HORIZON PHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

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

520 Lake Cook Road, Suite 520
Deerfield, Illinois
(Address of principal executive offices)

60015
(Zip Code)

(224) 383-3000
(Registrant's telephone number, including area code)

Number of shares of registrant’s common stock, par value $0.0001, outstanding as of August 7, 2012: 33,787,180.
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# PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

**HORIZON PHARMA, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**(UNAUDITED)**

(In thousands, except share data)

<table>
<thead>
<tr>
<th></th>
<th>As of June 30, 2012</th>
<th>December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSETS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CURRENT ASSETS:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$ 63,460</td>
<td>$ 17,966</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>750</td>
<td>750</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>622</td>
<td>2,372</td>
</tr>
<tr>
<td>Inventories, net</td>
<td>3,157</td>
<td>1,195</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>4,401</td>
<td>2,763</td>
</tr>
<tr>
<td>Total current assets</td>
<td>$ 72,390</td>
<td>$ 25,046</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>3,804</td>
<td>3,245</td>
</tr>
<tr>
<td>Developed technology, net</td>
<td>32,893</td>
<td>35,602</td>
</tr>
<tr>
<td>In-process research and development</td>
<td>35,586</td>
<td>36,638</td>
</tr>
<tr>
<td>Other assets</td>
<td>4,079</td>
<td>547</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>$ 148,752</td>
<td>$ 101,078</td>
</tr>
</tbody>
</table>

| LIABILITIES AND STOCKHOLDERS' EQUITY |                     |                   |
| CURRENT LIABILITIES:                |                     |                   |
| Accounts payable                    | $ 7,890             | $ 8,170           |
| Accrued expenses                    | 11,149              | 8,926             |
| Deferred revenues-current portion   | 3,608               | 3,281             |
| Notes payable-current portion       | 3,978               | 3,604             |
| Total current liabilities           | $ 26,625            | $ 23,981          |
| Notes payable, net of debt discount | 47,141             | 15,834            |
| Deferred revenues, net of current   | 8,044               | 5,666             |
| Deferred tax liabilities, net       | 8,948               | 9,561             |
| Other long term liabilities         | 121                 | 124               |
| **TOTAL LIABILITIES**               | $ 90,879            | $ 55,166          |

**COMMITMENTS AND CONTINGENCIES**

**STOCKHOLDERS' EQUITY:**

- Common stock, $0.0001 par value; 200,000,000 shares authorized; 33,746,493 and 19,627,744 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively
- Additional paid-in capital
- Accumulated other comprehensive loss
- Accumulated deficit
- Total stockholders' equity

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</strong></td>
<td>$ 148,752</td>
<td>$ 101,078</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these condensed consolidated financial statements.
HORIZON PHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands, except share and per share data)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>REVENUES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sale of goods</td>
<td>$ 4,556</td>
<td>$ 1,294</td>
</tr>
<tr>
<td>Contract revenue</td>
<td>52</td>
<td>41</td>
</tr>
<tr>
<td><strong>Gross sales</strong></td>
<td>4,608</td>
<td>1,335</td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(767)</td>
<td>(1,152)</td>
</tr>
<tr>
<td><strong>Net sales</strong></td>
<td>3,841</td>
<td>1,335</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>2,855</td>
<td>2,104</td>
</tr>
<tr>
<td><strong>Gross profit (loss)</strong></td>
<td>986</td>
<td>(769)</td>
</tr>
<tr>
<td><strong>OPERATING EXPENSES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>4,233</td>
<td>3,462</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>10,543</td>
<td>1,169</td>
</tr>
<tr>
<td>General and administrative</td>
<td>4,555</td>
<td>3,348</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td>19,331</td>
<td>7,979</td>
</tr>
<tr>
<td><strong>Operating loss</strong></td>
<td>(18,345)</td>
<td>(8,748)</td>
</tr>
<tr>
<td><strong>OTHER (EXPENSE) INCOME, NET:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(3,191)</td>
<td>(3,185)</td>
</tr>
<tr>
<td>Foreign exchange (loss) gain</td>
<td>(1,401)</td>
<td>110</td>
</tr>
<tr>
<td>Other expense</td>
<td>(4)</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total other expense, net</strong></td>
<td>(4,596)</td>
<td>(3,075)</td>
</tr>
<tr>
<td><strong>Loss before benefit for income taxes</strong></td>
<td>(22,941)</td>
<td>(11,823)</td>
</tr>
<tr>
<td><strong>BENEFIT FOR INCOME TAXES</strong></td>
<td>(159)</td>
<td>(186)</td>
</tr>
<tr>
<td><strong>NET LOSS</strong></td>
<td>$ (22,782)</td>
<td>$ (11,637)</td>
</tr>
<tr>
<td><strong>NET LOSS PER COMMON SHARE - Basic and diluted</strong></td>
<td>$ (0.68)</td>
<td>$ (7.78)</td>
</tr>
<tr>
<td><strong>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING - Basic and diluted</strong></td>
<td>33,715,703</td>
<td>1,496,278</td>
</tr>
<tr>
<td><strong>OTHER COMPREHENSIVE (LOSS) INCOME, NET OF TAX</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign currency translation adjustments</td>
<td>(832)</td>
<td>2,348</td>
</tr>
<tr>
<td>Other comprehensive (loss) income</td>
<td>(832)</td>
<td>2,348</td>
</tr>
<tr>
<td><strong>COMPREHENSIVE LOSS</strong></td>
<td>$ (23,614)</td>
<td>$ (9,289)</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these condensed consolidated financial statements.
HORIZON PHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(In thousands)

<table>
<thead>
<tr>
<th>Snyder</th>
<th>Six Months Ended June 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2012</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM OPERATING ACTIVITIES:</strong></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (46,508)</td>
</tr>
<tr>
<td><strong>Adjustments to reconcile net loss to net cash used in operating activities:</strong></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization expense</td>
<td>2,140</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>2,490</td>
</tr>
<tr>
<td>Non-cash interest expense</td>
<td>1,169</td>
</tr>
<tr>
<td>Paid in kind interest expense</td>
<td>1,079</td>
</tr>
<tr>
<td>Foreign exchange loss (gain)</td>
<td>900</td>
</tr>
<tr>
<td>Loss on disposal of assets</td>
<td>68</td>
</tr>
<tr>
<td>Changes in operating assets and liabilities:</td>
<td></td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>1,751</td>
</tr>
<tr>
<td>Inventories</td>
<td>(2,001)</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>(1,631)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>(255)</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>1,527</td>
</tr>
<tr>
<td>Deferred revenues</td>
<td>2,973</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>(349)</td>
</tr>
<tr>
<td>Net cash used in operating activities</td>
<td>(36,647)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM INVESTING ACTIVITIES:</strong></td>
<td></td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td>(1,043)</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>(1,043)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM FINANCING ACTIVITIES:</strong></td>
<td></td>
</tr>
<tr>
<td>Proceeds from issuance of notes payable, net of issuance costs</td>
<td>55,578</td>
</tr>
<tr>
<td>Proceeds from private equity offering, net of issuance costs</td>
<td>47,475</td>
</tr>
<tr>
<td>Repayment of notes payable</td>
<td>(19,814)</td>
</tr>
<tr>
<td>Proceeds from issuance of common stock</td>
<td>147</td>
</tr>
<tr>
<td>Proceeds from issuance of bridge notes payable to related parties</td>
<td>—</td>
</tr>
<tr>
<td>Deferred financing expenses</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from stock option exercises</td>
<td>—</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>83,386</td>
</tr>
<tr>
<td>Effect of foreign exchange rate changes on cash and cash equivalents</td>
<td>(202)</td>
</tr>
<tr>
<td><strong>NET INCREASE IN CASH AND CASH EQUIVALENTS</strong></td>
<td>45,494</td>
</tr>
<tr>
<td><strong>CASH AND CASH EQUIVALENTS, beginning of the period</strong></td>
<td>17,966</td>
</tr>
<tr>
<td><strong>CASH AND CASH EQUIVALENTS, end of the period</strong></td>
<td>$ 63,460</td>
</tr>
</tbody>
</table>

**Supplemental cash flow information:**

<table>
<thead>
<tr>
<th>Description</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash paid for interest</td>
<td>$ 3,932</td>
<td>$ 1,290</td>
</tr>
<tr>
<td>Cash paid for income taxes</td>
<td>28</td>
<td>25</td>
</tr>
<tr>
<td>Commitment fee paid on notes payable</td>
<td>600</td>
<td>170</td>
</tr>
</tbody>
</table>

**Supplemental non-cash flow information:**

<table>
<thead>
<tr>
<th>Description</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment in kind incremental borrowings</td>
<td>$ 333</td>
<td>$ —</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these condensed consolidated financial statements.
NOTE 1 – BASIS OF PRESENTATION

The unaudited condensed consolidated financial statements presented herein have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, all adjustments, including normal recurring adjustments, considered necessary for a fair statement of the financial statements have been included. Operating results for the three and six months ended June 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. The December 31, 2011 consolidated balance sheets were derived from audited financial statements, but do not include all disclosures required by GAAP. The unaudited condensed consolidated financial statements presented herein include the accounts of Horizon Pharma, Inc. (the “Company”) and its wholly-owned subsidiaries. All inter-company transactions and balances have been eliminated.

Condensed Consolidated Statements of Comprehensive Loss Revision

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

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended March 31, 2012</th>
<th>As Presented</th>
<th>As Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross sales</td>
<td>$2,669</td>
<td>$2,854</td>
<td></td>
</tr>
<tr>
<td>Add: Contract revenue</td>
<td>53</td>
<td>53</td>
<td></td>
</tr>
<tr>
<td>Less: Sales discounts and allowances</td>
<td>(199)</td>
<td>(384)</td>
<td></td>
</tr>
<tr>
<td>Net sales</td>
<td>$2,523</td>
<td>$2,523</td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$(23,726)</td>
<td>$(23,726)</td>
<td></td>
</tr>
</tbody>
</table>

Business Overview

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

The Company is a biopharmaceutical company that is developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases. On April 23, 2011, the U.S. Food and Drug Administration (“FDA”) approved DUEXIS®, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis (“RA”) and osteoarthritis and to decrease the risk of
The Company’s second product, RAYOS®, known as LODOTRA® outside the U.S., is a proprietary delayed 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, particularly when accompanied by morning stiffness. In addition, the Company has granted to Mundipharma commercialization rights to LODOTRA® in Asia and Latin America. On July 26, 2012, the FDA approved RAYOS for the treatment of a broad range of diseases, including RA, polymyalgia rheumatica (“PMR”), psoriatic arthritis (“PsA”), ankylosing spondylitis (“AS”), asthma and chronic obstructive pulmonary disease (“COPD”). The Company anticipates the launch of RAYOS in the United States in the fourth quarter of 2012. The Company’s strategy is to commercialize its products in the U.S. and to enter into licensing or additional distribution agreements for commercialization of its products outside the U.S.

On 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 the condensed consolidated financial statements and these notes, have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

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

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

The accompanying unaudited condensed consolidated financial statements are prepared on a going concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business. As of June 30, 2012, the Company had cash and cash equivalents totaling $63,460. The Company believes that it has sufficient liquidity and capital resources to operate into the first half of 2013. However, the Company is highly dependent in the near term on the commercial success of DUEXIS in the U.S. market, where it was only recently launched, and has insufficient commercial operating history to accurately predict its future performance. In February 2012, the Company entered into a $60,000 loan facility with a group of institutional investors (“Senior Secured Loan”) which includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end, beginning in the second quarter of 2012. As of June 30, 2012, the Company was in compliance with all financial loan covenants pursuant to the Senior Secured Loan. Should the Company not meet these quarterly minimum revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. The Company also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if the Company was unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on the Company’s financial position and results of operations. These uncertainties and lack of commercial operating history raise substantial doubt about the Company’s ability to continue as a going concern.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Segment Information

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

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

Foreign Currency Translation and Transactions

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

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

Gains and losses resulting from foreign currency transactions are reflected within the Company’s results of operations and have generally not had a material impact on the Company’s operating results, although during the three months ended June 30, 2012 the Company recorded a $1,401 foreign exchange loss, which represented approximately 6.1% of the net loss for the period. The Company does not currently utilize and has not in the past utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

Revenue Recognition

Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable, the right of return no longer exists or product returns can be reasonably estimated, which is the earlier of product being dispensed through patient prescriptions or the expiration of the right of return, collectability is reasonably assured and the Company has no further performance obligations. Some of the Company’s agreements contain multiple elements and in accordance with these agreements, the Company may be eligible for upfront license fees, marketing or commercial milestones and payment for product deliveries.

Revenue from up-front license fees

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

In June 2012, the Company received a non-refundable and non-creditable upfront payment associated with its entry into a collaboration, license and supply agreement with Grünenthal S.A. for the potential commercialization of DUEXIS in Latin America. The upfront payment was recorded to long-term deferred revenues. As of June 30, 2012 and December 31, 2011, deferred revenues from the sale of DUEXIS and the collaboration, license and supply agreement were $2,801 and $1,517, respectively.

Revenue from milestone receipts

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

Revenue from product deliveries

The Company recognizes revenue from the delivery of its products 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. 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.

As a result of the acquisition of Nitec in April 2010, the Company began recognizing revenues from the sale of LODOTRA. The Company anticipates revenues will continue to result from distribution, marketing, manufacturing and supply agreements with third parties in Europe and certain Asian, Latin American and other countries with respect to LODOTRA. The Company also recognizes revenues related to up-front license fees, milestone receipts and product deliveries.
Prior to 2011, revenues from the sale of LODOTRA made to the Company’s distribution partner, Mundipharma, were accounted for using the sell-through method. Under the sell-through method, the Company recognizes revenue based on an estimate of the amount of product sold through to the customers of the Company’s distribution partners and end users.

Under the manufacturing and supply agreements with Mundipharma Medical Company (“Mundipharma Medical”), Mundipharma Medical agreed to purchase LODOTRA exclusively from the Company at a price based on a specified percentage of the average net selling price (“ANSP”) for sales in a given country, subject to a minimum price. Mundipharma Medical has a nine-month period from purchase date to request an ANSP adjustment. If the ANSP is lower than the actual purchase price, then Mundipharma Medical would receive a price adjustment. Beginning in 2011, products sold to Mundipharma Medical have been recognized upon delivery at the minimum price, as no contractual right of return exists. The difference between the actual selling price and the minimum price is recorded as deferred revenue until such time as adjustments for product returns, rebates and discounts can be reliably estimated or the nine-month period ANSP adjustment passes at which time any previously deferred revenue would be recognized as revenue. As of June 30, 2012 and December 31, 2011, deferred revenues from the sale of LODOTRA and deferred revenues from milestone payments were $8,851 and $7,430, respectively.

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

The Company also defers the related cost of goods sold and records such amounts as other current assets until revenue is recognized. As of June 30, 2012 and December 31, 2011, the Company had a deferred cost of goods sold balance of $277 and $1,067, respectively.

**DUEXIS Product Sales Discounts and Allowances**

The Company currently records DUEXIS sales to wholesale pharmaceutical distributors and national and regional retail chains as deferred revenue. Allowances for product returns, rebates and discounts are also currently deferred at the time of sale to wholesale pharmaceutical distributors and national and regional retail chains. These deferred expenses are recognized to arrive at net product sales at the time revenue is recognized, which is currently at the earlier of DUEXIS being dispensed through patient prescriptions or the expiration of the right of return (twelve months after the expiration date of the product). The Company is required to make significant judgments and estimates in determining some of these allowances. If actual results differ from its estimates, the Company will be required to make adjustments to these allowances in the future.

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

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

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

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

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

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

7
Cost of Goods Sold

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

As a result of the commercial launch of DUEXIS in the U.S. in December 2011, the Company also began to recognize cost of goods sold in connection with its sale of DUEXIS. Cost of goods sold of DUEXIS includes all costs directly related to the acquisition of product from the Company’s third party manufacturers, including freight charges. The Company also defers the related DUEXIS cost of goods sold and records such amounts as other current assets until revenue is recognized.

Inventories

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

Inventories exclude product sample inventory, which is included in other current assets and is expensed as a component of sales and marketing expense when provided to physicians or healthcare providers. As of June 30, 2012 and December 31, 2011, the Company had product sample inventory of $2,131 and $629, respectively.

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

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

Cash and Cash Equivalents

Cash and cash equivalents primarily consist of cash balances and money market funds. Cash and cash equivalents were $63,460 and $17,966 as of June 30, 2012, and December 31, 2011, respectively. The Company’s policy is to invest excess cash in money market funds, which are generally of a short-term duration based upon operating requirements.

Restricted Cash

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

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation. Depreciation is recognized using the straight-line method over the estimated useful lives of the related assets for financial reporting purposes and an accelerated method for income tax reporting purposes. Upon retirement or sale of an asset, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operations. Repair and maintenance costs are charged to expenses as incurred and improvements are capitalized.
Leasehold improvements are amortized on a straight-line basis over the term of the applicable lease, or the useful life of the assets, whichever is shorter. Depreciation and amortization periods for the Company’s property and equipment are as follows:

<table>
<thead>
<tr>
<th>Asset Type</th>
<th>Useful Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery and equipment</td>
<td>5 to 7 years</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>3 to 7 years</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>3 years</td>
</tr>
<tr>
<td>Software</td>
<td>5 years</td>
</tr>
<tr>
<td>Trade show equipment</td>
<td>3 years</td>
</tr>
</tbody>
</table>

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

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 and medical affairs are charged to research and development expense as incurred.

Sales and Marketing Expenses

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

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that may potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents. The Company’s cash and cash equivalents are invested in deposits with various banks in the U.S., Switzerland and Germany that management believes are creditworthy. At times, deposits in these banks may exceed the amount of insurance provided on such deposits. To date, the Company has not experienced any losses on its deposits of cash and cash equivalents.

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

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

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

The Company is required to maintain compliance with applicable Swiss laws with respect to its Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. The Company reviews on a regular basis whether its Swiss subsidiary is overindebted. As of December 31, 2011, and June 30, 2012, the Company’s Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. The Company will continue to monitor and review steps to address any overindebtedness, until such time as its Swiss subsidiary generates positive income at a statutory level, which could require the Company to have cash at its Swiss subsidiary in excess of its near term operating needs and could affect the Company’s ability to have sufficient cash at its U.S. subsidiary to meet its near term operating needs.

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss) (“OCI”). OCI includes certain changes in stockholders’ equity (deficit) that are excluded from net income (loss), which consist of foreign currency translation adjustments. As of June 30, 2012, and December 31, 2011, accumulated other comprehensive loss was $4,620 and $3,788, respectively.
Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. For the periods presented, the Company’s potential dilutive shares, which include shares issuable upon the exercise of outstanding options and unvested restricted stock units, warrants to purchase common stock, 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.

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.

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 in accordance with ASC 260.

NOTE 3 – EARNINGS PER SHARE

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

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended June 30,</th>
<th>Six Months Ended June 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>Net loss</td>
<td>$(22,782)</td>
<td>$(11,637)</td>
</tr>
<tr>
<td>Weighted average of common shares outstanding</td>
<td>33,715,703</td>
<td>1,496,278</td>
</tr>
<tr>
<td>Basic and diluted net loss per share</td>
<td>$(0.68)</td>
<td>$(7.78)</td>
</tr>
</tbody>
</table>

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

- Outstanding stock options to purchase an aggregate of 2,545,797 and 1,304,713 shares of common stock at June 30, 2012 and 2011, respectively, and outstanding and unvested restricted stock units covering an aggregate of 820,549 shares of common stock at June 30, 2012.
- Outstanding warrants to purchase an aggregate of 7,120,887 shares of common stock at June 30, 2012.
- Outstanding warrants to purchase an aggregate of 446,122 shares of preferred stock at June 30, 2011.
- 10,514,431 shares of convertible preferred stock at June 30, 2011 were excluded for the 2011 periods presented. Upon the closing of the Company’s initial public offering on August 2, 2011, the outstanding shares of convertible preferred stock were converted into shares of the Company’s common stock, which were then included as part of the computation of basic and diluted earnings.

NOTE 4 – INVENTORIES

Inventories are stated at the lower of cost or market value. Inventories consist of raw materials, work-in-process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. The Company’s inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs. Inventories exclude product sample inventory, which are included in other current assets and are expensed as a component of sales and marketing expense when provided to physicians or healthcare providers.
The components of inventories as of June 30, 2012, and December 31, 2011, are summarized as follows:

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2012</th>
<th>December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw materials</td>
<td>$146</td>
<td>$75</td>
</tr>
<tr>
<td>Work-in-process</td>
<td>1,094</td>
<td>488</td>
</tr>
<tr>
<td>Finished goods</td>
<td>1,917</td>
<td>632</td>
</tr>
<tr>
<td><strong>Net inventories</strong></td>
<td><strong>$3,157</strong></td>
<td><strong>$1,195</strong></td>
</tr>
</tbody>
</table>

**NOTE 5 – PREPAID EXPENSES AND OTHER CURRENT ASSETS**

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

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2012</th>
<th>December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferred cost of goods sold</td>
<td>$277</td>
<td>$1,067</td>
</tr>
<tr>
<td>Product samples inventory</td>
<td>2,131</td>
<td>629</td>
</tr>
<tr>
<td>Prepaid clinical trial studies</td>
<td>755</td>
<td>—</td>
</tr>
<tr>
<td>Prepaid marketing expenses</td>
<td>390</td>
<td>509</td>
</tr>
<tr>
<td>Prepaid insurance</td>
<td>160</td>
<td>230</td>
</tr>
<tr>
<td>Prepaid FDA product and manufacturing fees</td>
<td>90</td>
<td>139</td>
</tr>
<tr>
<td>Other prepaid expenses</td>
<td>598</td>
<td>115</td>
</tr>
<tr>
<td>Prepaid insurance</td>
<td>160</td>
<td>230</td>
</tr>
<tr>
<td>Prepaid FDA product and manufacturing fees</td>
<td>90</td>
<td>139</td>
</tr>
<tr>
<td>Other prepaid expenses</td>
<td>598</td>
<td>115</td>
</tr>
<tr>
<td>Other current assets</td>
<td>—</td>
<td>74</td>
</tr>
<tr>
<td><strong>Total prepaid and other current assets</strong></td>
<td><strong>$4,401</strong></td>
<td><strong>$2,763</strong></td>
</tr>
</tbody>
</table>

**NOTE 6 – PROPERTY AND EQUIPMENT**

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

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2012</th>
<th>December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery and equipment</td>
<td>$1,801</td>
<td>$1,797</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>103</td>
<td>158</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>967</td>
<td>677</td>
</tr>
<tr>
<td>Software</td>
<td>706</td>
<td>286</td>
</tr>
<tr>
<td>Trade show equipment</td>
<td>228</td>
<td>228</td>
</tr>
<tr>
<td>Leasehold improvement</td>
<td>705</td>
<td>705</td>
</tr>
<tr>
<td>Construction in progress</td>
<td>378</td>
<td>165</td>
</tr>
<tr>
<td><strong>Total property and equipment</strong></td>
<td><strong>4,888</strong></td>
<td><strong>4,016</strong></td>
</tr>
</tbody>
</table>

Depreciation expense was $208 and $101 for the three months ended June 30, 2012, and 2011, respectively. Depreciation expense was $392 and $201 for the six months ended June 30, 2012, and 2011, respectively.
NOTE 7 – INTANGIBLE ASSETS

The Company’s intangible assets, which include its developed technology and in-process research and development (“IPR&D”), were acquired as a result of its acquisition of Nitec in April 2010. Developed technology is associated with the Company’s marketed product LODOTRA in Europe and is amortized on a straight-line basis over its estimated useful life of twelve years. IPR&D is associated with the Company’s U.S. rights to RAYOS, which was initially classified as an indefinite-lived asset. On July 26, 2012, the FDA approved RAYOS for the treatment of a broad range of indications. The approval will cause the Company to reclassify its IPR&D asset to a finite lived asset in July 2012 in addition to requiring the Company to conduct a fair value assessment related to the carrying value of the IPR&D asset during the third quarter of 2012.

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

During the six months ended June 30, 2012, the Company did not identify any events or circumstances that would indicate that its intangible assets might be impaired and an interim impairment test was not performed. If estimated cash flows related to the Company’s IPR&D asset decrease, the Company may be required to further impair this asset in the future. Additionally, changes in the broader economic markets or other adverse factors could result in further changes to our market value and projected cash flows, which would impact the estimated fair values and may require the Company to record additional impairment charges in the future.

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

<table>
<thead>
<tr>
<th></th>
<th>As of June 30, 2012</th>
<th>As of December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cost Basis</td>
<td>Accumulated Amortization</td>
</tr>
<tr>
<td>Developed technology</td>
<td>$40,482</td>
<td>$(7,590)</td>
</tr>
</tbody>
</table>

Amortization expense of the Company’s developed technology was $856 and $972 for the three months ended June 30, 2012, and 2011, respectively, and was $1,748 and $1,899 for the six months ended June 30, 2012, and 2011, respectively. As of June 30, 2012, estimated future amortization expense was as follows:

<table>
<thead>
<tr>
<th>Year</th>
<th>Amortization Expense</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>$1,745</td>
</tr>
<tr>
<td>2013</td>
<td>3,489</td>
</tr>
<tr>
<td>2014</td>
<td>3,489</td>
</tr>
<tr>
<td>2015</td>
<td>3,489</td>
</tr>
<tr>
<td>2016 and thereafter</td>
<td>20,681</td>
</tr>
<tr>
<td>Total</td>
<td>$32,893</td>
</tr>
</tbody>
</table>

Additionally, as of June 30, 2012 and December 31, 2011, the Company had $35,586 and $36,638, respectively, of intangible assets not subject to amortization related to its IPR&D asset.
NOTE 8 – OTHER ASSETS

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

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2012</th>
<th>December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferred financing costs</td>
<td>$3,541</td>
<td>$ —</td>
</tr>
<tr>
<td>Long-term inventory deposits</td>
<td>498</td>
<td>505</td>
</tr>
<tr>
<td>Long-term rent deposits</td>
<td>40</td>
<td>42</td>
</tr>
<tr>
<td>Total other assets</td>
<td>$4,079</td>
<td>$ 547</td>
</tr>
</tbody>
</table>

NOTE 9 – ACCRUED LIABILITIES

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

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2012</th>
<th>December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payroll related expenses</td>
<td>$3,557</td>
<td>$ 4,237</td>
</tr>
<tr>
<td>Sales and marketing expenses</td>
<td>1,095</td>
<td>1,199</td>
</tr>
<tr>
<td>Deferred rent</td>
<td>767</td>
<td>811</td>
</tr>
<tr>
<td>Accrued rebates and royalties</td>
<td>1,859</td>
<td>694</td>
</tr>
<tr>
<td>Clinical and regulatory expenses</td>
<td>336</td>
<td>439</td>
</tr>
<tr>
<td>Professional services</td>
<td>362</td>
<td>394</td>
</tr>
<tr>
<td>Contract manufacturing expenses</td>
<td>136</td>
<td>220</td>
</tr>
<tr>
<td>Taxes and licenses</td>
<td>73</td>
<td>196</td>
</tr>
<tr>
<td>Interest expense</td>
<td>2,536</td>
<td>163</td>
</tr>
<tr>
<td>Consulting services</td>
<td>212</td>
<td>150</td>
</tr>
<tr>
<td>Accrued other</td>
<td>216</td>
<td>423</td>
</tr>
<tr>
<td>Total accrued liabilities</td>
<td>$11,149</td>
<td>$8,926</td>
</tr>
</tbody>
</table>

NOTE 10 – FAIR VALUE MEASUREMENTS

The following tables set forth the Company’s financial instruments that are measured at fair value on a recurring basis within the fair value hierarchy under ASC Topic 820—Fair Value Measurements (“ASC 820”). Assets and liabilities are measured at fair value and are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The standard describes three levels of inputs that may be used to measure fair value:

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

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

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

The Company utilizes a market value approach to measure fair value for its money market funds. The market value approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities.
Assets measured at fair value on a recurring basis subject to the disclosure requirements ASC 820 at June 30, 2012, and December 31, 2011, were as follows:

<table>
<thead>
<tr>
<th>Assets</th>
<th>As of June 30, 2012</th>
<th>As of December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Level 1</td>
<td>Level 2</td>
</tr>
<tr>
<td>Money market funds</td>
<td>$55,049</td>
<td>$—</td>
</tr>
<tr>
<td><strong>Total assets at fair value</strong></td>
<td>$55,049</td>
<td>$—</td>
</tr>
</tbody>
</table>

**NOTE 11 – COMMITMENTS AND CONTINGENCIES**

**Lease Obligations**

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

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

**Purchase Commitments**

In August 2007, the Company entered into a manufacturing and supply agreement with Jagotec AG. Under the agreement, Jagotec or its affiliates are required to manufacture and supply RAYOS/LODOTRA exclusively to the Company in bulk. The Company committed to a minimum purchase of RAYOS/LODOTRA tablets from Jagotec for five years from the date of first launch of RAYOS/LODOTRA in a major country, as defined in the agreement, which was in April 2009. At June 30, 2012, the minimum remaining purchase commitment was $2,041 based on tablet pricing in effect under the agreement.

