HORIZON PHARMA, INC.
Form 10-Q
November 14, 2011
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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, 2011

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)

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 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.

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

As of November 10, 2011, the registrant had outstanding 19,528,624 shares of its common stock.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Horizon Pharma, Inc.

(formerly Horizon Therapeutics, Inc.)

Condensed Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	September 30, 2011	December 31, 2010
	(Unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 32,997	$ 5,384
Restricted cash	450	200
Accounts receivable	260	575
Inventory	1,130	306
Prepaid expenses and other current assets	1,613	903
Total current assets	36,450	7,368
Property and equipment, net	2,334	2,107
Developed technology	38,295	39,990
In-process research and development	111,577	108,746
Other assets	547	3,474
Total assets	$ 189,203	$ 161,685
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	$ 3,723	$ 2,514
Accrued expenses	6,434	6,733
Deferred revenues current portion	1,961	1,845
Notes payable current portion	2,386	4,220
Bridge notes payable to related parties		10,000
Total current liabilities	14,504	25,312
Long-term liabilities		
Notes payable, net of current	17,467	10,395
Deferred revenues, net of current	6,005	4,123
Deferred tax liabilities	24,895	24,798
Other long term liabilities	1	1
Total liabilities	62,872	64,629
Commitments and Contingencies (Note 8)		
Stockholders equity		
Preferred stock, $0.0001 par value per share; 10,000,000 and 0 shares authorized at September 30, 2011 (unaudited) and December 31, 2010, respectively; 0 shares issued and outstanding at September 30, 2011 (unaudited) and December 31, 2010		

Convertible preferred stock, $0.0001 par value per share; 0 and 27,400,000 shares authorized at September 30, 2011 (unaudited) and December 31, 2010, respectively; 0 and 24,961,340 shares issued and outstanding at September 30, 2011 (unaudited) and December 31, 2010, respectively (Liquidation preference: $0 and $177,002 at September 30, 2011 and December 31, 2010, respectively)		2
Common stock, $0.0001 par value per share; 200,000,000 and 35,400,000 shares authorized at September 30, 2011 (unaudited) and December 31, 2010, respectively; 19,528,624 and 1,490,551 shares issued and outstanding at September 30, 2011 (unaudited) and December 31, 2010, respectively	2	
Additional paid-in capital	268,955	206,336
Accumulated other comprehensive income (loss)	964	(2,230)
Accumulated deficit	(143,590)	(107,052)
Total stockholders equity	126,331	97,056
Total liabilities and stockholders equity	$ 189,203	$ 161,685

See the accompanying notes to the unaudited consolidated financial statements

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Horizon Pharma, Inc.

(formerly Horizon Therapeutics, Inc.)

Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(Unaudited)		(Unaudited)	
Revenues				
Sales of goods	$ 233	$ 689	$ 3,290	$ 2,346
Contract revenue	40		111	
Total revenues	273	689	3,401	2,346
Cost of goods sold	1,249	737	5,191	2,870
Gross loss	(976)	(48)	(1,790)	(524)
Operating Expenses				
Research and development	5,346	5,721	11,536	12,861
Sales and marketing	5,141	1,955	7,426	3,608
General and administrative	4,192	3,880	10,640	14,189
Total operating expenses	14,679	11,556	29,602	30,658
Loss from operations	(15,655)	(11,604)	(31,392)	(31,182)
Interest expense, net	(995)	(1,031)	(5,465)	(1,827)
Bargain purchase gain				19,326
Foreign exchange (loss) gain, net	(758)	164	(226)	202
Loss before income tax benefit (expense)	(17,408)	(12,471)	(37,083)	(13,481)
Income tax benefit (expense)	177	(16)	545	(29)
Net loss	$ (17,231)	$ (12,487)	$ (36,538)	$ (13,510)
Net loss per share-basic and diluted	$ (1.30)	$ (8.38)	$ (6.69)	$ (11.18)
Weighted average shares outstanding used in calculating net loss per share-basic and diluted	13,256,189	1,490,551	5,458,561	1,207,887

See the accompanying notes to the unaudited consolidated financial statements

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Horizon Pharma, Inc.

(formerly Horizon Therapeutics, Inc.)

Condensed Consolidated Statements of Cash Flows

(in thousands)

	Nine Months Ended September 30,	
	2011	2010
	(Unaudited)	
Cash flows from operating activities		
Net loss	(36,538)	$ (13,510)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	3,071	1,899
Stock-based compensation	1,827	2,034
Amortization of interest payment on notes payable	79	122
Amortization of debt discount	430	578
Loss from debt extinguishment	1,990	
Bargain purchase gain		(19,326)
Foreign exchange loss (gain), net	226	(202)
Changes in operating assets and liabilities, net of amounts acquired		
Accounts receivable	342	(1,608)
Inventory	(838)	959
Prepaid expenses and current assets	(706)	(754)
Accounts payable	1,180	824
Accrued expenses	656	(2,483)
Deferred revenues	1,909	2,065
Deferred tax liabilities	(567)	
Net cash used in operating activities	(26,939)	(29,402)
Cash flows from investing activities		
Purchase of property and equipment	(449)	(566)
Write-off of fixed assets		37
Restricted cash	(250)	(200)
Acquistion of Nitec Pharma AG, cash acquired		6,489
Net cash (used in) provided by investing activities	(699)	5,760
Cash flows from financing activities		
Net proceeds from issuance of notes payable	16,651	11,810
Proceeds from issuance of common stock in initial public offering, net of underwriting fees and issuance costs	46,035	
Deferred offering costs	(1,637)	(1,861)
Repayment of notes payable	(12,747)	(9,927)
Proceeds from issuance of bridge notes payable to related parties	6,766	10,000
Proceeds from issuance of convertible preferred stock, net of issuance costs		20,683
Proceeds from option exercises	45	
Net cash provided by financing activities	55,113	30,705
Effect of exchange rate changes on cash and cash equivalents	138	(27)
Net increase in cash and cash equivalents	27,613	7,036

Cash and cash equivalents		
Beginning of period	5,384	7,160
End of period	$ 32,997	$ 14,196
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 2,032	$ 1,264
Commitment fee paid on notes payable		120
Supplemental non-cash information		
Warrants issued in connection with notes payable	$ 1,124	$ 2,137
Convertible preferred stock and common stock issued to Nitec shareholders in connection with the Nitec acquisition		104,134
Conversion of bridge notes payable and accrued interest to common stock	18,156	
Unpaid deferred offering costs	400	550

See the accompanying notes to the unaudited consolidated financial statements

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HORIZON PHARMA, INC.

(FORMERLY HORIZON THERAPEUTICS, INC.)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except share and per share amounts)

1. The Company

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

The Company is a 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® (formerly HZT-501), a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis (RA) and osteoarthritis (OA) and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. On November 14, 2011, the Company and Sanofi-aventis U.S. LLC (Sanofi) announced the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. Sanofi will serve as the primary commercial manufacturer for DUEXIS in the U.S. The Company has hired its commercial organization, completed sales force training and expects to commercially launch DUEXIS in the U.S. in November 2011. The Company submitted a Marketing Authorization Application (MAA) for DUEXIS in the United Kingdom, the Reference Member State, through the Decentralized Procedure in October 2010 and the Company anticipates a decision on the MAA in the first half of 2012. The Company s other product, LODOTRA, is a proprietary programmed release formulation of low-dose prednisone that is currently marketed in Europe by its distribution partner, Mundipharma International Corporation Limited (Mundipharma), for the treatment of moderate to severe, active RA in adults when accompanied by morning stiffness. The Company has successfully completed two Phase 3 clinical trials of LODOTRA and submitted a new drug application (NDA) for LODOTRA to the FDA on September 26, 2011. The Company has worldwide marketing rights for DUEXIS and has retained exclusive marketing rights in the U.S. for all of its products. The Company s strategy is to commercialize its products in the U.S., to explore co-promotion opportunities for DUEXIS 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 (IPO) of 5,500,000 shares of common stock at an offering price of $9.00 per share. The Company received net proceeds of approximately $41,885, after deducting underwriting discounts of $3,465 and offering costs of $4,150.

The Company has incurred net operating losses and negative cash flows from operations during every year since inception. These factors raise substantial doubt about the Company s ability to continue as a going concern. In order to continue its operations, the Company must achieve profitable operations and/or obtain additional debt or equity financing. There can be no assurance, however, that such financing will be available on terms acceptable to the Company or at all.

Management believes that the Company s existing cash and cash equivalents, which include proceeds from the IPO, are sufficient to fund its operations into the second quarter of 2012.

Reverse Stock Split

On July 7, 2011, the Company effected a 1-for-2.374 reverse stock split of its common stock and a proportional adjustment to the existing conversion ratios for each series of preferred stock. Accordingly, all share and per share amounts for all periods presented in these condensed consolidated financial statements and notes thereto, have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

2. Restatement to Prior Period Financial Statements

As described in Note 4, the initial tax rate used to determine the amount of the deferred tax liability as of April 1, 2010 (the date of the Nitec acquisition) was the statutory tax rate in Switzerland of 27.5%. Upon gaining a better understanding of the Swiss tax laws, it was later determined that the Company would receive a deduction on each of its Swiss Federal and Cantonal tax returns for taxes paid to the other jurisdiction, which would lead to a lower overall effective tax rate than the rate initially used. Accordingly, the deferred tax liability and the bargain purchase gain were adjusted to reflect the lower effective tax rate. The misstated bargain purchase gain and deferred tax liability based on the initial tax rate of 27.5% was reported in the Company s consolidated financial statements for the nine months ended September 30, 2010, which appeared in Amendment No. 4 to the Company s Registration Statement on Form S-1, filed with the Securities and Exchange Commission (SEC) on November 5, 2010. The error was identified and corrected by the Company by restating the nine month period ended September 30, 2010, as provided below.

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In accordance with the SEC s Staff Accounting Bulletin No. 99 (SAB 99), the Company assessed the materiality of this error in the nine month period ended September 30, 2010 and concluded that the error was material to that period. The correction has been reflected in these consolidated financial statements for the nine months ended September 30, 2010 which resulted in a decrease of $4,735 in deferred tax liabilities and a corresponding increase in bargain purchase gain. Further, the correction resulted in a decrease of $1.65 in net loss per share for both basic and diluted (based on post-reverse stock split shares).

The table below shows a reconciliation of the as reported to the as restated net loss for the nine months ended September 30, 2010.

	For the Nine Months Ended September 30, 2010		
	As Reported	As Restated	Difference
Cost of goods sold (a)	(3,447)	(2,870)	577
General and administrative expense (b)	(13,756)	(14,189)	(433)
Bargain purchase gain (c)	$ 14,735	$ 19,326	$ 4,591
Net loss	(18,245)	(13,510)	4,735
Loss per common share-basic and diluted (post-split)	$ (6.36)	$ (4.71)	$ 1.65
Loss per common share-basic and diluted (pre-split)	$ (15.10)	$ (11.18)	$ 3.92

(a) In connection with the Company s fourth quarter 2010 review of acquired technology, it was determined that the useful life of the developed technology was 12 years based on an analysis of intellectual property exclusivity in the pharmaceutical industry. As such, the Company adjusted the amortization expense according to a 12-year useful life.

(b) Adjustment is to correctly record the fair value of Nitec s stock options as an expense subsequent to the closing of the Nitec acquisition instead of being recorded as a purchase price adjustment.

(c) Adjustment reflects the change in the Swiss statutory effective tax rate from 27.50% to 20.07%.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America (GAAP) and with the instructions for Form 10-Q and Regulation S-X. Accordingly, they do not include all of the information and notes required for complete financial statements. These interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company s Prospectus filed with the SEC on July 28, 2011.

Principles of Consolidation

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

Segment Information

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

Use of Estimates

The preparation of the accompanying 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).

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Gains and losses resulting from foreign currency transactions are reflected in net income (loss) and have not been significant for the reporting period. To date, the Company has not undertaken hedging transactions to cover its foreign currency exposure.

Revenue Recognition

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

As of April 1, 2010, as a result of the acquisition of Nitec, 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 and other countries. The Company will also recognize revenues related to up-front license fees, milestone receipts and product deliveries. During the three and nine months ended September 30, 2011 and 2010, substantially all revenues recognized were related to the sale of LODOTRA to the Company s distribution partners under existing arrangements (Note 15).

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 assured. Where continuing involvement by the Company is required in the form of technology transfer, product manufacturing or technical support, revenues are deferred and recognized over the term of the agreement.

Revenue from milestone receipts

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

Revenue from product deliveries

Upon initial launch of a product, the Company recognizes revenues 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. Upon establishing the ability to reasonably estimate such allowances, the Company recognizes revenue from the delivery of its products to its distribution partners when delivery has occurred, title has transferred to the partner, the selling price is fixed or determinable, collectability is reasonably assured and the Company has no further performance obligations. The Company records product sales net of allowances for product returns, rebates and discounts. 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.

Historically, 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 a manufacturing and supply agreement with Mundipharma Medical Company (Mundipharma Medical), Mundipharma Medical agreed to purchase LODOTRA exclusively from the Company at the price which is a specified percentage of the average net selling price for sales in a given country, subject to a minimum price. Beginning in 2011, products sold to Mundipharma Medical were recognized upon delivery at the minimum price. 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.

Cost of Goods Sold

On April 1, 2010, as a result of the acquisition of Nitec, the Company began to recognize cost of goods sold in connection with its sale of LODOTRA. Cost of sales includes all costs directly related to the manufacture and delivery of product and out-licensing of distribution and marketing rights to third parties. Cost of goods sold also includes amortization of developed technology related to the

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acquisition of Nitec. For the nine months ended September 30, 2011 and 2010, cost of goods sold included amortization of developed technology of $2,848 and $949, respectively, and the expected future amortization related to the developed technology annually is $3,191, based on Euro to U.S. dollar exchange rates as of September 30, 2011.

The cost in connection with product delivery to the Company s distribution partners consists of 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.

Inventories

Inventory is stated at the lower of cost (first-in, first-out) or market and includes raw materials, work-in-process and finished goods. Inventories include the direct purchase cost for materials and/or services processed in the current production stage (finished and work-in-process).

All raw materials and production supplies for the Company s products are purchased from third parties. Contract manufacturing and other supply chain services are rendered by third parties under corresponding agreements. These costs are capitalized in a manner similar to the purchase of materials.

If current market prices and/or limited usability of products indicate any impairment, the value of the inventory is written down to net realizable value.

Inventories exclude sample inventory, which is included in other current assets and is expensed as a component of sales and marketing expense. As of September 30, 2011 and December 31, 2010, the Company had no sample inventory in other current assets.

Preclinical Study 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

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. Based on the borrowing rates available to the Company for loans with similar terms and consideration of non-performance and credit risk, the carrying value of its notes payable approximates their fair value. The carrying amounts of the convertible preferred stock warrant liabilities represent their fair value.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents.

Restricted Cash

Restricted cash consists of an interest-bearing money market account, which is used as security for the corporate employee credit card program.

Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the related assets. Upon retirement or sale of assets, 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 terms of the 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	5 years
Computer equipment	3 years
Software	5 years
Trade show equipment	3 years

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

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 and manufacturing organizations to conduct clinical trials and expenses incurred to manufacture clinical trial materials. Costs related to research, design and development of products are charged to research and development expense as incurred.

Sales and Marketing Expenses

Sales and marketing expenses consist principally of trade show expenses, pre-launch marketing activities, distributed sample inventories and payroll and other personnel-related expenses.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that 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.

