HORIZON PHARMA, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)
520 Lake Cook Road, Suite 520
Deerfield, Illinois
(Address of principal executive offices)

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

60015
(zip code)

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

Common Stock, par value $0.0001 per share

The NASDAQ Global Market

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☐ Accelerated filer ☒
Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting common stock held by non-affiliates of the registrant, based upon the $2.46 per share closing sale price of the registrant's common stock on June 28, 2013 (the last business day of the registrant’s most recently completed second quarter), was approximately $128,221,687. Solely for purposes of this calculation, the registrant’s directors and executive officers and holders of 10% or more of the registrant’s outstanding shares of common stock have been assumed to be affiliates and an aggregate of 11,187,697 shares of the registrant’s voting common stock held by such persons on June 28, 2013 are not included in this calculation.

As of March 11, 2014, the registrant had outstanding 67,733,417 shares of its common stock.
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HORIZON PHARMA, INC.  
FORM 10-K — ANNUAL REPORT  
For the Fiscal Year Ended December 31, 2013  

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This Annual Report on Form 10-K contains “forward-looking statements”—that is, statements related to future, not past, events—as defined in Section 21E of the Securities Exchange Act of 1934, as amended, that reflect our current expectations regarding our future growth, results of operations, financial condition, cash flows, performance, business prospects, and opportunities, as well as assumptions made by, and information currently available to, our management. Forward-looking statements include any statement that does not directly relate to a current or historical fact. The Company has tried to identify forward-looking statements by using words such as “believe,” “may,” “could,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “seek,” “plan,” “expect,” “should,” or “would.” Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to successfully execute our sales and marketing strategy, including continuing to successfully recruit and retain sales and marketing personnel in the United States, and to successfully build the market for DUEXIS®, VIMOVO® and RAYOS® in the United States; whether we will be able to realize the expected benefits of our acquisition of the U.S. rights to VIMOVO, including whether and when the acquisition will be accretive to our net income; the rate and degree of market acceptance of, and our ability and our distribution and marketing partners’ ability to obtain reimbursement for, any approved products; our ability to maintain regulatory approvals for DUEXIS, VIMOVO and RAYOS, known as LODOTRA® outside the United States; our need for and ability to obtain additional financing; the accuracy of our estimates regarding expenses, future revenues and time to profitability; our ability to successfully execute our strategy to develop, acquire or in-license additional products or acquire companies; our ability to manage our anticipated future growth; the ability of our products to compete with generic products, especially those representing the active pharmaceutical ingredients in DUEXIS, VIMOVO and RAYOS/LODOTRA, as well as new products that may be developed by our competitors; our ability and our distribution and marketing partners’ ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products and product candidates; the performance of our third party distribution partners, licensees and manufacturers, over which we have limited control; our ability to obtain and maintain intellectual property protection for our products; our ability to defend our intellectual property rights with respect to our products and otherwise prevent the entry of generic versions of our products; our ability to operate our business without infringing the intellectual property rights of others; the loss of key commercial or management personnel; regulatory developments in the United States and other countries; and other risks detailed below in Part I—Item 1A. “Risk Factors.”

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Revision of Prior Period Financial Statements

In the course of preparing our Consolidated Statements of Comprehensive Loss for this Annual Report on Form 10-K, we determined that there had been a misclassification of certain fees in our financial statements for the previously reported quarters ended March 31, 2012 and 2013, June 30, 2012 and 2013 and September 30, 2012 and 2013, as well as our annual financial statements for the year ended December 31, 2012, or, collectively, the Affected Financial Statements.

The Affected Financial Statements classified wholesaler service fees as cost of goods sold. We determined that these fees should be classified as sales discounts and allowances, which are a reduction in revenue instead of an increase in cost of goods sold and have revised all identified prior period misclassifications in the periods in which they originated. The revision had no impact on our reported gross profit, net loss or cash flows.

In evaluating whether our previously issued consolidated financial statements were materially misstated, we considered the guidance in Financial Accounting Standards Board, or FASB, Accounting Standards Codification,
The following table includes selected line items from our financial statements illustrating the effect of the revision:

<table>
<thead>
<tr>
<th>Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2012</th>
<th>As Reported</th>
<th>Adjustment (in thousands)</th>
<th>As Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales discounts and allowances</td>
<td>(384)</td>
<td>(38)</td>
<td>(422)</td>
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<tr>
<td>Net Sales</td>
<td>2,523</td>
<td>(38)</td>
<td>2,485</td>
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<tr>
<td>Cost of goods sold</td>
<td>2,067</td>
<td>(38)</td>
<td>2,029</td>
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<table>
<thead>
<tr>
<th>Consolidated Statements of Comprehensive Loss for the Three Months Ended June 30, 2012</th>
<th>As Reported</th>
<th>Adjustment (in thousands)</th>
<th>As Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales discounts and allowances</td>
<td>(767)</td>
<td>(160)</td>
<td>(927)</td>
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<tr>
<td>Net Sales</td>
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<td>(160)</td>
<td>3,681</td>
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<tr>
<td>Cost of goods sold</td>
<td>2,855</td>
<td>(160)</td>
<td>2,695</td>
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<table>
<thead>
<tr>
<th>Consolidated Statements of Comprehensive Loss for the Three Months Ended September 30, 2012</th>
<th>As Reported</th>
<th>Adjustment (in thousands)</th>
<th>As Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales discounts and allowances</td>
<td>(790)</td>
<td>(202)</td>
<td>(992)</td>
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<tr>
<td>Net Sales</td>
<td>6,521</td>
<td>(202)</td>
<td>6,319</td>
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<tr>
<td>Cost of goods sold</td>
<td>3,810</td>
<td>(202)</td>
<td>3,608</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Consolidated Statements of Comprehensive Loss for the Three Months Ended December 31, 2012</th>
<th>As Reported</th>
<th>Adjustment (in thousands)</th>
<th>As Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales discounts and allowances</td>
<td>(1,405)</td>
<td>(388)</td>
<td>(1,793)</td>
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<tr>
<td>Net Sales</td>
<td>6,747</td>
<td>(388)</td>
<td>6,359</td>
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<tr>
<td>Cost of goods sold</td>
<td>3,931</td>
<td>(388)</td>
<td>3,543</td>
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</table>

<table>
<thead>
<tr>
<th>Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2013</th>
<th>As Reported</th>
<th>Adjustment (in thousands)</th>
<th>As Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales discounts and allowances</td>
<td>(1,527)</td>
<td>(478)</td>
<td>(2,005)</td>
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<tr>
<td>Net Sales</td>
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<td>(478)</td>
<td>8,693</td>
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<tr>
<td>Cost of goods sold</td>
<td>4,247</td>
<td>(478)</td>
<td>3,769</td>
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<table>
<thead>
<tr>
<th>Consolidated Statements of Comprehensive Loss for the Three Months Ended June 30, 2013</th>
<th>As Reported</th>
<th>Adjustment (in thousands)</th>
<th>As Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales discounts and allowances</td>
<td>(5,383)</td>
<td>(1,123)</td>
<td>(6,506)</td>
</tr>
<tr>
<td>Net Sales</td>
<td>12,254</td>
<td>(1,123)</td>
<td>11,131</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>3,517</td>
<td>(1,123)</td>
<td>2,394</td>
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<table>
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<th>Consolidated Statements of Comprehensive Loss for the Six Months Ended June 30, 2013</th>
<th>As Reported</th>
<th>Adjustment (in thousands)</th>
<th>As Revised</th>
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<td>Sales discounts and allowances</td>
<td>(6,910)</td>
<td>(1,601)</td>
<td>(8,511)</td>
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<td>Net Sales</td>
<td>21,425</td>
<td>(1,601)</td>
<td>19,824</td>
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<td>Cost of goods sold</td>
<td>7,764</td>
<td>(1,601)</td>
<td>6,163</td>
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</table>