In May 2011, the Company entered into a manufacturing and supply agreement with sanofi-aventis U.S. Pursuant to the agreement, sanofi-aventis U.S. is obligated to manufacture and supply DUEXIS to the Company in final, packaged form, and the Company is obligated to purchase DUEXIS exclusively from sanofi-aventis U.S. for our commercial requirements of DUEXIS in North America and certain countries and territories in Europe, including the European Union member states and Scandinavia, and South America. At June 30, 2012, the purchase commitment was $1,616 based on binding purchase orders issued from the Company to sanofi-aventis U.S. for DUEXIS to be delivered through September 2012.

**Royalty Agreement**

In connection with the August 2004 development and license agreement with SkyePharma AG (“SkyePharma”) and Jagotec AG, a wholly-owned subsidiary of SkyPharma, regarding certain proprietary technology and know-how owned by SkyPharma, Jagotec is entitled to receive a single digit percentage royalty on net sales of RAYOS/LODOTRA and on any sub-licensing income, which includes any payments not calculated based on the net sales of LODOTRA, such as license fees, and lump sum and milestone payments. Royalty expense recognized in cost of goods sold during the three months ended June 30, 2012 and 2011 was $98 and $107, respectively, and $259 and $255 for the six months ended June 30, 2012 and 2011, respectively.
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Contingencies

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

Indemnification

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

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

NOTE 12 – LEGAL PROCEEDINGS

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

NOTE 13 – DEBT AGREEMENTS

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

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2012</th>
<th>December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior Secured Loan</td>
<td>$60,333</td>
<td>$ —</td>
</tr>
<tr>
<td>Oxford Facility</td>
<td>—</td>
<td>16,598</td>
</tr>
<tr>
<td>Kreos Facility</td>
<td>—</td>
<td>2,840</td>
</tr>
<tr>
<td>Current debt maturities</td>
<td>(3,978)</td>
<td>(3,604)</td>
</tr>
<tr>
<td>Debt discount</td>
<td>(9,214)</td>
<td>—</td>
</tr>
<tr>
<td>Long-term debt, net of current maturities</td>
<td>$47,141</td>
<td>$15,834</td>
</tr>
</tbody>
</table>

On April 1, 2010, in connection with the acquisition of Nitec, Horizon Pharma AG renegotiated the payment terms of an existing 7,500 Euro debt facility (the “Kreos Facility”) with Kreos Capital III (UK) Limited (“Kreos”). In June 2011, in connection with the debt facility with Oxford Finance LLC (“Oxford”) and Silicon Valley Bank (“SVB”) described below (the “Oxford Facility”), the Company paid Kreos $1,450 (1,000 Euros) in exchange for Kreos’ consent to a partial assignment of the Kreos Facility.
to Horizon Pharma, Inc. As a result, Horizon Pharma, Inc. became a co-lender with Kreos to Horizon Pharma AG. The Company also issued a warrant to Kreos to purchase an aggregate of 100,000 shares of its Series B convertible preferred stock with an exercise price of $0.01 per share, which became a warrant to purchase an aggregate of 42,122 shares of common stock upon the completion of the Company’s initial public offering. In March 2012, Kreos exercised this warrant (see Note 14). Refer to Note 9 to the Company’s consolidated financial statements in the Company’s annual report on Form 10-K for the year ended December 31, 2011 for further discussion of the Kreos Facility and Oxford Facility.

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

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

The Senior Secured Loan restricts the Company’s ability to incur additional indebtedness, incur liens, pay dividends and engage in significant business transactions, such as a change of control, so long as the Company owes any amounts to the lenders under the related loan agreements. If the Company defaults under its Senior Secured Loan, its lenders may accelerate all of its repayment obligations and take control of the pledged assets. The Company’s lenders could declare the Company in default under its debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect upon it as defined under the loan agreements, thereby requiring the Company to repay the loan immediately or to attempt to reverse the lenders’ declaration through negotiation or litigation. Among other loan covenant requirements, the Senior Secured Loan also requires the Company to maintain a minimum level of liquidity in the near-term of at least $10,000 at all times during the term of the loan unless its quarterly consolidated EBITDA is at least $6,000 and to meet specified minimum net revenues during a trailing twelve-month period commencing on June 30, 2012. The negative covenants include, among other things, restrictions on transferring or licensing the Company’s assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on the Company’s assets, in each case subject to customary exceptions. In April 2012, the Company elected to pay the 12% interest in cash and the remaining 5% interest due of $333 was added to the principal loan balance as a payment in kind borrowing. At June 30, 2012, the outstanding balance on the Senior Secured Loan was $60,333 and the Company was in compliance with all applicable financial loan covenants.

NOTE 14 – STOCKHOLDERS’ EQUITY

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

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

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

NOTE 15 – RELATED PARTY TRANSACTIONS

The Company has entered into consulting agreements with three stockholders, two of whom previously served as directors of Horizon Pharma USA. Two of the consulting agreements terminated as of December 31, 2011, while one remains in effect. In addition, the Company’s wholly-owned subsidiary, Horizon Pharma AG, has entered into a consulting agreement with a former owner and majority shareholder of Nitec. Consulting fees paid to related parties during the three months ended June 30, 2012 and 2011 were $179 and $173, respectively, and $367 and $398 for the six months ended June 30, 2012 and 2011, respectively.
NOTE 16 – INCOME TAXES

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

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss before benefit for income taxes</td>
<td>(22,941)</td>
<td>(11,823)</td>
<td>(46,831)</td>
<td>(19,677)</td>
</tr>
<tr>
<td>Benefit for income taxes</td>
<td>(159)</td>
<td>(186)</td>
<td>(323)</td>
<td>(568)</td>
</tr>
<tr>
<td>Net loss</td>
<td>(22,782)</td>
<td>(11,637)</td>
<td>(46,508)</td>
<td>(19,309)</td>
</tr>
</tbody>
</table>

At June 30, 2012, the Company had a net deferred tax liability of $8,948 primarily related to temporary differences in indefinite-lived assets. The decrease in income tax benefit during the three months ended June 30, 2012, was due to foreign currency translation resulting from a decline in value of the Euro as compared to the prior year.

NOTE 17 – EQUITY INCENTIVE PLANS

Employee Stock Purchase Plan

In July 2010, the Company’s Board of Directors adopted the Employee Stock Purchase Plan (the “2011 Purchase Plan”) and in June 2011, the Company’s stockholders approved the 2011 Purchase Plan, and it became effective upon the signing of the underwriting agreement related to the Company’s initial public offering in July 2011. The Company reserved a total of 463,352 shares of common stock for issuance under the 2011 Purchase Plan. The 2011 Purchase Plan provides that an additional number of shares will automatically be added annually to the shares authorized for issuance under the 2011 Purchase Plan on January 1, from 2012 until 2021. The number of shares added each year will be equal to the least of: (a) 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (b) 1,053,074 shares of common stock; or (c) a number of shares of common stock that may be determined each year by the board of directors that is less than (a) and (b). Subject to certain limitations, the Company’s employees may elect to have 1% to 15% of their compensation withheld through payroll deductions to purchase shares of common stock under the 2011 Purchase Plan. Employees purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of the six-month offering period.

On December 15, 2011, the Company’s board of directors approved an additional 100,000 shares to be available for issuance under the 2011 Purchase Plan, effective as of January 1, 2012. As of June 30, 2012, 60,895 shares had been issued and an aggregate of 502,457 shares of common stock were authorized and available for issuance under the 2011 Purchase Plan.

In June 2012, the Company issued 43,123 shares of its common stock in connection with purchases under the Company’s 2011 Purchase Plan.

Stock-Based Compensation Plans

In October 2005, the Company adopted the 2005 Stock Plan (the “2005 Plan”). The 2005 Plan provides for the granting of stock options to employees, consultants and advisors of the Company. Options granted under the 2005 Plan may be either incentive stock options (“ISO”) or nonqualified stock options (“NSO”). Upon the signing of the underwriting agreement related to the Company’s initial public offering, on July 28, 2011, no further option grants were made under the 2005 Plan. As of July 28, 2011, the 460,842 shares of common stock reserved for future issuance and the 1,304,713 shares of common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan were transferred to the 2011 Equity Incentive Plan (the “2011 Plan”), as described below. All stock options granted under the 2005 Plan prior to the offering continue to be governed by the terms of the 2005 Plan.
In July 2010, the Company’s Board of Directors adopted the 2011 Plan and in June 2011, the Company’s stockholders approved the 2011 Plan, and it became effective upon the signing of the underwriting agreement related to the Company’s initial public offering, on July 28, 2011. The 2011 Plan had an initial reserve of 3,366,228 shares of common stock, including 460,842 shares of common stock previously reserved for future issuance under the 2005 Plan, 1,304,713 shares of common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan as of the 2011 Plan’s effective date and 1,600,673 new shares of common stock reserved. The 2011 Plan provides that an additional number of shares will automatically be added annually to the shares authorized for issuance on January 1, from 2012 until 2021. The number of shares added each year will be equal to the least of: (a) 5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (b) 1,474,304 shares of common stock; or (c) a number of shares of common stock that may be determined each year by the board of directors that is less than (a) and (b). On December 15, 2011, pursuant to the terms of the 2011 Plan, the Company’s board of directors approved additional shares available for issuance under the 2011 Plan of 672,500 shares, effective as of January 1, 2012. As of June 30, 2012, the Company had reserved 671,709 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.

Stock Option Plans

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

<table>
<thead>
<tr>
<th>Options</th>
<th>Weighted Average Exercise Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2011</td>
<td>2,532,262 $9.93</td>
</tr>
<tr>
<td>Granted</td>
<td>177,030 $3.98</td>
</tr>
<tr>
<td>Exercised</td>
<td></td>
</tr>
<tr>
<td>Forfeited</td>
<td>(163,495) $7.74</td>
</tr>
<tr>
<td>Cancelled</td>
<td></td>
</tr>
<tr>
<td>Outstanding as of June 30, 2012</td>
<td>2,545,797 $9.62</td>
</tr>
<tr>
<td>Exercisable as of June 30, 2012</td>
<td>1,023,836 $14.08</td>
</tr>
</tbody>
</table>

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The determination of the fair value of each stock option is affected by the Company’s stock price on the date of grant, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company’s expected stock price volatility over the expected life of the awards and actual and projected stock option exercise behavior. The weighted average fair value per share of stock option awards granted during the six months ended June 30, 2012, and 2011, and assumptions used to value stock options, are as follows:

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dividend yield</td>
<td>—</td>
</tr>
<tr>
<td>Risk-free interest rate</td>
<td>1.0%</td>
</tr>
<tr>
<td>Weighted average volatility</td>
<td>89.7%</td>
</tr>
<tr>
<td>Expected life (in years)</td>
<td>5.95</td>
</tr>
<tr>
<td>Weighted average grant date fair value per share of options granted</td>
<td>$3.12</td>
</tr>
</tbody>
</table>
Dividend yields

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

Risk-Free Interest Rate

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

Volatility

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

Expected Term

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

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

Restricted Stock Units

The following table summarizes restricted stock unit activity during the six months ended June, 2012 as follows:

<table>
<thead>
<tr>
<th></th>
<th>Number of Units</th>
<th>Weighted Average Grant-Date Fair Value Per Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2011</td>
<td>304,890</td>
<td>$ 4.96</td>
</tr>
<tr>
<td>Granted</td>
<td>520,000</td>
<td>$ 4.20</td>
</tr>
<tr>
<td>Vested</td>
<td>(72,000)</td>
<td>$ 4.20</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(4,341)</td>
<td>$ 4.96</td>
</tr>
<tr>
<td>Unvested shares outstanding as of June 30, 2012</td>
<td>748,549</td>
<td>$ 4.50</td>
</tr>
</tbody>
</table>

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

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

| Stock-based compensation expense:                         | Six Months Ended June 30, |
|                                                        | 2012 | 2011   |
| Research and development                               | $ 608 | $ 400  |
| Sales and marketing                                    | 523  | 148    |
| General and administrative                             | 1,359 | 677    |
| Net effect of stock-based compensation expense on net loss | $ 2,490 | $ 1,225 |
As of June 30, 2012, the Company estimates that pre-tax compensation expense of $8,656 for all unvested share-based awards, including both stock options and restricted stock units will be recognized through the third quarter of 2015. The Company expects to satisfy the exercise of stock options and future distribution of shares of restricted stock by issuing new shares of its common stock which have been reserved under the 2011 Plan.

NOTE 18 – RECENT ACCOUNTING PRONOUNCEMENTS

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

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

NOTE 19 – DISTRIBUTION, MANUFACTURING AND SUPPLY AGREEMENTS

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

On June 14, 2012, the Company entered into a co-promotion agreement with Mallinckrodt LLC (“Mallinckrodt”), the pharmaceutical business of Covidien plc (the “Mallinckrodt Agreement”), pursuant to which the Company engaged Mallinckrodt on a non-exclusive basis to promote DUEXIS in the United States, excluding any territories or possessions and excluding Puerto Rico. Under the terms of the Mallinckrodt Agreement, Mallinckrodt has agreed to use commercially reasonable efforts to promote DUEXIS to an agreed list of physician promotion targets. Mallinckrodt is required to achieve minimum levels of prescriptions from targeted physicians on a quarterly basis during the term of the Mallinckrodt Agreement, and the Company agreed not to grant to any third party the right to co-promote DUEXIS to those targeted physicians in the agreed upon territory during the term, other than an existing third party agreement. Under the terms of the Mallinckrodt Agreement, the Company is responsible for the manufacture, supply and distribution of DUEXIS.

NOTE 20 – SUBSEQUENT EVENTS

On July 26, 2012, the FDA approved RAYOS for the treatment of a broad range of diseases including RA, PMR, PsA, AS, asthma and COPD. The Company’s initial focus will be the launch of RAYOS in rheumatologic diseases such as RA and PMR in the fourth quarter of 2012.

On August 1, 2012, the Company filed a registration statement on Form S-3 which allows the Company to offer and sell up to an aggregate of $175,000 worth of common stock, preferred stock, debt securities and/or warrants in public offerings.
Item 2.  Management's Discussion and Analysis of Financial Condition and Results of Operations

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

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

OUR BUSINESS

We are a biopharmaceutical company that is developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases. On April 23, 2011, the U.S. Food and Drug Administration, or FDA, approved DUEXIS®, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis, or RA, and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. In the second half of 2011, we hired our initial commercial organization and completed sales force training, and we began detailing DUEXIS to physicians in December 2011 and held our launch meeting for DUEXIS in the U.S. in January 2012. In June 2012, we began expanding our commercial organization and expect to almost double its original size by the end of the third quarter of 2012, to approximately 150 field sales representatives. In June 2012, we also engaged Mallinckrodt LLC, the pharmaceutical business of Covidien plc, on a non-exclusive basis to co-promote DUEXIS in the U.S. and entered into an exclusive collaboration, license and supply agreement with Grünenthal S.A. for the potential commercialization of DUEXIS in Latin America. In October 2010, we submitted a Marketing Authorization Application, or MAA, for DUEXIS in the United Kingdom, or UK, the Reference Member State, through the Decentralized Procedure. In February 2012, we withdrew and updated the DUEXIS MAA submission to include the recently approved manufacturing site in Laval, Quebec through the National Procedure in the UK. We anticipate a decision on the MAA in the fourth quarter of 2012.

Our second product, RAYOS®, known as LODOTRA® outside the U.S., is a proprietary delayed 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, particularly when accompanied by morning stiffness. In addition, we have granted to Mundipharma commercialization rights to LODOTRA in Asia and Latin America. On July 26, 2012, the FDA approved RAYOS for the treatment of a broad range of diseases including RA, polymyalgia rheumatica, or PMR, psoriatic arthritis, ankylosing spondylitis, asthma and chronic obstructive pulmonary disease. We expect to commence commercial sales of RAYOS in the U.S. for rheumatologic diseases such as RA and PMR during the fourth quarter of 2012. Our strategy is to commercialize our products in the U.S. and to enter into licensing or additional distribution agreements for commercialization of our products outside the U.S.
RESULTS OF OPERATIONS
Comparison of Three Months Ended June 30, 2012 and 2011

The summary of selected financial data table below should be referenced in connection with a review of the following discussion of our results of operations for the three months ended June 30, 2012, compared to the three months ended June 30, 2011.

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended June 30,</th>
<th>Increase / (Decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>Gross sales</td>
<td>$4,608</td>
<td>$1,335</td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(767)</td>
<td>—</td>
</tr>
<tr>
<td>Net sales</td>
<td>3,841</td>
<td>1,335</td>
</tr>
<tr>
<td>Cost of good sold</td>
<td>2,855</td>
<td>2,104</td>
</tr>
<tr>
<td>Gross profit (loss)</td>
<td>986</td>
<td>(769)</td>
</tr>
<tr>
<td>Operating expenses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>4,233</td>
<td>3,462</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>10,543</td>
<td>1,169</td>
</tr>
<tr>
<td>General and administrative</td>
<td>4,555</td>
<td>3,348</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>19,331</td>
<td>7,979</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(18,345)</td>
<td>(8,748)</td>
</tr>
<tr>
<td>Other income (expense)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(3,191)</td>
<td>(3,185)</td>
</tr>
<tr>
<td>Foreign exchange (loss) gain</td>
<td>(1,401)</td>
<td>110</td>
</tr>
<tr>
<td>Other expense</td>
<td>(4)</td>
<td>—</td>
</tr>
<tr>
<td>Total other expense, net</td>
<td>(4,596)</td>
<td>(3,075)</td>
</tr>
<tr>
<td>Net loss before benefit for income taxes</td>
<td>(22,941)</td>
<td>(11,823)</td>
</tr>
<tr>
<td>Benefit for income taxes</td>
<td>(159)</td>
<td>(186)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (22,782)</td>
<td>$ (11,637)</td>
</tr>
</tbody>
</table>

Sales. During the three months ended June 30, 2012, gross sales and net sales were $4,608 and $3,841, respectively, compared to $1,335 in gross and net sales during the three months ended June 30, 2011. DUEXIS gross sales were $2,073 and net sales were $1,564 after deducting trade discounts and allowances of $252 and co-pay assistance costs of $257, and represented 45% of gross sales and 41% of net sales during the quarter ended June 30, 2012. Gross and net sales for LODOTRA increased 90% and 71%, respectively, during the three months ended June 30, 2012 compared to the same period in the prior year as a result of higher product shipments to our European distribution partner, Mundipharma.

We have determined that shipment of DUEXIS to wholesale distributors and retail chains does not currently meet the criteria for revenue recognition at the time of shipment which requires a reliable estimate of returns based on history. Therefore, we continue to defer DUEXIS revenue recognition until the right of return no longer exists, which is the earlier of DUEXIS being dispensed through patient prescriptions or the expiration of the right of return (twelve months after the expiration date of the product). As of June 30, 2012, we had $1,301 in deferred revenue on our balance sheet related to DUEXIS shipments.

Cost of Goods Sold. Cost of goods sold increased $751, from $2,104 during the three months ended June 30, 2011, to $2,855 during the three months ended June 30, 2012. The increase in cost of goods sold was primarily the result of $500 of DUEXIS direct product costs, which were absent in the prior year period and $300 in higher product costs for LODOTRA as a result of higher product sales.

Research and Development Expenses. Research and development expenses increased $771, from $3,462 during the three months ended June 30, 2011, to $4,233 during the three months ended June 30, 2012. The increase in research and development expenses was primarily associated with a $600 increase in medical education and related grants.

Sales and Marketing Expenses. Sales and marketing expenses increased $9,374, from $1,169 during the three months ended June 30, 2011, to $10,543 during the three months ended June 30, 2012. The increase in expense was primarily attributable to ongoing sales and promotional efforts related to our DUEXIS product launch, including a $4,600 increase in salaries and benefits expense associated with additional staffing of our sales and marketing functions, a $2,300 increase in market research and marketing programs, a $1,400 increase in consulting and outside service costs and a $800 increase in samples and marketing materials.

General and Administrative Expenses. General and administrative expenses increased $1,207, from $3,348 during the three months ended June 30, 2011, to $4,555 during the three months ended June 30, 2012. The increase in general and administrative expenses was primarily due to a $700 increase in stock-based compensation expense, a $400 increase in salaries and benefits expense
associated with an increase in administrative personnel, a $300 increase in legal costs associated with intellectual property related matters and public company compliance fees and $200 in higher rent and insurance costs, partially offset by a reduction in consulting expenses during the second quarter current of 2012.

**Interest Expense, Net.** Interest expense, net was $3,185 during the three months ended June 30, 2011, compared to $3,191 during the three months ended June 30, 2012. Interest expense during the three months ended June 30, 2012 was primarily the result of incremental interest expense associated with higher borrowing balances under our $60,000 senior secured loan with a group of institutional investors, or Senior Secured Loan, partially offset by the absence of debt extinguishment costs. During the three months ended June 30, 2011, we incurred $1,900 of interest expense related to extinguishment of our debt facility with Kreos Capital III (UK) Limited and Silicon Valley Bank, or Kreos-SVB facility.

**Foreign Exchange (Loss) Gain, Net.** During the three months ended June 30, 2012, foreign exchange loss was $1,401 compared to a foreign exchange gain of $110 during the three months ended June 30, 2011. The foreign exchange loss during the second quarter of 2012 was associated with a decline in the value of the Euro against the U.S. dollar during the three months ended June 30, 2012, which resulted in an unfavorable currency impact for our Horizon Pharma AG subsidiary.

**Income Tax Benefit.** Income tax benefit decreased $27, from $186 during the three months ended June 30, 2011, to $159 during the three months ended June 30, 2012. The decrease in income tax benefit was primarily due to foreign currency translation resulting from a decline in value of the Euro as compared to the prior year.

**Net Loss.** Net loss increased from $11,637 during the three months ended June 30, 2011, to $22,782 during the three months ended June 30, 2012, primarily as a result of the increase in expenses described above, and partially offset by higher sales and gross profit.

### Comparison of Six Months Ended June 30, 2012 and 2011

The summary of selected financial data table below should be referenced in connection with a review of the following discussion of our results of operations for the six months ended June 30, 2012, compared to the six months ended June 30, 2011.

<table>
<thead>
<tr>
<th></th>
<th>Six Months Ended June 30,</th>
<th>Increase / (Decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>Gross sales</td>
<td>$ 7,516</td>
<td>$ 3,127</td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(1,152)</td>
<td>—</td>
</tr>
<tr>
<td>Net sales</td>
<td>6,364</td>
<td>3,127</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>4,922</td>
<td>3,943</td>
</tr>
<tr>
<td>Gross profit (loss)</td>
<td>1,442</td>
<td>(816)</td>
</tr>
<tr>
<td>Operating expenses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>8,302</td>
<td>6,190</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>21,515</td>
<td>2,285</td>
</tr>
<tr>
<td>General and administrative</td>
<td>9,758</td>
<td>6,449</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>39,575</td>
<td>14,924</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(38,133)</td>
<td>(15,740)</td>
</tr>
<tr>
<td>Other income (expense)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(7,742)</td>
<td>(4,469)</td>
</tr>
<tr>
<td>Foreign exchange (loss) gain</td>
<td>(900)</td>
<td>532</td>
</tr>
<tr>
<td>Other expense</td>
<td>(56)</td>
<td>—</td>
</tr>
<tr>
<td>Total other expense, net</td>
<td>(8,698)</td>
<td>(3,937)</td>
</tr>
<tr>
<td>Net loss before benefit for income taxes</td>
<td>(46,831)</td>
<td>(19,677)</td>
</tr>
<tr>
<td>Benefit for income taxes</td>
<td>(323)</td>
<td>(368)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (46,508)</td>
<td>$ (19,309)</td>
</tr>
</tbody>
</table>
Sales. During the six months ended June 30, 2012, gross sales and net sales were $7,516 and $6,364, respectively, compared to $3,127 in gross sales and net sales during the six months ended June 30, 2011. DUEXIS gross sales were $3,211 and net sales were $2,502 after deducting trade discounts and allowances of $307 and co-pay assistance costs of $402, and represented 43% of gross sales and 39% of net sales during the six months ended June 30, 2012. Gross and net sales for LODOTRA increased 39% and 26%, respectively, during the six months ended June 30, 2012 compared to the same period in the prior year as a result of higher product shipments to the Company’s distribution partner, Mundipharma.

Cost of Goods Sold. Cost of goods sold increased $979, from $3,943 during the six months ended June 30, 2011, to $4,922 during the six months ended June 30, 2012. The increase in cost of goods sold was primarily the result of $800 of DUEXIS direct product costs, which were absent in the prior year period and $300 in higher product costs for LODOTRA as a result of higher product sales compared to the prior year period.

Research and Development Expenses. Research and development expenses increased $2,112, from $6,190 during the six months ended June 30, 2011, to $8,302 during the six months ended June 30, 2012. The increase in research and development expense was primarily associated with a $2,100 increase in salaries and benefits expense in support of our RAYOS new drug application and expenses associated with DUEXIS clinical studies.

Sales and Marketing Expenses. Sales and marketing expenses increased $19,230, from $2,285 during the six months ended June 30, 2011, to $21,515 during the six months ended June 30, 2012, which was primarily attributable to initial staffing of our sales and marketing functions during the fourth quarter of 2011, resulting in $10,700 in higher salaries and benefits expenses. In addition, primarily as a result of ongoing sales and promotional efforts for our DUEXIS product launch, during the six months ended June 30, 2012, advertising and promotional efforts increased $4,900, samples and marketing expenses increased $1,200, market research expenses increased $1,000 and consulting fees increased $800.

General and Administrative Expenses. General and administrative expenses increased $3,309, from $6,449 during the six months ended June 30, 2011, to $9,758 during the six months ended June 30, 2012 due to a $1,500 increase in salaries and benefits expense associated with an increase in administrative personnel, $900 in higher legal and consulting costs associated with intellectual property related matters and public company compliance costs and a $300 in higher insurance and rent expense.

Interest Expense, Net. Interest expense, net increased $3,273, from $4,469 during the six months ended June 30, 2011, to $7,742 during the six months ended June 30, 2012. The increase in interest expense was primarily attributable to higher borrowing balances under our Senior Secured Loan and higher debt extinguishment costs. During the six months ended June 30, 2011, there was $1,900 charge related to the loss on extinguishment of the Kreos-SVB facility compared to a $2,500 charge related to extinguishment of our debt facility with Oxford Finance LLC and Silicon Valley Bank, or Oxford facility, and our debt facility with Kreos Capital III (UK) Limited, or Kreos facility, during the six months ended June 30, 2012.

Foreign Exchange (Loss) Gain, Net. During the six months ended June 30, 2012, foreign exchange loss was $900 compared to a foreign exchange gain of $532 during the six months ended June 30, 2011. The foreign exchange loss reporting during the six months ended June 30, 2012 was associated with a continuing decline in the value of the Euro against the U.S. dollar during the current year, which resulted in an unfavorable currency impact for our Horizon Pharma AG subsidiary, compared to a gain in the Euro versus the U.S. dollar during the corresponding period in 2011.

Other Expense. Other expense was $56 during the six months ended June 30, 2012 and primarily represented a loss on disposal of office furniture recorded during the first quarter of 2012.

Income Tax Benefit. Income tax benefit decreased $45, from $368 during the six months ended June 30, 2011, to $323 during the six months ended June 30, 2012. The decrease in income tax benefit was primarily due to foreign currency translation resulting from a decline in value of the Euro vs. the U.S. dollar as compared to the prior year.

Net Loss. Net loss increased from $19,309 during the six months ended June 30, 2011, to $46,508 during the six months ended June 30, 2012, primarily as a result of the increase in expenses described above, partially offset by higher sales and gross profit.

SUMMARY OF CRITICAL ACCOUNTING POLICIES

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

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

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

Revenue from up-front license fees.

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

Revenue from milestone receipts.

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

Revenue from product deliveries.