Subsequent to its acquisition of Nitec, and prior to the anticipated launch of DUEXIS in the U.S. in the fourth quarter of 2011, the Company s sales contracts are and will be principally denominated in Euros and therefore, its revenues are subject to significant foreign currency risk. The Company also incurs certain operating expenses in currencies other than the U.S. dollar through its Horizon Pharma AG operating subsidiary; therefore, it is subject to volatility in cash flows due to fluctuations in foreign currency exchange rates, particularly changes in the Euro. To date, the Company has not entered into any hedging contracts since exchange rate fluctuations have had minimal impact on its results of operations and cash flows.

The products developed by the Company require approvals from the FDA or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Company s products will obtain the necessary regulatory approvals. If the Company s products were denied such approvals or such approvals were delayed, it could have a material adverse effect on the Company s operations.

As a result of the Nitec acquisition, the Company has one product, LODOTRA, available for sale in Europe through distribution partners. As of September 30, 2011, the Company had no other products available for sale. On September 26, 2011, the Company submitted an NDA for LODOTRA to the FDA. The Company s other lead product, DUEXIS, was approved for marketing by the FDA on April 23, 2011 and the Company expects to commercially launch DUEXIS in the U.S. in November 2011. The Company also submitted an MAA for DUEXIS in the United Kingdom, the Reference Member State, through the Decentralized Procedure in October 2010 and the Company anticipates a decision on the MAA in the first half of 2012.

To achieve profitable operations, the Company must successfully develop, obtain regulatory approval for, manufacture and market its products. There can be no assurance that any such 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 such products will be successfully marketed 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. The Company also relies on third parties to manufacture its commercial supplies of LODOTRA for sale in Europe. 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 s accounts receivable are currently derived from customers located in Europe. The Company performs ongoing credit evaluations of its customers, does not require collateral and maintains allowances for potential credit losses on customer accounts when deemed necessary. To date, there have been no such losses and the Company has not recorded an allowance for doubtful accounts.

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The following table summarizes the revenues from customers that accounted for more than 10% of the Company s revenues for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Mundipharma	100%	0%	52%	0%
Merck Serono GmbH	0%	100%	48%	100%

At September 30, 2011, Mundipharma accounted for 100% of total accounts receivable. At December 31, 2010, Mundipharma accounted for 93% of total accounts receivable. No other customer represented more than 10% of the Company s total accounts receivable as of these dates.

The Company must maintain compliance with Swiss laws with respect to its Horizon Pharma AG subsidiary, 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 the Swiss subsidiary is overindebted. The Company took steps to address overindebtedness through a subordinated loan to its Swiss subsidiary in June 2010. The Swiss subsidiary was also overindebted as of December 31, 2010 and September 30, 2011 and the Company is in the process of reviewing further steps to address the overindebtedness. The Company may need to continue taking steps to address overindebtedness until such time as its Swiss subsidiary generates positive income at a statutory level, which could cause the Company to have cash at its Swiss subsidiary in excess of its near term operating needs, including a portion of the net proceeds from the Company s IPO, and could affect its 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 is primarily foreign currency translation adjustments. As of September 30, 2011 and December 31, 2010, other comprehensive income (loss) was $3,194 and $(2,230), respectively.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss attributed to common stockholders by the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares of common stock used to calculate the basic net loss per share of common stock excludes those shares subject to repurchase. The Company s potential dilutive shares, which include shares issuable upon the exercise of outstanding common stock options and warrants to purchase convertible preferred stock and shares issuable upon conversion of outstanding convertible preferred stock and subordinated convertible promissory notes, 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. The Company s net loss per share has been retroactively adjusted for all periods presented to give effect to the recapitalization in connection with the acquisition of Nitec on April 1, 2010, where all shares of capital stock of Horizon Therapeutics, Inc. were converted into shares of Horizon Pharma, Inc., the newly formed holding company. Specifically, retroactive adjustment was given to the conversion of each share of common stock into 0.496 shares of common stock and 0.504 shares of Series A convertible preferred stock, as well as the conversion of each share of special preferred stock (Special Preferred) into one share of common stock, each of which occurred on April 1, 2010.

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 as described above. The number of shares outstanding in computing net loss per share was determined by calculating the weighted average shares outstanding in accordance with ASC 260 after applying the exchange ratio from the recapitalization to the common stock and Special Preferred outstanding for all accounting periods presented. The Company believes that by giving effect to the recapitalization of the common stock, the historical loss per share reflects the portion of the pre-recapitalization common stock that effectively was common stock and permits a consistent presentation of loss per share on a period by period basis.

On July 7, 2011, the Company effected a 1-for-2.374 reverse stock split of its common stock and a proportional adjustment to the existing conversion ratios for each series of preferred stock. Accordingly, all share and per share amounts for all periods presented in these condensed consolidated financial statements and notes thereto, have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

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The following table presents the numerator and denominator used in the computation of basic and diluted net loss per share (dollars in thousands, except shares):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Historical net loss per share				
Numerator				
Net loss attributed to common stockholders	$ (17,231)	$ (12,488)	$ (36,538)	$ (13,510)
Denominator				
Denominator for basic and diluted net loss per share weighted-average common shares	13,256,189	1,490,551	5,458,561	1,207,887

The weighted-average common shares used to compute basic and diluted net loss per share for the three and nine -month periods ended September 30, 2011 and 2010 were derived as follows:

			September 30, 2011			
			Three Months Ended		Nine Months Ended	
Weighted Average Common Shares Basic and Diluted	**Outstanding**	**Conversion Factor (A)**	**Number of Days Outstanding**	**Weighted Average Shares Outstanding**	**Number of Days Outstanding**	**Weighted Average Shares Outstanding**
Common shares outstanding	1,490,551	1.00000	92	1,490,551	273	1,490,551
Issuance of common stock in conjunction with exercise of stock options	4,212	1.00000	92	4,212	253	3,903
Issuance of common stock in conjunction with exercise of stock options	1,515	1.00000	92	1,515	191	1,060
Issuance of common stock in initial public offering	5,500,000	1.00000	60	3,586,957	60	1,208,791
Conversion of convertible preferred stock to common stock	10,514,431	1.00000	60	6,857,238	60	2,310,864
Issuance of common stock in conjunction with the conversion of bridge notes	2,017,242	1.00000	60	1,315,593	60	443,350
Issuance of common stock in conjunction with exercise of stock options	673	1.00000	17	124	17	42
Denominator for basic and diluted net loss per share, September 30, 2011				13,256,189		5,458,561

			September 30, 2010			
			Three Months Ended		Nine Months Ended	
Weighted Average Common Shares Basic and Diluted	**Outstanding**	**Conversion Factor (A)**	**Number of Days Outstanding**	**Weighted Average Shares Outstanding**	**Number of Days Outstanding**	**Weighted Average Shares Outstanding**
Common shares outstanding	842,458	0.49608	92	417,931	273	417,931
Conversion of special convertible preferred to common stock in April 2010 effected as of December 31, 2009	215,213	1.00000	92	215,213	273	215,213
Issuance of common stock in April 2010 in connection with acquisition of Nitec under the share exchange agreement	857,400	1.00000	92	857,400	183	574,740

Issuance of common stock in conjunction with exercise of stock options	7	1.00000	92	7	92	3
Denominator for basic net loss per share, September 30, 2010				1,490,551		1,207,887

(A) Represents the number of shares of common stock of Horizon Pharma, Inc. issued in exchange for each share of common stock of Horizon Therapeutics, Inc. in connection with the recapitalization of Horizon Therapeutics, Inc.

The following securities were excluded from the computation of diluted net loss per share for the three and nine months ended September 30, 2011 and 2010 because including them would have had an anti-dilutive effect:

	Three and Nine Months Ended September 30, 2011	Three and Nine Months Ended September 30, 2010
Options to purchase common stock	1,679,761	1,328,055
Warrants to purchase common stock (A)	459,003	
Warrants to purchase convertible preferred stock (on an as if converted basis) (A)		346,047
Convertible preferred stock (on an as if converted basis) (B)		10,514,431

(A) Upon the closing of the Company s IPO, on August 2, 2011, the convertible preferred stock warrants were converted into warrants to purchase shares of common stock.

(B) Upon the closing of the Company s IPO, on August 2, 2011, the shares of preferred stock were converted into shares of common stock.

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Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board (FASB) and International Accounting Standards Board (IASB), issued Accounting Standards Update (ASU) No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. ASU 2011-04 created a uniform framework for applying fair value measurement principles and clarified existing guidance in GAAP. ASU 2011-04 will be effective for the first reporting annual period beginning after December 15, 2011 and must be applied prospectively. The Company will adopt ASU 2011-04 in the first quarter of fiscal year 2012. The Company does not believe that the adoption of ASU 2011-04 will have a material impact on its condensed consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05*, Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income,* which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of OCI as part of the statement of stockholders equity. Instead, the Company must report comprehensive income in either a single continuous statement of comprehensive income, which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 will be effective during the interim and annual periods beginning after December 15, 2011 with early adoption permitted. The Company will adopt ASU 2011-05 in the first quarter of fiscal year 2012. The Company does not believe that the adoption of ASU 2011-05 will have a material impact on its condensed consolidated financial statements.

4. Acquisition

On April 1, 2010, pursuant to a share exchange agreement, the Company completed the acquisition of Nitec Pharma AG, a privately held biopharmaceutical company that currently markets LODOTRA in Europe through certain distribution partners. In connection with the acquisition, Horizon Therapeutics, Inc. was recapitalized and became a wholly-owned subsidiary of Horizon Pharma, Inc. Pursuant to the recapitalization and under the terms of the share exchange agreement (together, the Transactions), all existing shares of common and convertible preferred stock of Nitec and Horizon Therapeutics, Inc. were exchanged for shares of the Company s common stock and Series A convertible preferred stock. Immediately following the completion of the Transactions, the former stockholders and optionholders of Horizon Therapeutics, Inc. and Nitec owned 51% and 49%, respectively, of Horizon Pharma, Inc. on a fully diluted basis. Also, in connection with the Transactions, Horizon Therapeutics, Inc. changed its name to Horizon Pharma USA, Inc. and Nitec changed its name to Horizon Pharma AG. The Company incurred a total of $3,071 of transaction costs in connection with the Nitec acquisition. In connection with and following the Transactions, Horizon Pharma, Inc. also completed a Series B convertible preferred stock financing raising $19,844, net of offering costs.

As consideration in the acquisition, the Company paid a total purchase price of approximately $119,317 ($112,828, net of cash received of $6,489) consisting of the following: 857,400 shares of common stock valued at $11,050, 11,211,413 shares of Series A convertible preferred stock valued at $88,904, a discount of $2,044 on the sale of 1,229,920 shares of Series B convertible preferred stock sold to former stockholders of Nitec, warrants to purchase 118,496 shares of Series A convertible preferred stock valued at $894, options to purchase up to 328,087 shares of common stock valued at $2,137, and $14,288 in assumed liabilities and long-term debt. The financial position and operating results of Horizon Pharma AG have been included in the Company s financial position and operating results from the date of the acquisition.

The fair value of the common stock and Series A and B convertible preferred stock was determined with the assistance of consultants using an income approach.

Under the acquisition method of accounting, the total purchase price is required to be allocated to the underlying tangible and intangible assets acquired and liabilities assumed based upon their respective estimated fair market values as of the acquisition date. The Company performed appraisals necessary to derive preliminary fair values of the tangible and intangible assets acquired and liabilities assumed, the amounts of assets and liabilities arising from contingencies, the amount of goodwill or bargain purchase gain to be recognized as of the acquisition date and the related preliminary allocation of the purchase price. The table below shows how the Company originally allocated the total purchase price of approximately $119,317, net of cash acquired of $6,489, over the fair value of the assets acquired and liabilities assumed, the revisions the Company made as a result of subsequent information indicating a correction to a lower expected tax rate in Switzerland, and the final allocation of the purchase price:

Category	Preliminary Allocation	Revisions	Allocation As Revised
Net Tangible Assets (including cash acquired)	$ 9,657	$	$ 9,657
Developed Technology	43,500		43,500
In-Process Research and Development (IPR&D)	110,900		110,900

Property, Plant and Equipment	598		598
Deferred Tax Liabilities	(30,603)	4,591	(26,012)
Bargain Purchase Gain	(14,735)	(4,591)	(19,326)
Total Purchase Price	$ 119,317	$	$ 119,317

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The initial tax rate used to determine the amount of the deferred tax liability as of April 1, 2010 (the date of the Nitec acquisition) was the statutory tax rate in Switzerland of 27.5%. This is comprised of the Swiss Federal and Cantonal tax rates. Upon gaining a better understanding of the Swiss tax laws, it was later determined that the Company would receive a deduction on each of its Swiss Federal and Cantonal tax returns for taxes paid to the other jurisdiction, which would lead to a lower overall effective tax rate from what was initially used. Accordingly, the deferred tax liability was adjusted to reflect the appropriate effective tax rate.

The valuation of the developed technology acquired was based on management s estimates, information available at the time of the acquisition and reasonable and supportable assumptions. The allocation was generally based on the Company s estimated fair value of the rights to payments with respect to the Company s marketed product LODOTRA in Europe which were acquired in the acquisition of Nitec, determined using an income approach under the discounted cash flow method. Significant assumptions used in valuing the developed technology included revenue projections through 2026 based on existing partnerships in Europe and assumptions relating to pricing and reimbursement rates and market size and market penetration rates, cost of goods sold based on current manufacturing experience, allocated general and administrative expense without any sales and marketing expense as the product was fully out licensed in Europe, research and development expenses for clinical and regulatory support for obtaining reimbursement approval in Europe through 2010, a 39.3% blended tax rate, a 100% probability of cash flows as the product was already marketed in Europe, and a discount rate of 16%. The discount rate was selected based on a rate of return that reflects the relative risk of the investment as well as the time value of money. Of the total purchase price, $43,500 was allocated to developed technology, which was being amortized to cost of goods sold using a straight-line method over an initial estimated useful life of nine years. In connection with the Company s fourth quarter 2010 review of acquired intangible assets, the Company determined the useful life of the developed technology was twelve years after updating its expectations for market exclusivity based on data regarding intellectual property exclusivity in the pharmaceutical industry. As of December 31, 2010, developed technology had decreased $3,510 to $39,990 due to $2,634 of amortization expense, which was recorded in cost of goods sold, and $876 due to foreign exchange rate effects of the Euro to U.S. dollar translation. For the nine months ended September 30, 2011, developed technology decreased by a net amount of $1,695 to $38,295 due to amortization expense of $2,849 during the nine months ended September 30, 2011, partially offset by an increase of $1,154 related to foreign exchange rate effects of the Euro to U.S. dollar translation,

The Company also recorded $110,900 for IPR&D related to the U.S. rights to LODOTRA, which were acquired as a result of the Company s acquisition of Nitec. The value of acquired IPR&D was determined using an income approach. Significant assumptions used in valuing the IPR&D included revenue projections from 2012 through 2026 based on management s experience with products in the same category and the overall market size, cost of goods sold based on then-current manufacturing experience with the product in Europe, allocated general and administrative expense and sales and marketing expense based on the Company s intention to market the product directly in the U.S., estimated research and development expenses to complete submissions and approvals and for ongoing clinical and regulatory maintenance costs, a 39.3% blended tax rate, management s estimated probability of cash flows based on similar products that have completed Phase 3 trials, and a discount rate of 17%.

The IPR&D assets were initially recognized at fair value and will be classified as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts. The IPR&D will not be amortized, as the development efforts related to LODOTRA in the U.S. are ongoing. As of December 31, 2010, IPR&D had decreased $2,154 to $108,746 due to the foreign exchange rate effects of the Euro to U.S. dollar translation. As of September 30, 2011, IPR&D had increased by $2,831 to $111,577 due to the foreign exchange rate effects of the Euro to U.S. dollar translation.