<table>
<thead>
<tr>
<th>Consolidated Statements of Comprehensive Loss for the Three Months Ended September 30, 2013</th>
<th>As Reported</th>
<th>Adjustment (in thousands)</th>
<th>As Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales discounts and allowances</td>
<td>(5,306)</td>
<td>(2,106)</td>
<td>(7,412)</td>
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<td>Net Sales</td>
<td>26,218</td>
<td>(2,106)</td>
<td>24,112</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>5,313</td>
<td>(2,106)</td>
<td>3,207</td>
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Table of Contents

As Reported | Adjustment | As Revised
(in thousands)

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>As Reported</th>
<th>Adjusted</th>
<th>As Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales discounts and allowances</td>
<td>12,216</td>
<td>3,707</td>
<td>15,923</td>
<td></td>
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<tr>
<td>Net Sales</td>
<td>47,643</td>
<td>3,707</td>
<td>43,936</td>
<td></td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>13,077</td>
<td>3,707</td>
<td>9,370</td>
<td></td>
</tr>
</tbody>
</table>

Item 1. Business

Overview

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

On April 23, 2011, the U.S. Food and Drug Administration, or FDA, approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis, or RA, osteoarthritis, or OA, and to decrease the risk of developing upper gastrointestinal, or GI, ulcers in patients who are taking ibuprofen for these indications. In the second half of 2011, we hired our initial commercial organization, including approximately 80 sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal S.A., or Grünenthal, a private company focused on the promotion of pain products. In the third quarter of 2012, we expanded our sales force to approximately 150 representatives and have subsequently further expanded our sales force to approximately 290 representatives, most recently by adding approximately 115 representatives in connection with our acquisition of the U.S. rights to VIMOVO in November 2013. In March 2013, we announced that the United Kingdom, or UK, Medicines and Healthcare Products Regulatory Agency, or MHRA, granted a National Marketing Authorization, or MA, for DUEXIS in the UK. We will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain and inflammation products and the revenue being generated there by existing branded non-steroidal anti-inflammatory drugs, or NSAIDs, we do not expect a material level of sales from DUEXIS in European markets.

Our second approved product in the United States, RAYOS, known as LODOTRA outside the United States, is a proprietary delayed-release formulation of low-dose prednisone approved originally in Europe for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, polymyalgia rheumatica, or PMR, psoriatic arthritis, or PsA, ankylosing spondylitis, or AS, asthma and chronic obstructive pulmonary disease, or COPD, and a number of other conditions. We are focusing our promotion of RAYOS in the United States on rheumatology indications, including RA and PMR. We began detailing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of U.S. rheumatologists and key primary care physicians. LODOTRA is currently marketed outside the United States by our distribution partner, Mundipharma International Corporation Limited, or Mundipharma. In connection with our acquisition of the U.S. rights to VIMOVO, we increased our rheumatology sales force from 25 representatives to 40 representatives in January 2014.

On November 18, 2013, we entered into agreements with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other
pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs in the United States. VIMOVO (naproxen/esomeprazole magnesium) is a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, or PPI, layer surrounding the core. VIMOVO was originally developed by Pozen Inc., or Pozen, together with AstraZeneca pursuant to an exclusive global collaboration and license agreement under which AstraZeneca and Pozen agreed to co-develop VIMOVO and AstraZeneca obtained exclusive rights to commercialize VIMOVO worldwide. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of OA, RA and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

Under the asset purchase agreement with AstraZeneca, we acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the investigational new drug application, or IND, and new drug application, or NDA, for VIMOVO in the United States, AstraZeneca’s interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. In addition, AstraZeneca assigned to us its amended and restated collaboration and license agreement for the United States with Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States.

In December 2013, as a result of the acquisition of the U.S. rights to VIMOVO, we began the expansion of our sales force to approximately 250 primary care representatives and 40 rheumatology sales specialists and also recognized revenues under our transition agreement with AstraZeneca. We announced the availability of Horizon-labeled VIMOVO on January 2, 2014. We completed the hiring and training of our expanded sales force in January 2014 and began selling VIMOVO in early February 2014. Our primary care representatives will promote DUEXIS in a primary position to physician targets who are high branded NSAID prescribers and are also prescribers of DUEXIS and ibuprofen and they will promote VIMOVO in a second position among these target physicians. Our primary care representatives will promote VIMOVO in a primary position to physician targets who are high branded NSAID prescribers and are also prescribers of VIMOVO and naproxen and they will promote DUEXIS in a second position among these target physicians. Our analysis indicates that there is an approximate 30% overlap of physician targets who prescribe both DUEXIS and VIMOVO. In those cases, individual target-by-target promotional plans will be executed and both DUEXIS and VIMOVO will be promoted to these targets. Our strategy with respect to VIMOVO is to bring its pricing in-line with DUEXIS and thereby significantly increase the value realized per prescription while lowering the monthly out-of-pocket costs to patients taking VIMOVO. We have also expanded our rheumatology specialty sales force from 25 sales specialists to approximately 40 sales specialists, with these specialist representatives promoting RAYOS and VIMOVO to rheumatologists. We have also included VIMOVO in our Prescriptions-Made-Easy, or PME, specialty pharmacy program, along with DUEXIS and RAYOS, and offer co-pay assistance for all of our marketed products to ensure patients receive them at a reasonable out-of-pocket cost.

PME is a novel program that we have developed to address the impact of pharmacies switching from branded products prescribed by doctors to substitute products. In the fourth quarter of 2013, approximately 27% of DUEXIS prescriptions were processed through the three partner pharmacies that are contracted to run the PME pharmacy services. The three partner pharmacies are geographically located on the east coast, in the midwest and on the west coast. Physician offices can access PME either through electronic prescribing systems or a simple fax form that is linked to one of the partner pharmacies. Then, within four hours, the partner pharmacy places a call to the patient and the prescription is shipped overnight to the patient’s home. We have initiated this program for DUEXIS, VIMOVO and RAYOS. Over 85% of prescriptions submitted through the PME program are filled and sent to the patient. In comparison, approximately 62% of prescriptions written at retail pharmacies are filled and received by the patient.

We were incorporated as Horizon Pharma, Inc. in Delaware on March 23, 2010. We are a holding company that operates primarily through our two wholly-owned subsidiaries, Horizon Pharma USA, Inc., a Delaware
corporation, and Horizon Pharma AG, a company organized under the laws of Switzerland. Horizon Pharma AG owns all of the outstanding share capital of its wholly-owned subsidiary, Horizon Pharma GmbH, a company organized under the laws of Germany through which Horizon Pharma AG conducts most of its European operations.

Our principal executive offices are located at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015 and our telephone number is (224) 383-3000. Our website address is www.horizonpharma.com. The information contained in or that can be accessed through our website is not part of this report.

Unless the context indicates otherwise, as used in this report, the terms “Horizon,” “Horizon Pharma,” “we,” “us” and “our” refer to Horizon Pharma, Inc., a Delaware corporation, and its subsidiaries taken as a whole. Also, unless the context indicates otherwise, for historical periods prior to April 1, 2010, the terms “Horizon,” “Horizon Pharma USA,” “we,” “us” and “our” refer to Horizon Therapeutics, Inc.