We recognize revenue from the delivery of our products when delivery has occurred, title has transferred to the partner, distributor or retail chain, the selling price is fixed or determinable, the right of return no longer exists (which is the earlier of product being dispensed through patient prescriptions or the expiration of the right of return) or product returns can be reasonably estimated, collectability is reasonably assured and we have no further performance obligations. Products sold to our wholesale distributors and retail chains are recognized based on the amount of product sold through to the end user consumer until such time as a reasonable estimate of allowances for product returns, rebates and discounts can be made.

Cost of Goods Sold

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

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

Inventories

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

Provision for Income Taxes

We account for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are recognized for deductible temporary differences, and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the year that the change is enacted. We also account for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return.
Stock-Based Compensation

We account for employee stock-based compensation by measuring and recognizing compensation expense for all stock-based payments based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee’s requisite service period, which is generally the vesting period. We estimate the fair value of our share-based awards to employees using the Black-Scholes option pricing model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price, volatility, risk-free interest rate, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs.

We also account for stock options issued to non-employees based on the stock options’ estimated fair value determined using the Black-Scholes option pricing model. The fair value of the equity awards granted to non-employees is re-measured at each reporting date, and the resulting change in the fair value associated with awards, if any, is recognized as a corresponding increase or reduction to stock-based compensation during the period.

Recent Accounting Pronouncements

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

In December 2011, FASB issued ASU No. 2011-12, Comprehensive Income (ASC Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassification of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2010-11, which defers only those changes in ASC 220 that relate to the presentation of reclassification adjustments. We believe that the pronouncement will not have a material effect on our results of operations.

LIQUIDITY, FINANCIAL POSITION AND CAPITAL RESOURCES

We have incurred losses since our inception in June 2005 and, as of June 30, 2012, we had an accumulated deficit of $266,825. We anticipate that we will continue to incur net losses for at least the next few years. We expect that our development, sales and marketing, and general and administrative expenses will continue to increase as a result of our development and commercialization of DUEXIS and RAYOS/LODOTRA. As a result, we will need to generate significant net product sales, and royalty and other revenues to achieve profitability.

We have financed our operations to date through equity financings, debt financings and the issuance of convertible notes. As of June 30, 2012, we had $63,460 in cash and cash equivalents. In February 2012, we entered into the $60,000 Senior Secured Loan. We used $22,381 of the loan proceeds to repay the remaining obligations under the Oxford facility and the Kreos facility. Under the terms of the Senior Secured Loan, the outstanding principal accrues interest until maturity in January 2017 at a rate of 17% per annum, payable quarterly unless repaid earlier. The Senior Secured Loan allows us to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt. Beginning in April 2013, and for each quarter thereafter, the lenders may require us to repay $4,000 of the loan principal. We may prepay the loan at any time, subject to certain prepayment premiums. In connection with the Senior Secured Loan, we also issued warrants to the lenders to purchase up to an aggregate of approximately 3,277,191 shares of our common stock at an exercise price of $0.01 per share. The warrants will become exercisable 180 days after issuance and will remain exercisable until the maturity date of the Loan on January 22, 2017, subject to limited exceptions. The Senior Secured Loan is secured by a lien covering substantially all of our assets including intellectual property in addition to pledging all of our equity interests in Horizon Pharma USA, Inc. and 65% of our equity interests in Horizon Pharma AG.

The Senior Secured Loan restricts our ability to incur additional indebtedness, incur liens, pay dividends and engage in significant business transactions, such as a change of control, so long as we owe any amounts to the lenders under the related loan agreements. If we default under our Senior Secured Loan, our lenders may accelerate all of our repayment obligations and take control of our pledged assets. Our lenders could declare us in default under our debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect upon us as defined under the loan agreements, thereby requiring us to repay the loans immediately or to attempt to reverse the lenders’ declaration through negotiation or litigation. Among other loan covenant requirements, the Senior Secured Loan also requires us to maintain a minimum level of liquidity of at least $10,000 at all times during the term of the loan unless our quarterly consolidated EBITDA is at least $6,000 and to meet specified minimum net revenues during a trailing twelve-month period commencing on June 30, 2012. The negative covenants include, among other things, restrictions on transferring or licensing our assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions and creating other liens on our assets, in each case subject to customary exceptions. In April 2012, we elected to pay the 12% interest in cash and the remaining 5% interest of $333 was added to the principal loan balance as incremental debt. At June 30, 2012, the outstanding balance on the Senior Secured Loan was $60,333.

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

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

On August 1, 2012, we filed a registration statement on Form S-3 which allows us to offer and sell up to an aggregate of $175,000 worth of common stock, preferred stock, debt securities and/or warrants in public offerings.

We are required to maintain compliance with applicable Swiss laws with respect to our Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. We review on a regular basis whether our Swiss subsidiary is overindebted. As of December 31, 2011, and June 30, 2012, the Company’s Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. We will continue to monitor and review steps to address any overindebtedness, until such time as our Swiss subsidiary generates positive income at a statutory level, which could require us to have cash at our Swiss subsidiary in excess of its near term operating needs and could affect our ability to have sufficient cash at our U.S. subsidiary to meet its near term operating needs. The following table provides a summary of our cash flows for the six months ended June 30, 2012 and 2011, as follows:

<table>
<thead>
<tr>
<th>Cash provided by (used in):</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating activities</td>
<td>$(36,647)</td>
<td>$(10,646)</td>
</tr>
<tr>
<td>Investing activities</td>
<td>$(1,043)</td>
<td>$(36)</td>
</tr>
<tr>
<td>Financing activities</td>
<td>$83,386</td>
<td>$10,857</td>
</tr>
</tbody>
</table>

**Sources and Uses of Cash**

**Operating Cash Flows**

During the six months ended June 30, 2012 and 2011, net cash used in operating activities was $36,647 and $10,646, respectively. The increase in net cash used in operating activities was primarily attributable to higher sales and marketing costs during the six months ended June 30, 2012 in connection with our product launch of DUEXIS, which resulted in higher salaries and benefits expenses associated with staffing our sales and administrative functions in addition to higher marketing and promotional expenses compared to the prior year.

**Investing Cash Flows**

During the six months ended June 30, 2012 and 2011, net cash flows used in investing activities was $1,043 and $36, respectively, and the increase in the current period represented capital expenditures related to purchases associated with laptop computers for new employees and other computer hardware.

**Financing Cash Flows**

During the six months ended June 30, 2012 and 2011, net cash provided by financing activities was $83,386 and $10,857, respectively. The increase in net cash provided by financing activities was primarily the result of our debt refinancing and private equity offering completed during the first quarter of 2012. In February 2012, we entered into our $60,000 Senior Secured Loan with a group of institutional lenders. As part of the closing of the Senior Secured Loan, we repaid outstanding principal under the Oxford and Kreos debt facilities totaling $19,730. In March 2012, we received gross proceeds of $50,820 and net proceeds of $47,475, after deducting $3,345 in issuance costs from the sale of 14,033,829 shares of our common stock and warrants to purchase an aggregate of 3,508,448 shares of our common stock to certain institutional and accredited investors in a private equity placement.
Contractual Obligations

During the three months ended June 30, 2012, there were no material changes outside the ordinary course of business to our contractual obligations as previously disclosed in Part I, Item 2 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities, other than the indemnification agreements discussed in Note 11, “Commitments and Contingencies” in the notes to our condensed consolidated financial statements included in this report.

Quantitative and Qualitative Disclosures About Market Risk

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

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

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

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

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 June 30, 2012, 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.

Legal Proceedings

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc., or Par Pharmaceutical, advising that Par Pharmaceutical had filed an Abbreviated New Drug Application, or ANDA, with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par Pharmaceutical has not advised us as to the timing or status of the FDA’s review of its filing, or whether it has complied with FDA requirements for proving bioequivalence. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par Pharmaceutical and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS. A trial date is currently set for the first quarter of 2014. All of our issued U.S. patents covering DUEXIS are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Under the FDA’s rules and regulations, because we initiated a patent infringement suit to defend a patent identified in the Paragraph IV notice within 45 days after the FDA’s receipt of the notice, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the infringement case that the patent is not infringed or invalid.
You should consider carefully the risks described below, together with all of the other information included in this report, and in our other filings with the Securities and Exchange Commission, or SEC, before deciding whether to invest in or continue to hold our common stock. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing changes, including any material changes, from the risk factors previously disclosed in Item 1A of our annual report on Form 10-K for the year ended December 31, 2011, as filed with the SEC.

Risks Related to Our Business and Industry

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

DUEXIS and RAYOS/LODOTRA and our other product candidates, if approved, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. In the U.S. market, we began selling DUEXIS in December 2011 and are continuing to expand our sales force. We have not yet begun commercial sales of RAYOS, which was recently approved by the FDA in July 2012. Outside the U.S., LODOTRA has only been sold in a limited number of European countries. Sales of DUEXIS and LODOTRA have been limited to date and sales may not grow to expected levels, in part because, with respect to LODOTRA, we depend on our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for commercialization outside the U.S. We believe that the degree of market acceptance and our ability to generate revenues from any products for which we obtain marketing approval will depend on a number of factors, including:

- timing of market introduction of our products as well as competitive drugs;
- efficacy and safety of our products;
- continued projected growth of the arthritis, pain and inflammation markets;
- prevalence and severity of any side effects;
- acceptance by patients, primary care specialists and key specialists, including rheumatologists, orthopedic surgeons and pain specialists;
- the performance of our distribution and co-promotion partners, over which we have limited control;
- potential or perceived advantages or disadvantages of our products over alternative treatments, including cost of treatment and relative convenience and ease of administration;
- strength of sales, marketing and distribution support;
- the price of our products, both in absolute terms and relative to alternative treatments;
- the effect of current and future healthcare laws;
- availability of coverage and adequate reimbursement and pricing from government and other third-party payers; and
- product labeling or product insert requirements of the Food and Drug Administration, or FDA, or other regulatory authorities.

With respect to DUEXIS, studies indicate that physicians do not commonly co-prescribe GI protective agents to high-risk patients taking NSAIDs. We believe this is due in part to a lack of awareness among physicians prescribing NSAIDs of the risk of NSAID-induced upper GI ulcers, in addition to the inconvenience of prescribing two separate medications and patient compliance issues associated with multiple prescriptions. If physicians remain unaware of, or do not otherwise believe in, the benefits of combining GI protective agents with NSAIDs, our market opportunity for DUEXIS will be limited. Some physicians may also be reluctant to prescribe DUEXIS due to the inability to vary the dose of ibuprofen or if they believe treatment with NSAIDs or GI protective agents other than ibuprofen and famotidine, including those of our competitors, would be more effective for their patients. With respect to both DUEXIS and RAYOS/LODOTRA, their higher cost compared to the generic forms of their active ingredients alone may limit adoption by physicians, patients and healthcare payers. If DUEXIS, RAYOS/LODOTRA or 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.

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

Our strategy is to build a fully-integrated U.S.-focused biopharmaceutical company to successfully execute the commercial launches of DUEXIS and RAYOS, which was approved on July 26, 2012, in the U.S. market. We may not be able to successfully commercialize either DUEXIS or RAYOS in the U.S. Prior to initial detailing in December 2011 and our commercial launch of DUEXIS in the U.S. in December 2011, we did not have any experience commercializing pharmaceutical products on our own. LODOTRA was commercially launched in Europe by our exclusive distribution partners Merck Serono and Mundipharma. In order to commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. We currently have limited resources and the continued 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 successfully 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 RAYOS/LODOTRA, and we may not be able to successfully commercialize these products or successfully obtain additional marketing approvals for DUEXIS in Europe.*

To date, we have expended significant time, resources and effort on the development of DUEXIS and RAYOS, and a substantial majority of our resources are now focused on the commercialization of DUEXIS in the U.S. and seeking additional marketing approvals for DUEXIS. Our ability to generate significant product revenues and to achieve commercial success in the near term will initially depend almost entirely on our ability to successfully commercialize DUEXIS and RAYOS in the U.S. and to obtain European marketing approval for DUEXIS. 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, Australia and Israel, 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 reimbursement approvals in these countries. Even if we obtain additional marketing and reimbursement approvals, our product revenues in Europe are entirely dependent upon the marketing efforts of our exclusive distribution partner, over which we have no control. Before we can market and sell these products in a particular jurisdiction, we need to obtain necessary regulatory approvals (from the FDA in the U.S. and from similar foreign regulatory agencies in other jurisdictions) and in some jurisdictions, reimbursement authorization. There are no guarantees that we or our commercialization partners will obtain any additional regulatory approvals for our products. Even if we or our commercialization partners obtain additional regulatory approvals, we may never generate significant revenues from any commercial sales of our products. If we fail to successfully commercialize DUEXIS or RAYOS, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be adversely affected.

In February 2012, we entered into a $60 million senior secured loan facility with a group of institutional lenders, or Senior Secured Loan, that includes certain performance covenants, including minimum trailing twelve month revenue covenants at each quarter end. Should we not meet these quarterly minimum revenue covenants, in addition to an increase in the interest rate payable under the loan facility, the lenders have the right to demand repayment of the obligations under the loan. There can be no assurance that we will be able to satisfy the operating and financial covenants under the Senior Secured Loan for future periods. We also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if we were unable to meet the minimum quarterly revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations.

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

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

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

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

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

We rely on Mundipharma for commercialization of LODOTRA in various European countries and certain Asian, Latin American and other countries. We have limited contractual rights to force Mundipharma to invest significantly in commercialization of LODOTRA in its markets. In the event that Mundipharma or any other third party with any future commercialization rights to any of our products or product candidates fails to adequately commercialize those products or product candidates because it lacks adequate financial or other resources, decides to focus on other initiatives or otherwise, our ability to successfully commercialize our products or product candidates in the applicable jurisdictions could have a material adverse effect on our business.

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

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

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

To market any drugs outside of the U.S., we and current or future collaborators must comply with numerous and varying regulatory and compliance related requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.
Applications for regulatory approval, including a Marketing Authorization Application, or MAA, for marketing new drugs in Europe, must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. Regulatory authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

• may not deem a product candidate to be adequately safe and effective;
• may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
• may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we do;
• may not approve the manufacturing processes or facilities associated with our product candidates;
• may conclude that we have not sufficiently demonstrated long-term stability of the formulation for which we are seeking marketing approval;
• may change approval policies (including with respect to our product candidates’ class of drugs) or adopt new regulations; or
• may not accept a submission due to, among other reasons, the content or formatting of the submission.

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

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

While we anticipate that LODOTRA will be marketed in additional European Union countries as Mundipharma formulates its reimbursement strategy, the ability to market LODOTRA in additional European Union countries will depend on Mundipharma’s ability to obtain regulatory and reimbursement approvals in these countries. Similarly, our ability to market DUEXIS outside of the U.S. will depend on obtaining regulatory and reimbursement approval in each country where we expect DUEXIS to be marketed. However, certain countries have a very difficult reimbursement environment and we may not obtain reimbursement approval in all countries where we expect DUEXIS to be marketed, or we may obtain reimbursement approval at a level that would make marketing DUEXIS in certain countries not viable.
Our limited operating history makes evaluating our business and future prospects difficult, and may increase the risk of any investment in our common stock.*

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

As of December 31, 2010, we employed 41 full-time employees as a consolidated entity. In anticipation of the commercial launch of DUEXIS, we hired 80 sales representatives during the period from September 2011 through October 2011. As of December 31, 2011, and June 30, 2012, we employed 164 and 172 full-time employees, respectively, as a consolidated entity. We have also experienced, and may continue to experience, turnover on the original 80 sales representatives that we hired in connection with the commercial launch of DUEXIS, requiring us to train new sales representatives. Our management, personnel, systems and facilities currently in place may not be adequate to support this recent growth, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses.

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

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

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

As DUEXIS was commercially launched in December 2011 and we have not begun commercial sales of RAYOS, the members of our sales force have limited experience promoting DUEXIS and no experience promoting RAYOS. As a result, we are required to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense DUEXIS and RAYOS. In addition, we must train our sales force to ensure that a consistent and appropriate message about DUEXIS and RAYOS is being delivered to our potential customers. We have also experienced, and may continue to experience, turnover on the original 80 sales representatives that we hired in connection with the commercial launch of DUEXIS, requiring us to train new sales representatives. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of DUEXIS and RAYOS and their proper administration and label indication, our efforts to successfully commercialize DUEXIS and RAYOS could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.

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

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the U.S. and international markets, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or-in-licensing on an exclusive basis, products that are more effective and/or less costly than DUEXIS and RAYOS/LODOTRA or any product candidates that we are currently developing or that we may develop.

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

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

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

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

In addition, established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license and develop novel compounds that could make our products obsolete. Our ability to compete successfully with these companies and other potential competitors will depend largely on our ability to leverage our experience in 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 and regulatory compliance of our distributors or strategic partners;
• compliance with German laws with respect to our Horizon Pharma GmbH subsidiary through which Horizon Pharma AG conducts most of its European operations;
• foreign government taxes, regulations and permit requirements;
• U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
• economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;

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

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

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

• changes in diplomatic and trade relationships; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In Europe, the success of our products, including LODOTRA and, if approved, DUEXIS, will depend largely on obtaining and maintaining government coverage, because in many European countries patients are unlikely to use prescription drugs that are not covered by their government health care programs. To date, LODOTRA is approved in 16 European countries, Australia and Israel, and
reimbursement for LODOTRA has been obtained in Germany, Italy and Switzerland. Mundipharma is seeking coverage for LODOTRA in a number of countries in Europe and Israel and currently sells LODOTRA without coverage in a limited number of European countries. Negotiating coverage and reimbursement with governmental authorities can delay commercialization by 12 months or more. Coverage and reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and we expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceutical products, which we believe has impacted the reimbursement rates and timing to launch for LODOTRA to date, and we expect these discounts to continue as countries attempt to manage healthcare expenditures, especially in light of current economic conditions. For example, legislation was recently enacted in Germany that will increase the rebate on prescription pharmaceuticals and likely lower the revenues from the sale of LODOTRA in Germany that we would otherwise receive. As a result of these pricing practices, it may become difficult to achieve profitability or expected rates of growth in revenue or results of operations. Any shortfalls in revenue could adversely affect our business, financial condition and results of operations.

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

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

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

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers’ Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any payment or “transfer of value” made or distributed to teaching hospitals, prescribers and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection to be required no earlier than January 1, 2013 and reporting to be required at a later date;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;
- expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.
In June 2012, the United States Supreme Court heard a constitutional challenge to PPACA and upheld the constitutionality of PPACA, except that the Court held unconstitutional a provision of PPACA authorizing the Secretary of the Department of Health and Human Services to withdraw all of a state’s Medicaid funding if the state declines to participate in PPACA’s expansion of Medicaid eligibility. PPACA and/or certain of PPACA’s provisions may be modified or eliminated by future legislation or litigation. We anticipate that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for DUEXIS and any other approved product in the U.S. and could seriously harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers.

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

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

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

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

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

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

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

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

The facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities. We do not control the manufacturing processes of third-party manufacturers and are currently completely dependent on our third-party manufacturing partners Pharmacetics International, Inc., located in Hunt Valley, Maryland, and sanofi-aventis U.S. LLC, or sanofi-aventis U.S., operating through Valeant, its manufacturing partner located in Laval, Canada for production of DUEXIS, and Jagotec AG, a wholly-owned subsidiary of Skypharma PLC, located in Lyon, France, for production of LODOTRA. In August 2011, Skypharma leased their entire pharmaceutical manufacturing business to the Aenova France SAS, or Aenova. As such, Aenova is now a subcontractor for Jagotec for the manufacture of RAYOS/LODOTRA, with our consent. Bayer Schering Pharma AG in Germany has been qualified as a backup manufacturer. In December 2011, Valeant Pharmaceuticals International, Inc., or Valeant, acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. We purchase the primary active ingredients for DUEXIS from BASF Corporation in Bishop, Texas and Dr. Reddy’s Laboratories in India, and the primary active ingredients for RAYOS/LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and Sanofi-Aventis SA in France. If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities’ strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to supply our primary active ingredients or manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products.

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

Although we have entered into supply agreements for the manufacture of our products, our manufacturers may not perform as agreed or may terminate their agreements with us. Under our manufacturing and supply agreement with sanofi-aventis U.S., either we or sanofi-aventis U.S. may terminate the agreement upon an uncured breach by the other party or without cause upon two years prior written notice, so long as such notice is given after the third anniversary of the first commercial sale of DUEXIS. Under our manufacturing and supply agreement with Jagotec, either we or Jagotec may terminate the agreement in the event of an insolvency, liquidation or bankruptcy of the other party or upon an uncured breach by the other party. While we have the right to receive a continuing supply of RAYOS/LODOTRA from Jagotec for a period of 24 months after termination, we cannot assure you that we would be able to establish another commercial supply of RAYOS/LODOTRA in that time-frame, or qualify any new supplier with the applicable regulatory authorities on a timely basis or at all.

In addition, we do not have the capability to package DUEXIS, RAYOS/LODOTRA or any other product candidates for distribution. Consequently, we have entered into an agreement with Temmler Werke GmbH for packaging of RAYOS/LODOTRA in 16 European countries, Israel and in the U.S., as well as any additional countries as may be agreed to by the parties. We intend to sell
The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Though we believe we have resolved any stability issues with respect to the commercial formulation of DUEXIS, we cannot assure you that any other stability or other issues relating to the manufacture of any of our products will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize DUEXIS and RAYOS in the U.S. or provide any product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in our ability to market DUEXIS or RAYOS/LODOTRA will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

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

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

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

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

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

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

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

We have agreements with third-party contract research organizations, or CROs, to conduct our clinical programs 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 GCP or ICH regulations. The FDA enforces these GCP or ICH regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP or ICH regulations, the data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCP or ICH regulations. In addition, our clinical trials must be

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conducted with product produced under cGMP regulations, and require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

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

In addition, pursuant to a March 2011 letter agreement and in connection with our waiver of certain milestone payments, Mundipharma has agreed to conduct a separate 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 in Europe for LODOTRA for the treatment of PMR will be delayed, and our business prospects would be harmed. While we have the right to use any data resulting from the planned clinical trial, we may not own the results from the trial, which could make it more difficult to pursue the development of RAYOS/LODOTRA as a treatment for PMR on our own.

We also, as part of the April 23, 2011 FDA approval of DUEXIS, have a commitment under the Pediatric Research Equity Act, or PREA, to conduct an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients. Although we are committed to carrying out these commitments, there are challenges in conducting studies in pediatric patients including availability of patients and obtaining parental informed consent.

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

Clinical testing is expensive and can take many years to complete, and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of 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 RAYOS/LODOTRA or we conduct clinical development of our earlier stage product candidates or additional indications for RAYOS/LODOTRA, we may experience delays in these clinical trials. A ten patient investigator-initiated Phase 2 study was recently completed to investigate LODOTRA as a potential treatment for PMR and a manuscript is currently being prepared by the investigator. Pursuant to a March 2011 letter agreement, Mundipharma has agreed to conduct a separate clinical trial for RAYOS/LODOTRA in this indication, which we expect will be a Phase 3 clinical trial. Additionally, we have several earlier stage product candidates to treat pain-related diseases including TRUNOC (tarenflurbil) for the treatment of pain-related diseases and HZN-602, a single pill combination of naproxen and famotidine, for reducing the risk of NSAID-induced upper GI ulcers in patients with mild to moderate pain and arthritis who require the use of naproxen. While we are currently not focusing any resources on these potential product candidates, we do not know whether any additional clinical trials will be initiated in the future, begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement with the FDA on any SPAs we submit;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board or ethics committee approval at each site;
- recruiting suitable patients to participate in a trial;
Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians’ and patients’ perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our future clinical trials and while we intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

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

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

A key element of our strategy is to develop, acquire or in-license and commercialize a portfolio of other product candidates in addition to DUEXIS and RAYOS/LODOTRA. Since we do not have proprietary drug discovery technology, the success of this strategy depends in large part upon the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire 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 is inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

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

- decreased demand for our products or product candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- an event of default under our $60.0 million Senior Secured Loan;
- the inability to commercialize our products or product candidates; and
- a decline in our stock price.

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

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

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

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

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

Risks Related to Our Financial Position and Capital Requirements

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

We have a limited operating history. We have financed our operations primarily through equity and debt financings and have incurred significant operating losses since our inception. We had a net loss of $46.5 million during the six months ended June 30, 2012 and net losses of $113.3 million, $27.1 million and $20.5 million for the years ended December 31, 2011, 2010 and 2009, respectively. As of June 30, 2012, we had an accumulated deficit of $266.8 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 of DUEXIS and RAYOS/LODOTRA.

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

Our ability to become profitable depends upon our ability to generate revenues from sales of our products. DUEXIS was approved by the FDA on April 23, 2011, and we began generating limited revenues from sales of DUEXIS in late 2011 following the commercial launch in the U.S. LODOTRA is approved for marketing in Europe, Australia and Israel, and to date we have generated only limited revenues from sales of LODOTRA. RAYOS was approved by the FDA on July 26, 2012, and we have not yet begun marketing it in the U.S. We may never be able to successfully commercialize DUEXIS or RAYOS or develop or commercialize other products in the U.S., which we believe represents its most significant commercial opportunity, or sell DUEXIS in Europe. Our ability to generate future revenues depends heavily on our success in:

* commercializing DUEXIS, RAYOS/LODOTRA and any other product candidates for which we obtain approval;
We believe that our existing cash and cash equivalents, including net proceeds from our recently completed debt and equity financings, together with interest thereon, will be sufficient to fund our operations into the first half of 2013. We may need to raise additional funds sooner if we choose to expand our commercialization or development efforts more rapidly than we presently anticipate or our revenues do not meet expectations.
We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives. We also could be required to:

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

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

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

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

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

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

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

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

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

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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 June 30, 2012, we had $63.5 million of cash and cash equivalents consisting of cash and money market funds. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since June 30, 2012, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities owned by us.

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

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

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the U.S. or in other foreign countries. If this were to occur, early generic competition could be expected against DUEXIS, RAYOS/LODOTRA and other product candidates in development. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in DUEXIS and RAYOS/LODOTRA have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical advising that Par Pharmaceutical had filed an ANDA with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par Pharmaceutical has not advised us as to the timing or status of the FDA’s review of its filing, or whether it has complied with FDA requirements for proving bioequivalence. In March 2012, we filed a patent infringement lawsuit against Par Pharmaceutical and Par Pharmaceutical Companies, Inc. for filing an ANDA against DUEXIS. A trial date is currently set for the first quarter of 2014. All of our issued U.S. patents covering DUEXIS are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Under the FDA’s rules and regulations, because we initiated a patent infringement suit to defend a patent identified in the Paragraph IV notice within 45 days after the FDA’s receipt of the notice, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the infringement case that the patent is not infringed or invalid. We intend to vigorously defend our intellectual property rights relating to DUEXIS, but we cannot predict the outcome of this matter. Any adverse outcome in this matter could result in one or more generic versions of DUEXIS being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of DUEXIS and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.
Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to DUEXIS and RAYOS/LODOTRA fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them, and threaten our ability to commercialize, our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market DUEXIS and RAYOS/LODOTRA under patent protection could be reduced. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to DUEXIS and RAYOS/LODOTRA or our other product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the U.S. can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that 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 RAYOS/LODOTRA and/or our other product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

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

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of our Common Stock

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

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

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

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

- our failure to successfully execute our commercialization strategy with respect to our approved products, particularly our commercial launch of DUEXIS in the U.S.;
- any adverse development or perceived adverse development with respect to the Medicines and Healthcare products Regulatory Agency’s review of our MAA for DUEXIS filed in the European Union through the Decentralized Procedure, and amended in February 2012 through the National Procedure in the UK;
- disputes or other developments relating to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products and product candidates;
- unanticipated serious safety concerns related to the use of DUEXIS, RAYOS/LODOTRA or any of our other product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our products or product candidates, including but not limited to clinical trial requirements for approvals;
- inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;
- developments concerning our commercial partners, including but not limited to those with our sources of manufacturing supply;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse results or delays in clinical trials;
- our failure to successfully develop additional product candidates;
- introduction of new products or services offered by us or our competitors;
- our inability to effectively manage our growth;
- overall performance of the equity markets and general political and economic conditions;
- failure to meet or exceed revenue and financial projections we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- our inability to successfully enter new markets;
- the termination of a collaboration or the inability to establish additional collaborations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

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. We do not anticipate declaring or paying any cash dividends on our common stock.