After a preliminary assessment on April 1, 2010 (acquisition date) of (1) whether all of the assets acquired and liabilities assumed had been identified and recognized and (2) the consideration transferred in the Nitec acquisition, the Company initially recognized a bargain purchase gain, representing the amount by which the fair value of the identifiable net assets exceeded the purchase price, of approximately $14,735.

In accordance with its established accounting policies regarding review of intangible assets, in the fourth quarter of 2010 the Company performed its initial annual impairment test for IPR&D acquired in the Nitec acquisition and considered whether a triggering event had occurred which would necessitate performing an impairment test relating to its long-lived assets, primarily developed technology. As a result, the Company determined there was no impairment in the carrying amounts of the assets acquired. The Company s review of the intangible assets in the fourth quarter of 2010 also indicated that the useful lives of the assets were longer than originally believed, based on information the Company received subsequent to the acquisition date regarding average market exclusivity periods for similarly situated assets. This information summarized actual litigation outcome data from 2003-2009

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in cases involving generic challenges to branded drugs. The information showed that makers of branded drugs won a larger percentage of cases than generic drug challenges, which supported a longer period of exclusivity for branded drugs and for branded drugs with issued patents, than what we originally assumed in our projections leading us to increase the useful lives of our acquired assets. As a result, the Company incorporated the longer utilization period of those assets into the cash flow analysis used in its impairment test. Also in the fourth quarter of 2010, the Company revised the value of its deferred tax liabilities to reflect the appropriate effective tax rate in Switzerland, which resulted in the reduction in the original amount of deferred tax liabilities recorded in connection with the acquired intangible assets. This correction to its expected effective tax rate in Switzerland resulted in a net decrease in the initial amount of deferred tax liabilities of $4,591 to a revised amount of $26,012, and a net increase of $4,591 to the bargain purchase gain the Company had originally recorded, to $19,326.

Unaudited pro forma results

Unaudited pro forma financial information is presented below as if the acquisition of Nitec occurred at the beginning of fiscal year 2010. The pro forma information presented below does not purport to present what the actual results would have been achieved had the acquisition in fact occurred at the beginning of fiscal 2010, nor does the information project results for any future period. Further, the pro forma results exclude any benefits that may result from the acquisition due to synergies that were derived from the elimination of any duplicative costs. In addition, the consolidated results of Nitec were adjusted to reflect reclassifications and certain adjustments to conform with the Company s presentation under GAAP (in thousands, except per share data).

	Pro Forma Results Nine Months Ended September 30, 2010 As restated
Pro forma revenues	$ 2,799
Pro forma loss from operations	(40,890)
Pro forma net loss	(24,798)
Pro forma net loss per share basic and diluted	$ (20.53)

5. Fair Value Measurements

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

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

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

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

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

The following table sets forth the Company s financial assets and liabilities at fair value on a recurring basis as of September 30, 2011 and December 31, 2010 (in thousands):

	$31,016	$31,016	$31,016	$31,016
	September 30, 2011			
	Level 1	Level 2	Level 3	Total
Assets				

Money market funds	$ 31,016	$	$	$ 31,016
	$31,016	$31,016	$31,016	$31,016

	December 31, 2010			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 1,425	$	$	$ 1,425

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6. Balance Sheet Components

Inventory

Inventory consisted of the following (in thousands):

	September 30, 2011	December 31, 2010
Raw materials	$ 130	$ 134
Work in process	748	172
Finished goods	252	
	$ 1,130	$ 306

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2011	December 31, 2010
Deferred cost of goods sold	$	$ 626
Prepaid product study	816	
Other receivables	198	
Prepaid insurance	178	77
Prepaid FDA product and manufacturing fees	164	
Other prepaid expenses	164	122
Other current assets	93	78
	$ 1,613	$ 903

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	September 30, 2011	December 31, 2010
Machinery and equipment	$ 1,697	$ 1,661
Furniture and fixtures	87	86
Computer equipment	626	255
Software	287	179
Trade show equipment	228	228
Leasehold improvements	28	13
	2,953	2,422
Less: Accumulated depreciation	(619)	(315)
	$ 2,334	$ 2,107

Depreciation expense for the three months ended September 30, 2011 and 2010 was $98 and $55, respectively. Depreciation expense for the nine months ended September 30, 2011 and 2010 was $308 and $80, respectively.

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Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2011	December 31, 2010
Payroll related expenses	$ 2,395	$ 1,803
Clinical and regulatory expenses	448	921
Contract manufacturing services	264	874
Professional services	774	1,290
Consulting services	203	151
Promotional materials	925	
Sales and marketing expenses	291	445
Accrued rebates and royalties	645	441
Interest expense	163	525
Taxes and licenses	91	122
Other	235	161
	$ 6,434	$ 6,733

7. Intangible Assets

The Company s developed technology, an identifiable intangible asset, was acquired in connection with the acquisition of Nitec (see Note 4). Of the total purchase price, $43,500 has been allocated to developed technology, which is being amortized to cost of goods sold using a straight-line method over an estimated useful life of twelve years. As of December 31, 2010, developed technology had decreased $3,510 to $39,990 due to $2,634 of amortization expense, which the Company recorded in cost of goods sold, and $876 due to foreign exchange rate effects of the Euro to U.S. dollar translation. For the nine months ended September 30, 2011, developed technology decreased by a net amount of $1,695 to $38,295 due to amortization expense of $2,849 during the nine months ended September 30, 2011, partially offset by an increase of $1,154 related to foreign exchange rate effects of the Euro to U.S. dollar translation.

As of September 30, 2011 the total expected future amortization related to the developed technology, with no allowance for future potential foreign exchange rate effects, was as follows (in thousands):

2011 (October to December)	$ 798
2012	3,191
2013	3,191
2014	3,191
2015 and beyond	27,924
	$ 38,295

The Company has also recorded $110,900 for IPR&D related to the U.S. rights to LODOTRA, which were acquired as a result of the Company s acquisition of Nitec. The IPR&D assets were initially classified as indefinite-lived assets and will continue to be so classified until the successful completion or abandonment of the associated research and development efforts. As of December 31, 2010, IPR&D had decreased $2,154 to $108,746 due to foreign exchange rate effects of the Euro to U.S. dollar translation. As of September 30, 2011, IPR&D had increased by $2,831 to $111,577 due to foreign exchange rate effects of the Euro to U.S. dollar translation.

8. Commitments and Contingencies

Lease Obligations

In April 2009, the Company entered into a sublease agreement for its corporate headquarters in Northbrook, Illinois at a rate of $15 per month, expiring in April 2010. In January 2010, the Company exercised an option to extend the lease for an additional 20 months through December 31, 2011, at a monthly rent of $15 for the first 12 months of the renewal period and $16 per month for the last eight months of the renewal period. As of October 17, 2011, the Company has relocated its corporate headquarters to Deerfield, Illinois.

In September 2011, the Company entered into an office lease agreement for approximately 21,000 square feet of office space in Deerfield, Illinois, which was effective August 31, 2011. The initial term of the lease commences on December 1, 2011 and expires on June 30, 2018. The minimum rent will initially be 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.

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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 $11 (8 Euros) per month through December 31, 2011 and approximately $7 (5 Euros) per month through December 31, 2012, the expiration of the lease. Additionally the Company leases several company cars for its Reinach and Mannheim offices. All of these lease contracts expire no later than July 2013.

The Company recognizes rent expense on a monthly basis over the lease term based on a straight-line method. Rent expense was $114 and $98 for the three months ended September 30, 2011 and 2010, respectively, and $314 and $251 for the nine months ended September 30, 2011 and 2010, respectively.

The aggregate future minimum lease payments under noncancelable operating leases as of September 30, 2011 were as follows (in thousands):

2011 (October to December)	$ 143
2012	513
2013	472
2014	464
2015	424
2016 and beyond	1,016
	$ 3,032

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 LODOTRA exclusively to the Company in bulk. The Company committed to a minimum purchase of LODOTRA tablets from Jagotec for five years from the date of first launch of LODOTRA in a major country, as defined in the agreement, which was in April 2009. As of September 30, 2011, the minimum remaining purchase commitment was $3,750 based on tablet pricing in effect under the agreement as of September 30, 2011.

In November 2009, the Company entered into an agreement for $1,350 for engineering studies, installation qualification of equipment, validation batches and stability studies in connection with the manufacturing of DUEXIS. As of December 31, 2010, the Company recorded research and development expenses of $1,237 for milestones achieved under this agreement. Remaining total payments for stability studies of $113 are due over six years, of which $83 was due as of September 30, 2011.

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 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, 2011 and 2010 was $101 and $69, respectively, and $356 and $255 for the nine months ended September 30, 2011 and 2010, respectively.

Contingencies

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

Indemnification

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

action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company s request in such capacity. Additionally, the Company has entered, and intends to continue to enter, into separate indemnification agreements with its directors and executive officers. These agreements, among other things, require the Company to indemnify its directors and executive officers for certain expenses, including attorneys fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of the

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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.

9. Convertible Promissory Notes

In July 2010, the Company issued $10,000 of subordinated convertible promissory notes (the 2010 Notes), in January 2011 the Company issued an additional $5,030 of subordinated convertible promissory notes (the January 2011 Notes) and in April 2011, the Company issued an additional $1,735 of subordinated convertible promissory notes (the April 2011 Notes), each in private placements to certain of its existing investors in accordance with the Series B Preferred Stock and Convertible Note Purchase Agreement dated April 1, 2010, as amended by the First Amendment, Second Amendment and Third Amendment to Series B Preferred Stock and Convertible Note Purchase Agreement. The subordinated convertible promissory notes are considered hybrid instruments, which consist of a debt host instrument together with a conversion feature, thus giving the holder of a subordinated convertible note an option to convert into an equity instrument providing the holder a residual interest in the Company. Each holder of a subordinated convertible promissory note also has the option to present its subordinated convertible promissory note to the Company and demand payment under the terms of the note after a certain date (defined as the maturity date) or upon the occurrence of certain events such as the failure of the Company to make a payment on the note when due, bankruptcy or certain other liquidation events. The terms of the subordinated convertible promissory notes require that the conversion price be adjusted (reduced) upon occurrence of certain events (for example, upon issuance of convertible preferred stock at a price less than the conversion price of the outstanding preferred stock series, or upon an IPO). The Company concluded that the subordinated convertible promissory notes would be accounted for as a typical debt instrument with related interest expense recorded in the Company s consolidated statement of operations. If the contingency is met and the conversion feature is considered beneficial in a future accounting period, an additional cost of financing charge would be recorded for the beneficial conversion feature in the Company s consolidated statement of operations at that time. The 2010 Notes, January 2011 Notes and April 2011 Notes, including accrued interest, could have converted into shares of the Company s Series B preferred stock prior to the closing of the Company s IPO or the Company s common stock in connection with its IPO at the lesser of the price offered to the public in the IPO or $18.92 per share. The 2010 Notes, January 2011 Notes and April 2011 Notes bear interest at a fixed rate of 10% per annum and mature on July 12, 2011, January 7, 2012 and April 25, 2012, respectively, if not converted earlier. As of December 31, 2010 and September 30, 2011 $471 and $919, respectively, of interest expense was recorded in connection with the 2010 Notes, January 2011 Notes and April 2011 Notes. Upon the closing of the Company s IPO on August 2, 2011, the 2010 Notes, January 2011 Notes, April 2011 Notes, and accrued interest thereon, were converted into an aggregate of 2,017,242 shares of common stock which was based on the IPO price of $9.00 per share. The conversion of the notes did not trigger a contingency and an additional financing charge was not recognized during the three and nine months ended September 30, 2011.

10. Notes Payable

On April 1, 2010, in connection with the Transactions, the Company, Horizon Pharma USA, and Horizon Pharma AG entered into a new Loan and Security Agreement (the Kreos-SVB Facility) with two financial institutions allowing for borrowings of up to $12,000 at a 12.9% interest rate. The first loan of $7,000 was advanced on April 1, 2010, with 36 remaining equal monthly payments of $233 for principal and interest. The Kreos-SVB Facility is secured by a lien on substantially all of the assets, including intellectual property. The Company issued warrants to purchase 150,602 shares of Series B convertible preferred stock at an exercise price of $0.01 per share (Note 11). On September 3, 2010, the second loan for $5,000 was advanced with 36 equal monthly payments of $166 of principal and interest. In June 2011, in connection with the Oxford Facility described below, the Company repaid all $8,455 due under the Kreos-SVB Facility (including principal and interest), which included $7,842 of principal, $443 of interest and $170 of loan fees.

Also in connection with the Transactions, Horizon Pharma AG renegotiated the payment terms of an existing 7,500 Euro debt facility (the Kreos Facility). The Company was required to pay interest amounting to 50 Euros per calendar month, beginning May 2010 through December 2010. Thereafter, the Company is required to pay 35 equal monthly payments of 184 Euros, consisting of principal and interest. The Kreos Facility is secured by a lien on all of Horizon Pharma AG s trade receivables and intellectual property. Furthermore, the lender s warrant to purchase up to 37,244 shares of Nitec capital stock was cancelled and exchanged for a warrant to purchase up to 118,496 shares of the Company s Series A convertible preferred stock at an exercise price of $0.01 per share (Note 11). In June 2011, in connection with the Oxford Facility described below, the Company paid Kreos $1,450 (1,000 Euros) in exchange for Kreos consent to a partial assignment of the Kreos Facility to Horizon Pharma, Inc. As a result, Horizon Pharma, Inc. is now a co-lender with Kreos to Horizon Pharma AG. The Company also issued a warrant to Kreos to purchase an aggregate of 100,000 shares of its Series B convertible preferred stock with an exercise price of $0.01 per share, which will expire on June 2, 2021, unless earlier terminated as a result of certain acquisitions or changes in control, in exchange for Kreos consent to enter into the Oxford Facility.

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As a result of the extinguishment of the Kreos-SVB Facility and the partial pay down of the Kreos Facility, the Company incurred a total of $1,929 of extinguishment loss from the write-off of remaining debt discount, prepayment penalty interest and loan fees. The loss on the extinguishment of debt is included in interest expense in the consolidated statement of operations for the nine months ended September 30, 2011.

In June 2011, the Company entered into a new debt facility with Oxford Finance LLC (Oxford) and Silicon Valley Bank (SVB), and borrowed the full $17,000 available under this facility (the Oxford Facility). The debt under the Oxford Facility accrues interest at a fixed rate of 11.5% per annum, with interest only payments through June 1, 2012 followed by 36 equal monthly installments of principal and interest. The Oxford Facility is secured by a lien on substantially all of the Company s assets and those of Horizon Pharma USA, including intellectual property, but excluding the shares of Horizon Pharma AG. If the Company generates an annualized revenue run rate of at least $45,000 over three consecutive months from DUEXIS product sales, the lien on the assets may be released with the consent of the lenders, provided the Company is not in default under the Oxford Facility. With the loan proceeds, the Company repaid all $8,455 due under the Kreos-SVB Facility (including principal and interest). The Company also paid Kreos the $1,450 (1,000 Euros), described above. The remaining loan proceeds of $6,880, net of $215 of loan fees, are being used to fund the Company s operations. In connection with the Oxford Facility, the Company issued warrants to Oxford and SVB to initially purchase an aggregate of 80,007 shares of its Series B convertible preferred stock which became warrants to purchase an aggregate of 70,833 shares of common stock upon the completion of the Company s IPO. The warrants have a per share exercise price of $9.00.