“Horizon Pharma,” “Horizon Therapeutics,” a stylized letter “H,” “DUEXIS,” “RAYOS,” “LODOTRA” and “VIMOVO” are registered trademarks in the United States and/or certain other countries. This report also includes references to trademarks and service marks of other entities and those trademarks and service marks are the property of their respective owners.

Our Strategy

Our strategy is to utilize the commercial strengths and the infrastructure that have been put in place in creating a fully-integrated U.S.-focused specialty pharmaceutical company to successfully commercialize DUEXIS, VIMOVO and RAYOS in the U.S. market and also to expand and leverage these capabilities by developing, acquiring or in-licensing additional products or acquiring companies where we can execute a targeted commercial approach among specific target physicians such as primary care physicians, orthopedic surgeons and rheumatologists. We intend to enter into licensing or additional distribution arrangements for the commercialization of our products outside the United States, such as our relationship with Mundipharma for the commercialization of LODOTRA outside of the United States, excluding Japan and Canada, and our relationship with Grünenthal for the commercialization of DUEXIS in Latin America.

Our Strategic Relationships

We have entered into several strategic relationships with respect to the manufacturing, distribution and marketing of LODOTRA. We entered into separate transfer, license and supply agreements with Merck Serono GmbH, or Merck Serono, and Merck GesmbH for the commercialization of LODOTRA in each of Germany and Austria, respectively, and we subsequently consented to assignment of the agreements with respect to Germany and Austria to Mundipharma Laboratorites GmbH, or Mundipharma Laboratories. We also entered into distribution agreements with Mundipharma for the exclusive distribution and marketing rights pertaining to LODOTRA for Europe (originally excluding Germany and Austria) and certain Asian, Latin American and other countries and a manufacturing and supply agreement with Mundipharma Medical Company, or Mundipharma Medical, pursuant to which we supply LODOTRA to Mundipharma Medical. We have also entered into a manufacturing and supply agreement with Jagotec AG, or Jagotec, an affiliate of SkyPharma AG, or SkyPharma, from whom we purchase LODOTRA. In August 2011, SkyPharma leased its entire pharmaceutical manufacturing business to Aenova France SAS, or Aenova, with our consent to allow Jagotec to subcontract the manufacture of LODOTRA to Aenova. In March 2013, we entered into a back-up manufacturing agreement with Bayer Pharma AG, or Bayer.

In May 2011, we entered into a manufacturing and supply agreement with sanofi-aventis U.S. to manufacture and supply DUEXIS. In addition, we have entered into an exclusive agreement with Grünenthal for the commercialization of DUEXIS in Latin America.
In November 2013, we entered into agreements with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO in the United States. In connection with these agreements, we entered into a supply agreement with AstraZeneca pursuant to which AstraZeneca agreed to supply VIMOVO to us for commercialization in the United States through December 31, 2014. Also in November 2013, we entered into a master manufacturing services agreement and product agreement with Patheon Pharmaceuticals, Inc., or Patheon, the contract manufacturer of VIMOVO, pursuant to which Patheon will manufacture VIMOVO for us from the end of the AstraZeneca supply agreement through December 31, 2019.

Our Products

We believe that our products address unmet therapeutic needs in arthritis, pain and/or inflammatory diseases and provide significant advantages over existing therapies.

Our current product portfolio consists of the following:

<table>
<thead>
<tr>
<th>Products</th>
<th>Disease</th>
<th>Phase of Development</th>
<th>Marketing Rights</th>
<th>Territory</th>
</tr>
</thead>
<tbody>
<tr>
<td>DUEXIS</td>
<td>Signs and symptoms of OA and RA</td>
<td>NDA approved April 23, 2011</td>
<td>Horizon</td>
<td>Worldwide excluding Latin America</td>
</tr>
<tr>
<td></td>
<td></td>
<td>UK National MA approved on March 6, 2013</td>
<td></td>
<td>Grünenthal Latin America</td>
</tr>
<tr>
<td>RAYOS/LODOTRA</td>
<td>RA</td>
<td>NDA approved July 26, 2012, approved and marketed in Europe</td>
<td>Horizon</td>
<td>Worldwide, excluding Europe and certain Asian, Latin American and other countries</td>
</tr>
<tr>
<td></td>
<td>PMR and other indications</td>
<td>NDA approved July 26, 2012</td>
<td>Horizon</td>
<td>Mundipharma Europe and certain Asian, Latin American and other countries</td>
</tr>
<tr>
<td>VIMOVO</td>
<td>Signs and symptoms of OA, RA and AS</td>
<td>FDA approved April 30, 2010</td>
<td>Horizon</td>
<td>United States</td>
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</tbody>
</table>

Market Overview

Pain is a serious and costly public health concern affecting more people in the United States than diabetes, heart disease and cancer combined. In 2010, the U.S. National Center for Health Statistics reported that approximately 30% of U.S. adults 18 years of age and over reported recent symptoms of pain, aching or swelling around a joint within the past 30 days.
Some of the most common and debilitating chronic inflammation and pain-related diseases are OA, RA and acute and chronic pain. According to National Health Interview Survey data analyzed by the U.S. Centers for Disease Control and Prevention, 50 million U.S. adults 18 years of age and over had reported being diagnosed with some form of arthritis. With the aging of the U.S. population, the prevalence of arthritis is expected to rise by approximately 40% by 2030, impacting 67 million people in the United States. People with these diseases may become increasingly debilitated as the disease progresses, experiencing not only significant pain but also loss of mobility, independence and the ability to work, thereby potentially placing a significant burden on family caregivers and healthcare and social services. In addition, patients suffering from chronic inflammatory diseases tend to have shortened life expectancies as a direct result of these diseases. According to the American Pain Foundation Fact Sheet and the U.S. Centers for Disease Control and Prevention:

- the annual cost of chronic pain in the United States, including healthcare expenses, lost income and lost productivity is estimated to be $100 billion;
- arthritis and related conditions, such as OA, cost the U.S. economy nearly $128 billion per year in medical care and indirect expenses, including lost wages and productivity; and
- pain is the second leading cause of medically related work absenteeism, resulting in more than 50 million lost workdays each year.

In addition, the Arthritis Foundation reports 992,000 hospitalizations and 44 million office visits in the United States annually for arthritis alone.

**Osteoarthritis**

OA is a type of arthritis that is caused by the breakdown and eventual loss of the cartilage of one or more joints. Cartilage is a protein substance that serves as a cushion between the bones of the joints. OA is also known as degenerative arthritis. Among the over 100 different types of arthritis conditions, OA is the most common and occurs more frequently with age. Before age 45, OA occurs more frequently in males. After age 50, it occurs more frequently in females. OA commonly affects the hands, feet, spine and large weight-bearing joints, such as the hips and knees. Most cases of OA have no known cause and are referred to as primary OA.

Symptoms of OA manifest in patients as joint pain, tenderness, stiffness, limited joint movement, joint cracking or creaking (crepitation), locking of joints and local inflammation. OA can also lead to joint deformity in later stages of the disease. Many drugs are now used to treat the inflammation and pain associated with OA, including aspirin and other NSAIDs, such as ibuprofen and naproxen, that have a rapid analgesic and anti-inflammatory response.

**Rheumatoid Arthritis**

RA is a chronic disease that causes pain, stiffness and swelling, primarily in the joints. According to DataMonitor, 2.9 million people in the United States suffer from RA, of which 1.8 million are diagnosed and treated with various drugs. RA has no known cause, but unlike OA, RA is not associated with factors such as aging. RA occurs when the body’s immune system malfunctions, attacking healthy tissue and causing inflammation, which leads to pain and swelling in the joints and may eventually cause permanent joint damage and painful disability. The primary symptoms of RA include progressive immobility and pain, especially in the morning, with long-term sufferers experiencing continual joint destruction for the remainder of their lives. There is no known cure for RA. Once the disease is diagnosed, treatment is prescribed for life to alleviate symptoms and/or to slow or stop disease progression.

