceutical 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 Pharmaceutical 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 Pharmaceutical and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS. A trial date is currently set for the first 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 or a decision in the infringement case that the patent is not infringed or invalid. We intend to vigorously defend our intellectual property rights relating to DUEXIS, but we cannot predict the outcome of this matter. Any adverse outcome in this matter could result in one or more generic versions of DUEXIS being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of DUEXIS and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to DUEXIS and 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.

The Leahy-Smith America Invents Act, or the Leahy-Smith Act, was recently signed into law and includes a number of significant changes to U.S. patent law. These include changes in the way patent applications will be prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office is currently developing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our patent applications and our ability to enforce or defend our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. and Canada. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

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

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

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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.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of our Common Stock

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

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

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

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

- our failure to successfully execute our commercialization strategy with respect to our approved products, particularly our commercial launch of DUEXIS in the U.S.;
- any adverse development or perceived adverse development with respect to the Medicines and Healthcare products Regulatory Agency s review of our MAA for DUEXIS filed in the European Union through the Decentralized Procedure, and amended in February 2012 through the National Procedure in the UK;
- disputes or other developments relating to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products and product candidates;

unanticipated serious safety concerns related to the use of DUEXIS, 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;

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our failure to successfully develop additional product candidates;

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

our inability to effectively manage our growth;

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

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

actual or anticipated variations in quarterly operating results;

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

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

our inability to successfully enter new markets;

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

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

our inability to maintain an adequate rate of growth;

ineffectiveness of our internal controls;

additions or departures of key scientific or management personnel;

issuances of debt or equity securities;

significant lawsuits, including patent or stockholder litigation;

changes in the market valuations of similar companies;

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

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 32% of our outstanding voting stock as of December 31, 2011, and 23% as of September 30, 2012. 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

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

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

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

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

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

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

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

We expect that 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.

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

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

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

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

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

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

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

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

We completed the following issuances of unregistered securities during the three months ended September 30, 2012:

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

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

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

The offers, sales and issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D in that each issuance of securities was to an accredited investor and did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D.

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: November 13, 2012

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

(Principal Executive Officer)

Date: November 13, 2012

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.
10.1*	First Amendment to Lease, dated July 31, 2012, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.
10.2 (5)	Sales Agreement, dated August 14, 2012, between Horizon Pharma, Inc. and Cowen and Company, LLC.
10.3 (6)	Consent and Amendment, dated September 7, 2012, by and among Horizon Pharma USA, Inc. and Horizon Pharma, Inc., Cortland Capital Market Services, LLC, as administrative agent, and the Lenders listed therein.
10.4 (6)**	Second Letter Agreement, dated October 6, 2011, by and among Horizon Pharma AG, Mundipharma International Corporation Limited and Mundipharma Medical Company.
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.

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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
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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