The Kreos Facility and Oxford Facility restrict 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 agreement. If the Company defaults under its debt facility, the lenders may accelerate all of the Company s repayment obligations and take control of the Company s pledged assets. The lenders could declare a default under the Company s debt facility upon the occurrence of any event that the lenders interpret as having a material adverse effect upon the Company as defined under the loan agreement, thereby requiring the Company to repay the loan immediately or to attempt to reverse the lenders declaration through negotiation or litigation.

The future minimum payments under both the outstanding Kreos Facility and the Oxford Facility as of September 30, 2011 were as follows (in thousands):

2011 (October to December)	$ 894
2012	6,772
2013	8,782
2014	6,727
2015	3,710
	26,885
Less: Amount representing interest	6,495
	20,390
Less: Unamortized discount	537
	19,853
Less: Current portion	2,386
Long-term portion	$ 17,467

11. Stockholders Equity

Convertible Preferred Stock

Upon the closing of the Company s IPO on August 2, 2011, outstanding shares of convertible preferred stock, which are shown in the table below (dollars in thousands, except issue price) were automatically converted into an aggregate of 10,514,431 shares of common stock. The Company had reserved sufficient shares of common stock for issuance upon conversion of the convertible preferred stock.

Series	Date Issued	Original Issue Price	Shares Authorized	Shares Outstanding	Carrying Amount	Liquidation Preference	Dividend Rate
A	April 2010	$ 6.993	23,200,000	22,451,300	$ 176,708	$ 157,002	8%
B	April 2010	7.968	5,750,000	2,510,040	19,844	20,000	8%
			28,950,000	24,961,340	$ 196,552	$ 177,002	

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Convertible Preferred Stock Warrants

The following unexercised convertible preferred stock warrants were outstanding prior to the IPO and classified as permanent equity.

Underlying Stock	Exercise Price	Number of Shares
Series A convertible preferred	$ 10.692	62,176
Series A convertible preferred	$ 5.201	490,290
Series A convertible preferred	$ 0.010	118,496
Series B convertible preferred	$ 0.010	250,602
Series B convertible preferred	$ 7.968	80,007
		1,001,571

Upon the closing of the Company s IPO on August 2, 2011, the convertible preferred stock warrants were converted into warrants to purchase an aggregate of 459,003 shares of common stock as follows.

Underlying Stock	Exercise Price	Number of Shares
Common stock	$ 25.39	26,189
Common stock	$ 12.35	206,506
Common stock	$ 0.03	155,474
Common stock	$ 9.00	70,834
		459,003

On April 1, 2010, in connection with the recapitalization of Horizon Therapeutics, Inc., Series C and Series D convertible preferred stock warrants were converted on a 1:1.33 and 1:1 basis, respectively, into Series A convertible preferred stock warrants.

On April 1, 2010, in connection with the Kreos-SVB Facility, the Company issued warrants to purchase an aggregate of 150,602 shares of Series B convertible preferred stock. Also in connection with Kreos Facility and the Nitec acquisition, the lender s warrant to purchase up to 37,244 shares of Nitec capital stock was cancelled and exchanged for a warrant to purchase up to 118,496 shares of the Company s Series A convertible preferred stock in connection with the Nitec acquisition. Both the Series A and B warrants have an exercise price of $0.01 per share and expire on April 1, 2020 unless terminated earlier as a result of certain reorganizations or changes in control. The fair value of warrants was recorded as a debt issuance cost and was being amortized to interest expense over the term of the loans. As a result of the debt extinguishment described in Note 10, the Company wrote off of the remaining debt issuance cost of $567. The initial fair value of the Kreos-SVB Facility and the Kreos Facility warrants was estimated at an aggregate value of $1,200 and $936, respectively, using the Black-Scholes option pricing model with the following assumptions at the date of issuance: expected volatility of 56%, risk-free interest rate of 4.19%, contractual term of 10 years and dividend yield of 0%. The warrants are classified as permanent equity.

In connection with the Oxford Facility, the Company issued warrants to Oxford and SVB to initially purchase an aggregate of 80,007 shares of its Series B convertible preferred stock which became warrants to purchase an aggregate of 70,833 shares of common stock upon completion of the Company s IPO. The warrants have a per share exercise price of $9.00. The warrants will expire on June 2, 2021 unless terminated earlier as a result of certain reorganizations or changes in control as set forth in the warrants. The fair value of the warrants was recorded as a debt issuance cost and is being amortized to interest expense over the term of the loan. The initial fair value of the Oxford Facility warrants was estimated at an aggregate value of $443, using the Black-Scholes option pricing model with the following assumptions at the date of issuance: expected volatility of 64%, risk-free interest rate of 3.04%, contractual term of 10 years and dividend yield of 0%. The warrants are classified as permanent equity.

The Company also issued a warrant to Kreos to purchase an aggregate of 100,000 shares of its Series B convertible preferred stock with an exercise price of $0.01 per share, which will expire on June 2, 2021, unless earlier terminated as a result of certain acquisitions or changes in control, in exchange for Kreos consent to enter into the Oxford Facility. The initial fair value of the warrant was estimated at an aggregate value

of $681, using the Black-Scholes option pricing model with the following assumptions at the date of issuance: expected volatility of 64%, risk-free interest rate of 3.04%, contractual term of 10 years and dividend yield of 0%.

Interest expense related to the amortization of debt discount during the three months ended September 30, 2011 and 2010, was $58 and $243, respectively and during the nine months ended September 30, 2011 and 2010 was $430 and $578, respectively.

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Common Stock

On August 2, 2011, the Company closed its IPO of 5,500,000 shares of common stock at an offering price of $9.00 per share, resulting in net proceeds to the Company of approximately $41,885, after deducting underwriting discounts of $3,465 and offering costs of $4,150. Upon the closing of the IPO, the Company s outstanding shares of convertible preferred stock were automatically converted into an aggregate of 10,514,431 shares of common stock, the outstanding convertible preferred stock warrants were automatically converted into common stock warrants to purchase an aggregate of 459,003 shares of common stock and the outstanding subordinated convertible promissory notes were automatically converted into 2,017,242 shares of common stock.

Each share of common stock has the right to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No dividends have been declared by the Board from inception through September 30, 2011. As of September 30, 2011, the Company was authorized to issue a total of 200,000,000 shares of $0.0001 par value common stock.

12. Employee Equity Incentive Plans

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 IPO, 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 IPO, on July 28, 2011. The 2011 Plan has an initial reserve of 3,366,228 shares of common stock, including 460,842 shares of common stock previously reserved for future issuance under the 2005 Plan, 1,304,713 shares of common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan as of the 2011 Plan s effective date and 1,600,673 new shares of common stock reserved. The 2011 Plan provides that an additional number of shares will automatically be added annually to the shares authorized for issuance on January 1, from 2012 until 2021. The number of shares added each year will be equal to the least of: (a) 5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (b) 1,474,304 shares of common stock; or (c) a number of shares of common stock that may be determined each year by the board of directors that is less than (a) and (b). As of September 30, 2011, the Company had reserved 1,768,794 shares of common stock for issuance under the 2011 Plan. Under the 2011 Plan, the board of directors, or a committee of the board of directors, may grant incentive and nonqualified stock options, stock appreciation rights, restricted stock units, or restricted stock awards to employees, directors and consultants to the Company or any subsidiary of the Company. Under the terms of the 2011 Plan, the exercise price of stock options may not be less than 100% of the fair market value on the date of grant and their term may not exceed ten years.

The following summarizes the activities under the 2005 Plan and the 2011 Plan for the nine months ended September 30, 2011:

		Options Outstanding		
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
December 31, 2010	422,861	1,348,421	$ 14.02	$ 7,433
Options authorized	1,600,673			
Options granted	(381,740)	381,740	$ 7.57	
Options exercised		(6,400)	$ 7.05	
Options cancelled	44,000	(44,000)	$ 16.59	

September 30, 2011	**1,685,794**	**1,679,761**	**$ 12.51**	**$ 594**
Options vested and expected to vest at September 30, 2011		1,660,863	$ 12.57	$ 594
Options vested at September 30, 2011		914,411	$ 9.68	$ 301

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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 IPO 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.

Stock-Based Compensation Associated with Awards to Employees

During the three months ended September 30, 2011 and 2010, the Company granted stock options to purchase an aggregate of 354,600 and 20,796 shares of common stock, respectively, to employees with a weighted average grant date fair value of $7.48 and $16.98, respectively. During the nine months ended September 30, 2011 and 2010, the Company granted stock options to purchase an aggregate of 355,653 and 1,005,944 shares of common stock, respectively, to employees with a weighted average grant date fair value of $7.51 and $15.38, respectively.

The total fair value of options granted to employees that vested during the three months ended September 30, 2011 and 2010 was $540 and $369, respectively, and during the nine months ended September 30, 2011 and 2010 was $2,087 and $1,350, respectively.

As of September 30, 2011, the unrecognized stock-based compensation expense related to employee stock options expected to vest was $6,590 and will be recognized over an estimated weighted average amortization period of 3.0 years.

The fair value of each option grant was estimated on the date of grant using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Expected volatility	86%	79%	86%	80%
Risk-free interest rate	1.20%	2.10%	1.20%	2.30%
Expected term (in years)	6.02	6.25	6.02	5.03
Expected dividends	0%	0%	0%	0%

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.

Expected 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.

Expected Dividends

The Company has never paid dividends and does not anticipate paying any dividends in the near future.

Forfeitures

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

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Stock-based compensation expense related to options granted to employees was allocated to the following line items in the condensed consolidated statement of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010 As restated
Research and development	$ 177	$ 317	$ 562	$ 566
Sales and marketing	91	36	173	60
General and administrative	329	316	984	1,073
	$ 597	$ 669	$ 1,719	$ 1,699

No income tax benefit has been recognized relating to stock-based compensation expense and no tax benefits have been realized from exercised stock options, due to the Company s net loss position.

Stock-Based Compensation for Non-employees

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the service received. The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option pricing model using the following assumptions:

	September 30, 2011
Expected volatility	86%
Risk-free interest rate	1.4%
Contractual life (in years)	10.0
Expected dividends	0%

Stock-based compensation expense will fluctuate as the fair value of the common stock fluctuates. Stock-based compensation expense charged to operations for options granted to non-employees for the three months ended September 30, 2011 and 2010 was $4 and $275, respectively, and for the nine months ended September 30, 2011 and 2010 was $108 and $335, respectively.

During the three months ended September 30, 2011, the Company granted options to purchase an aggregate of 23,560 shares of common stock to non-employees with a weighted average grant date fair value of $7.48. During the three months ended September 30, 2010, the Company did not grant options to non-employees. During the nine months ended September 30, 2011 and 2010, the Company granted options to purchase an aggregate of 26,087 and 42,223 shares of common stock, respectively, to non-employees with a weighted average grant date fair value of $8.42 and $11.05, respectively.

13. 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 have terminated as of September 30, 2011. For the three months ended September 30, 2011 and 2010, the Company paid $173 and $293, respectively, in consulting fees to the related parties. For the nine months ended September 30, 2011 and 2010, the Company paid $573 and $719, respectively, in consulting fees to the related parties.

14. Distribution Agreements

Merck Serono

In December 2006 and March 2009, the Company entered into transfer, license and supply agreements with Merck Serono GmbH (Merck Serono) and Merck GesmbH, an affiliate of Merck Serono, for the commercialization of LODOTRA in Germany and Austria, respectively. The agreement covering Germany was amended in December 2008 to allow co-promotion of LODOTRA in Germany. Under the agreements, the Company granted Merck Serono and Merck GesmbH exclusive distribution and marketing rights pertaining to LODOTRA for Germany and Austria, respectively, and an exclusive license to use the trademark for LODOTRA in Germany and Austria. Merck Serono agreed to purchase LODOTRA commercial product exclusively from the Company. The Company supplies LODOTRA to Merck Serono at the price which is the higher of (1) a percentage of the list price of LODOTRA to final purchasers of LODOTRA from Merck Serono (excluding any discounts) and (2) the costs incurred for the production and delivery of LODOTRA to a Merck Serono supply depot,

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plus a profit mark-up. Subject to early termination, the terms of the agreements are 10 years from the launch of LODOTRA in Germany and Austria, as applicable. Thereafter, the agreements automatically renew until terminated by either party by giving specified prior written notice to the other party. Either party may also terminate either agreement in the event of a bankruptcy of the other party, certain events beyond the parties control that impair performance under the agreements, or upon material uncured breach by the other party.

The transfer, license and supply agreements related to Germany and Austria were assigned to Mundipharma from Merck Serono in April 2011 and September 2011, respectively, with the Company s consent. In addition, the German agreement was extended from 10 years to 15 years from the launch of LODOTRA.

Mundipharma

In March 2009, the Company entered into a distribution agreement with Mundipharma for the commercialization of LODOTRA in Europe, excluding Germany and Austria, and a manufacturing and supply agreement with Mundipharma Medical. The distribution agreement provides for an upfront payment less than ten million Euros, all of which has been paid by Mundipharma, and aggregate potential milestone payments in the tens of millions of Euros, of which approximately 37% has been earned by the Company and paid by Mundipharma. Under the distribution agreement, the Company granted Mundipharma the exclusive distribution and marketing rights pertaining to LODOTRA for: Albania, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, former Soviet Union countries, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Under the manufacturing and supply agreement, Mundipharma Medical agreed to purchase LODOTRA exclusively from the Company. The Company supplies finished packages of LODOTRA to Mundipharma Medical at the price which is a specified percentage of the average net selling price for sales in a given country. Subject to early termination, the terms of both agreements extend to March 2024. Thereafter, the agreements automatically renew until terminated by either party giving specified prior written notice to other party. Either party may also terminate either of the agreements in the event of a bankruptcy of the other party or upon an uncured material breach by the other party. In addition, Mundipharma has the right to terminate the distribution agreement in the event of material risk of personal injury to third parties or immediately by written notice with respect to any country if the market authorization for LODOTRA is cancelled in such country.

In November 2010, the Company entered into a second distribution agreement with Mundipharma for the commercialization of LODOTRA in several Asian and other countries and a second manufacturing and supply agreement with Mundipharma Medical. Under the distribution agreement, the Company was entitled to an upfront payment of less than five million dollars, all of which has been paid by Mundipharma, and is eligible to receive aggregate potential milestone payments of less than five million dollars, of which none had been received as of December 31, 2010. The Company has deferred recognition of the entire upfront payment and will begin recognizing revenue associated with its payment upon the first commercial sale of LODOTRA in the applicable territory.

Under the second distribution agreement, the Company granted Mundipharma the exclusive distribution and marketing rights pertaining to LODOTRA for: Australia, China, Hong Kong, Indonesia, Korea, Malaysia, New Zealand, the Philippines, Singapore, South Africa, Taiwan, Thailand and Vietnam. In addition, Mundipharma will be responsible for obtaining regulatory approvals in these countries. The Company also granted to Mundipharma an exclusive license to use its trademark for LODOTRA in these countries, and Mundipharma is allowed to commercialize LODOTRA under the LODOTRA trademark. Mundipharma is obligated to use commercially reasonable efforts to obtain regulatory approval for and market LODOTRA and is prohibited from launching other oral corticosteroids in these countries during the term of the distribution agreement. If Mundipharma does not meet specified minimum volume targets, which range from thousands of Euros to millions of Euros on a country by country basis, over specified periods of time, the marketing rights granted under the distribution agreement will become nonexclusive with respect to the applicable country unless Mundipharma pays the Company the shortfall.

Under the second manufacturing and supply agreement, Mundipharma Medical agreed to purchase LODOTRA exclusively from the Company with respect to the territory. The Company supplies bulk product of LODOTRA to Mundipharma Medical at an adjustable price per tablet and Mundipharma is responsible for final packaging and distribution in the territory.