RA treatments include medications, physical therapy, exercise, education and sometimes surgery. Early, aggressive treatment of RA can delay joint destruction. Treatment of RA usually includes multiple drug therapies taken concurrently. Disease-modifying anti-rheumatic drugs, or DMARDs, are the current standard of care for the treatment of RA, in addition to rest, exercise and anti-inflammatory drugs such as NSAIDs. Methotrexate is
the most commonly prescribed DMARD for the treatment of RA. Other common agents for the treatment of RA include corticosteroids and biologic agents. Corticosteroids, such as prednisone, effectively reduce joint swelling and inflammation and have been shown to slow the progression of RA, but at high doses are associated with potential for significant long-term adverse side effects such as osteoporosis, cardiovascular disease and weight gain. An additional limitation of RA treatment with corticosteroids is related to the time at which patients’ pro-inflammatory cytokines are at peak levels. Increased levels of pro-inflammatory cytokines during the early morning hours are a known cause of morning stiffness and decreased mobility of RA. Interleukin 6, or IL-6, levels are substantially increased in patients with RA in general and show a significant circadian variation in these levels. Over the last decade, the advent of biologic agents has transformed the treatment of RA. Tumor necrosis factor, or TNF, inhibitors are the primary biologic agents used today to treat RA. Although effective for treatment of RA, these agents are costly and, because they are very potent immunosuppressants, may increase the risk of infection.

Because RA has the potential to cause serious damage to joints and bones, physicians typically treat patients aggressively, including with combination therapies to reduce pain and inflammation and to slow the progression of the disease. Recent research sponsored by Mundipharma and conducted by Ipsos MORI involving 750 RA patients from 11 European countries found that 60% of surveyed patients with RA indicated that pain and morning stiffness control their lives. Additionally, 74% of people with pain and morning stiffness as a result of their RA indicated that they are either unemployed, retired early or are on sick leave as a result of RA and 58% say they are frustrated emotionally because they find it difficult to do everyday tasks due to morning stiffness caused by their RA.

**Polymyalgia Rheumatica**

PMR is an inflammatory disorder that causes significant muscle pain and stiffness. The pain and stiffness often occur in the shoulders, neck, upper arms and hip with pronounced morning stiffness lasting at least one hour. Symptoms of PMR usually begin within two weeks. Most people who develop PMR are older than 65 years of age. It rarely affects people younger than 50. There are approximately 1.1 million patients with PMR in the United States and it affects one in every 133 people over the age of 50. Prednisone is the standard of care for treating PMR and treatment is generally initiated at a relatively high dose (e.g., 10-20 mg per day) and reduced as clinical improvement is seen. Treatment usually lasts 18-24 months. Similar to RA, PMR is associated with circadian patterns of IL-6 elevation in early morning hours.

**DUEXIS**

DUEXIS is a proprietary single tablet formulation containing a fixed-dose combination of ibuprofen, one of the most widely prescribed NSAIDs, and famotidine, a well-established GI agent used to treat dyspepsia, gastroesophageal reflux disease, or GERD, and active ulcers, in one pill. Ibuprofen has proven anti-inflammatory and analgesic properties and famotidine reduces the stomach acid secretion that can cause upper GI ulcers. Both ibuprofen and famotidine have well documented and excellent long-term safety profiles and both products have been used for many years by millions of patients worldwide. Based on our clinical study results, DUEXIS has been shown to provide both effective pain relief and decrease stomach acidity, thus reducing the risk of NSAID-induced upper GI ulcers.

**VIMOVO**

VIMOVO is a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a PPI, layer surrounding the core. Naproxen has proven anti-inflammatory and analgesic properties and esomeprazole reduces the stomach acid secretions that can cause upper GI ulcers. Both naproxen and esomeprazole have well-documented and excellent long-term safety profiles in a significant number of patients worldwide. Based on Pozen’s and AstraZeneca’s clinical trial results, VIMOVO has been shown to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.
NSAIDs are very effective at providing pain relief, including pain associated with OA and RA; however, there are significant upper GI-associated adverse events that can result from the use of NSAIDs. As a result, COX-2 inhibitor drugs (i.e., Vioxx™, Merck & Co., Inc.; Celebrex and Bextra™, Pfizer Inc.) were introduced to the market in order to provide pain and arthritis relief with reduced risk of significant upper GI-associated adverse events. The COX-2 drugs generated approximately $6.3 billion in sales at their peak in 2004. However, safety concerns associated with COX-2 inhibitor drugs led to the withdrawal of Vioxx and Bextra from the market in 2004 and a significant decline in the use of Celebrex. In the United States alone, over $3 billion in sales of COX-2 inhibitor drugs were lost. As a result, demand for traditional prescription NSAIDs, such as ibuprofen and meloxicam, has increased dramatically.

According to a 2004 article published in Alimentary Pharmacology & Therapeutics, significant GI side effects, including serious ulcers, afflict up to approximately 25% of all chronic arthritis patients treated with NSAIDs for three months, and OA and RA patients are two to five times more likely than the general population to be hospitalized for NSAID-related GI complications. It is estimated that NSAID-induced GI toxicity causes over 16,500 related deaths in OA and RA patients alone and over 107,000 hospitalizations for serious GI complications each year. In more than 80% of patients with these serious GI complications, there are no prior symptoms.
Despite the fact that GI ulcers are one of the most prevalent adverse events resulting from the use of NSAIDs in the United States, according to a 2006 article published in BMC Musculoskeletal Disorders, eleven observational studies indicated that physicians do not commonly co-prescribe GI protective agents to high-risk patients. Physicians prescribe concomitant therapy to only 24% of NSAID users, and studies show sub-optimal patient compliance with concomitant prophylaxis therapy. According to a 2003 article published in Alimentary Pharmacology & Therapeutics, in a study of 784 patients, 37% of patients were non-compliant, a rate increasing to 61% in patients treated with three or more drugs. This noncompliance results in a substantial unmet clinical need, which we believe can be appropriately addressed with DUEXIS or VIMOVO, creating a simple solution for both patients and physicians.

Horizon Solution

DUEXIS

Ibuprofen: One of the World’s Most Widely Prescribed NSAIDs

Ibuprofen continues to be one of the most widely prescribed NSAIDs worldwide. According to Source Healthcare Analytics, or SHA, in the United States alone, there were over 37 million prescriptions written for ibuprofen in 2013. Ibuprofen prescription volumes in Europe approximately equal those in the United States. In the United States, both the 600 mg and 800 mg doses together account for approximately 90% of total ibuprofen prescriptions. In addition, ibuprofen’s flexible three times daily dosing allows it to be used for both chronic conditions such as arthritis and chronic back pain, and acute conditions such as sprains and strains.

Famotidine: A Safe and Effective GI Agent

Famotidine, the most potent marketed drug in the class of histamine-2 receptor antagonists, a class of drugs used to block the action of histamine on the cells in the stomach that secrete gastric acid, was chosen as the ideal GI protectant to be combined with ibuprofen as it is a well-studied compound with an estimated 18.8 million patients treated worldwide that provides distinct advantages including:

• rapid onset of action;
significant reduction in gastric acid levels in the GI tract for the treatment of dyspepsia, GERD and NSAID-induced upper GI ulcers;
well tolerated with a low incidence of adverse drug reactions and a demonstrated safety margin of up to eight times the approved prescription dose for an extended period of greater than 12 months; and
lower incidence of long-term adverse events, such as bone fracture, Clostridium difficile diarrhea and drug-drug interactions, reported recently with another class of GI agents referred to as PPIs.