Our officers, directors and funds affiliated with our directors held in the aggregate approximately 32% of our outstanding voting stock as of December 31, 2011, and 31% as of June 30, 2012. Therefore, these stockholders have the ability to influence us through this ownership position, including through matters requiring stockholder approval, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

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

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

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

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

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

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

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

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

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

On December 15, 2011, pursuant to the terms of our 2011 EIP and 2011 ESPP, our board of directors approved increases in the number of shares available for issuance under the 2011 EIP and 2011 ESPP. The number of shares available for issuance under the 2011 EIP and 2011 ESPP were initially registered on a registration statement on Form S-8 filed with the SEC on July 28, 2011.
Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

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

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

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

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

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

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 6. Exhibits

The exhibits listed on the Index to Exhibits following the signature page are filed as part of this Quarterly Report on Form 10-Q.
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HORIZON PHARMA, INC.

Date: August 10, 2012
By:  /s/ Timothy P. Walbert
    Timothy P. Walbert
    Chairman, President and Chief Executive Officer
    (Principal Executive Officer)

Date: August 10, 2012
By:  /s/ Robert J. De Vaere
    Robert J. De Vaere
    Executive Vice President and Chief Financial Officer
    (Principal Financial and Accounting Officer)
## INDEX TO EXHIBITS

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<td>Form of Warrant issued by Horizon Pharma, Inc. pursuant to the Loan and Security Agreement, dated February 22, 2012, by and among Horizon Pharma USA, Inc., Horizon Pharma, Inc., Cortland Capital Market Services, LLC, as administrative agent, and the Lenders listed therein.</td>
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+ Indicates management contract or compensatory plan.
Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(1) Incorporated by reference to Horizon Pharma, Inc.’s Registration Statement on Form S-1 (No. 333-168504), as amended.
(2) Incorporated by reference to Horizon Pharma, Inc.’s Current Report on Form 8-K, filed on August 2, 2011.
(3) Incorporated by reference to Horizon Pharma, Inc.’s Current Report on Form 8-K, filed on March 1, 2012.
This Executive Employment Agreement (hereinafter referred to as the “Agreement”), is entered into effective June 1, 2012 (the “Effective Date”) by and between Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation, each having a principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, IL 60015 (hereinafter referred to together as the “Company”), and Todd N. Smith, an individual residing at 31445 Reigate Lane, Green Oaks, IL 60044, domiciled in the State of Illinois (hereinafter referred to as the “Executive”). This Agreement supersedes in its entirety the Employment Offer Letter entered into by and between Horizon Pharma USA, Inc. and the Executive on September 24, 2010 (the “Prior Agreement”).

RECITALS

WHEREAS, the Company is a duly organized Delaware corporation, with its principal place of business within the State of Illinois, and is in the business of developing and marketing prescription medication; and

WHEREAS, the Executive is domiciled within the State of Illinois and is highly skilled and experienced in the business of developing and marketing health care related products and services; and

WHEREAS, the Company desires assurance of the continued association and services of the Executive in order to continue to retain the Executive’s experience, skills, abilities, background and knowledge, and is willing to continue to engage the Executive’s services on the terms and conditions set forth in this Agreement; and

WHEREAS, the Executive desires to be in the continued employ of the Company, and is willing to accept such continued employment on the terms and conditions set forth in this Agreement.

AGREEMENT

1. Employment.

1.1 Term. The Company hereby agrees to employ the Executive, and the Executive hereby accepts employment by the Company, upon the terms and conditions set forth in this Agreement. The Executive’s original date of hire was October 1, 2010 (the “Hire Date”). The Executive’s employment shall be governed under the terms set forth in this Agreement beginning on the Effective Date and shall continue until it is terminated pursuant to Section 4 herein (hereinafter referred to as the “Term”).
1.2 Title. The Executive shall have the title of Executive Vice President and Chief Commercial Officer (hereinafter referred to as “CCO”) of the Company and shall serve in such other capacity or capacities commensurate with his position as Executive Vice President and CCO as the President and CEO of the Company may from time to time prescribe.

1.3 Duties. The Executive shall do and perform all services, acts or things necessary or advisable to manage and conduct the business of the Company and shall have the authority and responsibilities which are generally associated with the position of Executive Vice President and CCO, including being responsible for the Company’s marketing and sales strategy and operations. The Executive shall report to the President and CEO.

1.4 Policies and Practices. The employment relationship between the Parties shall be governed by this Agreement and the policies and practices established by the Company and the Board of Directors (hereinafter referred to as the “Board”). In the event that the terms of this Agreement differ from or are in conflict with the Company’s policies or practices or the Company’s Employee Handbook, this Agreement shall control.

1.5 Location. The Executive shall perform the services the Executive is required to perform pursuant to this Agreement in the Company’s Deerfield, IL headquarters. The Company may from time to time require the Executive to travel outside the Company’s headquarters in Deerfield, IL and other locations in connection with the Company’s business.

2. Loyalty of Executive.

2.1 Loyalty. During the Executive’s employment by the Company, the Executive shall devote the Executive’s business energies, interest, abilities and productive time to the proper and efficient performance of the Executive’s duties under this Agreement. The Executive is permitted to serve on the board of directors of one other company, so long as the other company does not compete with the Company.

2.2 Exclusive Employment. Except with the prior written consent of the Board, the Executive shall not, during the term of this Agreement, undertake or engage in any other employment, occupation or business enterprise, other than ones in which the Executive is a passive investor. The Executive may engage in any civic and not-for-profit activities so long as such activities do not materially interfere with the performance of his duties hereunder or present a conflict of interest with the Company.

2.3 Agreement not to Participate in Company’s Competitors. During the Term of this Agreement, the Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by the Executive to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise or in any company, person or entity that is, directly or indirectly, in competition with the business of the Company or any of its affiliates.
3. Compensation to Executive.

3.1 Base Salary. The Company shall pay the Executive a base salary at the initial annualized rate of three hundred thirty-three thousand dollars ($333,000.00) per year, subject to standard deductions and withholdings, or such higher rate as may be determined from time to time by the Board or the compensation committee thereof (hereinafter referred to as the “Base Salary”). Such Base Salary shall be paid in accordance with the Company’s standard payroll practice. Payments of salary installments shall be made no less frequently than once per month. The Executive’s Base Salary will be reviewed annually each December and the Executive shall be eligible to receive a salary increase (but not decrease) annually in an amount to be determined by the Board or the compensation committee thereof in its sole and exclusive discretion. Once increased, the new salary shall become the Base Salary for purposes of this Agreement and shall not be reduced without the Executive’s written consent. Any reduction in the Base Salary of the Executive, without his written consent, shall be deemed Good Reason as set forth in and subject to Section 4.5.2 of this Agreement.

3.2 Discretionary Bonus. Provided the Executive meets the conditions stated in this Section 3.2, the Executive shall be eligible for an annual discretionary bonus (hereinafter referred to as the “Bonus”) with a target amount of forty percent (40%) of the Executive’s Base Salary, subject to standard deductions and withholdings, based on the Board’s determination, in good faith, and based upon the Executive’s individual achievement and company performance objectives as set by the Board or the compensation committee thereof, of whether the Executive has met such performance milestones as are established for the Executive by the Board or the compensation committee thereof, in good faith, in consultation with the Executive (hereinafter referred to as the “Performance Milestones”). The Performance Milestones will be based on certain factors including, but not limited to, the Executive’s performance and the Company’s financial performance. The Executive’s Bonus target will be reviewed annually and may be adjusted by the Board or the compensation committee thereof in its discretion, provided however, that the Bonus target may only be reduced upon the Executive’s written consent. The Executive must be employed on the date the Bonus is awarded to be eligible for the Bonus, subject to the termination provisions thereof. The Bonus shall be paid during the calendar year following the calendar year for which such Bonus was earned.

3.3 [Reserved].

3.4 Discretionary Grants. At least one time per year, the Board shall consider, in good faith, whether to grant additional equity awards to the Executive.

3.5 Legal Review. Upon the Executive’s submission of appropriate itemized proof and verification of reasonable and customary legal fees incurred by the Executive in obtaining legal advice associated with the review, preparation, approval, and execution of this Agreement, the Company shall pay for such legal fees subject to receipt of appropriate proof and verification of such legal fees no later than ninety (90) days after such expenses are incurred by the Executive. The Company agrees to pay all reasonable legal fees pursuant to Section 3.5 of this Agreement within thirty (30) days of receipt of an invoice for legal services from the Executive and/or his attorneys.
3.6 Changes to Compensation. The Executive’s compensation may be changed from time to time by mutual agreement of the Executive and the Company. In the event that the Executive’s base salary is materially decreased without his written consent, said decrease will be Good Reason for the Executive to terminate the Agreement as set forth in and subject to Section 4.5.2 of this Agreement.

3.7 Taxes. All amounts paid under this Agreement to the Executive by the Company will be paid less applicable tax withholdings and any other withholdings required by law or authorized by the Executive.

3.8 Benefits. The Executive shall, in accordance with Company policy and the terms of the applicable plan documents, be eligible to participate in benefits under any executive benefit plan or arrangement which may be in effect from time to time and made available to the Company’s executives or key management employees, provided, however, that the Executive shall be entitled to at least four (4) weeks of paid vacation annually.

4. Termination.

4.1 Termination by the Company. The Executive’s employment with the Company may be terminated only under the following conditions:

4.1.1 Termination for Death or Disability. The Executive’s employment with the Company shall terminate effective upon the date of the Executive’s death or “Complete Disability” (as defined in Section 4.5.1), provided, however, that this Section 4.1.1 shall in no way limit the Company’s obligations to provide such reasonable accommodations to the Executive and/or his heirs as may be required by law.

4.1.2 Termination by the Company For Cause. The Company may terminate the Executive’s employment under this Agreement for “Cause” (as defined in Section 4.5.3) by delivery of written notice to the Executive specifying the Cause or Causes relied upon for such termination, provided that such notice is delivered within two (2) months following the occurrence or discovery of any event or events constituting “Cause”. Any notice of termination given pursuant to this Section 4.1.2 shall effect termination as of the date of the notice or such date as specified in the notice. The Executive shall have the right to appear before the full Board before any termination for Cause becomes effective and binding upon the Executive.

4.1.3 Termination by the Company Without Cause. The Company may terminate the Executive’s employment under this Agreement at any time and for any reason or no reason subject to the requirements set out in Section 4.4 of this Agreement. Such termination shall be effective on the date the Executive is so informed or as otherwise specified by the Company, pursuant to notice requirements set forth in Section 6 of this Agreement.
4.2 Termination by the Executive. The Executive may terminate his employment with the Company at any time and for any reason or no reason, including, but not limited to, the following conditions:

4.2.1 Good Reason. The Executive may terminate his employment under this Agreement for “Good Reason” (as defined below in Section 4.5.2) by delivery of written notice to the Company specifying the Good Reason relied upon by the Executive for such termination in accordance with the requirements of such section.

4.2.2 Without Good Reason. The Executive may terminate the Executive’s employment hereunder for other than Good Reason upon thirty (30) days written notice to the Company.

4.3 Termination by Mutual Agreement of the Parties. The Executive’s employment pursuant to this Agreement may be terminated at any time upon a mutual agreement in writing of the Parties. Any such termination of employment shall have the consequences specified in such mutual agreement.

4.4 Compensation to Executive Upon Termination.

4.4.1 Death or Complete Disability. If the Executive’s employment shall be terminated by death or Complete Disability as provided in Section 4.1.1, the Company shall pay to the Executive, and/or the Executive’s heirs, all earned but unpaid Base Salary, any earned but unpaid discretionary bonuses for any prior period at such time as bonuses would have been paid if the Executive remained employed, all accrued but unpaid business expenses, and all accrued but unused vacation time earned through the date of termination at the rate in effect at the time of termination (hereinafter referred to as the “Accrued Amounts”), less standard deductions and withholdings. The Executive shall also be eligible to receive a pro-rated bonus for the year of termination, as determined by the Board or the Compensation Committee of the Board based on actual performance and the period of the year he was employed (hereinafter referred to as the “Pro-rata Bonus”), less standard deductions and withholdings, to be paid as a lump sum within thirty (30) days after the date of termination.

4.4.2 With Cause or Without Good Reason. If the Executive’s employment shall be terminated by the Company for Cause, or if the Executive terminates employment hereunder without Good Reason, the Company shall pay the Executive’s Base Salary, accrued but unpaid business expenses and accrued and unused vacation benefits earned through the date of termination at the rate in effect at the time of termination, less standard deductions and withholdings.

4.4.3 Without Cause or For Good Reason. If the Company terminates the Executive’s employment without Cause or the Executive terminates his employment for Good Reason, the Company shall pay the Accrued Amounts subject to standard deductions and withholdings, to be paid as a lump sum no later than thirty (30) days after the date of termination. In addition, subject to the limitations stated in this Agreement and upon the Executive’s furnishing to the Company an executed waiver and release of...
claims (the form of which is attached hereto as Exhibit A) (the “Release”) within the applicable time period set forth therein, but in no event later than forty-five days following termination of employment and permitting such Release to become effective in accordance with its terms (the “Release Effective Date”), and subject to the Executive entering into no later than the Release Effective Date a non-competition agreement to be effective during the Severance Period, substantially similar to Section 2.3, and continuing to abide by its terms during the Severance Period, the Executive shall be entitled to:

(i) the equivalent of the Executive’s annual Base Salary in effect at the time of termination for a period of twelve (12) months following the date of termination (hereinafter referred to as the “Severance Period”), less standard deductions and withholdings, to be paid during the Severance Period according to the Company’s regular payroll practices, subject to any delay in payment required by Section 4.6 in connection with the Release Effective Date;

(ii) in the event the Executive timely elects continued coverage under COBRA, the Company will continue to pay the same portion of the Executive’s COBRA health insurance premium as the percentage of health insurance premiums that it paid during the Executive’s employment, including any amounts that the Company paid for benefits to the qualifying family members of the Executive, up until the earlier of either (i) the last day of the Severance Period or, (ii) the date on which the Executive begins full-time employment with another company or business entity which offers comparable health insurance coverage to the Executive; and

(iii) notwithstanding anything to the contrary set forth herein, the Severance Period, and the Company’s provisions of cash severance benefits to the Executive under this Section 4.4.3 shall immediately cease upon the date that the Executive begins full-time employment with another company or business entity which offers base compensation to the Executive of at least ninety-five percent (95%) of the Executive’s annual Base Salary amount in effect at the time of termination. The Executive agrees to immediately notify the Company in writing of any such employment.

4.4.4 Equity Award Acceleration.

(i) In Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason within the ninety (90) days immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of any equity award shares granted to the Executive prior to such termination shall be fully accelerated and such awards shall become immediately exercisable by the Executive.

(ii) Release and Waiver. Any equity vesting acceleration pursuant to this Section 4.4.4 shall be conditioned upon and subject to the Executive’s delivery to the Company of a fully effective Release in accordance with the terms specified by Section 4.4.3 hereof and such vesting acceleration benefit shall be in addition to the benefits provided by Section 4.4.3 hereof.
4.5 Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

4.5.1 Complete Disability. “Complete Disability” shall mean the inability of the Executive to perform the Executive’s duties under this Agreement, whether with or without reasonable accommodation, because the Executive has become permanently disabled within the meaning of any policy of disability income insurance covering employees of the Company then in force. In the event the Company has no policy of disability income insurance covering employees of the Company in force when the Executive becomes disabled, the term “Complete Disability” shall mean the inability of the Executive to perform the Executive’s duties under this Agreement, whether with or without reasonable accommodation, by reason of any incapacity, physical or mental, which the Board, based upon medical advice or an opinion provided by a licensed physician, determines to have incapacitated the Executive from satisfactorily performing all of the Executive’s usual services for the Company, with or without reasonable accommodation, for a period of at least one hundred eighty (180) days during any twelve (12) month period that need not be consecutive.

4.5.2 Good Reason. “Good Reason” for the Executive to terminate the Executive’s employment hereunder shall mean the occurrence of any of the following events without the Executive’s consent:

(i) a material reduction in the Executive’s duties, authority, or responsibilities relative to the duties, authority, or responsibilities in effect immediately prior to such reduction, including by way of example, having the same title, duties, authority and responsibilities at a subsidiary level following a Change in Control;

(ii) the relocation of the Executive’s primary work location to a point more than fifty (50) miles from the Executive’s current work location set forth in Section 1.5 that requires a material increase in the Executive’s one-way driving distance; and

(iii) a material reduction by the Company of the Executive’s base salary or annual target Bonus opportunity, without the written consent of the Executive, as initially set forth herein or as the same may be increased from time to time pursuant to this Agreement.

Provided, however that, such termination by the Executive shall only be deemed for Good Reason pursuant to the foregoing definition if (i) the Company is given written notice from the Executive within sixty (60) days following the first occurrence of the condition that he considers to constitute Good Reason describing the condition and the Company fails to satisfactorily remedy such condition within thirty (30) days following such written notice, and (ii) the Executive terminates employment within thirty (30) days following the end of the period within which the Company was entitled to remedy the condition constituting Good Reason but failed to do so.
4.5.3 Cause. “Cause” for the Company to terminate the Executive’s employment hereunder shall mean the occurrence of any of the following events, as determined reasonably and in good faith by the Board or a committee designated by the Board:

(i) the Executive’s gross negligence or willful failure to substantially perform his duties and responsibilities to the Company or willful and deliberate violation of a Company policy;

(ii) the Executive’s conviction of a felony or the Executive’s commission of any act of fraud, embezzlement or dishonesty against the Company or involving moral turpitude that is likely to inflict or has inflicted material injury on the business of the Company, to be determined by the sole discretion of the Company;

(iii) the Executive’s unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party that the Executive owes an obligation of nondisclosure as a result of the Executive’s relationship with the Company; and

(iv) the Executive’s willful and deliberate breach of the obligations under this Agreement that causes material injury to the business of the Company.

4.5.4 Change in Control. For purposes of this Agreement, “Change in Control” means: (i) a sale of all or substantially all of the assets of the Company; (ii) a merger or consolidation in which the Company is not the surviving entity and in which the holders of the Company’s outstanding voting stock immediately prior to such transaction own, immediately after such transaction, securities representing less than fifty percent (50%) of the voting power of the entity surviving such transaction or, where the surviving entity is a wholly-owned subsidiary of another entity, the surviving entity’s parent; (iii) a reverse merger in which the Company is the surviving entity but the shares of Common Stock outstanding immediately preceding the merger are converted by virtue of the merger into other property, whether in the form of securities of the surviving entity’s parent, cash or otherwise, and in which the holders of the Company’s outstanding voting stock immediately prior to such transaction own, immediately after such transaction, securities representing less than fifty percent (50%) of the voting power of the Company or, where the Company is a wholly-owned subsidiary of another entity, the Company’s parent; or (iv) an acquisition by any person, entity or group (excluding any employee benefit plan, or related trust, sponsored or maintained by the Company or subsidiary of the Company or other entity controlled by the Company) of the beneficial ownership of securities of the Company representing at least seventy-five percent (75%) of the combined voting power entitled to vote in the election of Directors; provided, however, that nothing in this paragraph shall apply to a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.
4.6 Application of Internal Revenue Code Section 409A. Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under this Agreement (the “Severance Benefits”) that constitute “deferred compensation” within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the “Code”), and the regulations and other guidance thereunder and any state law of similar effect (collectively “Section 409A”) shall not commence in connection with the Executive’s termination of employment unless and until the Executive has also incurred a “separation from service” (as such term is defined in Treasury Regulation Section 1.409A-1(h)) (“Separation From Service”), unless the Company reasonably determines that such amounts may be provided to the Executive without causing the Executive to incur the additional 20% tax under Section 409A.

It is intended that each installment of the Severance Benefits payments provided for in this Agreement is a separate “payment” for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the Severance Benefits set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulation Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Company (or, if applicable, the successor entity thereto) determines that the Severance Benefits constitute “deferred compensation” under Section 409A and the Executive is, on the termination of service, a “specified employee” of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance Benefit payments shall be delayed until the earlier to occur of: (i) the date that is six months and one day after the Executive’s Separation From Service, or (ii) the date of the Executive’s death (such applicable date, the “Specified Employee Initial Payment Date”), the Company (or the successor entity thereto, as applicable) shall (A) pay to the Executive a lump sum amount equal to the sum of the Severance Benefit payments that the Executive would otherwise have received through the Specified Employee Initial Payment Date if the commencement of the payment of the Severance Benefits had not been so delayed pursuant to this Section and (B) commence paying the balance of the Severance Benefits in accordance with the applicable payment schedules set forth in this Agreement.

Notwithstanding anything to the contrary set forth herein, the Executive shall receive the Severance Benefits described above, if and only if the Executive duly executes and returns to the Company within the applicable time period set forth therein, but in no event more than forty-five days following Separation From Service, the Company’s standard form of release of claims in favor of the Company (attached to this Agreement as Exhibit A) and permits the release of claims contained therein to become effective in accordance with its terms. Notwithstanding any other payment schedule set forth in this Agreement, none of the Severance Benefits will be paid or otherwise delivered prior to the effective date of the Release. Except to the extent that payments may be delayed until the Specified Employee Initial Payment Date pursuant to the preceding paragraph, on the first regular payroll pay day following the effective date of the Release, the Company will pay the Executive the Severance Benefits the Executive would otherwise have received under the Agreement on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the Severance Benefits being paid as originally scheduled.
4.7 Application of Internal Revenue Code Section 280G. If any payment or benefit the Executive would receive pursuant to a Change in Control from the Company or otherwise (“Payment”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then such Payment shall be equal to the Reduced Amount. The “Reduced Amount” shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Executive’s receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting “parachute payments” is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for the Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, the Executive agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, the Executive will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

Unless the Executive and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to the Executive and the Company within fifteen (15) calendar days after the date on which the Executive’s right to a Payment is triggered (if requested at that time by you or the Company) or such other time as requested by the Executive or the Company.

4.8 Indemnification Agreement. The Company and the Executive have previously entered into an indemnification agreement which shall continue to govern the terms of the Executive’s employment following the Effective Date, and a copy of which is attached hereto as Exhibit B.
4.9 Confidential Information and Invention Assignment Agreement. The Executive has previously executed the Company’s Confidential Information and Invention Assignment Agreement the terms of which shall continue to govern the terms of the Executive’s employment following the Effective Date, and a copy of which is attached as Exhibit C.

5. Assignment and Binding Effect.

This Agreement shall be binding upon the Executive and the Company and inure to the benefit of the Executive and the Executive’s heirs, executors, personal representatives, assigns, administrators and legal representatives. Because of the unique and personal nature of the Executive’s duties under this Agreement, neither this Agreement nor obligations under this Agreement shall be assignable by the Executive. This Agreement shall be binding upon and inure to the benefit of the Company and its successors, assigns and legal representatives, provided that the Agreement may only be assigned to an acquirer of all or substantially all of the Company’s assets. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, “successor” means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company.


For the purposes of this Agreement, notices, demands, and all other forms of communication provided for in this Agreement shall be in writing and shall be deemed to have been duly given when delivered or (unless otherwise specified) mailed by registered mail, return receipt requested, postage prepaid, or by confirmed facsimile, addressed as set forth below, or to such other address as any party may have furnished to the other in writing in accordance herewith, except that notices of address shall be effective only upon receipt, as follows:

If to the Company:
Horizon Pharma, Inc.
520 Lake Cook Road, Suite 520
Deerfield, IL 60015
Attention: Timothy P. Walbert, Chairman, President & CEO
Fax: 224-383-3001

If to the Executive:
Todd N. Smith
31445 Reigate Lane
Green Oaks, IL 60044
Any such written notice shall be deemed given on the earlier of the date on which such notice is personally delivered or five (5) days after its deposit in the United States mail as specified above. Either Party may change its address for notices by giving written notice to the other Party in the manner specified in this section.

7. Choice of Law.

This Agreement shall be governed by the laws of the State of Illinois, without regard to any conflicts of law principals thereof that would call for the application of the laws of any other jurisdiction. The Parties consent to the exclusive jurisdiction and venue of the federal court in the Northern District of Illinois, and state courts located in the state of Illinois, county of Cook. Nothing in this Section 7 limits the rights of the Parties to seek appeal of a decision of an Illinois court outside of Illinois that has proper jurisdiction over the decision of a court sitting in Illinois.

8. Integration.

This Agreement, including Exhibit A, Exhibit B, Exhibit C and the Plan and applicable stock option agreements, contains the complete, final and exclusive agreement of the Parties relating to the terms and conditions of the Executive’s employment and the termination of the Executive’s employment, and supersedes all prior and contemporaneous oral and written employment agreements or arrangements between the Parties.

9. Amendment.

This Agreement cannot be amended or modified except by a written agreement signed by the Executive and the Company.

10. Waiver.

No term, covenant or condition of this Agreement or any breach thereof shall be deemed waived, except with the written consent of the Party against whom the waiver is claimed, and any waiver or any such term, covenant, condition or breach shall not be deemed to be a waiver of any preceding or succeeding breach of the same or any other term, covenant, condition or breach.

11. Severability.

The finding by a court of competent jurisdiction of the unenforceability, invalidity or illegality of any provision of this Agreement shall not render any other provision of this Agreement unenforceable, invalid or illegal. Such court shall have the authority to modify or replace the invalid or unenforceable term or provision with a valid and enforceable term or provision, which most accurately represents the Parties’ intention with respect to the invalid, unenforceable, or illegal term or provision.
12. Interpretation; Construction.

The headings set forth in this Agreement are for convenience of reference only and shall not be used in interpreting this Agreement. This Agreement has been drafted and negotiated by legal counsel representing the Company and the Executive. The Parties acknowledge that each Party and its counsel has reviewed and revised, or had an opportunity to review and revise, this Agreement, and any rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Agreement.

13. Execution by Facsimile Signatures and in Counterparts.

The parties agree that facsimile signatures shall have the same force and effect as original signatures. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.
IN WITNESS WHEREFORE, the parties have signed this Agreement on the date first written above.

COMPANY:

HORIZON PHARMA, INC.
HORIZON PHARMA USA, INC.

By: /s/ Timothy P. Walbert
Title: Chairman, President and CEO
Print Name: Timothy P. Walbert
Date: 6/1/12

EXECUTIVE:

TODD N. SMITH

/s/ Todd N. Smith
Todd N. Smith, individually
Date: 6/1/12
RELEASE AND WAIVER OF CLAIMS

In consideration of the payments and other benefits set forth in the Executive Employment Agreement effective June 1, 2012, (the “Employment Agreement”), to which this form is attached, I, Todd N. Smith, hereby furnish Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (together the “Company”), with the following release and waiver (“Release and Waiver”).

In exchange for the consideration provided to me by the Employment Agreement that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, Affiliates, and assigns from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring relating to my employment or the termination thereof prior to my signing this Release and Waiver. This general release includes, but is not limited to: (1) all claims arising out of or in any way related to my employment with the Company or the termination of that employment; (2) all claims related to my compensation or benefits from the Company, including, but not limited to, salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including, but not limited to, claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including, but not limited to, claims for discrimination, harassment, retaliation, attorneys’ fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) (“ADEA”), and the California Fair Employment and Housing Act (as amended). Notwithstanding the foregoing, this Release and Waiver, shall not release or waive my rights: to indemnification under the articles and bylaws of the Company or applicable law, including without limitations, California Labor Code Sections 2800 and 2802; to payments under Sections 2800 and 2802 of the Employment Agreement; under any provision of the Employment Agreement that survives the termination of that agreement; under the California Workers’ Compensation Act; under any option, restricted share or other agreement concerning any equity interest in the Company; as a shareholder of the Company or any other right that is not waivable under applicable law.

I also acknowledge that I have read and understand Section 1542 of the California Civil Code which reads as follows: “A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor.” I hereby expressly waive and relinquish all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to any claims I may have against the Company.
I acknowledge that, among other rights, I am waiving and releasing any rights I may have under ADEA, that this Release and Waiver is knowing and voluntary, and that the consideration given for this Release and Waiver is in addition to anything of value to which I was already entitled as an executive of the Company. If I am 40 years of age or older upon execution of this Release and Waiver, I further acknowledge that I have been advised, as required by the Older Workers Benefit Protection Act, that: (a) the release and waiver granted herein does not relate to claims under the ADEA which may arise after this Release and Waiver is executed; (b) I should consult with an attorney prior to executing this Release and Waiver; and (c) I have twenty-one (21) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier); (d) I have seven (7) days following the execution of this Release and Waiver to revoke my consent to this Release and Waiver; and (e) this Release and Waiver shall not be effective until the seven (7) day revocation period has expired unexercised. If I am less than 40 years of age upon execution of this Release and Waiver, I acknowledge that I have the right to consult with an attorney prior to executing this Release and Waiver (although I may choose voluntarily not to do so); and (c) I have five (5) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier).