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

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to terminate the distribution agreement with respect to any country in the territory if within a specified period of time, Mundipharma fails to submit appropriate filings to obtain marketing authorization in the country or fails to initiate a clinical trial required for marketing authorization in the country.

15. Subsequent Events

On November 14, 2011, the Company and Sanofi announced the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. Sanofi will serve as the primary commercial manufacturer for DUEXIS in the U.S. The Company has hired its commercial organization, completed sales force training and expects to commercially launch DUEXIS in the U.S. in November 2011.

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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. We do not assume any obligation to update any forward-looking statements.

Overview

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® (formerly HZT-501), a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis, or RA, and osteoarthritis, or OA, and to decrease the risk of developing upper gastrointestinal, or GI, ulcers in patients who are taking ibuprofen for these indications. On November 14, 2011, we and Sanofi-aventis U.S. LLC, or Sanofi, announced the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. Sanofi will serve as the primary commercial manufacturer for DUEXIS in the U.S. We have hired our commercial organization, completed sales force training and expect to commercially launch DUEXIS in the U.S. in November 2011. We submitted a Marketing Authorization Application, or MAA, for DUEXIS in the United Kingdom, the Reference Member State, through the Decentralized Procedure in October 2010 and we anticipate a decision on the MAA in the first half of 2012. Our other lead product, LODOTRA, is a proprietary programmed release formulation of low-dose prednisone that is currently marketed in Europe by our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for the treatment of moderate to severe, active RA in adults when accompanied by morning stiffness. We have successfully completed two Phase 3 clinical trials of LODOTRA and we submitted a new drug application, or NDA, for LODOTRA to the FDA on September 26, 2011. We have worldwide marketing rights for DUEXIS and have retained exclusive marketing rights in the U.S. for all of our products. Our strategy is to commercialize our products in the U.S., to explore co-promotion opportunities for DUEXIS in the U.S. and to enter into licensing or additional distribution agreements for commercialization of our products outside the U.S.

On April 1, 2010, we effected a recapitalization and acquisition pursuant to which Horizon Pharma, Inc. became a holding company that operates through its wholly-owned subsidiaries Horizon Pharma USA, Inc. (formerly Horizon Therapeutics, Inc.) and Horizon Pharma AG (formerly Nitec Pharma AG, or Nitec). Our LODOTRA product was developed and is owned by Horizon Pharma AG and our historical financial statements and results of operations do not reflect the results of operations of Nitec for any period prior to the recapitalization and acquisition in April 2010. As a result of the acquisition of Nitec and organic growth, our organization has grown from 12 full-time employees as of March 31, 2010 to 133 full-time employees as of September 30, 2011 and to 161 as of November 7, 2011. Our development efforts have also expanded significantly through the acquisition of Nitec. Consequently, we expect our expenses to increase from prior periods. As a result of the recapitalization and acquisition, our future operations will be impacted by both the operations of our U.S. subsidiary Horizon Pharma USA and our Swiss subsidiary Horizon Pharma AG.

We market LODOTRA in Europe through three separate agreements. Pursuant to two separate agreements, we granted Merck Serono GmbH, or Merck Serono, and Merck GesmbH, an affiliate of Merck Serono, exclusive rights to distribute and market LODOTRA in each of Germany and Austria, respectively, and pursuant to the third agreement, we granted Mundipharma exclusive rights to distribute and market LODOTRA in the rest of Europe. In April 2011 and September 2011, we consented to Merck Serono s assignment of the agreements with respect to Germany and Austria, respectively, to Mundipharma. Pursuant to another agreement, we granted Mundipharma exclusive rights to distribute and market LODOTRA in certain Asian and other countries. We also have a manufacturing and supply agreement with Jagotec AG, or Jagotec, under which Jagotec or its affiliates manufacture and supply LODOTRA exclusively to us as bulk tablets. We have committed to certain minimum orders under the agreement, and we also supply the active ingredient to Jagotec for use in the manufacture of LODOTRA.

We are focusing our efforts and capital resources on obtaining additional approvals for DUEXIS and LODOTRA and commercializing these products in the U.S. In addition to DUEXIS and LODOTRA, we have a pipeline of earlier stage product candidates to treat pain-related diseases and chronic inflammation. We are currently evaluating the development pathway for these product candidates, but do not intend to develop them

further until such time as we generate sufficient cash from our operations or other sources.

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We are subject to risks common to biopharmaceutical companies in the development stage, including, but not limited to, obtaining regulatory approval for our product candidates, dependence upon market acceptance of our products, risks associated with intellectual property, pricing and reimbursement, intense competition, development of markets and distribution channels and dependence on key personnel. We have a limited operating history and have yet to generate significant revenues. To date, we have been funded predominantly by equity and debt financings. Our ultimate success is dependent upon our ability to successfully develop, obtain approval for and market our products. We anticipate we will continue to incur net losses for at least the next several years as we:

- establish sales and marketing capabilities for the anticipated U.S. commercial launches of DUEXIS and LODOTRA;
- expand our corporate infrastructure to support our growth and our commercialization activities;
- evaluate the potential use of LODOTRA for the treatment of other diseases and conduct additional clinical trials with respect to the same;
- incur expenses as we seek regulatory approval of LODOTRA in the U.S. and DUEXIS in Europe; and
- advance the clinical development of other product candidates either currently in our pipeline or that we may in-license or acquire in the future.

As of September 30, 2011, we had cash and cash equivalents of $33.0 million, including net proceeds of $41.9 million from our IPO after deducting underwriter discounts and offering costs.

On July 7, 2011, we effected a 1-for-2.374 reverse stock split of our common stock and a proportional adjustment to the existing conversion ratios for each series of preferred stock. Accordingly, all share and per share amounts, except as noted, have been retroactively adjusted to give effect to the reverse stock split.

On August 2, 2011, we completed our IPO, and we sold 5,500,000 shares of common stock at an offering price of $9.00 per share, resulting in net proceeds of approximately $41.9 million, after deducting underwriting discounts of $3.5 million and offering costs of $4.1 million. Upon the consummation of our IPO, all outstanding shares of preferred stock were automatically converted into common stock, and all outstanding preferred stock warrants were automatically converted into warrants to purchase an aggregate of 459,003 shares of common stock. In addition, the convertible promissory notes in the aggregate principal amount $10.0 million issued in July 2010, or 2010 notes, the convertible promissory notes in the aggregate principal amount $5.0 million issued in January 2011, or January 2011 notes, and the convertible promissory notes in the aggregate principal amount of $1.7 million issued in April 2011, or April 2011 notes, and interest accrued thereon, were converted into an aggregate of 2,017,242 shares of common stock, based on a conversion price of $9.00 per share.

We believe that our existing cash and cash equivalents (including the net proceeds from the IPO), together with interest thereon, will be sufficient to fund our operations into the second quarter of 2012. In addition to the near-term funding we will need to support the anticipated commercialization of DUEXIS in the U.S., we will need additional future financing in the event that we do not obtain additional regulatory approvals for DUEXIS and LODOTRA when expected or if the future sales of DUEXIS, LODOTRA and any additional products we may develop do not generate sufficient revenues to fund our operations. Our failure to raise capital if and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies. In its report on our financial statements for the year ended December 31, 2010, our independent registered public accounting firm included an explanatory paragraph regarding our ability to continue as a going concern.

Unless otherwise indicated, historical amounts presented with respect to Nitec are presented in accordance with accounting principles generally accepted in the U.S., or U.S. GAAP. With respect to certain amounts that are set forth in Swiss francs, we have included a corresponding amount in U.S. Dollars. Where the amounts relate to a specific date, the exchange rate between the Swiss franc and U.S. Dollar on such date was used to effect the conversion. Where the amounts relate to a period, the average exchange rate between the Swiss franc and U.S. Dollar during such period was used to effect the conversion.

Financial Overview

Prior to our acquisition of Nitec we had no revenues and incurred significant operating losses since inception. Before our acquisition of Nitec, as of March 31, 2010, we had an accumulated deficit of $87.9 million. Giving effect to our acquisition of Nitec and, as of September 30, 2011, we had an accumulated deficit of $143.6 million, after giving effect to the $19.3 million bargain purchase gain we recognized in connection with the Nitec acquisition.

Revenue and Cost of Goods Sold

As of April 1, 2010, as a result of our acquisition of Nitec, we began recognizing revenues from the sale of LODOTRA. We recognize revenues from out-licensing marketing and distribution rights to third parties in Europe and certain Asian and other countries, including upfront fees, milestone payments and product sales. Upfront fees and payments for non-substantive milestones

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are recorded as deferred revenue when paid and recognized over the remaining life of the marketing and distribution agreement or manufacturing and supply agreement, as applicable. Milestone payments are considered non-substantive if any portion of the associated milestone payment is determined to not relate solely to past performance or if a portion of the consideration earned from achieving the milestone may be refunded. During the three and nine months ended September 30, 2010 all revenues recognized, and during the three and nine months ended September 30, 2011, substantially all revenues recognized, were related to the sale of LODOTRA to our distribution partners. Cost of goods sold consists of raw materials, manufacturing and other supply chain costs for the manufacture of LODOTRA, and royalty amounts payable to SkyePharma AG on LODOTRA sales and upon receipt of certain milestone payments. In addition, cost of goods sold includes amortization of developed technology relating to our acquisition of Nitec. We expect to record approximately $3.5 million annually related to amortization of developed technology. We will adjust the rate of amortization if there are changes in our expected LODOTRA sales in Europe that indicate impairment of the developed technology or change in the expected useful life of the developed technology. The use of material is charged applying the first-in first-out (FIFO) method on capitalized inventory stock. We expect the per unit cost of goods sold for LODOTRA to decrease as sales volumes increase, due to lower per-unit manufacturing costs at higher volumes.

We expect our revenues and cost of goods sold to increase beginning in late 2011 or 2012 following the anticipated commercial launch of DUEXIS in the U.S. in November 2011. The process of commercializing products is costly and time consuming. The probability of success may be affected by a variety of factors, including, among others, competition, pricing and reimbursement, manufacturing capabilities and commercial viability. As a result of these uncertainties, we are unable to determine when, or to what extent, we will generate significant revenues from the commercialization and sale of any of our products. We are also currently focused on obtaining U.S. regulatory approval of LODOTRA. However, we will need to raise substantial additional capital in the future in order to fully commercialize DUEXIS and obtain U.S. regulatory approval for LODOTRA. We would also need to raise substantial additional capital to the extent that we decide to pursue further development and commercialization of our other product candidates.

Research and Development Expenses

Research and development expenses consist of: (1) expenses incurred under agreements with contract research organizations, or CROs, and investigative sites, which conduct our clinical trials and our preclinical studies; (2) the cost of manufacturing clinical trial materials; (3) payments to consultants; (4) employee-related expenses, which include salaries and benefits and (5) stock-based compensation expense. All research and development costs are expensed as incurred. Conducting a significant amount of research and development has been central to our business model, which in the past had focused primarily on clinical research and trials and more recently has focused on development work, including regulatory approval and manufacturing activities. We expect that this trend will continue through the fourth quarter of 2011 as we focus on obtaining additional regulatory approvals for DUEXIS and LODOTRA. Through September 30, 2011, we had incurred approximately $91.4 million in research and development expenses since our inception in 2005. The following table summarizes our research and development expenses for the three and nine months periods ended September 30, 2011 and 2010:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
External Research and Development Expenses				
LODOTRA-Rheumatoid Arthritis	$ 2,578	$ 1,968	$ 4,315	$ 3,971
LODOTRA-Severe Asthma		3	10	6
TRUNOC	6	(92)	24	(92)
DUEXIS	989	2,551	2,874	6,467
Total External Research and Development Expenses	3,573	4,430	7,223	10,352
Total Internal Research and Development Expenses	1,773	1,291	4,313	2,509
Total Research and Development Expenses	$ 5,346	$ 5,721	$ 11,536	$ 12,861

Substantially all of our research and development expenses prior to our acquisition of Nitec were attributable to development of DUEXIS. A portion of our internal costs, including indirect costs relating to our product candidates, are not tracked on a project basis and are allocated based on management estimates of where the benefit accrues, or as a percentage of direct project costs. Our research and development expenses increased in 2010 as a result of our acquisition of Nitec. We expect these research and development expense levels to continue into 2011 and to be primarily attributable to the development of LODOTRA, including expenses related to obtaining additional regulatory approvals for LODOTRA and post-marketing studies of DUEXIS.

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We generally consider our development of a product to be complete when we receive approval from regulatory authorities to market the product in the applicable jurisdiction. As a result, we are unable to reasonably estimate our additional research and development costs to complete our development work with respect to LODOTRA in the U.S. and DUEXIS in Europe, including our regulatory approval and manufacturing activities. Such estimates depend on numerous factors that are outside of our control, such as whether regulatory authorities will change their approval criteria for products in the same class as DUEXIS or LODOTRA, whether our applications for marketing approval will be accepted for review by regulatory authorities, whether regulatory authorities will require that we complete additional studies before or after granting marketing approval, and when, if ever, regulatory authorities will approve any applications for marketing approval that we submit. For similar reasons, we are unable to reasonably estimate when, if ever, our development work with respect to DUEXIS and LODOTRA will be complete or when we may receive material net cash inflows related to our on-going development work with respect to DUEXIS and LODOTRA. We submitted an MAA in selected European countries in October 2010 to market DUEXIS, and we submitted an NDA for LODOTRA in the U.S. on September 26, 2011. However, we cannot estimate when, if ever, the applicable regulatory authorities will grant marketing approvals based on these submissions.

If we experience delays in submitting or receiving approval of our marketing applications for DUEXIS or LODOTRA, our ability to generate significant revenues from these product candidates will also be delayed, which will negatively affect our financial position and liquidity. If the FDA or other regulatory authorities require that we complete additional studies prior to approving our marketing applications, the costs of such studies could have a further material adverse effect on our capital resources and financial position. We believe that if we experience delays in receiving marketing approval for our product candidates, our ability to raise additional funds to continue our operations would also be adversely affected.

Sales and Marketing Expenses

Sales and marketing expenses of Horizon Pharma USA and Horizon Pharma AG historically have consisted principally of business development expenses, trade show expenses and pre-launch marketing activities, including market research and pricing reimbursement studies in anticipation of our market launch for DUEXIS and LODOTRA in the U.S. Sales and marketing expenses also consist of stock-based compensation expense. As of September 30, 2011, our sales and marketing headcount was 92 full-time equivalents and as of November 7, 2011, our sales and marketing headcount increased to 118 full-time equivalents, primarily as a result of recruiting and hiring our sales organization. We expect these expenses to increase significantly as we continue to establish sales and marketing capabilities to commercialize DUEXIS and LODOTRA in the U.S.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, accounting, information technology and human resources functions. Other general and administrative expenses include facility costs, professional fees for legal, consulting and auditing and tax services. General and administrative expenses also consist of stock-based compensation expense. As a result of our acquisition of Nitec, our general and administrative headcount changed from six full-time equivalents as of March 31, 2010 to 13 full-time equivalents as of April 1, 2010. In connection with our acquisition of Nitec on April 1, 2010, we eliminated three redundant executive management positions in Europe. As of September 30, 2011, our general and administrative headcount was 17 full-time equivalents and as of November 7, 2011, our general and administrative headcount increased to 18 full-time equivalents. We expect general and administrative expenses to increase as we continue to build our corporate infrastructure in support of our activities relating to commercializing DUEXIS and obtaining regulatory approval of and commercializing LODOTRA in the U.S., and as a result of operating a public company. These increases likely will include salaries and related expenses, legal and consultant fees, accounting fees, director fees, increased directors and officers insurance premiums, fees for investor relations services and costs of enhanced business and accounting systems.