Despite these advantages, famotidine had not yet been approved to reduce the incidence of NSAID-induced upper GI ulcers in patients taking NSAIDs. As a result, we conducted two pivotal Phase 3 clinical trials demonstrating that treatment with DUEXIS significantly reduced the incidence of NSAID-induced upper GI ulcers in patients with mild to moderate pain or arthritis compared to ibuprofen alone. Based on the data from our Phase 3 clinical trials of DUEXIS, in March 2010 we submitted an NDA requesting approval to market DUEXIS in the United States. On April 23, 2011, the FDA approved DUEXIS for the relief of signs and symptoms of RA and OA and to decrease the risk of developing upper GI ulcers in patients who are taking ibuprofen for these indications.

Benefits of a Fixed-Dose Combination Therapy

Numerous studies have demonstrated that fixed-dose combination therapy provides significant advantages over taking multiple pills. Specifically, fixed-dose combinations can reduce the number of pills, ensure that the correct dosage of each component is taken at the correct time and improve compliance, often associated with better treatment outcomes. DUEXIS has been formulated to provide an optimal dosing regimen of ibuprofen and famotidine together in the convenience of a single pill.

Commercial Status

DUEXIS is indicated for the relief of signs and symptoms of RA and OA and to decrease the risk of developing GI ulcers in patients who are taking ibuprofen for these indications. In the second half of 2011, we hired our initial commercial organization, including approximately 80 sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In the third quarter of 2012, we expanded our sales force to approximately 150 representatives and under a co-promotion agreement with Mallinckrodt LLC, or Mallinckrodt, the pharmaceutical business of Covidien plc, or Covidien, Mallinckrodt began calling on 25,000 exclusive physician targets. Our sales force expansion, along with the Mallinckrodt co-promotion agreement, expanded our called-on physician targets for DUEXIS from approximately 10,000 to approximately 50,000. In June 2013, we provided written notice to Mallinckrodt of the termination of our co-promotion agreement with Mallinckrodt, effective 30 days after the date of such notice. The co-promotion agreement was terminated because Mallinckrodt did not achieve minimum levels of prescriptions from targeted physicians for two consecutive quarters during the period prior to September 30, 2013. We detail the physicians previously targeted by Mallinckrodt through the hiring of approximately 20 additional field sales representatives and reallocation of efforts of our existing sales force. As of January 2014, we had approximately 250 field sales representatives detailing DUEXIS to physicians in the United States. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal, a private company focused on the promotion of pain products. In March 2013, we announced that the UK MHRA granted a MA for DUEXIS in the UK. We will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded NSAIDs, we do not expect a material level of sales from DUEXIS in European markets.

VIMOVO

Naproxen: One of the World’s Most Widely Prescribed NSAIDs

Naproxen is one of the most widely prescribed NSAIDs worldwide. According to SHA, in the United States alone, there were over 15 million prescriptions written for naproxen in 2013. In the United States, the 375 mg
and 500 mg doses together account for approximately 90% of total naproxen prescriptions. In addition, naproxen’s twice daily dosing allows it to be used for chronic conditions such as arthritis and AS.

**Esomeprazole: A Safe and Effective GI Agent**

Esomeprazole, a gastroprotective agent, is a PPI that works by inhibiting the secretion of gastric acid thus decreasing the amount of acid in the stomach. PPIs are considered to be very potent inhibitors of acid secretion.

**Benefits of a Fixed-Dose Combination Therapy**

VIMOVO is specifically formulated to allow esomeprazole to achieve its gastroprotective impact before naproxen is released into the system. The product is a single-tablet formulation comprising an enteric coated naproxen core surrounded by an immediate release esomeprazole mantle. VIMOVO’s design is intended to produce a sequential delivery of gastroprotective esomeprazole before systemic (or local) exposure to naproxen.

**Commercial Status**

On April 30, 2010, the FDA approved VIMOVO delayed release tablets, 375 mg/20 mg and 500 mg/20 mg for relief of signs and symptoms of OA, RA and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers. In December 2013, as a result of our acquisition of U.S. rights to VIMOVO, we began the expansion of our sales force to approximately 250 primary care representatives and 40 rheumatology sales specialists, all of which began promoting VIMOVO in early February 2014.

**RAYOS/LODOTRA**

RAYOS, known as LODOTRA outside the United States, is a proprietary delayed-release formulation of low-dose prednisone for the treatment of moderate to severe, active RA in adults particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, PMR, PsA, AS, asthma, COPD and a number of other conditions. We focus our promotion of RAYOS in the United States on rheumatology indications, including RA and PMR. We began detailing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of rheumatologists and high-value primary care physicians. LODOTRA is currently marketed outside the United States by our distribution partner, Mundipharma.

**Market Opportunity and Limitations of Existing Treatments**

According to DataMonitor, there are approximately 4.9 million RA patients in the United States, Japan, France, Italy, Spain, Germany and the UK, of which approximately 3.1 million are diagnosed. Common agents for the treatment of RA include NSAIDs, DMARDs, biologic agents and corticosteroids such as prednisone. Physicians are increasingly supportive of prescribing multiple therapies as some RA patients are able to achieve a clinical remission with multiple treatments. A Medical Marketing Economics May 2008 study of 150 RA patients in the United States, which we sponsored, showed that despite the use of a combination of currently available treatments for RA, over 90% of the patients reported suffering from morning stiffness, pain and immobility.

In addition, according to DataMonitor, approximately 50% of RA patients in the United States, Japan, France, Italy, Spain, Germany and the UK are prescribed combination therapy which often includes corticosteroids, with prednisone being one of the most common. Corticosteroids, including prednisone, are used to suppress various autoimmune, inflammatory and allergic disorders by inhibiting the production of various pro-inflammatory cytokines, such as IL-6 and TNF-alpha. Joint inflammation in RA is driven by excessive production of inflammatory mediators and cytokines such as IL-6 and TNF-alpha. While corticosteroids are
potent and effective agents to treat patients with RA, they are often used at high doses to treat RA flares or significant inflammation. High-dose oral corticosteroid treatment is not a viable long-term treatment option due to adverse side effects such as osteoporosis, cardiovascular disease and weight gain. However, clinical studies have shown that the long-term use of low-dose prednisone (<10 mg per day) does not dramatically increase total adverse events. In addition, low-doses, typically less than 10 mg daily, of corticosteroids such as prednisone have been shown to treat the symptoms of RA while slowing the overall progression of the disease.

An additional limitation of RA treatment with corticosteroids is related to the time at which patients’ pro-inflammatory cytokines are at peak levels. Increased levels of pro-inflammatory cytokines during the early morning hours are a known cause of morning stiffness and decreased mobility of RA. IL-6 levels are substantially increased in patients with RA in general and show a significant circadian variation in these levels. Peak IL-6 levels tend to occur in the early morning hours and low levels typically occur in the afternoon and evening. Therefore, we believe an optimal treatment would reduce IL-6 levels in the early morning hours.

RAYOS/LODOTRA Solution

The proprietary formulation technology of RAYOS/LODOTRA enables a delayed-release of prednisone approximately four hours after administration. The RAYOS/LODOTRA proprietary delivery system synchronizes the prednisone delivery time with the patient’s elevated cytokine levels, thereby taking effect at a physiologically optimal point to inhibit cytokine production, and thus significantly reduces the signs and symptoms of RA and PMR.