I acknowledge my continuing obligations under my Confidential Information and Inventions Agreement dated September 28, 2010. Pursuant to the Confidential Information and Inventions Agreement I understand that among other things, I must not use or disclose any confidential or proprietary information of the Company and I must immediately return all Company property and documents (including all embodiments of proprietary information) and all copies thereof in my possession or control. I understand and agree that my right to the payments and other benefits I am receiving in exchange for my agreement to the terms of this Release and Waiver is contingent upon my continued compliance with my Confidential Information and Inventions Agreement.

This Release and Waiver, including my Confidential Information and Inventions Agreement dated September 28, 2010, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated herein. This Release and Waiver may only be modified by a writing signed by both me and a duly authorized officer of the Company.

Date: 6/8/2012

By: /s/ Todd N. Smith

Todd N. Smith
CO-PROMOTION AGREEMENT

THIS CO-PROMOTION AGREEMENT ("Agreement") is entered into effective on and as of June 14, 2012 ("Effective Date") by and between Horizon Pharma USA, Inc. ("Horizon") and Mallinckrodt LLC ("Mallinckrodt"). Each of Horizon and Mallinckrodt are sometimes referred to herein, individually, as a "Party" and, collectively, as the "Parties".

WHEREAS, Horizon is the owner of a branded pharmaceutical dosage product that is a proprietary single-tablet combination of the non-steroidal anti-inflammatory drug ibuprofen and the histamine H2-receptor antagonist famotidine, indicated for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications, and marketed under the name DUEXIS® in the United States ("Product");

WHEREAS, the Parties have determined that it is in their mutual interest to enter into a relationship whereby Mallinckrodt's sales force will promote the Product on the terms and conditions set forth herein,

NOW THEREFORE, in consideration of the foregoing premises and the comments set forth herein below, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE I

DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

1.1 "Act" means the United States Food, Drug and Cosmetic Act, 21 U.S.C 301, et seq., as it has been or may be amended or supplemented from time-to-time, and all rules and regulations promulgated or issued under or in connection therewith.
1.2 “Adverse Drug Experience” means, with respect to the use of the Product, an unexpected side effect, injury, toxicity, sensitivity reaction, or unexpected incidence or severity of side effects, or any unfavorable and unintended sign, symptom or disease temporarily associated with the use of medical treatment, regardless of whether it is considered to be related to such treatment; it also includes failure of a drug product to exhibit expected pharmacological action or any adverse event occurring from abuse or overdose of the drug product, whether accidental or intentional. A “Serious Adverse Drug Experience” means, with respect to the Product, an Adverse Drug Experience that results in death, a life threatening adverse drug experience, in-patient hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect, or any other event that may require surgical or other medical intervention to prevent any of the foregoing listed outcomes.

1.3 “Affiliate” means, with respect to any Person, any other Person that, directly or indirectly, controls, is controlled by or is under common control with the former Person, where “control” (and the correlative terms “controlling” and “controlled by”) mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting securities of such Person, by contract or otherwise.

1.4 “Agreement” has the meaning set forth in the preamble hereof.

1.5 “Agreement Quarter” means any consecutive three (3) calendar month period elapsing during the Term hereof coincident with calendar quarters, except that (i) the first such Agreement Quarter shall commence on the Effective Date hereof and end on September 30, 2012 and (ii) the last Agreement Quarter may be shorter than a full three (3) calendar month period if this Agreement expires or is terminated effective on a date that occurs before what would otherwise be the last day of such Agreement Quarter.
1.6 “Agreement Year” means each consecutive four (4) Agreement Quarters elapsing during the Term hereof, except that the final Agreement Year may be shorter than a four (4) Agreement Quarter period if this Agreement expires or is terminated effective on a date that occurs before what would otherwise be the last day of the fourth Agreement Quarter of such Agreement Year.

1.7 “Alliance Manager” has the meaning set forth in Section 3.4 below.

1.8 “Auditor” has the meaning set forth in Section 7.3(b) below.

1.9 “cGMP” means current Good Manufacturing Practice as that term is defined from time-to-time by the FDA and/or any other relevant Government Authority having jurisdiction over the manufacture or sale of Product in the Territory, as reflected by any applicable law, rules, regulations or guidelines promulgated and/or administered by the FDA and/or any other relevant Government Authority in the Territory.

1.10 “Change of Control” shall, with respect to either Party, be deemed to occur when:

   (i) any “person” or “group” (as such terms as defined below in this Section 1.10) is or becomes the “beneficial owner” (as defined below in this Section 1.10), directly or indirectly, of shares of capital stock or other interests of such Party then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers, or similar supervisory positions of such Party representing more than fifty percent (50%) of the total voting power of all outstanding classes of voting stock or equity of such Party,

   (ii) such Party consummates a merger, consolidation or similar transaction with another Person (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction the Persons that beneficially owned, directly or indirectly, the shares of voting stock or equity of such Party immediately prior to such transaction do not beneficially own, directly or indirectly, shares of voting stock
or equity of the surviving Person representing at least a majority of the total voting power of all outstanding classes of voting stock or equity of the surviving Person,

(iii) such Party sells or transfers to any Third Party, in one or more related transactions, properties or assets representing all or substantially all of such Party’s assets, or

(iv) the holders of capital stock or equity of such Party approve a plan or proposal for the liquidation or dissolution of such Party.

For the purpose of this Section 1.10, (A) “person” and “group” have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term “group” includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the United States Securities Exchange Act of 1934, (B) a “beneficial owner” shall be determined in accordance with Rule 13d-3 under the United States Securities Exchange Act of 1934, and (C) the term “beneficially owned” and “beneficially own” shall have the meaning correlative to that of “beneficial owner.”

1.11 “Compliance Materials” means, as to either Party, such Party’s internal compliance policies and procedures as recorded in such Party’s books and records.

1.12 “Confidentiality Agreement” means that certain Confidentiality Agreement between Horizon and Mallinckrodt dated [...***...].

1.13 “Co-promotion Fee” means the fee paid by Horizon hereunder to Mallinckrodt, as more fully described in Section 7.1 below.

1.14 “Detail” or “Detailing” means an in-person, face-to-face sales presentation of the Product made by a Sales Representative of Mallinckrodt to a healthcare professional who is permitted by applicable law to write a prescription for such Product.
1.15 “Direct Cost” shall mean either or both of Direct Cost for Promotional Materials or Direct Cost for Samples, as the context shall reasonably require.

1.16 “Direct Cost for Promotional Materials” has the meaning set forth in Section 4.7(a) below.

1.17 “Direct Cost for Samples” has the meaning set forth in Section 6.3 below.

1.18 “Disclosing Party” has the meaning set forth in Section 1.53 below.

1.19 “Effective Date” has the meaning set forth in the preamble hereof.

1.20 “Enforcement Action” has the meaning set forth in Section 10.2(b) below.

1.21 “Exclusive Target” means and refers to any prescribing healthcare professional listed on the Mallinckrodt Call List and designated as an Exclusive Target.

1.22 “FDA” means the United States Food and Drug Administration or any successor agency performing comparable regulatory functions in the Territory.

1.23 “Generic Drug Act” means the Generic Drug Enforcement Act of 1992, 21 U.S.C. §335a, as it has been or may be amended or supplemented from time-to-time.

1.24 “Governmental Authority” means any court, agency, authority, department, regulatory body or other instrumentality of any federal, state or local government which has competent and binding authority to regulate, enforce or otherwise control the activities of the Parties as contemplated herein.

1.25 “Horizon” has the meaning set forth in the preamble hereto.

1.26 “Indemnitee” has the meaning set forth in Section 12.3 below.

1.27 “Indemnitor” has the meaning set forth in Section 12.3 below.
“JAMS” has the meaning set forth in Section 13.6(b) below.

“Joint Management Committee” or “JMC” has the meaning set forth in Section 3.1 below.

“Legal Requirements” means, as they are now in effect or as they may hereafter be amended or supplemented, any or all of the following as they may be applicable in any particular circumstances: (i) the PhRMA Code, (ii) the OIG Guidelines, (iii) the Act, (iv) the Generic Drug Act, (v) PDMA, (vi) OPDP’s applicable promotional guidelines, (vii) all applicable regulations, guidelines and directives of the FDA, including those concerning the marketing and advertising of prescription drug products, (viii) the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. §1320a-7(b), (ix) the statutes, regulations and directives of Medicare, Medicaid and all other government funded or sponsored healthcare programs in the Territory, (x) the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), (xi) the False Claims Act, 31 U.S.C. §3729 et seq., (xii) comparable state laws and implementing regulations for referenced laws, and (xiii) all other federal, state and local laws, rules and regulations that are in effect in the Territory and are applicable in any manner to the performance by either or both of the Parties of their obligations or the exercise of their rights under this Agreement, all as have been or may be amended or supplemented from time-to-time.

“Loss” has the meaning set forth in Section 12.1 below.

“Mallinckrodt” has the meaning set forth in the preamble hereto.

“Mallinckrodt Call List” means that list of healthcare professionals with the legal right to prescribe pharmaceutical dosage products in the Territory, which list has been agreed upon by the Parties and exchanged [...***...] and [...***...].

“Mallinckrodt Forecast” has the meaning set forth in Section 6.3 below.
1.35 "Measurement Period" means, with respect to any Supply Failure (as defined herein) any consecutive [...] calendar month period elapsing during the Term.

1.36 "[...***...] Report" has the meaning set forth in Section 7.1(a) below.

1.37 "NSAID Product" has the meaning set forth in Section 6.5(a) below.

1.38 "OIG Guidelines" means the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, dated April 2003, as it has or may be amended as supplemented from time-to-time.

1.39 "OPDP" means the FDA’s Office of Prescription Drug Promotion (formerly the Division of Drug Marketing, Advertising and Communications or DDMAC) or any successor Governmental Authority performing comparable functions.

1.40 “Paragraph IV Notice” has the meaning set forth in Section 9.2(v) below.

1.41 “Party” and “Parties” has the meaning set forth in the preamble hereto.

1.42 “Payment Report” has the meaning set forth in Section 7.1(b) below.

1.43 “PDMA” means the federal Prescription Drug Marketing Act, as it has been or may be revised or supplemented from time-to-time.

1.44 “Person” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership, or other business entity, or any government or agency or political subdivision thereof.

1.45 “PhRMA Code” means the PhRMA Code on Interactions with Healthcare Professionals, as it has been or may be revised or supplemented from time-to-time.

1.46 “PIR” has the meaning set forth in Section 5.5(a) below.
1.47 “PPACA” has the meaning set forth in Section 6.3 below.

1.48 “Product” has the meaning set forth in the preamble hereto.

1.49 “Product Complaint” means any written, electronic or verbal communication from any customer, user, prescriber or other Third Party that alleges deficiencies concerning the identity, quality, durability, appearance, reliability, effectiveness, performance or any side effects of or concerning the Product.

1.50 “Promote”, “Promotional”, “Promotion”, “Promoting”, and any variation thereof, shall mean and refer to those activities undertaken by a pharmaceutical company (in this Agreement, either Horizon and/or Mallinckrodt, as the context may require) to encourage appropriate use of the Product, including detailing, sampling, advertising, the provision of discounts and all other lawful and appropriate forms of advertising and promotion.

1.51 “Promotion Commencement Date” has the meaning set forth in Section 4.2(a) below.

1.52 “Promotional Materials” means those informational, advertising, marketing, educational and training materials developed and used by Horizon which are necessary and/or useful in connection with the Promotion of the Product, including (without limitation) Detailing aids, leave behind educational items, journal advertising, educational programs, appropriate reprints, monographs, patient support kits, exhibit materials, direct mail, training courses and formulary binders.

1.53 “Proprietary and Confidential Information” means any proprietary and confidential information communicated by or on behalf of one Party or any of its Affiliates (the “Disclosing Party”) to the other Party or any of its Affiliates (the “Recipient Party”) in connection or relating to this Agreement (including discussions and negotiations relating hereto), whether communicated prior to, on, or following the Effective Date, including financial, marketing, business, technical and scientific information or data, information related to compensation of sales representatives, information contained within any commercial plan, budget or financial statements, and the information exchanged pursuant to this Agreement, in any case whether communicated in writing, orally, electronically or
by means of inspection. For the avoidance of doubt, the commercial data and information generated by each Party in connection with its activities under this Agreement are the Proprietary and Confidential Information of that Party (except that all commercial data and information specific to the Product shall be the Proprietary and Confidential Information of Horizon), the terms of this Agreement are the Proprietary and Confidential Information of both Parties, and Compliance Materials provided by the Disclosing Party to the Recipient Party are the Proprietary and Confidential Information of the Disclosing Party. Notwithstanding the immediately foregoing, Proprietary and Confidential Information shall not include information that the Recipient Party, having the burden of proof, can show through written documentation:

(i) at the time of disclosure, is publicly known,

(ii) after the time of disclosure, becomes part of the public domain, except by breach of any agreement between the Disclosing Party and the Recipient Party (including this Agreement),

(iii) is or was in the possession of the Recipient Party at the time of disclosure by the Disclosing Party and was not acquired directly or indirectly from the Disclosing Party or from any Third Party under an agreement of confidentiality to the Disclosing Party, and

(v) is or was developed by the Recipient Party without use of or reference to the Disclosing Party’s Proprietary and Confidential Information.

1.54 “Quarterly Minimum Prescription Levels” has the meaning set forth in Section 4.4(a) below.

1.55 “Recipient Party” has the meaning set forth in Section 1.53 above.
“Regulatory Approval” means any and all consents or other authorizations and approvals required from a Governmental Authority to allow the Product lawfully to be marketed and sold in the Territory.

“Relevant Records” has the meaning set forth in Section 7.3(a) below.

“Residual Fee” has the meaning set forth in Section 7.2(a) below.

“Residual Fee Measurement Period” has the meaning set forth in Section 7.2(a) below.

“Sales Representatives” means the sales representatives of Mallinckrodt who will be performing the Promotional activities contemplated to be performed by Mallinckrodt with respect to the Product in accordance herewith, and may also mean and refer to any personnel of a Third Party that are used to supplement Mallinckrodt’s Promotional efforts hereunder, if and as permitted in accordance herewith.

“SEC Reports” means the annual, quarterly and current reports filed by Horizon with the U.S. Securities and Exchange Commission.

“Source” means Source Healthcare Analytics, LLC (formerly known as Wolters Kluwer).

“Supply Failure” has the meaning set forth in Section 4.3(e) below.

“Target Commencement Date” has the meaning set forth in Section 4.2(a) below.

“Term” has the meaning set forth in Section 8.1 below.

“Territory” means the United States of America, excluding any territories or possessions and excluding Puerto Rico.

“Third Party” means any Person other than Horizon or Mallinckrodt or their respective Affiliates.
ARTICLE II

GRANT OF CO-PROMOTION RIGHTS

2.1 Grant of Co-promotion Rights

During the Term, and subject to and in accordance with the terms and conditions hereof, Horizon hereby grants to Mallinckrodt and Mallinckrodt hereby accepts a non-exclusive right to Promote the Product under the Horizon Trademarks to the Exclusive Targets in the Territory. For clarity, except as and to the extent set forth in Section 6.6, Horizon shall continue to have the right to, and to grant to one or more Third Parties the right to, Promote, sell and market the Product throughout the Territory.

2.2 Subcontracting of Performance

Neither Party may subcontract or delegate the performance of its obligations hereunder without the advance written consent of the other Party, except (i) in connection with an assignment of its rights and obligations hereunder to the extent permitted pursuant to Section 13.1 below, (ii) that either Party may perform any or all of its obligations and may exercise any of its rights hereunder through any of its Affiliates, as long as the other Party is notified in writing of the details of such performance and exercise, it being understood the Party delegating such performance and exercise shall remain fully responsible for the performance of its obligations under this Agreement, and (iii) that Horizon may subcontract with, delegate to and/or rely upon the services of one or more Third Parties for performance of its obligations with respect to the manufacture, production or supply of its Product, Product samples and
Promotional Materials. Mallinckrodt may propose to subcontract with one or more Third Parties to supplement its Promotion efforts for the Product by notifying Horizon in writing of the proposed subcontracting arrangement and, subject to Horizon’s prior written consent, Mallinckrodt may proceed with the subcontracting arrangement with such Third Party on the terms proposed to Horizon, it being understood Mallinckrodt shall remain fully responsible for the performance of its obligations under this Agreement, including any performance by such Third Party subcontractor; provided that, Horizon’s consent shall not be required for any subcontracting arrangement put in place by Mallinckrodt with any Third Party if and to the extent any such subcontracting arrangement involves Promotion of the Product by the employees or agents of such Third Party with respect to less than [...***...] percent ([...***...%]%) of the Exclusive Targets on the Mallinckrodt Call List.

2.3 Retention of Rights.

Horizon retains all proprietary interests in the Product and Mallinckrodt shall not have nor represent that it has any control or proprietary interest in the Product, except for any rights explicitly granted hereunder. Except as expressly set forth herein, nothing in this Agreement shall be deemed to grant to Mallinckrodt, by implication, a license or other right in any patent, Trademark or similar property of Horizon or its Affiliates.

ARTICLE III

CO-PROMOTION COORDINATION

3.1 Establishment of Joint Management Committee.

Except for any specific agreement by the Parties to the contrary as set forth herein, the activities and resources of each Party shall be controlled and managed by such Party, acting independently and in its individual capacity. Subject to the immediately preceding sentence, as soon as possible after the Effective Date but no later than [...***...] days thereafter, the Parties will establish a “Joint Management Committee” or “JMC” which shall have the purpose of

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coordinating, monitoring, reviewing and discussing the strategic and operational elements of the Promotional activities of the Parties.

3.2 Role and Authority of the JMC.

The JMC’s role shall be:

(i) to facilitate the exchange of any information and data (including Proprietary and Confidential Information) between the Parties as required to allow each Party efficiently to perform its obligations and exercise its rights hereunder and to establish appropriate procedures, restrictions and safeguards relative to the exchange of any information and data,

(ii) to review and discuss any marketing plans and Promotional strategies established by Horizon for the Product to ensure consistent messaging and positioning of the Product by Mallinckrodt and to facilitate a consistent approach to pharmacovigilance and regulatory activities,

(iii) to review, discuss and approve any changes to be made to the Mallinckrodt Call List, which changes shall be made no more frequently than [...***...] per [...***...] unless otherwise agreed by the Parties,

(iv) to serve as a forum for the Parties to discuss opportunities and challenges encountered by Mallinckrodt in the Promotion of the Product and to ensure that Horizon’s marketing plans, Promotional strategy, messaging and positioning for its Product are made known to Mallinckrodt hereunder,

(v) to serve as a forum for the Parties to discuss the possible resolution of disputes that may arise between them relative to the administration and the intent of this Agreement (but not to displace the dispute resolution procedures set forth elsewhere herein, including those set forth in Section 13.6 below),
(vi) to establish such subcommittees or working groups as the Parties may agree are necessary to achieve the objectives and intent of this Agreement, and

(vii) to perform such other functions as may be agreed upon by the Parties in writing.

Notwithstanding the preceding portions of this Section 3.2, except for the authority granted to the JMC in clause (iii) of the immediately preceding sentence and except as may otherwise be specifically and unambiguously provided herein, it is agreed by the Parties that the JMC shall not have the power or authority to amend, modify or waive any of the terms or conditions of this Agreement. For purposes of clarity, Horizon will have sole responsibility for establishing the overall marketing and Promotional strategy, messaging and positioning for its Product.

3.3 JMC Membership and Procedures.

(a) Subject to Section 3.2, the JMC shall make diligent efforts to operate by unanimous consensus between the representatives of Horizon, on the one hand, and the representatives of Mallinckrodt, on the other hand. For the avoidance of doubt, each Party shall [...], regardless of the number of representatives of that Party present or voting. No decision of the JMC shall be valid unless each Party is represented by at least one (1) member at the meeting at which the decision is made. The Parties shall cause their respective representatives on the JMC to use their good faith efforts to resolve all matters appropriately presented to them in an expeditious manner.

(b) The JMC will be comprised of [...], selected by each Party. Each Party has, prior to the Effective Date, provided to the other Party its initial appointments to the JMC. A Party may change any of its representatives to the JMC at any time by [...]. The total number of members on the JMC may be changed by [...], from time-to-time, provided that, each Party has the right, in its sole discretion, to appoint an equal number of members to the JMC. The members appointed to the JMC by each Party shall be employees of such Party and shall have the requisite experience and seniority to discuss issues on behalf of such Party or to make decisions with respect to issues

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falling within the jurisdiction of the JMC; provided that, either Party may appoint non-employee representatives or consultants to serve as members of the JMC with the prior written consent of the other Party, such consent not to be unreasonably withheld.

(c) The chair of the JMC will be an employee of Horizon. The chair of the JMC shall have the authority and responsibility to call meetings of the JMC, to propose agendas for (and any other member of the JMC may add items to such agendas) and preside over such meetings, and to appoint a secretary to record minutes for such meetings. Minutes of any meetings of the JMC will not be considered final until representatives of both Parties have reviewed them and confirmed the accuracy of such minutes in writing. [...***...].

(d) Meetings of the JMC may be called by the chair of the JMC from time-to-time and, upon no less than [...***...] days’ notice, shall otherwise be called when requested by a Party; provided that, the JMC shall meet at least [...***...] during every [...***...], and otherwise as required to discuss disputes or other issues judged to be of relative importance by one or both Parties. Meetings may be held in person or by video or telephone conference. Unless otherwise agreed, the location of in-person meetings shall alternate between the corporate offices of the Parties. The format of the meetings and all other procedural matters shall be decided by the JMC. Each Party shall bear its own travel and related costs incurred in connection with participation in the JMC.

(e) Communications among members of the JMC in connection with the conduct of the day-to-day business of the JMC shall not be subject to the notice provisions set forth in Section 13.4, but shall be governed by procedures agreed upon unanimously by the members of the JMC.

(f) For the avoidance of doubt, disputes between the Parties with respect to performance under or interpretation of this Agreement shall be decided pursuant to the provisions set forth in Section 13.6 below, or with respect to certain matters herein, in accordance with specific dispute resolution procedures expressly established herein for the
resolution of disputes concerning such matters, and not by the JMC in the first instance unless the Parties specifically and unambiguously agree in writing to the contrary.

3.4 Alliance Manager.

Each Party shall, as soon as possible after the Effective Date, appoint a single individual to coordinate all daily, ordinary course of business interactions between the Parties that may be necessary to administer this Agreement effectively and carry out the intent and objectives of the Parties (for each Party, an “Alliance Manager”). Each Alliance Manager shall be experienced in project management, be knowledgeable about the marketing and sale of branded pharmaceutical dosage products in general and may also serve as one of his/her Party’s representatives on the JMC. Each Party may change its Alliance Manager effective upon written notice to the other Party.

ARTICLE IV
PRODUCT PROMOTION

4.1 Promotional Efforts Generally.

Mallinckrodt shall, during the Term and from and after the Promotion Commencement Date as set forth below in Section 4.2, use commercially reasonable efforts to Promote the Product within the Territory in a manner consistent with the marketing and Promotional strategies and Product positioning established by Horizon for its Product as communicated through meetings of the JMC and contacts between representatives of the Parties, including their Alliance Managers. Mallinckrodt shall focus its efforts on Detailing the Product to the Exclusive Targets on the Mallinckrodt Call List. Mallinckrodt shall cause its Sales Representatives and its employees and agents (including those of its Affiliates) to comply with the terms and conditions of this Agreement and all applicable Legal Requirements in connection with any Promotional activities performed by or on behalf of Mallinckrodt. Mallinckrodt understands and agrees that it will be responsible for the acts or omissions to act by any of its Sales Representatives and its employees and agents (including those of its Affiliates) in connection with performance under
this Agreement. Furthermore, Mallinckrodt agrees that it will be responsible for all of its own costs and expenses related to the performance of its Detailing and Promotional activities hereunder, including (without limitation) costs and expenses associated with any meals, meetings and conferences, except as may otherwise be specifically set forth herein.

4.2 Promotion Commencement.

(a) Mallinckrodt shall use commercially reasonable efforts to commence Promotional activities with respect to the Product on a date that is no later than […] days after the Effective Date and, in any event, shall be required to commence Promotion of the Product on or before September 30, 2012. For purposes hereof, the actual date upon which Mallinckrodt begins Promotion of the Product shall be known as the “Promotion Commencement Date” and the date on which Mallinckrodt is required to commence Promotion of the Product shall be known as the “Target Commencement Date.”

(b) Notwithstanding any other provision hereof, in the event Mallinckrodt has failed to commence significant Promotional activity with respect to the Product on or before the Target Commencement Date, as set forth immediately above in Section 4(a), then Horizon shall have the right, effective immediately upon notice to Mallinckrodt, to terminate this Agreement in its entirety, subject to the consequences of such termination as set forth in Section 8.3 below.

4.3 Supply Failures.

If, during any Measurement Period occurring during the Term, in at least […] months of such Measurement Period or in any […] months occurring during any such Measurement Period, there is an occurrence of insufficient volume (as determined by standards to be developed by the Parties within […] days after the Effective Date) of Product in the retail distribution channel or in any significant portion of the retail distribution channel to meet orders for Product, as determined from a review of all relevant information, including information contained in Horizon’s warehouse inventory reports and in relevant EDI-852 forms (any such occurrence with respect to the Product during any particular
Measurement Period, a “Supply Failure”), then Mallinckrodt shall have the right, within [...***...] days after the end of any such Measurement Period in which a Supply Failure occurs, to terminate this Agreement in its entirety effective upon [...***...] days written notice to Horizon, subject to the consequences of such termination as set forth in Section 8.3 below.

4.4 Prescription Volume

(a) Mallinckrodt shall be required to achieve a certain minimum level of filled prescriptions attributable to Exclusive Targets during each Agreement Quarter elapsing during the Term hereof, except for the first Agreement Quarter (i.e., the period from the Effective Date through September 30, 2012) and the last Agreement Quarter if such Agreement Quarter is less than three (3) full months (“Quarterly Minimum Prescription Levels”). Specifically, Mallinckrodt shall meet the Quarterly Minimum Prescription Levels for each applicable Agreement Quarter with respect to the Product as set forth on Exhibit A attached hereto. The Parties will determine, with respect to a particular relevant Agreement Quarter, whether or not the Quarterly Minimum Prescription Level has been met using data provided to Horizon by Source, it being understood that Horizon shall disclose to Mallinckrodt only such data as is necessary to determine whether or not the Quarterly Minimum Prescription Level has been met, all Source data provided by Horizon to Mallinckrodt shall be Proprietary and Confidential Information of Horizon, and Mallinckrodt shall enter into a Third Party Data Use Agreement with Source and Horizon in the form attached hereto as Exhibit B (with modifications as agreed by Source, Horizon and Mallinckrodt) with respect to such data. No assessment will be made by either Party as to whether or not the Quarterly Minimum Prescription Level for any given Agreement Quarter has been achieved until [...***...] days have elapsed after both Parties have had access to the Source data and any other data reasonably available to the Parties that is necessary to determine whether or not the Quarterly Minimum Prescription Level has been achieved for such Agreement Quarter so that data can be fully correlated with the Exclusive Targets. If the relevant Source data shows that, during the period of time commencing on October 1, 2012 and ending on September 30, 2013, the Quarterly Minimum Prescription Level has not been achieved with respect to any two (2) consecutive Agreement Quarters, then Horizon shall have the right, upon [...***...] days advance notice to Mallinckrodt, to terminate this
Agreement in its entirety, subject to the consequences of such termination as set forth in Section 8.3 below. If the relevant Source data shows that, during the period of time commencing on October 1, 2013 and ending on September 30, 2014, the Quarterly Minimum Prescription Level has not been achieved with respect to any two (2) consecutive Agreement Quarters, then either Party shall have the right, upon [...] days advance notice to the other Party, to terminate this Agreement in its entirety, subject to the consequences of such termination as set forth in Section 8.3 below.

(b) In the event that, during the first full calendar month after the expiration of one (1) year from and after the Promotion Commencement Date, the monthly prescription volume for the Product in the United States (as determined from applicable Source data) is not equal to or greater than [...] prescriptions, Mallinckrodt shall have the right to terminate this Agreement in its entirety effective upon [...] days advance written notice to Horizon unless, within the first [...] days of such notice period, the Parties are able to renegotiate this Agreement on mutually acceptable terms, which renegotiation both Parties will attempt in good faith. If, despite their exercise of good faith efforts, the Parties are unable, within such [...] day period, to enter into a mutually acceptable agreement, this Agreement shall terminate effective on and as of the end of the [...] day notice period, subject to the consequences of such termination as set forth in Section 8.3 below.