Interest Expense

Interest expense, both historically and prospectively, is related to interest and fees on certain debt facilities outstanding at both Horizon Pharma USA and Horizon Pharma AG. Through August 2, 2011, we were incurring interest expense on the 2010 notes, the January 2011 notes, and the April 2011 notes. Upon the closing of our IPO on August 2, 2011, the outstanding convertible promissory notes were converted into common stock and therefore, we are no longer incurring interest on these notes. In June 2011, we entered into a $17.0 million debt facility with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, which we refer to as the Oxford facility, which will incrementally increase interest expense in 2011 by approximately $1.1 million. Additionally, we will incur interest expense related to the Oxford facility of $1.9 million, $1.3 million, $0.7 million and $32,000 in the years 2012, 2013, 2014 and 2015, respectively.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reported period. We evaluate our estimates and judgments on an ongoing basis. Actual results could differ materially from those estimates.

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While our significant accounting policies are more fully described in Note 3 to our condensed consolidated financial statements, we believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements:

- revenue recognition;
- cost of goods sold;
- preclinical study and clinical trial accruals;
- valuation of stock-based compensation and common stock; and
- provision for income taxes.

Recent Accounting Pronouncements

In May 2011 the Financial Accounting Standards Board, or FASB, and International Accounting Standards Board, or IASB, issued Accounting Standards Update, or ASU, No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS*. ASU 2011-04 created a uniform framework for applying fair value measurement principles and clarified existing guidance in GAAP. ASU 2011-04 will be effective for the first reporting annual period beginning after December 15, 2011 and must be applied prospectively. We will adopt ASU 2011-04 in the first quarter of fiscal year 2012. We do not believe that the adoption of ASU 2011-04 will have a material impact on our condensed consolidated financial statements.

In June 2011 the FASB issued ASU No. 2011-05*, Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income,* which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of stockholders equity. Instead, companies must report comprehensive income in either a single continuous statement of comprehensive income, which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 will be effective during the interim and annual periods beginning after December 15, 2011 with early adoption permitted. We will adopt ASU 2011-05 in the first quarter of fiscal year 2012. We do not believe that the adoption of ASU 2011-05 will have a material impact on our condensed consolidated financial statements.

Results of Operations

Comparison of Three Months Ended September 30, 2011 and 2010

	Three Months Ended September 30, 2011	2010	Increase/ (Decrease)	% Increase/ (Decrease)
	(in thousands, except percentages)			
Revenues	$ 273	$ 689	$ (416)	(60%)
Cost of goods sold	1,249	737	512	69%
Research and development expenses	5,346	5,721	(375)	(7%)
Sales and marketing expenses	5,141	1,955	3,186	163%
General and administrative expenses	4,192	3,880	312	8%
Interest expense, net	(995)	(1,031)	(36)	(3%)
Foreign exchange (loss) gain, net	(758)	164	(922)	(562%)

Revenues. During the three months ended September 30, 2011 and 2010, substantially all revenues recognized were from the sale of LODOTRA in Europe. Revenues decreased by $0.4 million during the three months ended September 30, 2011 compared to the same period in 2010

primarily due to the timing of purchases by our distribution partners.

Cost of Goods Sold. Our cost of goods sold during the three months ended September 30, 2011, compared to the same period in 2010, increased $0.5 million primarily due to a one-time $0.4 million LODOTRA inventory adjustment written off against cost of sales.

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Research and Development Expenses. The decrease of $0.4 million in research and development expenses during the three months ended September 30, 2011, compared to the same period in 2010, was primarily due to a decrease of $1.2 million for contract manufacturing and pharmacovigilance studies for DUEXIS. The decrease was partially offset by an increase of $0.3 million in regulatory and clinical consultant expenses and an increase of $0.4 million in personnel-related costs to support DUEXIS development and regulatory activities.

Sales and Marketing Expenses. The increase of $3.2 million in sales and marketing expenses during the three months ended September 30, 2011, compared to the same period in 2010, was due to an increase of $1.6 million in personnel related costs resulting from increased headcount to establish sales and marketing capabilities to commercialize DUEXIS in the U.S. and an increase of $1.6 million in consulting and promotional activities expenditures associated with pre-commercialization activities for DUEXIS in the U.S.

General and Administrative Expenses. The increase of $0.3 million in general and administrative expenses during the three months ended September 30, 2011, compared to the same period in 2010, was primarily due to an increase of $0.5 million in personnel-related costs and an increase of $0.3 million in facility-related costs in connection with the building of our corporate infrastructure, partially offset by a decrease of $0.5 million for lower audit and consulting fees following our IPO.

Interest Expense, Net. Interest expense, net during the three months ended September 30, 2011, compared to the same period in 2010, remained relatively unchanged primarily due to $0.5 million of lower interest expense under an existing 7.5 million Euro debt facility between Kreos and Nitec, which we refer to as the Kreos facility, and a $12.0 million debt facility with Kreos and SVB, which we refer to as the Kreos-SVB facility, and an increase of $0.1 million related to the 2010 notes in the aggregate principal amount of $10.0 million, the January 2011 notes in the aggregate principal amount of $5.0 million, and the April 2011 notes in the aggregate principal amount of $1.7 million , offset by a $0.6 million incremental interest expense under the Oxford facility.

Foreign Exchange (Loss) Gain, Net. The foreign exchange loss for the three months ended September 30, 2011 was primarily a result of the increase in value of the U.S. dollar against the Euro in connection with remeasuring foreign currency transactions during the three months ended September 30, 2011, compared to the same period in 2010 during which we had a foreign exchange gain due to a decrease in the value of the U.S. dollar against the Euro.

Comparison of Nine Months Ended September 30, 2011 and 2010

	Nine Months Ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2011	2010 As restated		
	(in thousands, except percentages)			
Revenues	$ 3,401	$ 2,346	$ 1,055	45%
Cost of goods sold	5,191	2,870	2,321	81%
Research and development expenses	11,536	12,861	(1,325)	(10%)
Sales and marketing expenses	7,426	3,608	3,818	106%
General and administrative expenses	10,640	14,189	(3,549)	(25%)
Interest expense, net	(5,465)	(1,827)	3,638	199%
Bargain purchase gain		19,326	19,326	*
Foreign exchange (loss) gain, net	(226)	202	(428)	(212%)

* Percentage change is not meaningful.

Revenues. During the nine months ended September 30, 2011 and 2010, substantially all revenues recognized were from the sale of LODOTRA in Europe. Revenues increased by $1.1 million during the nine months ended September 30, 2011, compared to the same period in 2010, primarily due to $1.8 million of incremental LODOTRA product sales generated by our distribution partner, Mundipharma, beginning in 2011, offset by $0.7 million of lower sales to Merck Serono.

Cost of Goods Sold. Our cost of goods sold during the nine months ended September 30, 2011, compared to the same period in 2010, increased by $2.3 million primarily due to $1.1 million of incremental amortization of developed technology recognized in the 2011 period, and an increase of $1.0 million of cost of goods sold as a result of higher LODOTRA product sales generated by Mundipharma in 2011. We had no revenue or cost of goods sold prior to our acquisition of Nitec on April 1, 2010.

Research and Development Expenses. The decrease of $1.3 million in research and development expenses during the nine months ended September 30, 2011, compared to the same period in 2010, was primarily due to a decrease of $0.7 million of expenses related to regulatory and clinical activities and a decrease of $2.0 million for contract manufacturing and pharmacovigilance studies for DUEXIS. The decrease was partially offset by an increase of $1.5 million in personnel costs resulting from increased headcount to support DUEXIS development and regulatory activities and as a result of the Nitec acquisition.

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Sales and Marketing Expenses. The increase of $3.8 million in sales and marketing expenses during the nine months ended September 30, 2011, compared to the same period in 2010, was due to an increase of $2.6 million in personnel-related costs to establish sales and marketing capabilities to commercialize DUEXIS in the U.S., and due to the Nitec acquisition, and an increase of $2.1 million in consulting and advertising related expenditures associated with pre-commercialization activities for DUEXIS in the U.S. The increase was partially offset by a decrease of $0.8 million in spending associated with market research activities for DUEXIS and LODOTRA.

General and Administrative Expenses. The decrease of $3.5 million in general and administrative expenses during the nine months ended September 30, 2011, compared to the same period in 2010, was primarily due to a decrease of $3.0 million for acquisition-related expenses, which consisted of $1.1 million for investment banking fees and $1.9 million for legal and consulting fees, a decrease of $1.5 million for lower legal, audit and consulting fees following our IPO. The decrease was partially offset by an increase of $0.7 million in personnel-related costs and $0.4 million increase in facility-related costs in connection with the building of our corporate infrastructure.

Interest Expense, Net. The increase of $3.6 million in interest expense during the nine months ended September 30, 2011, compared to the same period in 2010, was due to $0.3 million of incremental interest expense under the Kreos facility and the Kreos-SVB facility, $1.9 million of interest expense related to the loss on extinguishment of the Kreos-SVB facility and a portion of the Kreos facility, $0.8 million interest expense related to the Oxford facility, and an increase of $0.7 million for interest expense related to the 2010 notes, the January 2011 notes, and the April 2011 notes.

Bargain Purchase Gain. The bargain purchase gain of $19.3 million was recognized during the nine months ended September 30, 2010 in connection with the Nitec acquisition as a result of the fair market value of the acquired tangible and intangible assets exceeding the purchase price. There was no bargain purchase gain recorded during the corresponding period in 2011.

Foreign Exchange (Loss) Gain, Net. The foreign exchange loss during the nine months ended September 30, 2011 was primarily a result of the increase in value of the U.S. dollar against the Euro in connection with remeasuring foreign currency transactions during the nine months ended September 30, 2011 as compared to the same period in 2010 during which we had a foreign exchange gain due to a decrease in the value of the U.S. dollar against the Euro.

Liquidity and Capital Resources

We have incurred losses since our inception in June 2005 and, as of September 30, 2011, we had an accumulated deficit of $143.6 million. We anticipate that we will continue to incur net losses for at least the next several years. We expect that our development, sales and marketing, and general and administrative expenses will continue to increase as a result of our acquisition of Nitec in April 2010, and our development and commercialization of DUEXIS and 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, 2011, we had $33.0 million in cash and cash equivalents.

On August 2, 2011, we completed our IPO and we sold 5,500,000 shares of common stock at a price of $9.00 per share. We received net proceeds of approximately $41.9 million from the initial public offering, net of underwriting discounts, commissions, and offering costs.

In connection with our acquisition of Nitec, we renegotiated the payment terms of Nitec s outstanding Kreos facility. The Kreos facility is secured by a lien on all of Horizon Pharma AG s trade receivables and intellectual property. The loan bears interest at 11.9% per annum. We were required to pay only interest on the Kreos facility through December 31, 2010 and are currently required to pay equal monthly installments of principal and interest through November 2013. In June 2011, in connection with the Oxford facility described below, we paid Kreos $1.4 million (1.0 million Euros) in exchange for Kreos consent to a partial assignment of the Kreos facility to Horizon Pharma, Inc. As a result, Horizon Pharma, Inc. is now a co-lender with Kreos to Horizon Pharma AG.

Through September 30, 2011, we have received net proceeds of $96.4 million from the issuance of convertible preferred stock as follows: in October 2005, we issued an aggregate of 1,192,118 shares of Series A convertible preferred stock at a purchase price of $5.075 per share, for net proceeds of approximately $6.0 million; in November 2006, we issued an aggregate of 1,482,213 shares of Series B convertible preferred stock at a purchase price of $10.12 per share, for net proceeds of approximately $14.9 million; in July 2007, we issued an aggregate of 2,109,706 shares of Series C convertible preferred stock at a purchase price of $14.22 per share, for net proceeds of approximately $29.9 million and in December 2009 and January 2010, we issued an aggregate of 4,978,674 shares of Series D convertible preferred stock at a purchase price of $5.201 per share, for net proceeds of approximately $25.8 million.

As of April 1, 2010, we recapitalized all of our outstanding shares of Series A, B, C and D convertible preferred stock, and converted those shares into a new Series A convertible preferred stock in connection with our recapitalization and acquisition of Nitec. We also concurrently completed a Series B convertible preferred stock financing in which we issued an aggregate of 2,510,040 shares of Series B convertible preferred stock at a purchase price of $7.968 per share, raising net proceeds of $19.8 million.

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In July 2010, January 2011 and April 2011, we issued the 2010 notes, the January 2011 notes and the April 2011 notes, respectively, to holders of our Series B convertible preferred stock in accordance with our Series B Preferred Stock and Convertible Note Purchase Agreement dated April 1, 2010. The 2010 notes, the January 2011 notes and the April 2011 notes converted into an aggregate of 2,017,242 shares of our common stock upon the closing of our IPO. Upon the closing of our IPO, all of the outstanding shares of our Series A and Series B convertible preferred stock converted into common stock and all of our outstanding warrants were adjusted and became exercisable for shares of our common stock.

In June 2011, we entered into the Oxford facility and borrowed the full $17.0 million available under this facility. The debt under the Oxford facility accrues interest at a fixed rate of 11.5% per annum, with interest only payments through June 1, 2012, followed by 36 equal monthly installments of principal and interest. The Oxford facility is secured by a lien on substantially all of our assets and those of Horizon Pharma USA, including intellectual property, but excluding the shares of Horizon Pharma AG. If we generate an annualized revenue run rate of at least $45.0 million over three consecutive months from DUEXIS product sales, the lien on the assets may be released with the consent of the lenders, provided we are not in default under the Oxford facility. With the loan proceeds, we repaid all $8.5 million due under the Kreos-SVB facility. We also paid Kreos $1.4 million (1.0 million Euros) and Horizon Pharma, Inc. assumed from Kreos a like amount of debt under the Kreos facility (becoming a co-lender with Kreos to Horizon Pharma AG), as partial consideration for Kreos consent to enter into the Oxford facility. The remaining loan proceeds of $6.9 million (net of $0.2 million loan fees) are being used to fund our operations.

The Oxford facility and the Kreos facility restrict 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 debt facilities, our lenders may accelerate all of our repayment obligations and take control of our pledged assets. Our lenders could declare a default under our debt facilities 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.

Cash in excess of our immediate requirements is either held as cash or in money market funds.

In addition, we must maintain compliance with 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. In June 2010, we took steps to address overindebtedness through a subordinated loan to our Swiss subsidiary. As of December 31, 2010 and September 30, 2011, our Swiss subsidiary continued to be overindebted and we are in the process of reviewing further steps to address the overindebtedness. We may need to continue taking steps to address overindebtedness until such time as our Swiss subsidiary generates positive income at a statutory level, which could cause us to have cash at our Swiss subsidiary in excess of its near term operating needs, including a portion of our net proceeds from our IPO, and could affect our ability to have sufficient cash at our U.S. subsidiary to meet its near term operating needs.

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2011	2010 As restated
Cash and cash equivalents	$ 32,997	$ 14,196
Cash provided by (used in):		
Operating activities	(26,939)	(29,402)
Investing activities	(699)	5,760
Financing activities	55,113	30,705

Net cash used in operating activities. During the nine months ended September 30, 2011 and 2010, our operating activities used cash of $26.9 million and $29.4 million, respectively. The use of cash in both periods primarily resulted from our net income (loss) and changes in our working capital accounts. The decrease in cash used in operations during the nine months ended September 30, 2011, as compared to September 30, 2010, was primarily due to decreases in general and administrative expenses related to investment banking fees and professional fees associated with the acquisition of Nitec, and legal, audit and consulting fees. Additionally, the decrease was partially attributable to lower regulatory and clinical activities, contract manufacturing and pharmacovigilance studies for DUEXIS.