RAYOS/LODOTRA was developed utilizing SkyePharma’s proprietary GeoClock™ and GeoMatrix™ technologies, for which we hold an exclusive worldwide license for the delivery of corticosteroids. RAYOS/LODOTRA is comprised of an active core containing prednisone, which is encapsulated by an inactive porous shell. The inactive shell acts as a barrier between the product’s active core and a patient’s GI fluids. RAYOS/LODOTRA is intended to be administered at bedtime. At approximately four hours following bedtime administration of RAYOS/LODOTRA, water in the digestive tract diffuses through the shell, causing the active core to expand, which leads to a weakening and breakage of the shell and allows the release of prednisone from the active core. Our pharmacokinetic studies have shown that the blood concentration of prednisone from RAYOS/LODOTRA is similar to immediate release prednisone except for the intended time delay of product release after administration.

Commercial Status

LODOTRA received its first approval in Europe in March 2009 and is currently approved for marketing in over 30 countries outside the United States where it is being commercialized by Mundipharma.

RAYOS/LODOTRA in Other Indications

We also conducted a small Phase 2 clinical trial to evaluate the potential use of RAYOS/LODOTRA to treat severe asthma compared to immediate-release prednisone. Severe asthma sufferers are frequently prescribed very high doses of oral corticosteroids. However, high-dose oral corticosteroid treatment is limited by side effects which include, among others, osteoporosis and its various negative effects. Data from seven patients who had been treated with 5 mg to 45 mg of daily immediate release prednisone in accordance with the study protocol showed improvements in nocturnal symptoms, asthma control and asthma-related quality of life when switched to an equivalent dose of RAYOS/LODOTRA. We currently do not have plans at this time to pursue commercialization of RAYOS for the treatment of severe asthma.
Commercial Agreements

Merck Serono License Agreements (Assigned to Mundipharma Laboratories)

In December 2006 and March 2009, we entered into separate transfer, license and supply agreements with Merck Serono and Merck GesmbH, an affiliate of Merck Serono, for the commercialization of LODOTRA in Germany and Austria, respectively. The agreement covering Germany was amended in December 2008 to allow co-promotion of LODOTRA in Germany. Under the agreements, we granted Merck Serono and Merck GesmbH exclusive distribution and marketing rights pertaining to LODOTRA for each of Germany and Austria, respectively, and an exclusive license to use the trademark for LODOTRA in Germany and Austria. The transfer, license and supply agreements related to Germany and Austria were assigned to Mundipharma Laboratories from Merck Serono and Merck GesmbH in April 2011 and September 2011, respectively, with our consent. Mundipharma Laboratories is obligated to commercialize LODOTRA in Germany and Austria, as applicable, exclusively under the LODOTRA trademark. Mundipharma Laboratories is obligated to use commercially reasonable efforts to market LODOTRA in Germany and Austria, and is prohibited from launching other oral corticosteroids for the treatment of RA for the first three years following the launch of LODOTRA. With respect to the agreement covering Germany, if Mundipharma Laboratories does not meet specified minimum sales targets over specified periods of time, the marketing rights to LODOTRA will become nonexclusive unless Mundipharma Laboratories pays us the shortfall. With respect to the agreement covering Austria, if Mundipharma Laboratories does not meet specified minimum sales targets over specified periods of time, after good faith discussions to modify the agreement, we have the right to terminate the agreement.

Mundipharma Laboratories has agreed to purchase LODOTRA commercial product exclusively from us. We supply LODOTRA to Mundipharma Laboratories at the price which is the higher of (1) a percentage of the list price of LODOTRA sold to final purchasers of LODOTRA from Mundipharma Laboratories (excluding any discounts) and (2) the costs we incur for the production and delivery of LODOTRA to a Mundipharma Laboratories supply depot, as applicable, plus a profit mark-up.

Subject to early termination, the terms of the agreements are 15 years from the launch of LODOTRA in Germany and 10 years from the launch of LODOTRA in Austria. Thereafter, the agreements automatically renew until terminated by a party by giving specified prior written notice to the other party to the agreement. Under both agreements a party may also terminate an agreement in the event of a bankruptcy of the other party, certain events beyond the parties’ control that impair performance under an agreement, or upon material uncured breach by a party.

For the years ended December 31, 2013, 2012 and 2011, Merck Serono accounted for 0%, 0% and 20% of total gross revenues, respectively.

Mundipharma Agreements

In March 2009, we entered into a distribution agreement with Mundipharma for the commercialization of LODOTRA in Europe, excluding Germany and Austria, and a manufacturing and supply agreement with Mundipharma Medical. The distribution agreement, which was amended in July 2009 and March 2011, provides for an upfront payment of 5.0 million Euros, all of which has been paid by Mundipharma, and aggregate potential milestone payments of up to an additional 11.0 million Euros, which includes a credit in the amount of 1.0 million Euros we agreed to provide to Mundipharma to be applied towards certain future milestone payments in connection with the March 2011 amendment. As of December 31, 2013, we have received 4.9 million Euros in milestone payments under the distribution agreement.

Under the distribution agreement, we granted Mundipharma the exclusive distribution and marketing rights pertaining to LODOTRA in: Albania, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Liechtenstein, Lithuania, Luxemburg, Macedonia, Malta, Montenegro, Netherlands, Norway, Poland, Portugal,
Romania, Serbia, former Soviet Union countries, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the UK. We also granted Mundipharma an exclusive license to use our trademark for LODOTRA in these countries, and Mundipharma is allowed to commercialize LODOTRA under the LODOTRA trademark. Mundipharma is obligated to use commercially reasonable efforts to market LODOTRA in the territory and is prohibited from launching other oral corticosteroids during the term of the distribution agreement. If Mundipharma does not meet specified minimum sales targets, which range from single digit millions of Euros to tens of millions of Euros on a country by country basis, over specified periods of time, the marketing rights granted under the distribution agreement will become nonexclusive with respect to the applicable country unless Mundipharma pays us the shortfall.

Under the manufacturing and supply agreement, which was subsequently amended in March 2011, Mundipharma Medical agreed to purchase LODOTRA exclusively from us with respect to the territory. We supply LODOTRA to Mundipharma Medical at the price which is a specified percentage of the average net selling price for sales in a given country.

Subject to early termination, the terms of both of the March 2009 agreements extend to March 2024. Thereafter, the agreements automatically renew until terminated by either party giving specified prior written notice to other party. Either party may also terminate either of the agreements in the event of a bankruptcy of the other party or upon an uncured material breach by the other party. In addition, Mundipharma has the right to terminate the distribution agreement in the event of material risk of personal injury to third parties or immediately by written notice with respect to any country if the market authorization for LODOTRA is cancelled in such country.

In November 2010, we entered into a second distribution agreement with Mundipharma for the commercialization of LODOTRA in several Asian countries, Australia, New Zealand and South Africa, and a second manufacturing and supply agreement with Mundipharma Medical. Under the distribution agreement, we received an upfront payment of $3.5 million and may be entitled to additional aggregate milestone payments of up to $4.5 million. In March 2012, we amended the distribution agreement and the manufacturing and supply agreement to include certain Latin American countries. Under the March 2012 amendment to the distribution agreement, we may receive aggregate upfront and milestone payments of up to $2.0 million. In October 2013, we further amended the distribution agreement and the manufacturing and supply agreement to include an additional 55 countries in the Middle Eastern and African regions. As of December 31, 2013, under our distribution agreement we have received $0.2 million in milestone payments and $1.2 million associated with an upfront payment under the March 2012 amendment.