4.5 Representations to Customers

Mallinckrodt shall, in connection with its Promotion of the Product, refrain from making (i) any false or misleading representations to healthcare providers, customers or others regarding Horizon or the Product, (ii) any representations, warranties, or guarantees with respect to the specifications, features, or capabilities of the Product other than those expressly set forth in the Promotional Materials being used by Mallinckrodt to Promote such Product and the applicable then-current FDA approved labeling and package insert or (iii) any representations, warranties or guarantees that are not consistent with any applicable Legal Requirements. Most importantly, Mallinckrodt agrees only to promote and to cause its Sales Representatives only to Promote the Product for its approved FDA indications and subject to any restrictions or limitation in its FDA-
approved package insert, and not to suggest, imply or otherwise indicate that the use of such Product for any off-label indication or any use inconsistent with
its FDA-approved package insert is permitted.

4.6 Staffing and Training

(a) Mallinckrodt shall be solely responsible for all costs and expenses incurred to compensate its Sales Representatives, including, without limitation, the payment of all salary and benefits, including any incentive compensation or bonus payments, and the withholding of all taxes associated with any compensation paid to any Sales Representatives.

(b) From time-to-time, Mallinckrodt shall, in consultation with Horizon, establish training objectives and training plans for its Sales Representatives with respect to the Product. In that regard, Horizon shall supply to Mallinckrodt training materials and training assistance with respect to the Product […***…], in an amount, in a manner and at times to be determined by the Alliance Managers or other appropriate representatives of the Parties; but, at a minimum, Horizon shall provide to all of Mallinckrodt’s Sales Representatives, […***…] and before the Promotion Commencement Date, at least […***…] of […***…] training in a format and at a location to be reasonably agreed upon. Further, Horizon agrees during the Term to amend or supplement training materials and provide additional training assistance with respect to the Product, […***…], when and as required, to reflect changes in Legal Requirements or any changed circumstances with respect to the Product, and Mallinckrodt will disseminate such training materials to its Sales Representatives. Training materials provided shall address all matters relating to the Product required to ensure full compliance by Mallinckrodt Sales Representatives with applicable Legal Requirements (it being understood that Mallinckrodt remains solely responsible for any and all training of Sales Representatives with respect to applicable Legal Requirements other than those Legal Requirements relating to the Product) and to ensure Mallinckrodt Sales Representatives have full Product knowledge concerning disease states, appropriate indications and competitive product knowledge required effectively to Promote the Product. Mallinckrodt shall provide to its Sales Representatives such
reinforcements and refresher training with respect to the Product as and when it may be reasonably required, with the prompt assistance of Horizon.

(c) Mallinckrodt shall ensure that only those Sales Representatives who have reviewed the training materials, completed training with respect to the Product and demonstrate an adequate knowledge of the Product shall be allowed to Promote the Product hereunder.

(d) During the Term hereof and for a period of one (1) year thereafter, neither Party shall actively recruit or solicit for employment any then-current member of the sales force of the other Party or any other staff member of the other Party who is engaged or had been engaged in the Promotion or Detailing of the Product. For the avoidance of doubt, nothing in this Agreement shall limit a Party from engaging in general recruitment through advertisements or recruiting through “head-hunters” so long as the staff members of the other Party are not specifically targeted in such recruitment effort.

4.7 Promotional Materials

(a) At least [...***...] days prior to the Target Commencement Date hereunder and thereafter as reasonably required by Mallinckrodt, Horizon shall provide [...***...] to Mallinckrodt such amounts of all then-available Promotional Materials as Mallinckrodt shall request, and Mallinckrodt shall within [...***...] days of receipt of any invoice (subject to the right to dispute any incorrect amount reflected in such invoice) reimburse Horizon for [...***...], excluding in the case of Promotional Materials costs of [...***...] and of [...***...] herein below. All Promotional Materials shall prominently display the Trademark(s) of Horizon and shall only display any one or more of the Trademarks of Mallinckrodt hereunder upon the advance written consent of Mallinckrodt. The Parties agree that Horizon will only be obligated to provide Mallinckrodt Promotional Materials that Horizon has created for its own use, as available from time to time, and will not have any obligation to change the Promotional Materials for Mallinckrodt’s use or create any customized materials for Mallinckrodt.
(b) All Promotional Materials provided to Mallinckrodt shall have been reviewed and approved by the promotional and review committee (or any bodies exercising similar functions) of Horizon. Mallinckrodt shall review any Promotional Materials prior to use and within a reasonable period of time (not to exceed [...***...] days) from the date such Promotional Materials are first provided by Horizon, and Mallinckrodt shall not be required to use any Promotional Materials that are not reviewed by and acceptable to Mallinckrodt’s promotional review committee or any group or individuals with appropriate expertise within Mallinckrodt delegated to review such materials, although the obligation of Mallinckrodt to review the Promotional Materials shall be limited to a review of Legal Requirements and shall not involve a review of the factual or scientific basis underlying any claims set forth in any such Promotional Materials. In the event that, as a result of such review by Mallinckrodt hereunder (including any materials introduced after the Promotion Commencement Date), Mallinckrodt reasonably believes that changes to any such Promotional Materials are necessary or advisable to meet Legal Requirements or any regulatory requirements, such proposed changes shall be advanced for determination in accordance with procedures to be established by the Parties, with a view to limiting both Parties’ internal personnel resources and external costs associated with the review of Promotional Materials in any case while ensuring that all such Promotional Materials meet all applicable Legal Requirements and applicable regulatory standards.

(c) Mallinckrodt shall not be required to use any portion of the Promotional Materials provided by Horizon that (i) have not been approved by both its own and Horizon’s promotional and review committee (or similar body) or (ii) are not in compliance with applicable Legal Requirements and regulatory standards. Mallinckrodt shall only use Promotional Materials in the form so approved and in a manner consistent with the training provided pursuant to Section 4.5 and Mallinckrodt shall not unilaterally change, modify or supplement such Promotional Materials in any way following such approval and training (including by underlining or otherwise highlighting any text or graphics or adding any notes thereto). Notwithstanding anything in this Agreement to the contrary, Mallinckrodt shall not be required to take any action if Mallinckrodt reasonably determines that such action would violate applicable Legal...
Requirements or applicable regulatory standards, including any such action involving the use or dissemination of any Promotional Materials or training materials.

(d) Horizon shall at all times use commercially reasonable efforts to ensure sufficient quantities of Promotional Materials are available for use by Mallinckrodt in performing its obligations hereunder. In the event that, after the Promotion Commencement Date, changes in Legal Requirements or any other circumstance makes the revision or supplementing of Promotional Materials necessary or advisable, Horizon agrees to perform such revision or supplementation to the Promotional Materials as soon as reasonably possible and to make such revisions and supplements available to Mallinckrodt for review and approval in accordance herewith and consequent use as soon as that can reasonably be done. In no event shall Horizon be required to make any change, revision or supplementation to the Promotional Materials that Horizon reasonably believes is not necessary or advisable or would violate applicable Legal Requirements or applicable regulatory standards.

(e) Horizon shall own all copyrights and other intellectual property rights in and to all Promotional Materials (other than any licensed Third Party copyrights), whether or not created before or during the Term of this Agreement.

4.8 License to Use Horizon Trademarks for Promotional Activities.

(a) Horizon Trademarks must appear on all Promotional Materials that make reference to the Product, to the extent such Promotional Materials would typically contain any Trademark, as defined hereunder. In no event shall Mallinckrodt have any right to use any Trademark other than a Horizon Trademark in connection with the Product or the Promotion thereof, absent the prior written consent of Horizon. Horizon hereby grants to Mallinckrodt (and to the extent provided in Section 2.2(ii), Affiliates of Mallinckrodt performing Promotional activities) a non-exclusive, royalty-free right and license to use, in the Territory, the Horizon Trademarks and to use, reproduce and distribute Promotional Materials and any other Product-related materials made available by Horizon to Mallinckrodt, in each case solely for the Promotion of the Product in accordance with the terms and conditions of this Agreement, which license shall not be sublicensable, assignable, or transferable (except to the extent permitted
pursuant to Section 13.1 below), except that Mallinckrodt may grant a limited non-exclusive sublicense under such license, limited in the same manner as such license to Mallinckrodt, to any Third Party providing Sales Representatives to the extent permitted in accordance with the terms of Section 2.2 above. Such license (and any sublicense thereunder granted to any Third Party) shall expire immediately upon the expiration or termination in its entirety of this Agreement for any reason. Mallinckrodt recognizes Horizon’s rights in and to the Horizon Trademarks, its Promotional Materials and other Product-related materials, and shall not at any time, during or after the Term, intentionally do or knowingly suffer to be done any act or thing which would impair the rights of Horizon in or to the Horizon Trademarks or any such materials. Mallinckrodt acknowledges and agrees that it and its Affiliates and permitted Third Party subcontractors shall not acquire and shall not claim any title to the Horizon Trademarks or any such materials adverse to Horizon by virtue of the rights granted under this Agreement or through use of the Horizon Trademarks or any such materials hereunder, it being the intention of the Parties that all goodwill and improved reputation generated by Mallinckrodt or any of its Affiliates and permitted Third Party subcontractors and its and their use of the Horizon Trademarks shall inure to the benefit of Horizon.

(b) Mallinckrodt (and any of its Affiliates and permitted Third Party subcontractors), with respect to its use of the Horizon Trademarks, will maintain quality standards for all of its uses of the Horizon Trademarks in connection with the Promotion of the Product that are consistent with quality standards that are (i) used by Horizon in connection with its pharmaceutical products, (ii) communicated by Horizon to Mallinckrodt and (iii) reasonable. Subject to the foregoing and to the other provisions of this Agreement, Mallinckrodt acknowledges and agrees that Horizon has the right, at any time, to modify or supplement such quality standards and that Mallinckrodt, as the licensee hereunder, must implement such new standards or changes following receipt of notice of such additions or changes; provided that, [...***...] associated with such modifications and supplements and that such modifications and supplements are reasonable.

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ARTICLE V
COMPLIANCE AND REGULATORY AFFAIRS

5.1 Regulatory Approvals.
Horizon shall use commercially reasonable efforts during the Term to maintain and continue all Regulatory Approvals for the Product.

5.2 Compliance with Regulatory Requirements.
Unless otherwise required by applicable Legal Requirements or expressly provided by this Agreement, Horizon will retain exclusive authority over and responsibility for complying with all regulatory requirements and maintaining all contacts with Governmental Authorities with respect to the Product, including the maintenance and updating of the Regulatory Approval, the reporting of any Adverse Drug Experiences to the FDA, the compliance of Promotional Materials with Legal Requirements, and the filing of Promotional Materials with OPDP and the FDA; provided that the foregoing does not limit any obligation of Mallinckrodt under this Agreement or under applicable Legal Requirements.

5.3 Compliance Materials.
(a) Each Party has, prior to the Effective Date, provided to the other Party access to its Compliance Materials, and shall from time-to-time thereafter promptly provide updates to such Compliance Materials if and as they are amended or supplemented. Each Party shall ensure that relevant portions of its Compliance Materials comply at all times with all applicable Legal Requirements.

(b) In performing its duties hereunder, each Party shall, and shall cause its Affiliates, and its and their employees, agents, representatives (including, in the case of Mallinckrodt, Sales Representatives) and contractors to comply with applicable Legal Requirements and with Horizon’s Compliance Materials as applicable to the activities of the Parties contemplated by
this Agreement. Without limiting the foregoing, Mallinckrodt shall ensure that none of it or its Affiliates, and its and their employees, agents, representatives (including Sales Representatives), and contractors shall offer, pay, solicit or receive any remuneration to or from any healthcare provider (as that term is defined in the PhRMA Code) in order to induce or reward referrals of or purchase of a Product in violation of applicable Legal Requirements, including any anti-kickback laws. In particular, Mallinckrodt shall train its Sales Representatives on all applicable Legal Requirements and requirements of Horizon’s Compliance Materials as applicable to Promotional activities contemplated by this Agreement prior to any such Sales Representatives engaging in Promotion of the Product hereunder. Mallinckrodt and its Sales Representatives will not make any payments or transfers of value to any healthcare provider or to any employee, agent, or immediate family member of a healthcare provider other than providing Promotional Materials and/or Product samples as provided for herein, and if Mallinckrodt or any of its Sales Representatives makes such a payment or transfer of value, Mallinckrodt shall (i) maintain documentation of such payment or transfer of value and (ii) immediately notify and provide a copy of such documentation to Horizon.

(c) Notwithstanding any other term or condition of this Agreement, neither Party shall be required to participate in, fund or support any sales or marketing activities that, in such Party’s judgment, would conflict with or be inconsistent with such Party’s own Compliance Materials. Notwithstanding anything herein to the contrary, Mallinckrodt shall not be obligated to use Promotional Materials that, in its judgment, conflict with or are inconsistent with its own Compliance Materials.

5.4 Communications with Regulatory Authorities.

Except to the extent set forth in this Section 5.4, all communications with Government Authorities concerning the Product shall be the sole responsibility of Horizon. Mallinckrodt shall not, without the consent of Horizon, correspond or communicate with the FDA or with any other Governmental Authority, whether within the Territory or otherwise, concerning the Product, or otherwise take any action concerning any Regulatory Approval under which the Product is sold; provided that, Mallinckrodt shall have the right to do so (i) if it believes in good faith that it is necessary to do so to comply with the terms of this Agreement or any Legal
Requirement, or (ii) at the request of a Governmental Authority (provided that, where practicable, it shall have requested that such Governmental Authority communicate with Horizon instead), and in either such case ((i) or (ii)), to the extent not prohibited by Legal Requirements and not prohibited by the Governmental Authority, Mallinckrodt shall give Horizon notice [...***...] of such communication and, to the extent practicable, shall permit Horizon to take part in any such communications and receive copies of all such communications. Mallinckrodt shall, within [...***...] days after receipt of any communication from the FDA or from any other Governmental Authority relating to the Product, to the extent not prohibited by Legal Requirements and not so prohibited by the FDA or the applicable Governmental Authority, forward a copy of the same to Horizon and reasonably respond to all inquiries by Horizon relating thereto. Mallinckrodt shall comply with any and all reasonable direction of Horizon concerning any meeting or written or oral communication with the FDA or any other Governmental Authority relating to the Product, unless otherwise required by Legal Requirements or otherwise requested by the FDA or the other Governmental Authority.

5.5 Medical Inquiries.

(a) Horizon shall be solely responsible for all medical affairs activities relating to the Product including medical information support and medical communications and publishing activities, which activities shall be performed by or on behalf of Horizon [...***...]. The Parties acknowledge that Mallinckrodt may receive requests for medical information concerning the Product from members of the medical profession and consumers. Horizon shall have the exclusive right to respond to questions and requests for information about the Product that are received from such Persons that either (i) warrant a response beyond the understanding of the Sales Representatives or (ii) are beyond the scope of the FDA-approved Product labeling and package inserts (each such request, a “PIR”). If PIRs are received by Mallinckrodt hereunder, the request will be referred to Horizon’s medical information department or an appointed Third Party vendor to which Horizon has instructed Mallinckrodt in writing to refer PIRs, within [...***...] days after PIRs are received by a Sales Representative or other employee or contractor of Mallinckrodt.

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(b) Within […***…] days after the Effective Date hereof, the Parties will enter into a mutually agreeable safety data exchange agreement, that is consistent in all respect with the terms hereof. In the event of any conflict or inconsistency between the terms of this Agreement and such safety data exchange agreement, this Agreement shall prevail in every case.

5.6 Product Complaints

Mallinckrodt shall refer any Product Complaints which it receives to Horizon within […***…] days of its receipt thereof. Mallinckrodt shall not take any other action in respect of any such Product Complaint without the consent of Horizon unless otherwise required by applicable Legal Requirements, and in such case will immediately notify Horizon of the nature of any such action taken, if legally possible under the circumstances. At Horizon’s request, Mallinckrodt will reasonably cooperate with Horizon to resolve any Product Complaints and […***…]. All Product Complaints shall be directed to the attention of those individuals and at the locations and numbers specified in any pharmacovigilance agreement to be entered into between the parties in accordance with Section 5.7(d) below. Horizon shall provide Mallinckrodt with a summary of all Product Complaints received, directly or indirectly, by Horizon no less than […***…] per […***…].

5.7 Adverse Drug Experience Reports

(a) Mallinckrodt shall notify Horizon: (i) of all Serious Adverse Drug Experiences within twenty four (24) hours of the time such Serious Adverse Drug Experiences become known to Mallinckrodt (including its Sales Representatives or other employees) and (ii) of all Adverse Drug Experiences that are not Serious Adverse Drug Experiences within […***…] days of the time such Adverse Drug Experiences become known to Mallinckrodt (including its Sales Representatives or other employees).

(b) Except as may otherwise be required by Legal Requirements, (i) Mallinckrodt shall not disclose any information concerning any Adverse Drug Experience or Serious Adverse Drug Experience to any Person or Governmental Authority without the prior written consent of ** 28

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Horizon, and (ii) Horizon shall determine, in its sole discretion, whether any Product Complaint, Adverse Drug Experience or Serious Adverse Drug Experience must be reported to the FDA or any other Governmental Authority.

(c) All follow-up investigations concerning any Adverse Drug Experience and/or Serious Adverse Drug Experience shall be conducted by Horizon or its appointed Third Party vendor to which Horizon has delegated such authority. At Horizon’s request, Mallinckrodt shall provide all reasonable cooperation with any such follow-up investigation, and Horizon shall reimburse Mallinckrodt for its reasonable, out-of-pocket expenses for such cooperation.

(d) Within [...] days after the Effective Date, the Parties will enter into a separate and more detailed pharmacovigilance agreement, consistent with the terms of this Agreement (which the Parties may agree to combine with the safety data exchange agreement contemplated by Section 5.5(b) into one agreement). In the event of any conflict or inconsistency between the terms of this Agreement and such pharmacovigilance agreement, this Agreement shall prevail in every case. Horizon shall maintain, at its sole expense, the global safety database relating to the Product, and shall be responsible for complying with all reporting and other applicable Legal Requirements related thereto.

5.8 Recalls or Other Corrective Action.

Horizon shall have sole responsibility for and shall make all decisions with respect to any recall (including recall of packaging and Promotional Materials), market withdrawals or any other corrective action related to the Product. Horizon shall promptly consult with Mallinckrodt with respect to any such actions proposed to be taken by Horizon in the Territory (and in all events reasonably in advance of the taking of such actions), including all such actions that are reasonably likely to result in a [...] on the Promotion of the Product in the Territory. At Horizon’s request, Mallinckrodt shall provide reasonable assistance to Horizon in conducting such recall, market withdrawal, or other corrective action (including retrieving Product samples distributed by Mallinckrodt’s Sales Representatives to healthcare providers), and [...].

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ARTICLE VI
SALE, SUPPLY AND PRICING OF PRODUCTS AND OTHER COVENANTS

6.1 Manufacturing Obligations.

In accordance with the provisions of this Agreement and all applicable Legal Requirements, Horizon shall, at its cost and expense, use [...***…] efforts to perform or cause to be performed all manufacture, labeling, packaging, warehousing, distribution and return, order entry, invoicing payment processing, customer services and all other activities required to supply and distribute the Product in the Territory as necessary or appropriate to enable Mallinckrodt to perform its obligations and to secure its rights under or as contemplated by this Agreement. Horizon shall use [...***…] efforts to ensure timely supply of the Product to customers and Product samples ordered by Mallinckrodt in accordance with Section 6.3. In the event that, for any period of time during the Term, there is a shortage of or a failure to supply Product in a quantity sufficient timely to meet existing or forecasted orders for the Product, Horizon shall (i) immediately notify Mallinckrodt in writing of the nature of any such event, its expected duration, and the percentage of normal trade demand for the Product affected by any such event and (ii) shall use [...***…] efforts to rectify any such failure to supply or shortage as soon as possible.

6.2 Product Sales and Pricing.

Horizon or its Affiliates shall book all sales of the Product in the Territory and shall be responsible for entering into any contracts and other arrangements with any Person regarding the sale of the Product. Horizon shall have the exclusive right to establish the pricing of the Product and approve the form, content and terms and conditions of contracts and other arrangements, including any discount, allowance, rebate, chargeback, or other term granted therein.
6.3 Product Samples

Horizon shall provide or cause to be provided to Mallinckrodt, as ordered by Mallinckrodt hereunder, samples of the Product that are not for sale and are distributed with no fee, to be distributed by Mallinckrodt solely in connection with the performance of Details to healthcare providers in accordance with this Agreement. Mallinckrodt shall place written purchase orders for samples of the Product with Horizon at least [...***...] days in advance of the required date of delivery. Samples of the Product shall be provided [...***...] by Horizon to Mallinckrodt at [...***...] for the manufacture, packaging, labeling and shipping of such samples [...***...] herein below. At least [...***...] days before the beginning of each [...***...] hereunder (or within [...***...] days after the Effective Date with respect to the first [...***...]), Mallinckrodt shall provide Horizon, [...***...], with a [...***...] month [...***...] forecast of Mallinckrodt’s anticipated need for samples of the Product during the next [...***...] Agreement Quarters ("Mallinckrodt Forecast"), which Mallinckrodt Forecast shall [...***...] but shall set forth in good faith and based on all known factors Mallinckrodt’s best estimate of its Product sample needs during the forecasted period. Unless Horizon consents, Mallinckrodt shall not order for delivery in any Agreement Quarter a quantity of samples in excess of the estimate for such Agreement Quarter as set forth in the most recent Mallinckrodt Forecast. Within [...***...] days after an order for Product samples is received by Horizon, Horizon shall be deemed to have accepted such sample order, provided that such sample order complies with the ordering requirements of this Section 6.3. Horizon shall deliver all samples of Product ordered by Mallinckrodt to Mallinckrodt by the required delivery date specified in each sample order. Mallinckrodt shall be responsible for distributing the samples of Product to its Sales Representatives in a timely manner. Horizon shall invoice Mallinckrodt, at the time of shipment, for each shipment of samples at the applicable price consistent with this Section 6.3(a) and payment by Mallinckrodt to Horizon shall be due to Horizon within [...***...] days after the invoice date. Upon its receipt of samples, Mallinckrodt shall be solely responsible for accountability and compliance under the PDMA with respect to its Sales Representatives, and under other applicable Legal Requirements relating to the distribution of such samples by its Sales Representatives. Mallinckrodt will track all
Product samples supplied to Mallinckrodt in a manner sufficient to allow Horizon to comply with Sections 6002 and 6004 of the Patient Protection and Affordable Care Act ("PPACA") and their implementing regulations that have been issued prior to the Effective Date and that are issued after the Effective Date. Mallinckrodt shall also be responsible for securing the return and appropriate disposal of and reconciling existing sample inventories from discontinued Mallinckrodt Sales Representatives and from all Mallinckrodt Sales Representatives upon the expiration or termination of this Agreement in its entirety. Each Party shall be responsible for reporting directly to the FDA any known thefts or significant losses of Product samples in their possession, as the same is required by the then applicable FDA regulations, and Mallinckrodt shall promptly provide to Horizon a complete copy of any such report concerning Product.

6.4 [...***... on Purchase of Promotional Materials and Samples...

 [...***...], Mallinckrodt shall not be required, with respect to the [...***...], (i) to [...***...], unless and to the extent the [... ***...], and billed to Mallinckrodt [...***...], with respect to both (i) and (ii) considered in the aggregate, is [...***...]; i.e., the [...***...], and [...***...] purchased by Mallinckrodt in each of the [...***...] will be [...***...].

6.5 Restriction on Commercialization.

(a) For the duration of the Term and for a period of one hundred eighty (180) days after the expiration or termination hereof, Mallinckrodt and its Affiliates shall not, directly or indirectly, commercialize or have commercialized in the Territory any oral solid NSAID prescription dosage pharmaceutical product containing a gastro-protective agent and with an indication only for the treatment of the signs and symptoms of rheumatoid arthritis and
osteoarthritis ("NSAID Product"), provided that the foregoing covenant is subject to the exceptions and limitations set forth in Section 6.5(b), immediately below.

(b) Notwithstanding the covenant set forth above in Section 6.5(a), neither Mallinckrodt nor any Affiliate of Mallinckrodt shall be prohibited from:

(i) acquiring any securities required to be registered under the Securities Exchange Act of 1934, as amended, of any Person to the extent such acquisitions do not result in Mallinckrodt or any Affiliate owning in the aggregate more than [...] percent ( [...] %) of all issued and outstanding capital stock of such Person, or

(ii) acquiring (through merger, stock purchase, purchase of assets or otherwise) ownership of, or any equity interest in, any Person if the combined annual revenues of such Person and its subsidiaries derived from the sale of any one or more NSAID Products do not exceed [...] percent ( [...] %) of the combined total annual revenues of such Person and its subsidiaries for the most recent full fiscal year then ended, or

(iii) engaging in the marketing and sale of any pharmaceutical product other than an NSAID Product, as defined herein, or

(iv) engaging in any type of pharmaceutical drug product development activities or in the manufacture of any pharmaceutical drug product, whether or not it is an NSAID Product, as defined herein.

6.6 Restriction on Grant of Co-Promotion Rights for Exclusive Targets to Third Parties

Neither Horizon nor any of its Affiliates will, during the Term hereof, grant to any Third Party any right to co-promote the Product to Exclusive Targets in the Territory; provided that the Parties acknowledge and agree that Horizon has entered into an agreement with a Third Party prior to the Effective Date for such Third Party to provide promotional services to Horizon with respect to the Product, and performance of such services (including such Third Party’s promotion
of the Product to Exclusive Targets in the Territory) shall not be restricted by this Agreement or be considered a breach of this Agreement by Horizon; provided that, it is further understood that such existing agreement of Horizon with such Third Party shall have no effect on the Mallinckrodt Call List or Mallinckrodt’s rights hereunder to be paid for prescriptions filled with respect to Exclusive Targets as contemplated pursuant to Section 7.1(a) below. In the event that either Horizon or its Affiliates are, at any time during the Term, in breach of the covenant set forth in the immediately preceding sentence, Mallinckrodt shall have the right, effective immediately upon notice to Horizon, to terminate this Agreement in its entirety, subject to the consequences of such termination as set forth in Section 8.3.

ARTICLE VII

COMPENSATION FOR CO-PROMOTION

7.1 Co-promotion Fee.

(a) In consideration of the performance by Mallinckrodt of its obligations hereunder and in addition to any consideration to which Mallinckrodt is entitled under Section 7.2 below, Horizon shall pay to Mallinckrodt a Co-promotion Fee in an amount payable for any given Agreement Quarter equal to […] for each […] Exclusive Targets and […] during such Agreement Quarter (regardless of whether or not such Exclusive Targets have been Detailed by Mallinckrodt or by Horizon (or anyone else on Horizon’s behalf), or by both, as such amount may be adjusted pursuant to Section 7.1(c) below; provided that, each […] will be calculated at an assumed […] for the purpose of calculating the Co-promotion Fee hereunder (for example, a […] and another one for […] would not count as […] but as […]). The number of […] for any given Agreement Quarter shall be determined from (i) available data generated by […] by Horizon to Mallinckrodt, within […] days after the end of each […] during the Term, setting forth a calculation of the […] during the […] for which the report is submitted, indicating the respective

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number of [...***...] with respect to Exclusive Targets during such [...***...], accompanied by such supporting documentation as may be necessary to support the calculation (for any given [...***...], a "[...***...] Report").

(b) The Co-promotion Fee for any given Agreement Quarter shall be paid by Horizon to Mallinckrodt within [...***...] days after the end of the Agreement Quarter to which such payment is applicable, in United States dollars, and to an account and in a manner reasonably agreed upon by the Parties. Payment of the Co-promotion Fee for a given Agreement Quarter shall be accompanied by a written statement from Horizon, setting forth the calculation of the Co-promotion Fee payable to Mallinckrodt for such Agreement Quarter, consistent with the applicable provisions of Section 7.1(a) and all relevant terms defined in Article 1 above and such other information and supporting documentation as may be required to support the calculation and agreed upon in writing by the Parties (for any given Agreement Quarter, a "Payment Report").

(c) In the event that, at any time during the Term and each time it occurs, Horizon makes a price increase or decrease with respect to the Product, it shall notify Mallinckrodt in writing of the amount thereof and its effective date and, from and after the effective date of any such changed price for the Product, the [...***...] shall be [...***...] from the then current amount by [...***...]. Further, if any increase or decrease in the price of the Product becomes effective on a [...***...] of any Agreement Quarter, the amount of the [...***...] with respect to such Agreement Quarter shall be [...***...] accordingly.