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Net cash (used in) provided by investing activities. Net cash used in investing activities during the nine months ended September 30, 2011 was primarily related to the purchase of property and equipment. The cash provided by investing activities in the nine months ended September 30, 2010 was primarily due to $6.5 million of cash acquired in the Nitec acquisition.

Net cash provided by financing activities. Net cash provided by financing activities during the nine months ended September 30, 2011 was primarily attributable to the receipt of the net proceeds of $46.0 million from our IPO, $6.8 million proceeds from the issuance of the January 2011 notes and April 2011 notes, $16.7 million in net proceeds from the Oxford facility, net of repayments made on outstanding loan amounts of $12.7 million, and deferred financing expenses related to our IPO of $1.6 million. Net cash provided by financing activities in the nine months ended September 30, 2010 was primarily attributable to the gross proceeds from the issuance of Series B convertible preferred stock of $20.7 million, debt financing proceeds of $11.8 million, and proceeds from issuance of the 2010 notes to related parties of $10.0 million, net of repayments made on outstanding loan amounts of $9.9 million and deferred financing expenses related to our IPO of $1.9 million.

Operating Capital and Capital Expenditure Requirements

We have incurred net operating losses and negative cash flows from operations during every year since inception. These factors raise substantial doubt about our ability to continue as a going concern. In order to continue our operations, we must achieve profitable operations and/or obtain additional debt or equity financing. There can be no assurance, however, that such a financing will be successfully completed on terms acceptable to us or at all.

We are working toward our objective of realizing revenues and then profitability by commercializing DUEXIS in the U.S. and obtaining regulatory approval to commercialize LODOTRA in the U.S. The failure to successfully launch DUEXIS in the U.S. or to obtain regulatory approvals for DUEXIS in Europe and LODOTRA in the U.S. and to commercialize these products in a manner that maximizes our potential sales or at all could have a material adverse effect on our business, results of operations, future cash flows, financial condition and our ability to continue as a going concern.

We anticipate we will continue to incur net losses for at least the next several years as we incur expenses to build and maintain commercial capabilities and launch DUEXIS in the U.S., pursue the development and regulatory approval of DUEXIS in Europe and LODOTRA in the U.S. and expand our corporate infrastructure. We may not be able to launch and commercialize DUEXIS in the U.S. in an optimal manner if we do not have sufficient working capital and we may not be able to complete the development and initiate commercialization of these programs if, among other things, the MAA for DUEXIS or the NDA for LODOTRA are not approved when we expect, or at all.

We believe that our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations into the second quarter of 2012. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Our current cash and cash equivalents alone may not be sufficient to fund our operations through the successful commercialization of DUEXIS and development and commercialization of LODOTRA (if approved) in the U.S. or any other products we develop on our own or in-license. As a result, we may need to raise additional capital to fund our operations and to potentially conduct clinical trials to support regulatory approval of any other product candidates. To raise additional capital, we may seek to sell additional equity or debt securities or incur additional indebtedness. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may also seek funding through collaborations or other similar arrangements with third parties.

If we are unable to raise sufficient additional capital, we may need to substantially curtail our planned operations. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in Risk Factors.

Because of the numerous risks and uncertainties associated with development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the costs of establishing sales and marketing capabilities, the resources available to invest in these capabilities and the extent of our sales and marketing activities;

the cost and timing of our development and regulatory activities related to DUEXIS in Europe and LODOTRA in the U.S.;

whether we enter into co-promotion arrangements for DUEXIS in the U.S., and the timing and terms of such arrangements;

the costs under commercial manufacturing and supply arrangements for our products;

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the success of our commercialization efforts with respect to our products and the revenue we are able to generate from these efforts;

our ability to establish and maintain strategic collaborations, including out-licensing of marketing rights for product candidates for territories other than the U.S. and other arrangements; and

the costs involved in enforcing or defending patent claims or other intellectual property rights.

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 8, Commitments and Contingencies .

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, our only product that is currently commercialized, are principally denominated in Euros and therefore, until we derive material revenues from sales of DUEXIS and, if approved, LODOTRA, 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 Securities Exchange Act of 1934, as amended, or 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, 2011, the end of the period covered by this report.

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

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not a party to any material legal proceeding.

Item 1A. Risk Factors

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission.

Risks Related to Our Business and Industry

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

DUEXIS, LODOTRA and our other product candidates, if approved, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. We have not yet sold DUEXIS in any market and LODOTRA has only been sold in a limited number of European countries. Sales of LODOTRA in these markets have been limited to date and sales in Europe may not grow to expected levels, in part because we depend on our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for the commercialization of LODOTRA in these markets. 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;
- potential or perceived advantages or disadvantages of our products over alternative treatments, including cost of treatment and relative convenience and ease of administration;
- strength of sales, marketing and distribution support;
- the price of our products, both in absolute terms and relative to alternative treatments;

the effect of current and future healthcare laws;

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

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

With respect to DUEXIS, studies indicate that physicians do not commonly co-prescribe GI protective agents to high-risk patients taking NSAIDs. We believe this is due in part to a lack of awareness among physicians prescribing NSAIDs of the risk of NSAID-induced upper GI ulcers, in addition to the inconvenience of prescribing two separate medications and patient compliance issues associated with multiple prescriptions. If physicians remain unaware of, or do not otherwise believe in, the benefits of combining GI protective agents with NSAIDs, our market opportunity for DUEXIS will be limited. Some physicians may also be reluctant to prescribe DUEXIS due to the inability to vary the dose of ibuprofen or if they believe treatment with NSAIDs or GI protectants other than ibuprofen and famotidine, including those of our competitors, would be more effective for their patients. With respect to both DUEXIS and 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, LODOTRA or our other product candidates that are approved 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 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, if approved by the FDA, LODOTRA in the U.S. market. While we expect to commercially launch DUEXIS in the U.S. in November 2011 and have completed preparations for the launch, we currently do not have any experience commercializing pharmaceutical products on our own.

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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 or make arrangements with third parties to perform these services. We currently have limited resources and the establishment and development of our own commercial organization to market these products and any additional products we may develop will be expensive and time-consuming and could delay any product launch, and we cannot be certain that we will be able to successfully develop this capability. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. We also face competition in our search for potential co-promoters of our products. 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 develop 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 LODOTRA, and we may not be able to successfully commercialize these products or successfully obtain additional marketing approvals for DUEXIS in Europe or LODOTRA in the U.S.

To date, we have expended significant time, resources and effort on the development of DUEXIS and LODOTRA, and a substantial majority of our resources are now focused on planning for potential commercialization of DUEXIS in the U.S. and seeking additional marketing approvals for DUEXIS and LODOTRA. Our ability to generate significant product revenues in the near term will depend almost entirely on our ability to successfully commercialize DUEXIS and LODOTRA in the U.S., obtain European marketing approval for DUEXIS and obtain U.S. marketing approval for LODOTRA. 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. Although LODOTRA is approved for marketing in 16 European countries, to date it has only been marketed in a limited number of European countries. While we anticipate that LODOTRA will be marketed in additional European countries as our distribution partner, Mundipharma, formulates its reimbursement strategy, the ability to market LODOTRA in additional European countries will depend on Mundipharma s ability to obtain regulatory and 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 partners, over which we have no control. LODOTRA is not approved for marketing in the U.S., which we believe represents its largest commercial opportunity. Before we can market and sell these products in a particular jurisdiction, we will 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 will obtain any additional regulatory approvals for our products. Even if we 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 LODOTRA, 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 products and product candidates are subject to extensive regulation, and we may not obtain additional regulatory approvals for DUEXIS or 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.

We are not permitted to market LODOTRA or any of our other product candidates in the U.S. until we obtain regulatory approval from the FDA. To market a new drug in the U.S., we must submit to the FDA and obtain FDA approval of a new drug application, or NDA. To market a new drug in Europe, we must submit to the applicable regulatory authority in the designated Reference Member State and obtain approval of, a Marketing Authorization Application, or MAA. An NDA or MAA 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.

Regulatory approval of an NDA or an MAA is not guaranteed. The number and types of preclinical studies and clinical trials that will be required for NDA or MAA 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. The FDA and similar foreign 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;

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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.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is 10 months for a standard application and six months for a priority review application. The FDA s review goals are subject to change, and it is unknown whether the review of an NDA filing for any of our product candidates will be completed within the FDA s review goals or will be delayed. Moreover, the duration of the FDA s review may depend on the number and types of other NDAs that are submitted to the FDA around the same time period.

In October 2010, we submitted an MAA for DUEXIS in the United Kingdom, the Reference Member State, through the Decentralized Procedure. In connection with our MAA for DUEXIS, and consistent with an identical request we made in our NDA for DUEXIS, we are requesting the Medicines and Healthcare products Regulatory Agency in the United Kingdom 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 continue to complete CMC studies with the new formulation, and we cannot assure you 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.

Even though we submitted the NDA for LODOTRA to the FDA on September 26, 2011, with the exception of our recently approved DUEXIS NDA, we have never obtained FDA approval for any drug other than DUEXIS. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for LODOTRA or our other product candidates. 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 the FDA or any other U.S. or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. In addition, the FDA s regulatory review of NDAs for product candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. 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.

To market any drugs outside of the U.S., we and current or future collaborators must comply with numerous and varying regulatory 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, including the risk that our product candidates may not be approved for all indications requested and that such approval may be

subject to limitations on the indicated uses for which the drug may be marketed. 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.

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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. Moreover, we have only two products approved for commercial sale. LODOTRA has only been approved in select countries within Europe, 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 no revenues for DUEXIS to date. 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 may not realize the benefits we expected from our recapitalization and acquisition of Nitec.

In April 2010, we completed our recapitalization and acquisition of Nitec pursuant to which Horizon Pharma USA and Horizon Pharma AG became our wholly-owned subsidiaries. The integration of the businesses of our subsidiaries continues to be complex, time-consuming and expensive and may cause disruptions in the combined business. We will need to overcome significant challenges in order to realize any benefits or synergies from the acquisition of Nitec. These challenges include the timely, efficient and successful execution of a number of tasks, including the following:

- integrating the business, operations and technologies of the companies;
- managing the regulatory and reimbursement approval processes, intellectual property protection strategies and commercialization activities of the companies, including compliance with the laws of a number of different jurisdictions;
- retaining strategic partners of each company and attracting new strategic partners;
- creating uniform standards, controls, procedures, policies and information systems, including with respect to disclosure controls and procedures and internal control over financial reporting;
- managing international operations; and
- meeting the challenges inherent in efficiently managing an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits and compliance programs.

Many of these challenges are exacerbated by the fact that Horizon Pharma USA is a U.S.-based company and Horizon Pharma AG is a company based in Switzerland, with most of its European operations occurring through its subsidiary, Horizon Pharma GmbH, in Germany.

We may encounter difficulties successfully managing a substantially larger and internationally diverse organization and may encounter significant delays in achieving successful management of our organization. Integration of our subsidiaries operations has involved considerable risks and may not be successful. These risks include the following:

the potential disruption of ongoing business and distraction of our management;

the potential strain on our financial and managerial controls and reporting systems and procedures;

our inability to manage the research and development, regulatory and reimbursement approval, both in the U.S. and in Europe, and commercialization activities of our subsidiaries;

unanticipated expenses and potential delays related to integration of the operations, technology and other resources of two subsidiaries;

the impairment of relationships with employees and suppliers as a result of any integration of new management personnel or other activities;

greater than anticipated costs and expenses related to the integration of our subsidiaries businesses; and

potential unknown liabilities associated with the strategic combination and the combined operations.

We may not succeed in addressing these risks or any other problems encountered in connection with the integration of our subsidiaries businesses. The inability to integrate successfully the operations, technology and personnel of our businesses, or any significant delay in achieving integration, could have a material adverse effect on our business, results of operations and prospects, and on the market price of our common stock.

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

As of December 31, 2010, we employed 41 full-time employees as a consolidated entity. In anticipation of the commercial launch of DUEXIS, we hired 80 sales representatives during the period from September 2011 through October 2011. Our management, personnel, systems and facilities currently in place may not be adequate to support this recent growth, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses. As of November 7, 2011, we employed 161 full-time employees as a consolidated entity.

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:

- manage the NDA review process for LODOTRA and the MAA review process for DUEXIS;
- build or retain through a third party an appropriate commercial organization and manage the sales and marketing efforts for DUEXIS and LODOTRA, subject to receipt of applicable regulatory approvals;
- enhance our operational, financial and management controls, reporting systems and procedures;
- expand our international resources;
- successfully identify, recruit, hire, train, maintain, motivate and integrate additional employees;
- establish and increase our access to commercial supplies of our products and product candidates;
- expand our facilities and equipment; and
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators, distributors and other third parties.

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

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

As DUEXIS is a newly approved drug, none of the members of our sales force has ever promoted DUEXIS. 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. In addition, we must train our sales force to ensure that a consistent and appropriate message about DUEXIS is being delivered to our potential customers. 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 its proper administration, our efforts to successfully commercialize DUEXIS 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 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. In addition, DUEXIS 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. 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.

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We expect 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 LODOTRA s principal competition will be prednisone, the active pharmaceutical ingredient in LODOTRA, or other oral corticosteriods, which, while they may be suboptimal, are or are expected to be less expensive than 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 LODOTRA. We will not successfully execute on our business objectives if the market acceptance of DUEXIS or LODOTRA is inhibited by price competition, if physicians are reluctant to switch from existing products to DUEXIS or LODOTRA, or if physicians switch to other new products or choose to reserve DUEXIS or 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 drug discovery and development to:

- discover and develop medicines that are superior to other products in the market;
- attract qualified scientific, product development 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;

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 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;

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- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the 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 Senior Vice President, Marketing and Business Development, Todd Smith and our Senior Vice President, Sales and Managed Care, 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.

Our scientific team in particular has expertise in many different aspects of drug discovery, development and commercialization, and may be difficult to retain or replace. We conduct our operations at our facilities in Deerfield, Illinois, Reinach, Switzerland and Mannheim, Germany and may face challenges recruiting personnel to these geographic locales. Moreover, these regions are headquarters to many other biopharmaceutical companies and many academic and research institutions and therefore we face increased competition for personnel in those geographies. Competition for skilled personnel in our markets is very intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms.

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. T he loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. We do not maintain key man insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior sales and marketing and scientific and medical personnel.

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

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

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

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We are, with respect to DUEXIS, and 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, LODOTRA and 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, 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 or the imposition of civil or criminal penalties.

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.

Reimbursement may not be available, or may be available at only limited levels, for DUEXIS, LODOTRA or any other product candidates that we develop, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of DUEXIS, LODOTRA or any other product candidates that we may develop 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. In particular, in the U.S., private health insurers and other third-party payers often provide reimbursement for treatments based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the U.S., the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the U.S. and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

In Europe, the success of our products, including LODOTRA and, if approved, DUEXIS, will depend largely on obtaining and maintaining government reimbursement, because in many European countries patients are unlikely to use prescription drugs that are not reimbursed by their governments. To date, LODOTRA is approved in 16 European countries and Israel and reimbursement for LODOTRA has been obtained in Germany and Italy. Mundipharma is seeking reimbursement in a number of countries in Europe and Israel and currently sells LODOTRA without reimbursed pricing in a limited number of European countries. Negotiating prices with governmental authorities can delay commercialization by 12 months or more. 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 expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently,

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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 reimbursement policies of governments and third-party payers, we cannot be sure that 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 reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize DUEXIS, 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;

- new requirements to report certain financial arrangements with physicians, including reporting any transfer of value made or distributed to prescribers and other healthcare providers, effective March 30, 2013, and reporting any investment interests held by physicians and their immediate family members during the preceding calendar year;

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

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.

We anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we 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, LODOTRA and any other products that we may develop, 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 LODOTRA or any other product candidates that we may develop. 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.

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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 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 education 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.

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 the marketing and promotion of pharmaceutical products and report gifts to individual physicians in the states. Other states 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.

We rely on third parties to manufacture commercial supplies of DUEXIS and 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.

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 Pharmaceutics International, Inc., located in Hunt Valley, Maryland, and sanofi-aventis U.S. LLC, or Sanofi, and operating through its affiliate sanofi-aventis Canada, located in Laval, Canada for production of DUEXIS, and Jagotec AG, a wholly-owned subsidiary of SkyePharma PLC and operating through its affiliate SkyePharma SAS, located in Lyon, France, for production of LODOTRA. In July 2011, Valeant Pharmaceuticals International, Inc., or Valeant, announced that it was acquiring the Dermik dermatology unit of Sanofi, which includes the Laval, Canada site. In August 2011, SkyePharma announced that Aenova France SAS would be taking over management and operations at the Lyon, France facility, and would supply products to SkyePharma and its affiliates so

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that they may continue to comply with their third party manufacturing agreements. 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 LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China. 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 for the manufacture of DUEXIS. In July 2011, Valeant announced it was acquiring the Dermik dermatology unit of Sanofi, which includes the Laval, Canada site.

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 either we or Sanofi 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 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 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, LODOTRA or any other product candidates for distribution. Consequently, we have entered into an agreement with Temmler Werke GmbH for packaging of LODOTRA in 16 European countries and in the U.S. if LODOTRA is approved by the FDA, as well as any additional countries as may be agreed to by the parties. If we obtain marketing approval from the applicable regulatory authorities including the FDA, we intend to sell drug product finished and packaged by either Temmler Werke GmbH or an alternate packager. Sanofi-aventis Canada will manufacture and supply 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 launch DUEXIS and LODOTRA 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 LODOTRA will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

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Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

We are dependent on Mundipharma to commercialize LODOTRA in Europe and certain Asian 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 and other countries. We have limited contractual rights to force Mundipharma to invest significantly in commercialization of LODOTRA in its markets. In the event that Mundipharma or any other third party with any future commercialization rights to any of our products or product candidates fails to adequately commercialize those products or product candidates because it lacks adequate financial or other resources, decides to focus on other initiatives or otherwise, our ability to successfully commercialize our products or product candidates in the applicable jurisdictions would be limited, which would adversely affect our business, financial condition, results of operations and prospects. We also rely on Mundipharma s ability to obtain regulatory approval for LODOTRA in certain Asian 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.

DUEXIS, 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.

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 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 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, 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 LODOTRA, our ability to generate significant revenues from the sale of these products would be significantly harmed.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, 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 and anticipate that we may enter into other such agreements in the future regarding our 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 GCPs. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with

applicable GCP 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 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.

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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 clinical trial for LODOTRA for the potential treatment of polymyalgia rheumatica, or PMR, which we expect will be a Phase 3 clinical trial. 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 for LODOTRA for the treatment of PMR will be delayed, and our business prospects would be harmed. While we have the right to use any data resulting from the planned clinical trial, we may not own the results from the trial, which could make it more difficult to pursue the development of LODOTRA as a treatment for PMR on our own.

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 our 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 LODOTRA or we conduct clinical development of our earlier stage product candidates or additional indications for LODOTRA, we may experience delays in these clinical trials. We are in the process of investigating LODOTRA through an investigator-initiated Phase 2 study as a potential treatment for PMR and pursuant to a March 2011 letter agreement, Mundipharma has agreed to conduct a separate clinical trial for LODOTRA in this indication, which we expect will be a Phase 3 clinical trial. Additionally, we have a pipeline of earlier stage product candidates to treat pain-related diseases and plan to investigate 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 NSAID-induced upper GI ulcers in patients with mild to moderate pain and arthritis who require the use of naproxen. We do not know whether any additional clinical trials will be initiated, 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.

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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.

The FDA may not ultimately approve our proposed trade names for our product candidates.

Any trade names that we intend to use for our product candidates must be approved by the FDA irrespective of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or PTO. The FDA conducts a rigorous review of proposed product names and may reject a proposed product name for a variety of reasons, including if it believes that the name inappropriately implies medical claims or if it poses the potential for confusion with other product names. Although we utilize the name LODOTRA in Europe, the FDA has rejected our usage of this product name in the U.S. and, if approved, LODOTRA will be sold under another name in the U.S., losing in the U.S. market the benefit of any brand equity it may develop in Europe. In addition, if the FDA determines that the trade names of other product candidates that are approved prior to the approval of our product candidates may present a risk of confusion with any of our proposed trade names, the FDA may not ultimately approve those proposed trade names. If the FDA does not approve any of our proposed product names prior to their applicable NDA approval dates, we may be required to launch commercial sales of such products without brand names, and our efforts to build successful brand identities for, and commercialize, such products may consequently be adversely impacted.

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 and commercialize a portfolio of other product candidates in addition to DUEXIS and 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 or in-license 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 or licensing promising product candidates requires substantial technical, financial and human resources and technical expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management s time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects will be limited.

Moreover, any product candidate we identify, select and acquire or license 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 are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

In addition, if we fail to successfully commercialize and further develop DUEXIS and 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 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

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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 Hunt Valley, Maryland, Laval, Quebec, Canada, St. Louis, Missouri and Lyon, France, to produce our products. Our ability to obtain commercial supplies of our products could be disrupted, and our results of operations and financial condition could be materially and adversely affected if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The ultimate impact of such events on us, our significant suppliers and our general infrastructure is unknown.

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

We face an inherent risk of product liability as a result of the commercial sales of LODOTRA and the clinical testing of our product candidates, and will face an even greater risk if we commercialize DUEXIS and LODOTRA in the U.S. or other additional jurisdictions or if we engage in the clinical testing of new product candidates or commercialize any additional products. 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;

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

loss of revenue;

exhaustion of any available insurance and our capital resources;

the inability to commercialize our products or product candidates; and

a decline in our stock price.

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 LODOTRA in

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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 $36.5 million for the nine months ended September 30, 2011 and net losses of $27.1 million, $20.5 million and $27.9 million for the years ended December 31, 2010, 2009 and 2008, respectively. Nitec had a net loss of CHF 25.9 million ($24.8 million) for the nine months ended March 31, 2010, and a net loss of CHF 22.1 million ($19.7 million) for the year ended June 30, 2009. On a pro forma basis giving effect to the acquisition of Nitec, we would have had a net loss of $38.4 million for the year ended December 31, 2010. As of September 30, 2011, we had an accumulated deficit of $143.6 million. Before our acquisition of Nitec, as of March 31, 2010, we had an accumulated deficit of $87.9 million and Nitec had an accumulated deficit of CHF 65.8 million ($61.7 million). We do not know whether or when we will become profitable. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders deficit and working capital. Our losses have resulted principally from costs incurred in our development activities for our products and product candidates. We anticipate that our operating losses will substantially increase over the next several years as we execute our plan to expand our development and commercialization activities, including the planned commercialization of DUEXIS and LODOTRA, and as we transition into operating as a public company.

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Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements.

Our report from our independent registered public accounting firm for the year ended December 31, 2010 includes an explanatory paragraph stating that our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and it is likely that investors will lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

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 do not anticipate generating revenues from sales of DUEXIS until late 2011 or 2012 following the expected commercial launch in the U.S. in November 2011. LODOTRA is approved for marketing in Europe, and to date we have generated only limited revenues from sales of LODOTRA. We may never be able to successfully commercialize DUEXIS or develop or commercialize other products or sell LODOTRA in the U.S., which we believe represents its most significant commercial opportunity, or sell DUEXIS in Europe. Our ability to generate future revenues depends heavily on our success in:

- commercializing DUEXIS, LODOTRA and any other product candidates for which we obtain approval;
- securing U.S. and additional foreign regulatory approvals for LODOTRA and foreign regulatory approvals for DUEXIS; and
- developing and commercializing a portfolio of other product candidates in addition to DUEXIS and 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 debt facilities place restrictions on our operating and financial flexibility, and if we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In April 2010, we amended an existing debt facility between Kreos Capital III (UK) Limited, or Kreos, and Nitec, which we refer to as the Kreos facility, to permit us to acquire Nitec and to enter into another debt facility. The loans under this facility are currently payable in equal monthly installments of principal and interest through November 2013. The Kreos facility is secured by a lien on trade receivables and intellectual property.

In June 2011, we entered into a $17.0 million debt facility with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, which we refer to as the Oxford facility, and concurrently borrowed the full $17.0 million under this facility, of which $8.5 million was used to repay an existing debt facility in its entirety, and $1.4 million was used to pay Kreos for a partial assignment of the Kreos facility from Kreos to Horizon Pharma, Inc. Immediately following the partial assignment, the outstanding principal balance of the Kreos facility was approximately $3.9 million. The outstanding principal balance under the Oxford facility accrues interest at a fixed rate of 11.5% per annum, with interest only payments through June 1, 2012 followed by 36 equal monthly installments of principal and interest. The Oxford facility is secured by a lien on substantially all of our assets and those of Horizon Pharma USA, including intellectual property, but excluding the shares of Horizon Pharma AG. If we generate an annualized revenue run rate of no less than $45.0 million over three consecutive months from DUEXIS product sales, the lien on the assets may be released with the consent of the lenders, provided we are not in default under the Oxford facility.

The Oxford facility and the Kreos facility restrict 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. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. In addition, if we default under our debt facilities, 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 debt facilities 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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If we fail to obtain additional financing, we may be unable to successfully commercialize or further develop DUEXIS and 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, if approved, LODOTRA in the U.S., including building our own sales force in the U.S.;
- complete the regulatory approval process, and any future required clinical development related thereto, for DUEXIS and LODOTRA;
- launch and commercialize any other product candidates for which we obtain regulatory approval; and
- continue our research and development programs to advance our product pipeline in the future, including future clinical trials with respect to LODOTRA for additional indications.

We believe that our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations into the second quarter of 2012. We may need to raise additional funds sooner if we choose to expand our commercialization or development efforts more rapidly than we presently anticipate. We will also require additional capital if the FDA requires us to conduct additional clinical trials with respect to LODOTRA.

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.

Our report from our independent registered public accounting firm for the year ended December 31, 2010 includes an explanatory paragraph stating that our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain additional financing on commercially reasonable terms, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment.

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. Our Swiss subsidiary was overindebted as of September 30, 2011 and we are in the process of reviewing steps to address the overindebtedness. In order to comply with these laws, we may be required to have cash at our Swiss subsidiary in excess of its near term operating needs and could limit the amount of cash available to our U.S. subsidiary. If we are unable to allocate sufficient cash to our U.S. subsidiary, even if we have sufficient cash on a consolidated basis, our ability to execute our U.S. business plan may be harmed.

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.

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We have broad discretion in the use of our cash and may not use it effectively.

Our management has broad discretion in the application of our cash, and investors will be relying on the judgment of our management regarding the use of our cash. Our management may not apply our cash in ways that ultimately increase the value of any investment in our securities. We expect to use our existing cash to fund U.S. commercialization activities for DUEXIS and pre-commercialization activities for LODOTRA, to fund additional regulatory approvals of DUEXIS and LODOTRA, to fund development of 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.

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 $31.8 million, $18.1 million, $18.1 million and $16.9 million for 2011, 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. 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, 2011, we had $33.0 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, 2011, 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, 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

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prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in DUEXIS and LODOTRA have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. 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 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 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 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.

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 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

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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 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 LODOTRA.

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

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

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

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

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

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in

abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent

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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 is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this Risk Factors section and elsewhere in this prospectus, these factors include:

- our failure to successfully execute our commercialization strategy with respect to our approved products, particularly our planned commercial launch of DUEXIS in the U.S.;
- any adverse development or perceived adverse development with respect to the FDA s review of our LODOTRA NDA or the Medicines and Healthcare products Regulatory Agency s review of our MAA for DUEXIS filed in the European Union through the Decentralized Procedure;
- 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, LODOTRA or any of our other product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our products or product candidates, including but not limited to clinical trial requirements for approvals;

inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;

developments concerning our commercial partners, including but not limited to those with our sources of manufacturing supply;

our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

adverse results or delays in clinical trials;

our failure to successfully develop 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 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;

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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 debt facilities, 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 directors and principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Immediately upon completion of our initial public offering, our directors, five percent or greater stockholders and their respective affiliates held in the aggregate approximately 61.7% of our outstanding voting stock (assuming no exercise of the underwriters overallotment option). Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or 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.

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 Securities and Exchange Commission, or 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.

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

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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 after the lock-up and other legal restrictions on resale lapse, the trading price of our common stock could decline. Upon completion of our initial public offering, we had outstanding a total of 19,527,951 shares of common stock, assuming no exercise of the underwriters overallotment option and no exercise of outstanding options and warrants. Of these shares, only certain of the shares of common stock sold by us in our initial public offering are or will be freely tradable, without restriction, in the public market. Our underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

We expect that the lock-up agreements pertaining to our initial public offering will expire 180 days from August 2, 2011, the closing date of our initial public offering (subject to extension upon the occurrence of specified events). After the lock-up agreements expire, up to an additional 13,646,982 shares of common stock will be 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 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements 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, subject to the 180-day lock-up agreements described above. 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 significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in subsequent transactions, our existing stockholders may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our 2011 equity incentive plan, 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 equity incentive plan 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. 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.

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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.

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

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-168504) that was declared effective by the Securities and Exchange Commission on July 28, 2011, which registered $75.9 million worth of shares of our common stock. On August 2, 2011, we sold 5,500,000 shares of common stock at an initial public offering price of $9.00 per share, for aggregate gross proceeds of $49.5 million. Of the net proceeds, as of September 30, 2011, we had used $13.7 million for working capital and general corporate expenses. The remainder of net proceeds has been invested in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government in accordance with our investment policy. We expect our use of the net proceeds from the IPO will conform to the intended use of proceeds as described in the final prospectus for the offering filed with the SEC pursuant to Rule 424(b).

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Item 6. 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 Kreos Capital III Limited.
4.8(1)	Warrant issued by Horizon Pharma, Inc. on April 1, 2010 to Kreos Capital III Limited.
4.9(1)	Warrant issued by Horizon Pharma, Inc. on April 1, 2010 to Silicon Valley Bank.
4.10(1)	Investors Rights Agreement, dated April 1, 2010, by and among Horizon Pharma, Inc. and certain of its stockholders.
4.11(1)	Form of Warrant issued by Horizon Pharma, Inc. on June 2, 2011 to Oxford Finance LLC.
4.12(1)	Warrant issued by Horizon Pharma, Inc. on June 2, 2011 to Silicon Valley Bank.
4.13(1)	Warrant issued by Horizon Pharma, Inc. on June 2, 2011 to Kreos Capital III Limited.
4.14(1)	Conversion and Amendment Agreement, dated June 16, 2011, by and among Horizon Pharma, Inc. and certain of its stockholders.
10.1*	Standard Office Lease, effective August 31, 2011, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.
10.2	Consent and First Loan Modification Agreement, dated August 17, 2011, by and among Horizon Pharma USA, Inc., Horizon Pharma, Inc., Horizon Pharma (UK) Limited and Oxford Finance LLC.
10.3	Second Loan Modification Agreement, dated October 7, 2011, by and among Horizon Pharma USA, Inc., Horizon Pharma, Inc., Horizon Pharma (UK) Limited and Oxford Finance LLC.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

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

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

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SIGNATURE

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

HORIZON PHARMA, INC.

Date: November 14, 2011

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

(Principal Financial Officer)