Under the distribution agreement, as amended, we granted Mundipharma the exclusive distribution and marketing rights pertaining to LODOTRA for: Australia, China, Hong Kong, Indonesia, Korea, Malaysia, New Zealand, the Philippines, Singapore, South Africa, Taiwan, Thailand, Vietnam, Mexico, Brazil, Argentina, Colombia, Venezuela, Peru, Chile, Ecuador, Dominican Republic, Guatemala, Costa Rica, Uruguay, Bolivia, Panama, Nicaragua, El Salvador, Honduras and the Middle Eastern and African regions. Mundipharma will be responsible for obtaining regulatory approvals in these countries. We also granted Mundipharma an exclusive license to use our trademark for LODOTRA in these countries, and Mundipharma is allowed to commercialize LODOTRA under the LODOTRA trademark. Mundipharma is obligated to use commercially reasonable efforts to obtain regulatory approval for and market LODOTRA and is prohibited from launching other oral corticosteroids in these countries during the term of the distribution agreement. If Mundipharma does not meet specified minimum volume targets, which range from thousands of tablets of product to millions of tablets of product on a country by country basis, over specified periods of time, the marketing rights granted under the distribution agreement will become nonexclusive with respect to the applicable country unless Mundipharma pays us the shortfall.
Under the manufacturing and supply agreement, as amended, Mundipharma Medical agreed to purchase LODOTRA exclusively from us with respect to the territories. We supply bulk product of LODOTRA to Mundipharma Medical at an adjustable price per tablet and Mundipharma is responsible for final packaging and distribution in the territory.

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

For the years ended December 31, 2013, 2012 and 2011, Mundipharma and Mundipharma Laboratories accounted for approximately 8%, 39% and 79%, respectively, of our consolidated gross sales.

Grüenthal Agreement

In June 2012, we entered into a collaboration, license and supply agreement with Grüenthal for the potential commercialization of DUEXIS in certain Latin American and Caribbean countries. Under the terms of the agreement, we will supply DUEXIS to Grüenthal exclusively in the territory at an agreed upon price and they will have the exclusive right to distribute DUEXIS in the territory. Subject to early termination, the term of the agreement is 10 years from launch with certain automatic 2-year renewal provisions.

AstraZeneca and Pozen Agreements

AstraZeneca Asset Purchase Agreement

In November 2013, we entered into an asset purchase agreement with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs in the United States. Pursuant to the transactions contemplated by the asset purchase agreement, we acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the IND and NDA for VIMOVO in the United States, AstraZeneca’s interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. Under the asset purchase agreement, we are also entitled to the benefit of a covenant not to sue granted by Merck Sharp & Dohme Corp. and certain of its affiliates, or collectively Merck, to AstraZeneca, with respect to certain patents owned by AstraZeneca but exclusively licensed to Merck, that cover the manufacture and commercialization of VIMOVO in the United States. In addition, under the asset purchase agreement, AstraZeneca assigned to us its amended and restated collaboration and license agreement for the United States with Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States. The terms of the amended and restated collaboration and license agreement for the United States with Pozen, or the Pozen license agreement, are described below.
In November 2013, in connection with the closing of the transactions contemplated by the asset purchase agreement, we also entered into a license agreement with AstraZeneca, a supply agreement with AstraZeneca’s affiliate, AstraZeneca LP, and certain other agreements that are described below. We also executed a transition agreement with AstraZeneca pursuant to which AstraZeneca transitioned to us regulatory and commercial responsibility for VIMOVO in the United States. From the closing of the transaction until December 31, 2013, AstraZeneca continued to commercialize VIMOVO in the United States under AstraZeneca’s existing pricing and paid to us the net profits recognized on sales of VIMOVO in the United States. Beginning January 1, 2014, we commenced commercialization of VIMOVO in the United States on our own behalf and under new pricing for VIMOVO.

In consideration for the U.S. rights to VIMOVO, we paid to AstraZeneca a one-time upfront cash payment of $35.0 million.

Following the closing of the transactions contemplated by the asset purchase agreement, we became responsible for and will control matters relating to VIMOVO in the United States, including responsibility for commercialization of VIMOVO in the United States, responsibility for ongoing developmental and regulatory activities with respect to VIMOVO in the United States and responsibility for the current VIMOVO litigation with respect to the patents we purchased under the asset purchase agreement and the patents we licensed from Pozen under the Pozen license agreement. AstraZeneca continues to be responsible for and will retain control of VIMOVO outside the United States.

AstraZeneca License Agreement

In November 2013, in connection with the closing of the transactions contemplated by the asset purchase agreement, we entered into a license agreement with AstraZeneca, or the AstraZeneca license agreement, pursuant to which AstraZeneca granted us an exclusive license under certain intellectual property (including patents, know-how, trademarks, copyrights and domain names) of AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States. AstraZeneca also granted us a non-exclusive license under certain intellectual property of AstraZeneca and its affiliates to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States. In addition, AstraZeneca granted us a non-exclusive right of reference and use under certain regulatory documentation controlled by AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States and to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States.

Under the AstraZeneca license agreement, we granted AstraZeneca a non-exclusive sublicense under such licensed intellectual property and a non-exclusive right of reference under certain regulatory documentation controlled by us to manufacture, import, export and perform research and development activities with respect to VIMOVO in the United States but solely for purposes of commercializing VIMOVO outside the United States.

Under the AstraZeneca license agreement, we and our affiliates are subject to certain limitations and restrictions on our ability to develop, commercialize and seek regulatory approval with respect to VIMOVO or other products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs (excluding DUEXIS). These limitations and restrictions include, among other things, restrictions on indications for which we may commercialize VIMOVO or any such other products, restrictions on our ability to develop or seek regulatory approval with respect to such other products that contain esomeprazole, restrictions on our ability to develop or seek regulatory approval for VIMOVO for any indications other than the indications for which NSAIDs are indicated, and restrictions on our marketing activities with respect to VIMOVO and any such other products.
The AstraZeneca license agreement continues in full force and effect until terminated in accordance with its terms. Under the AstraZeneca license agreement, the parties may terminate upon mutual written agreement by the parties, or either party may terminate rights granted to us with respect to licensed trademarks and licensed domain names under the AstraZeneca license agreement upon uncured material breach by the other party of certain specified provisions of the AstraZeneca license agreement.

Amended and Restated Collaboration and License Agreement with Pozen; Letter Agreement with AstraZeneca and Pozen

Under the Pozen license agreement, Pozen granted us an exclusive, royalty-bearing license under certain of Pozen’s intellectual property in the United States to manufacture, develop and commercialize VIMOVO and other products controlled by us that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs, excluding DUEXIS, in the United States.

Under the Pozen license agreement, we are required to pay Pozen a flat 10% royalty based on net sales of VIMOVO and such other products sold by us, our affiliates or sublicensees during the royalty term, subject to minimum annual royalty obligations of $5.0 million in 2014 and $7.5 million each year thereafter, which minimum royalty obligations will continue for each year during which one of Pozen’s patents covers such products in the United States and there are no competing products in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing products. Our obligation to pay royalties to Pozen will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in the United States. In addition, we will be obligated to reimburse Pozen for costs, including attorneys’ fees, incurred by Pozen in connection with VIMOVO patent litigation moving forward, subject to agreed caps.

We are responsible for and will be required to use diligent and reasonable efforts to commercialize VIMOVO or another qualified product in the United States. We will also own and maintain all regulatory filings and marketing approvals in the United States for any such products, including all INDs and NDAs for VIMOVO. Pozen covenanted that it will not at any time prior to the expiration of the royalty term, and will ensure that its affiliates do not, directly or indirectly, develop or commercialize or license any third party to develop or commercialize certain competing products in the United States.