7.2 Residual Fee

(a) In addition to the Co-promotion Fees payable to Mallinckrodt in accordance with Section 7.1 set forth immediately above, subject to the provisions of this Section 7.2 and subject to the provisions of Section 8.3 below, Horizon shall pay to Mallinckrodt a fee ("Residual Fee") in an amount equal to (i) [...***...] Percent ([...***...]% of the Co-promotion Fees that were payable to Mallinckrodt with respect to the last [...***...] elapsing prior to the
expiration or termination of this Agreement (including the [...***... in which such expiration or termination occurred) or (ii) if any expiration of termination hereof does not coincide with the end of any full [...***...], then in an amount equal to the sum of (x) [...***...] Percent ( [...] percent) of the Co-promotion Fees that were payable to Mallinckrodt for the last [...***...] prior to termination or expiration immediately prior to, and not including, the [...***...] in which such expiration or termination occurred and (y) [...***...] Percent ( [...] percent) of the amount of any Co-promotion Fee that was payable to Mallinckrodt for the [...***...] in which any termination or expiration occurs, such amount multiplied by a fraction, the numerator of which is the number of [...***...] that would have been in such [...***...] absent termination or expiration and the denominator which is the number of [...***...] that elapsed in such [...***...] prior to and including the effective date of termination or expiration. The period for measurement of any Residual Fee as set forth in clause (i) or clause (ii) of the immediately preceding sentence, or as it may be altered under the circumstances described in Section 7.2(c) below, shall be referred to herein as the “Residual Measurement Period.”

(b) In the event this Agreement is terminated in its entirety prior to the elapse of [...***...], the Residual Fee payable to Mallinckrodt hereunder shall be calculated with reference to the number of [...***...] that have occurred from the Effective Date through the effective date of termination hereof and with reference to the Co-promotion Fees payable to Mallinckrodt during that shortened period of time, which shortened period of time shall, if it occurs because of the timing of any early termination hereof, be considered an appropriate Residual Measurement Period for calculation of any Residual Fee due Mallinckrodt hereunder.

(c) Notwithstanding any of the preceding provisions of this Section 7.2 or any other provisions of this Agreement to the contrary, should it be determined that Mallinckrodt has taken any actions that are in violation of the covenant set forth in Section 6.5 or if this Agreement is terminated by Horizon (i) pursuant to Section 4.2(b) or 8.2(h) or (ii) pursuant to Section 4.4(a) with respect to failure to achieve the Quarterly Minimum Prescription Level for any two (2) consecutive Agreement Quarters during the period of time commencing on October 1, 2012 and ending on September 30, 2013, then Horizon shall not be liable to pay to Mallinckrodt the
Residual Fee that would otherwise be payable to Mallinckrodt in accordance with this Section 7.2.

(d) The Residual Fee shall be paid by Horizon to Mallinckrodt [...***...].

7.3 Maintenance of Records and Audit Rights

(a) Horizon shall maintain, for a period of [...***...] years after the calendar year to which they pertain and for such additional period as specified by any applicable Legal Requirements, such books and records of Horizon (or anyone functioning on Horizon’s behalf) that relate in any manner to (i) Horizon’s payment and calculation hereunder of any Co-promotion Fees and Residual Fee to Mallinckrodt hereunder, including (without limitation) all books and records related to the [...***...] with respect to Exclusive Targets for all applicable periods and all supporting documents with respect to any Payment Report and [...***...] Report and, (ii) the amounts invoiced by Horizon to Mallinckrodt for Product samples and Promotional Materials and all records demonstrating the Direct Cost to Horizon for the same, all items referred to in clauses (i) and (ii) of this sentence, Horizon’s “Relevant Records”. Horizon shall ensure that its Relevant Records (including those in the possession of any Third Party acting on behalf of Horizon, to the extent it is possible with exercise of commercially reasonable efforts by Horizon) are complete and accurate, reflecting fairly the transactions they record and are maintained in accordance with Horizon’s accounting practices, consistently applied.

(b) Mallinckrodt shall have the right, upon reasonable prior written notice, no more than [...***...] in any calendar year, during Horizon’s regular business hours and through the use of an independent accounting firm or other appropriate Third Party expert (“Auditor”) acceptable to Horizon (which acceptance shall not unreasonably be withheld or delayed), to review, examine and audit the Relevant Records of Horizon (including those in possession of any Third Party...
acting on behalf of Horizon to the extent, through the exercise of commercially reasonable efforts by Horizon, such records can be made available for audit, review or examination) pertaining to no more than the [...] years immediately preceding the date of such notice for the sole purposes of (i) verifying the accuracy of calculation and payment by Horizon of any Co-promotion Fees (in particular, as reflected on any Payment Report) or the Residual Fee that may be due to Mallinckrodt hereunder with respect to such period and (ii) verifying the accuracy of Direct Costs invoiced by Horizon to Mallinckrodt for Product samples and Promotional Materials during such period. Mallinckrodt shall not audit any one period of time with respect to any subject of audit on more than one occasion. Mallinckrodt shall pay the fees and expenses of the Auditor associated with any review, examination or audit, except that Horizon shall pay any such fees and expenses allocable to a particular subject being audited for any particular period if, with respect thereto, the audit discloses, and it is finally determined in accordance herewith that, an amount due or charged to Mallinckrodt is more than [...] percent ([(...%]) in error and in Horizon’s favor. In the event the Auditor concludes, with respect to any given period of time, that additional payments were owed to Mallinckrodt or excess charges were invoiced to Mallinckrodt, the Auditor shall deliver to both Parties a written report setting forth its conclusions in detail and accompanied by all necessary supporting documentation. In the event that, within [...] days after its receipt of any Auditor’s report, Horizon fails to object to the conclusions and details set forth in such report by delivering a written notice to Mallinckrodt of its specific objections to such report, the conclusions set forth in the Auditor’s report shall be deemed final and binding on both Parties and determinative of their obligations hereunder, and if any additional payment or refunds are required to be made to Mallinckrodt such amounts shall be paid by Horizon no later than [...] days after the receipt by Horizon of the Auditor’s report. If, on the other hand, Horizon, within [...] days of its receipt of any Auditor’s report, gives written notice to Mallinckrodt and in detail of its good faith dispute concerning one
or more of the conclusions set forth in the Auditor’s report, then Horizon may withhold payment or refund to Mallinckrodt of any amounts with respect to which it has timely objected in good faith, but shall promptly pay or refund any amounts to which it has not so objected and therefore are not in dispute. If Horizon has timely provided notice to Mallinckrodt of dispute as to one or more items in the Auditor’s report, the Parties shall thereafter, for a period of no more than […] days after Mallinckrodt’s receipt of any written objections from Horizon, and in good faith, attempt to resolve any such disputes and, if they are unable to do so with respect to any one or more matters in dispute, then the matter(s) will be referred for final resolution to Third Party accounting firms and/or other experts (as appropriate to the dispute) selected by mutual agreement of the Parties, the written decision of which firms or experts will be final and binding upon the Parties and the fees and expenses of which firms or experts shall be paid as shall be reasonably directed in the final written decision submitted by such firms and experts.

ARTICLE VIII
TERM AND TERMINATION

8.1 Term.

The term of this Agreement shall commence on the Effective Date and shall end on and as of the close of business on December 31, 2014, unless extended or unless earlier terminated as otherwise set forth herein ("Term"). The Term shall be automatically renewed for additional and successive six (6) calendar month periods (i.e., for additional periods spanning two (2) consecutive Agreement Quarters), unless either Party provides to the other Party, at least […] days prior to the end of the initial Term or any renewal Term, as applicable, written notice of its intention that this Agreement not be renewed for any additional period of time.

8.2 Rights of Termination.

(a) Mallinckrodt shall have the right to terminate this Agreement in its entirety, pursuant and subject to the applicable provisions of Section 4.3, 4.4(b) or 6.6 above.
(b) Horizon shall have the right to terminate this Agreement in its entirety, pursuant and subject to the applicable provisions of Section 4.2(b) or 4.4(a) above.

(c) Either Party shall have the right to terminate this Agreement in its entirety, pursuant and subject to the applicable provisions of Section 4.4(a) above or Section 13.3 below.

(d) Either Party shall have the right to terminate this Agreement in its entirety effective immediately upon written notice to the other Party (setting forth with particularity the reasons for termination) in the event any Governmental Authority takes any action or makes any objection, order, demand or directive that prevents either or both of the terminating Party or the other Party from performing its or their obligations hereunder in all material respects, or that makes or might make performance hereunder by either Party in violation of Legal Requirements, or that raises a reasonable apprehension in the terminating Party that continued performance of any one or more of its obligations hereunder might subject such Party to any penalty, claim, investigation or other action by any Governmental Authority or any Person acting on behalf of any Governmental Authority.

(e) Either Party shall have the right to terminate this Agreement in its entirety effective immediately upon written notice to the other Party (setting forth with particularity the reasons for termination) if a Third Party either (i) asserts in writing that the using, making, having made, selling, marketing or offering for sale of the Product infringes an issued United States patent owned or controlled by such Third Party and such other Party’s counsel has not, within [...] days after receipt by either Party of any such assertion by the Third Party, provided in writing an unqualified opinion that the assertions of infringement are without merit or (ii) files a lawsuit or other action alleging that the using, making, having made, selling, marketing or offering for sale of the Product infringes an issued United States patent owned or controlled by such Third Party.

(f) Either Party shall have the right to terminate this Agreement in its entirety effective upon [...] days prior written notice to the other Party in the event either the other Party or the terminating Party has been subject to a Change of Control; provided that, neither Party shall have the right to terminate this Agreement as a consequence of the public spin-off of
Mallinckrodt and its Affiliates from Covidien plc, as publicly announced by Covidien plc (Mallinckrodt’s ultimate parent entity) in December 2011.

(g) Mallinckrodt shall have the right to terminate this Agreement in its entirety effective upon [...***...] days prior written notice to Horizon from and after the date on which any Third Party commercially launches in the Territory a generic product that is AB-rated to the Product.

(h) In addition to any other rights of termination that are specifically enumerated or referenced in this Section 8.2, this Agreement may be terminated in its entirety by either Party effective upon notice (i) by reason of a material breach of this Agreement (other than as provided in clauses (ii) or (iii) below) if the breaching Party fails to remedy such breach within [...***...] days after written notice thereof by the non-breaching Party, (ii) if the breaching Party fails to make any payments of any kind as and when due hereunder and such failure is not remedied within [...***...] days after written notice thereof by the non-breaching party (unless and to the extent there exists a good faith dispute as to the amount of any such payment due), or (iii) upon the bankruptcy, insolvency, dissolution or winding up of the other Party, except, in the case of a petition relative to any of the immediately foregoing filed involuntarily against a Party if such petition is dismissed within [...***...] days of the date of its filing. Notwithstanding Section 8.2(h)(i) and (ii), a Party shall not be deemed to be in breach hereof if any acts or omissions to act that would otherwise constitute a breach hereunder are the subject of a good faith dispute that is subject to resolution in accordance with internal procedures established herein unless and until such internal procedures have been fully exhausted.

8.3 Consequences of Termination or Expiration.

(a) In the event this Agreement is terminated in its entirety by either Party or by the mutual written agreement of both Parties or this Agreement expires, at least the following shall be the consequences of any such termination or expiration:

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(i) Mallinckrodt shall end, and shall take all necessary steps to ensure that its Affiliates and all Third Parties acting hereunder on its behalf end, all Promotional activities hereunder with respect to the Product on and as of the effective date of termination or expiration or on such earlier date as the Parties shall agree, and control of all Promotional activities with respect to the Products will revert exclusively to Horizon,

(ii) Mallinckrodt shall return, and shall take all necessary steps to ensure that its Affiliates and all Third Parties acting hereunder on its behalf return, to Horizon or its designee all undistributed Product samples and undistributed Promotional Materials, and each Party shall return to the other Party copies of all Compliance Materials of the other Party and all embodiments of any Proprietary and Confidential Information of the other Party,

(iii) the JMC shall cease operation and be disbanded on and as of the effective date of any termination or expiration,

(iv) Horizon shall purchase from Mallinckrodt all of its undistributed and returned inventory of Product samples and Promotional Materials relative to the Product, at Mallinckrodt’s actual cost of acquisition hereunder for such inventories from Horizon, taking into account the effect of the provisions of Section 6.4 hereof,

(v) Mallinckrodt shall, subject to and in accordance with the applicable provisions of Section 7.2, remain eligible to receive payment from Horizon of the Residual Fee after any expiration or termination of this Agreement, except in the case of termination of this Agreement by Horizon pursuant to Section 4.2(b), the penultimate sentence of Section 4.4(a) or Section 8.2(h), or if it is determined that Mallinckrodt has taken any actions that are in violation of the covenant set forth in Section 6.5, and

(vi) no termination or expiration of this Agreement shall affect any obligations, including (but not limited to) any obligations of payment, by one Party to the other Party that have accrued prior to the effective date of termination or expiration or
that may accrue through the exercise by Mallinckrodt of its rights under Section 7.3(b) at any time after such effective date of termination or expiration.

(b) In addition to the consequences of termination enumerated above in Section 8.3(a), as they may be applicable, the Parties will, in good faith and in the event of any termination of this Agreement, take such additional actions as may be necessary to conclude any relevant business and matters hereunder in a manner that is consistent with the intent and business objectives of both Parties as reflected by the terms and conditions hereof.

(c) In the event of any termination of this Agreement and except as may otherwise specifically be provided herein, no termination fee, liquidated damages or penalty of any kind shall be owed by either Party to the other Party solely by virtue of the exercise of any right of termination.

(d) Upon expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate, except that the following provisions shall survive the termination or expiration hereof: Sections 2.3, 4.6(d) (for a period of one (1) year after the date of such expiration or termination), 4.7(e), 6.5 (for a period of one hundred eighty (180) days following expiration or termination), 7.1 (until all payment obligations thereunder have been settled), 7.2 (until all payment obligations thereunder have been settled), 7.3 (for the period after the date of such expiration or termination specified therein), 8.3 and 9.4 and Articles I (for interpretational purposes), XI (for the period after the date of such expiration or termination specified therein), XII and XIII. Neither expiration nor termination of this Agreement shall relieve either party of any obligation accruing prior to such expiration or termination.

ARTICLE IX
REPRESENTATIONS AND WARRANTIES

9.1 **Representations and Warranties of Mallinckrodt.**

Mallinckrodt hereby represents and warrants to Horizon as of the Effective Date, and covenants to Horizon, as follows:
(i) **Organization.** Mallinckrodt is a limited liability company duly organized, validly existing and in good standing under the laws of the state of Delaware, and has all necessary corporate power and corporate authority to own its properties and to conduct its business as currently conducted.

(ii) **Authorization.** The execution, delivery and performance of this Agreement are within the corporate power of Mallinckrodt and have been duly authorized by all necessary corporate action, and this Agreement has been duly authorized, executed and delivered by Mallinckrodt.

(iii) **No Conflict.** Where it would have any adverse effect on the consummation of the transactions contemplated herein or on the performance by Mallinckrodt of its obligations hereunder, the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby do not (w) conflict with or result in a breach of any provision of Mallinckrodt’s organizational documents, (x) result in a material breach of any material agreement to which Mallinckrodt is party, (y) require Mallinckrodt to obtain any material approval or consent from any Governmental Authority or Third Party other than those consents and approvals which have been obtained prior to the date hereof or (z) violate any Legal Requirement applicable to Mallinckrodt.

(iv) **Enforceability.** This Agreement constitutes the valid and binding obligation of Mallinckrodt, enforceable against Mallinckrodt in accordance with its terms, subject to bankruptcy, reorganization, insolvency and other similar laws affecting the enforcement of creditors’ rights in general and to general principles of equity (regardless of whether considered in a proceeding in equity or an action at law).

(v) **Litigation.** There is no litigation, arbitration proceeding, governmental investigation, action or claims of any kind pending or, to the knowledge of Mallinckrodt, threatened, by or against Mallinckrodt or any of its Affiliates that would reasonably be expected materially to affect Mallinckrodt’s ability to perform its obligations hereunder.
(vi) **Generic Drug Act.** Pursuant to the Generic Drug Act,

(x) none of Mallinckrodt, its Affiliates, or, to the knowledge of Mallinckrodt, any Person under its direction or control is currently debarred by the FDA under the Generic Drug Act,

(y) none of Mallinckrodt, its Affiliates, or, to the knowledge of Mallinckrodt, any Person under its direction or control is currently using or will use in any capacity any Person that is debarred by FDA under the Generic Drug Act, and

(z) there have been no convictions of Mallinckrodt, its Affiliates, or to the knowledge of Mallinckrodt, any Person under its direction or control for any of the types of crimes set forth in the Generic Drug Act within the five (5) years prior to the Effective Date.

(vii) **Legal Requirements.** None of Mallinckrodt, its Affiliates, or, to the knowledge of Mallinckrodt, any Person under its direction or control is currently or has been excluded from a federal or state health care program under Section 1128 or 1156 of the Social Security Act, 42 U.S.C. §§ 1320a-7, 1320c-5 as amended or supplemented. None of Mallinckrodt, its Affiliates, or, to the knowledge of Mallinckrodt, any Person under its direction or control is otherwise currently excluded or has otherwise been excluded from contracting with the federal government. None of Mallinckrodt, its Affiliates, or, to the knowledge of Mallinckrodt, any Person under its direction or control is otherwise currently or has otherwise been excluded, suspended, or debarred from any federal or state program. Mallinckrodt shall immediately notify Horizon if, at any time during the Term,

(x) Mallinckrodt or its Affiliates is convicted of an offense that would subject Mallinckrodt to exclusion, suspension or debarment from any federal or state program, or

(y) Mallinckrodt becomes aware that any Person under the direction or control of Mallinckrodt or its Affiliates is convicted of an offense that would subject Mallinckrodt to exclusion, suspension or debarment from any federal or state program, or
9.2 Representations and Warranties of Horizon.

Horizon hereby represents and warrants to Mallinckrodt as of the Effective Date, and covenants to Mallinckrodt, as follows:

(i) **Organization.** Horizon is a corporation duly organized, validly existing and in good standing under the laws of the state of Delaware, and has all necessary corporate power and corporate authority to own its properties and to conduct its business, as currently conducted.

(ii) **Authorization.** The execution, delivery and performance of this Agreement are within the corporate power of Horizon and have been duly authorized by all necessary corporate action, and this Agreement has been duly authorized, executed and delivered by Horizon.

(iii) **No Conflict.** Where it would have any adverse effect on the consummation of the transaction contemplated herein or on the performance by Horizon of its obligations hereunder, the execution of this Agreement and the consummation of the transactions contemplated hereby do not (A) conflict with or result in a breach of any provision of Horizon’s organizational documents, (B) result in a material breach of any material agreement to which Horizon is party, (C) require Horizon to obtain any material approval or consent from any Governmental Authority or Third Party other than those consents which have been obtained prior to the date hereof or (D) violate any Legal Requirements applicable to Horizon.

(iv) **Enforceability.** This Agreement constitutes the valid and binding obligation of Horizon, enforceable against Horizon in accordance with its terms, subject to bankruptcy reorganization, insolvency, and other similar laws affecting the
enforcement of creditors’ rights in general and to general principles of equity (regardless of whether considered in a proceeding in equity or an action at law).

(v) **Intellectual Property.** To the knowledge of Horizon, the manufacture of the Product and the Promotion, offer for sale and sale of the Product in the Territory in accordance with this Agreement does not and will not infringe any issued patents, trademarks or other intellectual property rights of any Third Party in the Territory. Horizon has not received any actual or threatened claim or demand from any Third Party alleging that any infringement, violation or misappropriation of such Third Party’s intellectual property rights has occurred as a result of or in connection with the manufacture, use, offer for sale, sale or importation of the Product in the Territory. Except with respect to the matters described in the SEC Reports, (A) Horizon is not aware of any actual, alleged or threatened infringement, violation or misappropriation by a Third Party of any Horizon intellectual property rights covering the Product or its manufacture, use, offer for sale or sale, and (B) Horizon has not received any actual or threatened claim or demand from any Third Party alleging invalidity or unenforceability of any patents or patent applications owned or otherwise controlled by Horizon covering the Product or its manufacture, use or sale, including any Paragraph IV notice received from a Third Party pursuant to the Act (§ 505(j)(2)(B)), as amended by the Hatch-Waxman Amendments and the Medicare Modernization Act, and FDA’s implementing regulations (21 C.F.R. § 314.95), wherein an Abbreviated New Drug Application sponsor whose application contains a Paragraph IV certification must send notice of such certification to the NDA holder and patent owner (each, a “Paragraph IV Notice”).

(vi) **Litigation.** Except with respect to the matters described in the SEC Reports, there is no litigation, arbitration proceeding, governmental investigation, action or claims of any kind pending or, to the knowledge of Horizon, threatened, by or against Horizon or any of its Affiliates that would reasonably be expected materially to affect Horizon’s ability to perform its obligations hereunder or Mallinckrodt’s performance of its obligations to Promote the Product hereunder.

(vii) **Generic Drug Act.** Pursuant to the Generic Drug Act,
(A) none of Horizon, its Affiliates, or, to the knowledge of Horizon, any Person under its direction or control is currently debarred by the FDA under the Generic Drug Act,

(B) none of Horizon, its Affiliates, or, to the knowledge of Horizon, any Person under its direction or control is currently using or will use in any capacity in connection with the Product any Person that is debarred by FDA under the Generic Drug Act, and

(C) there have been no convictions of Horizon, its Affiliates, or, to the knowledge of Horizon, any Person under its direction or control for any of the types of crimes set forth in the Generic Drug Act within the five (5) years prior to the Effective Date.

(viii) Legal Requirement. None of Horizon, its Affiliates, or, to the knowledge of Horizon, any Person under its direction or control is currently excluded or has been from a federal or state health care program under Sections 1128 or 1156 of the Social Security Act, 42 U.S.C. §§ 1320a-7, 1320c-5 as amended or supplemented. None of Horizon, its Affiliates, or, to the knowledge of Horizon, any Person under its direction or control is otherwise currently excluded or has otherwise been excluded from contracting with the federal government. None of Horizon, its Affiliates, or, to the knowledge of Horizon, any Person under its direction or control is otherwise currently or has otherwise been excluded, suspended or debarred from any federal or state program. Horizon shall immediately notify Mallinckrodt if, at any time during the Term, (x) Horizon or its Affiliates is convicted of an offense that would subject Horizon to exclusion, suspension, or debarment from any federal or state program, or (y) Horizon becomes aware that any Person under the direction or control of Horizon or its Affiliates is convicted of an offense that would subject Horizon to exclusion, suspension, or debarment from any federal or state program or (z) Horizon is, or is notified by any relevant Government Authority that it will be, excluded, suspended or debarred from any federal or state program.
(ix) **No Other Co-Promotion Rights.** Except as referenced in Section 6.6 herein above and for subcontractors performing marketing or promotional activities on behalf of Horizon that are not in person and face-to-face, none of Horizon or its Affiliates has, on and as of the Effective Date hereof, entered into nor is there currently in effect any binding agreement or other arrangement between Horizon or its Affiliates and any Third Party granting to such Third Party any right to market or promote the Product to the Exclusive Targets in the Territory.

(x) **No Line Extensions.** Horizon is not currently in the process of developing nor does it have any present intention of developing or commercializing any additional strength(s) or other line extension(s) of Product.

9.3 **Product Sample Warranty.**

Horizon warrants to Mallinckrodt that, at the time of delivery of all Product samples to Mallinckrodt hereunder, (u) such Product samples will be in conformity with the applicable specifications therefor and the Regulatory Approval for the Product, (v) such Product samples will have been manufactured in material compliance with cGMP and in compliance with all other applicable Legal Requirements, (w) such Product samples will have been manufactured in facilities that are in material compliance with all applicable Legal Requirements at the time of such manufacture, (x) such Product samples will not be adulterated or misbranded under the Act, (y) such Product samples may be introduced into interstate commerce pursuant to the Act and (z) the expiration date of such Product samples shall be no earlier than [...***…] months after the date of delivery thereof.

9.4 **Horizon Disclaimer.**

EXCEPT AS EXPRESSLY PROVIDED HEREIN, HORIZON DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, WITH REGARD TO THE PRODUCT OR OTHERWISE, INCLUDING ANY WARRANTY OF MERCHANTABILITY, ANY 49

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ARTICLE X
INTELLECTUAL PROPERTY MATTERS

10.1 Intellectual Property Prosecution and Maintenance.
Horizon shall, at its own expense, use commercially reasonable efforts to prosecute and maintain, in the Territory, all Horizon intellectual property owned by Horizon that is related to the Product or its manufacture, use, marketing, offer for sale or sale in the Territory (including any patents, the Horizon Trademarks and any copyrights associated with the Promotional Materials). Horizon shall keep Mallinckrodt informed regarding material events with respect to the ongoing prosecution and maintenance of Horizon patents, to the extent they relate to the Product or its manufacture, use, marketing, offer for sale or sale in the Territory.

10.2 Infringement.
(a) If either Party shall learn of a claim or assertion that the manufacture, use, marketing, offer for sale or sale of the Product in the Territory infringes or otherwise violates the intellectual property rights of any Third Party (“Third Party Infringement Claim”), then the Party becoming so informed shall promptly, but in all events within [...***...] days thereof, notify the other Party to this Agreement of the Third Party Infringement Claim. It shall be the sole responsibility of Horizon to determine the nature of and direct any defense against any such Third Party Infringement Claim with respect to the Product, at Horizon’s sole cost and expense and at its election and discretion. In the event any Third Party Infringement Claim is filed against Horizon with respect to the Product, Mallinckrodt shall cooperate with Horizon in the defense of such action at the reasonable cost and expense of Horizon if requested by Horizon.

(b) In the event of any infringement of Horizon’s patent or other intellectual property rights related to the Product or the manufacture, use, marketing, offer for sale or sale of such
Product in the Territory, which infringement involves a product that could or does compete with the Product and/or could adversely affect either or both of the Parties’ interests under this Agreement with respect to the Product (including a Paragraph IV Notice received as a result of an Abbreviated New Drug Application filed by a Third Party for a generic version of the Product), Horizon shall, in its sole discretion, determine whether or not and in what manner to take appropriate legal action to redress such infringement (an “Enforcement Action”). In the event any such Enforcement Action is initiated, Horizon shall use commercially reasonable efforts to prosecute such matter and Horizon shall keep Mallinckrodt promptly informed regarding such Enforcement Action. At Horizon’s reasonable request, Mallinckrodt shall cooperate fully with Horizon with respect to any such Enforcement Action, and Horizon shall reimburse Mallinckrodt for its reasonable out-of-pocket costs and expenses incurred in providing such cooperation. Any recovery received as a result of any Enforcement Action shall belong to Horizon.

ARTICLE XI
CONFIDENTIALITY

11.1 Protection of Proprietary and Confidential Information.

(a) Except as may otherwise be provided in this Article XI, during the Term of this Agreement and for a period of [...] years thereafter (or longer as required with respect to any Third Party information), each Recipient Party receiving Proprietary and Confidential Information shall maintain in confidence and use only for purposes specifically authorized under this Agreement all Proprietary and Confidential Information of the Disclosing Party. In protecting the Proprietary and Confidential Information of the Disclosing Party, the Recipient Party shall use the same degree of care as it employs in protecting in its own similar information, but in any event no less than a reasonable degree of care.

(b) To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, a Recipient Party may disclose Proprietary and Confidential Information it is otherwise obligated under this Section 11.1 not to disclose to its *** Confidential Treatment Requested
Affiliates, consultants, agents and representatives, only on a need-to-know basis and only on condition that such Persons agree to keep the Proprietary and Confidential Information confidential for the same time periods and to the same extent as such Recipient Party and further agree to use such Proprietary and Confidential Information only for purposes relevant to the performance by a Recipient Party of its obligations under this Agreement. A Recipient Party shall be fully responsible for any improper disclosure or use of Proprietary and Confidential Information by its Affiliates, consultants, agents and representatives.

(c) If a Recipient Party is required under applicable Legal Requirements to disclose any Proprietary and Confidential Information of the Disclosing Party to any Governmental Authority in connection with bona fide legal process, then the Recipient Party may do so only if (i) it limits disclosure of the Proprietary and Confidential Information only to that information required to be disclosed, and (ii) it gives the Disclosing Party, if practicable and legal under the circumstances, prompt written notice of any instance of such a requirement in reasonable time for the Disclosing Party to attempt to object to or to limit such disclosure, with the cooperation of the Recipient Party and at the Disclosing Party’s cost and expense.

(d) The Parties have agreed upon the form and content of a press release(s) to be issued promptly following the execution of this Agreement. Any publicity, news release, public comment or other announcement, whether to the press, to stockholders or otherwise relating to this Agreement, including activities conducted hereunder, shall first be reviewed and approved by both Parties, except no approval shall be required for such publicity, news release, public comment or other public announcement which, in accordance with the advice of legal counsel to the Party making such disclosure, is required by applicable law, rule or regulation or for appropriate market disclosure. For clarity, any Party making any announcement which is required by applicable law, rule or regulation or for appropriate market disclosure will, unless prohibited by law, give the other Party an opportunity to review the form and content of such announcement and comment before it is made. The Parties shall work together to coordinate filings with governmental agencies, including the United States Securities and Exchange Commission, as to the contents and existence of this Agreement in such manner as the Parties shall reasonably deem necessary or appropriate, and each Party shall provide the other Party a
reasonable opportunity to comment on any proposed filings, including redactions proposed thereto.

(e) Except as and if compelled by applicable law, rule or regulation or as provided in Section 11.(d) or this Section 11.1(e), each Party agrees not to disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party. Each Party may disclose the terms or conditions of this Agreement to Third Parties in connection with due diligence or similar investigations of such Party by such Third Parties, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Third Party shall be subject, in writing, to obligations of confidentiality and non-use with respect to the information disclosed to it at least as restrictive with respect to such information as the provisions of this Agreement.

(f) The Parties hereto agree that remedies at law may be inadequate to protect a party against any breach by the other Party (or any other Person acting in concert with such other Party or on its behalf) of any of the provisions of this Section 11.1. Accordingly, each Party shall be entitled to seek the granting of injunctive relief or other equitable relief (or any similar remedy) from a court of competent jurisdiction against any action that constitutes any breach of this Section 11.1, in addition to any monetary damages or other similar relief to which a party may be entitled, without the necessity of posting a bond or any other form of financial assurance.

(g) In the event of any conflict or inconsistency between the provisions of this Section 11.1 and this Agreement in general, on the one hand, and the terms and conditions of the Confidentiality Agreement, on the other hand, this Agreement shall prevail in every case.

ARTICLE XII
INDEMNIFICATION AND LIABILITY

12.1 Indemnification by Mallinckrodt

Subject to the applicable provisions of this Article XII, Mallinckrodt, at its own expense, hereby agrees to defend, indemnify and hold Horizon and its Affiliates and their respective
directors, officers, employees and agents harmless from and against any and all claims, actions, causes of action, losses, damages, injuries, liabilities, costs and expenses, including reasonable attorneys’ and experts’ fees and expenses ("Loss") incurred by any such Person entitled to indemnification under this Section 12.1, directly or indirectly, arising out of or resulting from:

(i) any breach or violation of any of the representations, warranties and/or covenants of Mallinckrodt set forth herein,

(ii) any actual or asserted violation by Mallinckrodt and/or its Affiliates of any Legal Requirements, including any violation of any Legal Requirements by any Sales Representatives or Third Parties acting by on behalf of Mallinckrodt and/or its Affiliates in connection herewith,

(iii) any actions or omissions to act by any Sales Representative of Mallinckrodt and/or its Affiliates related to the Promotion of the Product (including, without limitation, any Promotion of the Product for any “off-label” indications or claims or any other false or misleading representations to healthcare providers or others regarding the Product or Horizon), and

(iv) any negligent or wrongful act or omission to act by Mallinckrodt or its Affiliates, or anyone acting on behalf of any of them, in connection with performance hereunder;

except for any Loss for which Horizon has the obligation to defend, indemnify and hold harmless pursuant to Section 12.2 below.

12.2 **Indemnification by Horizon**.

Subject to the applicable provisions of this Article XII, Horizon, at its own expense, hereby agrees to defend, indemnify and hold Mallinckrodt and its Affiliates and their respective directors, officers, employees and agents harmless from and against any and all Loss incurred by
any such Person entitled to indemnification under this Section 12.2, directly or indirectly, arising out of or resulting from:

(i) any breach or violation of any of the representations, warranties and/or covenants of Horizon set forth herein,

(ii) any actual or asserted violation by Horizon and/or its Affiliates of any Legal Requirements, including any violation of any Legal Requirements by any sales representatives or Third Parties acting by on behalf of Horizon and/or its Affiliates in connection with Horizon’s Promotion, manufacture, marketing, offer for sale or sale of the Product,

(iii) any actions or omissions to act by any sales representative of Horizon and/or its Affiliates related to the Promotion of the Product (including, without limitation, any Promotion of the Product for any “off-label” indications or claims or any other false or misleading representations to healthcare providers or others regarding the Product),

(iv) any claim, lawsuit or other action made by any Third Party alleging that (A) the manufacture, use, offer for sale, sale or marketing of the Product by Horizon and/or (B) Mallinckrodt’s use of the Promotional Materials in the form provided by Horizon to promote the Product in compliance with the terms of this Agreement infringes or misappropriates any patent, trademark or other intellectual property rights of a Third Party (except with respect to clause (B), to the extent that Horizon directs Mallinckrodt to stop use of such Promotional Materials and Mallinckrodt does not do so),

(v) any claim, lawsuit or other action made by any Third Party alleging that the use of the Product has caused any Adverse Drug Experience, Serious Adverse Drug Experience or any other personal injury or death, or that the labeling of the Product fails properly or fully to warn users or prescribers of the Product of the risks associated with its use, or any other claim with respect to the Product that is in the nature of product liability,

(vi) any claim, lawsuit or other action alleging that any Promotional Materials provided by Horizon and used in accordance with this Agreement make false, unlawful or
unsupported claims about the Product or otherwise violate any applicable Legal Requirements, and

(vii) any negligent or wrongful act or omission to act by Horizon or its Affiliates, or anyone act on behalf of any of them, in connection with performance hereunder,

except for any Loss for which Mallinckrodt has the obligation to defend, indemnify and hold harmless pursuant to Section 12.1 above.

12.3 Indemnification Procedures

Unless and to the extent otherwise specifically provided herein, a Party or any other Person entitled to indemnification under this Article XII (the “Indemnitee”) that intends to claim indemnification under this Article XII with respect to any Third Party claim, lawsuit or action shall promptly notify the indemnifying Party (the “Indemnitor”) of any Loss arising out of any Third Party claim, lawsuit or action in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have the sole right and responsibility to assume the defense thereof with counsel of its own choosing; provided, however, that an Indemnitee shall have the right to participate in the defense and to retain its own counsel, at its own expense. An Indemnitee shall not be entitled to indemnification under this Article XII if any settlement or compromise of a Third Party claim, lawsuit or action is effected by the Indemnitee without the consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed. An Indemnitee shall not be entitled to indemnification with respect to any Third Party claim, lawsuit or action seeking only monetary changes in an amount in excess of the amount which such Third Party has unequivocally and in writing agreed with the Indemnitor it is willing to accept in settlement or compromise of any such Third Party claim. An Indemnitor (i) shall not enter into any settlement or compromise of any Third Party claim, lawsuit or action or consent to the entry of any judgment or other order with respect thereto unless it contains, as a part thereof, an unconditional release of the Indemnitee for liability for all Loss that may arise from such claim and (ii) shall not enter into any settlement or compromise of any Third Party claim, lawsuit or action or consent to the entry of any judgment or other order with respect thereto which contains any injunctive or other non-monetary relief that might in any way interfere with the future
12.4 Consequential Damages.

NEITHER MALLINCKRODT NOR HORIZON, NOR THEIR RESPECTIVE AFFILIATES, NOR THE DIRECTORS, OFFICERS, EMPLOYEES OR AGENTS OF ANY OF THE FOREGOING, SHALL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT OR PUNITIVE DAMAGES OF ANY KIND THAT MAY ARISE UNDER OR BE RELATED TO THIS AGREEMENT, WHETHER OR NOT ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND WHETHER OR NOT SUCH DAMAGES MAY HAVE BEEN REASONABLY FORESEEABLE; PROVIDED THAT, THE FOREGOING LIMITATION SHALL NOT BE APPLICABLE TO ANY DAMAGES FOR BREACH OF ARTICLE XI OR LOSS ARISING DUE TO FRAUD OR WILFUL MISCONDUCT OR TO THE OBLIGATIONS FOR INDEMNIFICATION UNDER SECTION 12.1 OR 12.2 WITH RESPECT TO THIRD PARTY CLAIMS, LAWSUITS OR ACTIONS.

ARTICLE XIII
MISCELLANEOUS

13.1 Assignment.

This Agreement, and a Party’s right and obligations hereunder, may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party, except that either Party may, without such prior written consent, assign or otherwise transfer this Agreement (i) in connection with a corporate reorganization to any Affiliate, provided that the
assigning Party shall remain liable and responsible to the non-assigning Party for the performance and observance of all such duties and obligations by such Affiliate, or (ii) to an unrelated Third Party in connection with a merger, consolidation or sale of substantially all of a Party’s business or assets to which this Agreement relates to such unrelated Third Party. Any purported assignment in violation of the preceding sentence shall be void. This Section 13.1 shall have no effect on the right of either Party to terminate this Agreement pursuant to Section 8.2(f) above.

13.2 Severability.

Should one or more provisions of this Agreement be or become invalid or unenforceable, the Parties hereto shall substitute, by mutual consent, valid and enforceable provisions for such invalid or unenforceable provisions which new provisions, in their economic and other effects, are sufficiently similar to the invalid or unenforceable provisions that it can be reasonably assumed that the Parties would have originally entered into this Agreement with such new provisions. In case such new provisions cannot be agreed upon, the invalidity or unenforceability of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole or the validity of any portions hereof, unless the invalid or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that one or both of the Parties would not originally have entered into this Agreement without such invalid or unenforceable provisions.

13.3 Force Majeure.

Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, except for the timely payment hereunder of any money due by one Party to the other, when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party (an “event of force majeure”), including but not limited to fire, floods, embargoes, war, acts of war (whether war is declared or not), insurrections, riots, civil commotions, the existence or administration of any laws, rules or regulations, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any Governmental Authority or the other Party; provided, however, that the Party so affected shall use reasonable
commercial efforts to avoid or remove such causes of nonperformance, and shall continue performance hereunder with reasonable dispatch whenever such causes are removed. Each Party shall provide the other party with prompt written notice of any delay or failure to perform that occurs by reason of an event of force majeure. If an event of force majeure causes a failure or delay in performance hereunder by a Party for more than one hundred twenty (120) consecutive days, which failure or delay has a material adverse effect on the other Party’s performance and/or the realization of its benefits hereunder, such other Party, at its option, may terminate this Agreement effective upon written notice to the Party experiencing an event of force majeure, subject to the consequences of such termination as set forth in Section 8.3 above.

13.4 Notices.

Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties hereto to the other, except for any notices required in connection with any pharmacovigilance or safety data exchange agreement between the Parties, shall be in writing, delivered personally, or by electronic transmission if receipt is confirmed electronically, or by courier, or by certified mail (postage prepaid) addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor, and shall be effective in all cases upon receipt by the addressee.

If to Horizon:  
Horizon Pharma USA, Inc.
520 Lake Cook Road, Suite 520
Deerfield, IL 60015
Attn: Timothy P. Walbert, Chairman, Chief Executive Officer and President
Telephone: (847) 772-0050
E-mail: twalbert@horizonpharma.com

with a copy to:  
Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Attn: L. Kay Chandler
Telephone: (858) 550-6014
E-mail: kchandler@cooley.com
13.5 Governing Law.

This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to its conflict of laws provisions that might apply the law of another jurisdiction (except for the conflict of laws provisions contained in Section 5-1401 and 5-1402 of the New York General Obligations Law).

13.6 Dispute Resolution.

(a) The Parties hereby agree that they will attempt in good faith to resolve any controversy or claim arising out of or relating to this Agreement promptly by negotiations and, where specifically provided for, in accordance with any specific provisions for dispute resolution set forth elsewhere in this Agreement with respect to any particular matter or Article or Section hereof. If a controversy or claim should arise hereunder, and if a dispute resolution provision is not otherwise provided herein for settlement of such controversy or claim, the representatives of the Parties will confer at least once and will attempt to resolve the matter. Except as specifically provided elsewhere in this Agreement, if the matter has not been resolved within [...***...] days **60*** Confidential Treatment Requested
of their first meeting, the representatives shall refer the matter to appropriate members of their senior management. If the matter has not been resolved within […***…] days by members of the Parties' senior management, any controversy or claim arising out of or relating to this Agreement may be settled as set forth in Section 13.6(b) set forth immediately below, if both Parties agree in writing.

(b) If and as the Parties agree to submit any dispute to arbitration, any such dispute arising between the Parties hereunder shall be settled by binding arbitration in accordance with the Judicial Arbitration and Mediation Services (“JAMS”) Comprehensive Arbitration Rules and Procedures, as such rules may be modified by this Section 13.6(b) or by written agreement of the Parties. The Parties shall mutually select a single independent, conflict-free arbitrator, who shall have sufficient background and experience to resolve the matter(s) in dispute. If the Parties are unable to reach agreement on the selection of the arbitrator within […***…] days after submission of a dispute to arbitration, then either or both Parties shall immediately request JAMS to select an arbitrator with the requisite background, experience and expertise. Notwithstanding the applicable JAMS rules, (i) the arbitrator shall resolve the dispute as expeditiously as reasonably possible, and in any event no later than […***…] days following referral of the dispute to the arbitrator and (ii) the arbitrator shall resolve the dispute in a manner that is fair and reasonable to the Parties in light of the totality of the circumstances and the terms of this Agreement. The place of arbitration shall be Chicago, Illinois, and all proceedings and communications shall be in English. Either Party may apply to the arbitrator for interim injunctive relief or may seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending resolution of the matter pursuant to this Section 13.6(b). The Parties shall have the right to be represented by counsel. Any judgment or award rendered by the arbitrator shall be final and binding on the Parties, and shall be governed by the terms and conditions hereof, including the limitation on damages set forth in Section 12.4 above. The Parties agree that such a judgment or award may be enforced in any court of competent jurisdiction. The statute of limitations of the State of New York applicable to the commencement of a lawsuit shall apply to the commencement of arbitration under this Section 13.6(b). Each Party shall bear its own costs and expenses and attorneys’ fees, and, unless otherwise agreed by the Parties or determined by the arbitrator, the Party that does not prevail in the arbitration proceeding shall pay the arbitrator’s fees and any administrative fees

*** Confidential Treatment Requested
of arbitration. All proceedings and decisions of the arbitrator(s) shall be deemed Proprietary and Confidential Information of each of the Parties, and shall be subject to Article XI above.

(c) For the avoidance of doubt, any dispute arising hereunder for which there is a specific dispute resolution procedure provided herein shall besettled only by application of such procedure and not by resort to the dispute resolution mechanics set forth in this Section 13.6.

(d) Any dispute which cannot be resolved by the Parties in accordance with Section 13.6(a) above and the Parties do not agree will be submitted to arbitration to be settled in accordance with the requirements of Section 13.6(b) above, may be settled through litigation brought by one or both of the Parties in a court of appropriate jurisdiction and venue, or by any other means agreed upon by the Parties.

13.7 Entire Agreement and Amendment.

This Agreement, together with the exhibits attached hereto, contains the entire understanding of the parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly merged in and made a part of this Agreement. This Agreement may be amended, or any term hereof modified or supplemented, only by a written instrument duly executed by authorized representatives of both Parties hereto, and shall not be deemed to be amended by any course of dealing or usage that arises between the Parties.

13.8 Headings.

The captions to the several articles, sections and clauses hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several articles and sections hereof.
13.9 **Waiver.**

The waiver by a Party hereto of any right hereunder or the failure of a Party to object on any occasion to a breach or failure of performance by the other Party shall not be deemed a waiver of a Party’s other rights hereunder or its right, on any subsequent occasion, to object to a breach by the other Party of any terms hereof or to insist upon the performance by the other Party of its obligations hereunder.

13.10 **Counterparts.**

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. An executed signature page of this Agreement delivered by facsimile transmission or by electronic mail in “portable document format” (“.pdf”) shall be as effective as an original executed signature page.

13.11 **Construction.**

The Parties acknowledge and agree that: (i) each Party and its representatives have reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revisions, and (ii) the terms and provisions of this Agreement will be construed fairly as to each Party hereto and not in favor of or against either Party regardless of which Party was generally responsible for the preparation or drafting of this Agreement. Unless the context of this Agreement otherwise requires: (v) words of any gender include the other gender, (w) words using the singular or plural number also include the plural or singular number, respectively, (x) the terms “hereof,” “herein,” “hereby,” and derivative or similar words refer to this entire Agreement, (y) the terms “Article,” “Section,” “Exhibit,” or “clause” refer to the specified Article, Section, Exhibit, or clause of this Agreement, and (z) the term “including” or “includes” means “including without limitation” or “includes without limitation.” Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless business days are specified.
13.12 **Relationship Between Parties.**

The Parties hereto are acting and performing as independent contractors, and nothing in this Agreement creates the relationship of partnership, joint venture, sales agency or principal and agent. Neither Party is the agent of the other, and neither Party may hold itself out as such to any other Person. All financial obligations associated with each Party’s business will be the sole responsibility of such Party except and as expressly otherwise stated.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

MALLINCKRODT LLC

By: /s/ Mark C. Trudeau [Illegible Signature]
Mark C. Trudeau
President, Pharmaceuticals

HORIZON PHARMA USA, INC.

By: /s/ Timothy P. Walbert
Timothy P. Walbert
Chairman, Chief Executive Officer and President
EXHIBIT A
Quarterly Minimum Prescription Levels

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All references to quarters in the above table are to Agreement Quarters, as defined in Section 1.5. Prescriptions will be calculated based on the requirements of Section 7.1(a).

*** Confidential Treatment Requested
This Third Party Data Use Agreement ("Agreement") is by and among Source Healthcare Analytics, LLC, a Delaware corporation with its principal place of business at 2394 East Camelback Road, Phoenix, Arizona 85016 ("SHA"), Insert Client Name, with its principal place of business at Insert Client Address ("Client"), and Insert Third Party Name with its principal place of business at Insert Third Party Address ("Contractor"). This Agreement shall only become effective as of the date last signed by all parties ("Effective Date").

Scope of this Agreement. SHA provides certain data to Client pursuant to an agreement which, among other things, prohibits the disclosure of such data to third parties without entry into a Third Party Data Use Agreement ("License Agreement"). Client has requested SHA’s permission to disclose such data to Contractor for the purpose described below. By the signature below of an authorized representative of SHA, this Agreement constitutes SHA’s prior written permission to Client to disclose such data to Contractor subject to the terms and conditions contained in this Agreement.

DESCRIPTION OF LICENSE AGREEMENT
As used in this Agreement, “License Agreement” refers to the following agreement between SHA and Client:

Dated:

DESCRIPTION OF DATA AND USE
As used in this Agreement, “Data” refers to the following SHA data provided to Client pursuant to the License Agreement:

Contractor may only use the data for the following permitted use and only on behalf of Client pursuant to Section 1 and Section 2 of the Terms and Conditions on page 2 ("Permitted Use"): 

DESCRIPTION OF CONTRACTOR’S LOCATION WHERE DATA WILL RESIDE (if different from above)
Address, City, State, Zip:

SHA, Client and Contractor acknowledge their receipt and acceptance of the terms and conditions of this Agreement by the signature below of their respective authorized representatives.

CONTRACTOR:
By: _________________________________
Printed Name: _______________________________
Title: _________________________________
Date: _________________________________

CLIENT:
By: _________________________________
Printed Name: _______________________________
Title: _________________________________
Date: _________________________________

SOURCE HEALTHCARE ANALYTICS, LLC:
By: _________________________________
Printed Name: _______________________________
Title: _________________________________
Date: _________________________________
THIRD PARTY DATA USE AGREEMENT

Terms and Conditions

1. **Contractor's Use of Data.**

   (a) Subject to the terms and conditions of this Agreement, Contractor agrees to use the Data only for the Permitted Use set forth in this Agreement. Under no circumstances shall Contractor use any of the Data, or any information derived therefrom, for Contractor’s own direct benefit or for the direct benefit of any other person or entity other than Client. SHA shall have no obligation to support Contractor’s use of the Data. If upon the request of Contractor, SHA in its sole discretion elects to support Contractor’s use of the Data, SHA may charge Contractor its then standard rates for such support.

   (b) Under no circumstances may Contractor resell, sublicense or otherwise distribute, disclose or permit access by any third party to any of the Data. The Data shall be delivered by SHA to Contractor, or by Client to Contractor, as applicable, only in de-identified format in compliance with the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (“HIPAA”). Contractor represents and warrants that it shall not attempt, directly or indirectly, to re-identify any Data to identify a patient, pharmacy or a hospital provider. SHA may suspend delivery of any Data immediately upon notice from Contractor or Client, or in the event that SHA has good faith reason to reasonably believe, that identifiable data would be or is included in any Data. Contractor shall ensure that the Data will not be used by or on behalf of Contractor in any way to exhibit, reference, access or generate any patient, pharmacy or hospital level data. Contractor represents and warrants that it will not attempt to link, on an individual basis, any other information to the Data; and it maintains, and will continue to maintain, appropriate access controls to physically, technically, and administratively separate any such information from the Data, and from any products produced using all or any part of the Data.

2. **Confidentiality.** Contractor shall use its commercially reasonable efforts to ensure any employee of Contractor receiving any Data is apprised of and appreciates the confidential and proprietary nature of the Data, and shall require each such employee to refrain from disclosing or discussing the Data with anyone other than the employees of Contractor, Client or SHA. Contractor’s employees shall only receive those portions of the Data necessary to fulfill Contractor’s obligations to Client as described herein. All copies of any of the Data, including any data derived therefrom, shall include SHA’s confidentiality notice and any other copyright notice or other proprietary notice, if any, appearing on the copy of the Data provided by SHA. In addition, any documents or materials prepared by Contractor or Contractor’s employees, agents or representatives which contain information derived from any of the Data, shall be conspicuously marked with confidential and/or proprietary notices substantially similar to those notices contained in the original deliverable received from SHA. No part of the Data shall be: (a) published by Contractor, (b) quoted, made or reproduced by Contractor for advertising, promotional or public relations purposes, (c) reproduced or placed in any data retrieval systems by Contractor, except as expressly provided herein; or (d) used in any legal proceedings, except where the production of any such Data or information is compelled under process or request by a court or administrative agency of competent jurisdiction, in which event Contractor shall promptly give notice of such process, adhere to SHA’s policies governing the use of SHA data in litigation, and cooperate with SHA in obtaining a protective order or other mechanism for the protection of any such Data.

3. **Term and Termination.** The term of this Agreement shall begin on the Effective Date and shall terminate at the earlier of: (a) the termination of the License Agreement, however occurring; (b) the termination of Contractor's services to Client relating to the use of the Data; or (c) thirty (30) days after written notice by Client or SHA to the other two parties indicating Client’s or SHA’s intention to terminate this Agreement. Prior to termination, Contractor shall destroy or return to Client all Data in Contractor’s control or possession, and an authorized representative of Contractor shall certify in writing to SHA, with a copy to Client, that Contractor has destroyed or returned to Client all Data in its possession or control.

4. **No Warranty.** ANY DATA PROVIDED TO Contractor IN CONNECTION WITH THIS AGREEMENT IS PROVIDED TO Contractor “AS-IS” AND SHA MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, TO Contractor IN CONNECTION WITH THE DATA, INCLUDING THE IMPLIED WARRANTIES OR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

5. **Limitation of Liability.** Contractor acknowledges and agrees that SHA shall have no liability to Contractor under this Agreement, including but not limited to, any liability arising from the inaccuracy or incompleteness of the Data. In no event shall SHA be liable to Contractor under this Agreement for any incidental or consequential damages, including but not limited to, lost business, lost profits or third party claims, whether foreseeable or not, even if SHA has been advised of the possibility of such damages. The parties acknowledge and agree that a breach by Contractor of the provisions of this Agreement above will cause SHA and/or its affiliates irreparable injury and damage which may not be compensable by money damages, and, therefore, Contractor agrees that SHA and/or its affiliates shall be entitled to injunctive or other relief against Contractor to prevent such a breach by Contractor and to secure enforcement of the terms of this Agreement, in addition to any other remedies which may be available. Without limiting the availability to SHA of any other rights or remedies, if Contractor breaches any of the terms of this Agreement, SHA reserve the right to immediately terminate this Agreement upon notice to Client and Contractor.

6. **Inspection Rights.** SHA may upon reasonable notice to Contractor send a representative to Contractor’s place of business to verify compliance with the terms of this Agreement; provided, that SHA shall keep any information learned by SHA in the course of such inspection confidential and shall not use such information for any purpose except to confirm compliance with this Agreement and not disclose such information to any third party. Such verification shall be performed during the normal business hours of Contractor upon no less than five business’ days prior written notice to Client and Contractor.
7. **Indemnification.** Contractor agrees to indemnify SHA and hold SHA harmless for any and all third party claims, damages, costs, demands, or other liabilities (each, a “Claim”) arising from or relating to any breach of this Agreement by Contractor, including reasonable attorney’s fees. SHA shall promptly notify Client and Contractor of each such Claim at the time each Claim becomes known to SHA.

8. **Notices.** All notices, demands or other communications required hereunder shall be given or made in writing and shall be delivered personally or sent prepaid (i) by certified or registered first class mail with return receipt requested or (ii) by a nationally-recognized common carrier’s overnight courier service, addressed to the receiving party at the address first written above or such other address as the receiving party may advise in writing to use hereunder.

9. **Miscellaneous.** This Agreement sets forth the entire agreement between the parties and supersedes prior proposals, agreements and representations related to the subject matter of this Agreement, whether written or oral, except for the License Agreement. No modifications, amendments or waiver of any of the provisions of this Agreement shall be binding upon the parties unless made in writing and duly executed by authorized representatives of Contractor, Client and SHA. Contractor may not assign, transfer or sublicense any portion of this Agreement or the Data provided hereunder without the express written consent of Client and SHA. Any attempt to assign, transfer or sublicense by Contractor in violation of this Section 9 shall be void. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same document. The headings of the paragraphs hereof are used for convenience only and shall not affect the meaning or interpretation of the content thereof. This Agreement and the relationship of the parties in connection with the subject matter of this Agreement shall be governed by and determined in accordance with the laws of the State of New York, excluding its conflicts of laws principles. THE PARTIES WAIVE TRIAL BY JURY IN CONNECTION WITH ANY CLAIM, ACTION OR SUIT ASSERTED, BROUGHT OR ARISING UNDER THIS AGREEMENT. The failure to enforce at any time the provisions of this Agreement or to require at any time performance by the other parties of any of the provisions hereof shall in no way be construed to be a waiver of such provisions or to affect either the validity of this Agreement (or any part hereof), or the right of any of the parties thereafter to enforce each and every provision in accordance with the terms of this Agreement. If any provision of this Agreement is held to be invalid or unenforceable by any judgment of a tribunal of competent jurisdiction, the remainder of this Agreement shall not be affected by such judgment, and the Agreement shall be carried out as nearly as possible according to its original terms and intent. However, if the original intent of the parties cannot be preserved, this Agreement shall terminate upon the effective date of such judgment.
I, Timothy P. Walbert, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Horizon Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   c. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 10, 2012

/s/ Timothy P. Walbert

Timothy P. Walbert
President, Chief Executive Officer and Chairman of the Board
Certification

I, Robert J. De Vaere, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Horizon Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   c. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 10, 2012

/s/ Robert J. De Vaere

Robert J. De Vaere
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)
CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and 18 U.S.C. Section 1350, I, Timothy P. Walbert, President, Chief Executive Officer and Chairman of the Board of Horizon Pharma, Inc. (the “Company”), certify to the best of my knowledge that:

1. the Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2012, to which this Certification is attached as Exhibit 32.1 (the “Report”), fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 10, 2012

/s/ Timothy P. Walbert
Timothy P. Walbert
President, Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.
CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and 18 U.S.C. Section 1350, I, Robert J. De Vaere, Executive Vice President and Chief Financial Officer of Horizon Pharma, Inc. (the “Company”), certify to the best of my knowledge that:

1. the Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2012, to which this Certification is attached as Exhibit 32.2 (the “Report”), fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 10, 2012

/s/ Robert J. De Vaere
Robert J. De Vaere
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.