The Pozen license agreement, unless earlier terminated, will expire upon expiration of the royalty term for all such products in the United States. Either party has the right to terminate the agreement upon uncured material breach by the other party or upon the bankruptcy or similar proceeding of the other party. We also have the right to terminate the Pozen license agreement for cause upon certain defined product failures.

In November 2013, in connection with the asset purchase agreement and the Pozen license agreement, we, AstraZeneca and Pozen entered into a letter agreement in which Pozen consented to AstraZeneca’s assignment of the Pozen license agreement to us and that addresses the rights and responsibilities of the parties in relation to the Pozen license agreement and the amended and restated collaboration and license agreement between Pozen and AstraZeneca for territories outside the United States, or the Pozen-AstraZeneca license agreement. Under the letter agreement, we and AstraZeneca agreed to pay Pozen milestone payments upon the achievement by us and AstraZeneca, collectively, of certain annual aggregate global net sales thresholds ranging from $550.0 million to $1.25 billion with respect to products licensed by Pozen to us under the Pozen license agreement and to AstraZeneca under the Pozen-AstraZeneca license agreement. The aggregate milestone payment amount that may be owed by AstraZeneca and us, collectively, under the letter agreement is $260.0 million, with the amount payable by each of us and AstraZeneca with respect to each milestone to be based upon the proportional sales achieved by each of us and AstraZeneca, respectively, in the applicable year.

The letter agreement will terminate with respect to Pozen and us upon the termination of the Pozen license agreement and will terminate with respect to Pozen and AstraZeneca upon the termination of the Pozen-AstraZeneca license agreement.
Supply Agreement with AstraZeneca

In November 2013, in connection with the asset purchase agreement, we entered into a supply agreement with AstraZeneca pursuant to which AstraZeneca agreed to supply VIMOVO to us for commercialization in the United States through December 31, 2014. Under the supply agreement, AstraZeneca will supply the quantity of VIMOVO that we order, both for our own use and for use by our sublicensees, on a transitional basis through December 31, 2014. We will pay a set transfer price agreed by us and AstraZeneca for quantities of VIMOVO supplied by AstraZeneca under the supply agreement.

The supply agreement will expire on December 31, 2014, unless terminated earlier as described herein. The supply agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party. Additionally, we have the right to terminate the supply agreement at any time upon 120 days prior written notice to AstraZeneca or immediately upon written notice if the existing regulatory approval of VIMOVO is suspended for any reason or if any regulatory authority provides a warning letter or other official documentation expressing major and significant concerns from a regulatory perspective with AstraZeneca’s or its affiliates’ or third party manufacturer’s manufacturing of VIMOVO. Additionally, the supply agreement will automatically terminate upon any termination of the AstraZeneca license agreement.

Patheon Agreement

In November 2013, we entered into a master manufacturing services agreement and product agreement, or, collectively, the Patheon manufacturing agreement, with Patheon, who is AstraZeneca’s contract manufacturer of VIMOVO, for the manufacture and supply of VIMOVO. Under the Patheon manufacturing agreement, we agreed to purchase a specified percentage of our VIMOVO requirements for the United States from Patheon or its affiliates. In addition, under the terms of the Patheon manufacturing agreement, we are able to enter into individual product agreements with Patheon for the manufacture of specific products in addition to VIMOVO if agreed by us and Patheon.

Pursuant to the Patheon manufacturing agreement, we are required to supply Patheon with any active materials for VIMOVO. We must pay an agreed price for final, packaged VIMOVO supplied by Patheon as set forth in the Patheon manufacturing agreement, subject to adjustments, including certain unilateral adjustments by Patheon, such as annual adjustments for inflation and adjustments to account for certain increases in the cost of components of VIMOVO other than active materials.

The Patheon manufacturing agreement will be effective until December 31, 2019 and will automatically renew for successive terms of three years each if there is any product agreement in effect, unless either party gives written notice to the other party of its intention to terminate the agreement at least 24 months prior to the termination date. Either party may terminate the Patheon manufacturing agreement or any product agreement early for uncured material breach by the other party or upon the other party’s bankruptcy or insolvency. We may terminate any product agreement if any regulatory authority takes any action or raises any objection that prevents us from commercializing the product. Additionally, Patheon may terminate the Patheon manufacturing agreement or any product agreement early if we assign our rights or obligations under the Patheon manufacturing agreement or such product agreement to a competitor of Patheon or to a party that, in the reasonable opinion of Patheon, is not a credit worthy substitute for us, or in certain other circumstances where we assign the Patheon manufacturing agreement or product agreement without Patheon’s consent.

SkyePharma and Jagotec Agreements

Development and License Agreement

In August 2004, we entered into a development and license agreement with SkyePharma and Jagotec, a wholly-owned subsidiary of SkyePharma, regarding certain proprietary technology and know-how owned by SkyePharma for the delayed release of corticosteroids. The agreement replaced a similar agreement entered into between Merck and SkyePharma in 1998, which Merck assigned to us.
Under the agreement, which was amended in August 2007, we received an exclusive, sub-licensable worldwide license to the oral formulation of any corticosteroid, including prednisone, prednisolone, methylprednisolone and/or cortisone, with delayed release technology covered by intellectual property rights and know-how owned by SkyePharma. We were also granted an option to acquire a royalty-free, exclusive and sub-licensable right to license and manufacture RAYOS/LODOTRA which we can exercise any time upon specified prior written notice, expiring no earlier than five years after the first launch of RAYOS/LODOTRA. We have exercised the option to acquire the manufacturing license, which license will become effective in April 2014.

In return for the grant of the license, Jagotec has the right to manufacture, package and supply RAYOS/LODOTRA to us in accordance with terms and conditions of a separate manufacturing and supply agreement we entered into with Jagotec. In addition, Jagotec is entitled to receive a single digit percentage royalty on net sales of RAYOS/LODOTRA and on any sub-licensing income, which includes any payments not calculated based on the net sales of RAYOS/LODOTRA, such as license fees, and lump sum and milestone payments.

The agreement expires on the later of August 20, 2014 or, on a country by country basis, upon the expiration of the last patent rights for RAYOS/LODOTRA, which patent rights will expire between 2024 and 2028. In the event of expiration, the licenses under the agreement will be perpetual, fully paid-up and royalty-free. Either party may also terminate the agreement in the event of a liquidation or bankruptcy of the other party or upon an uncured breach by the other party.

Manufacturing and Supply Agreement

In August 2007, we entered into a manufacturing and supply agreement with Jagotec for the purchase of RAYOS/LODOTRA. Under the agreement, which was amended in March 2011, Jagotec or its affiliates manufacture and supply RAYOS/LODOTRA to us in bulk. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to Acanova, a large contract manufacturing organization, and Acanova is now a subcontractor for Jagotec for the manufacture of RAYOS/LODOTRA, with our consent. We are required to purchase RAYOS/LODOTRA exclusively from Jagotec through April 2014, after which we will be able to purchase RAYOS/LODOTRA from other manufacturers if we choose. As of December 31, 2013 our total remaining minimum purchase commitment was approximately $3.4 million based on tablet pricing under the agreement as of that date, which amount is subject to volume and price adjustments due to, among other things, inflation, order quantities and launch and approval in certain European Union countries. We also supply the active pharmaceutical ingredient, or API, prednisone to Jagotec at our expense for use in the manufacture of RAYOS/LODOTRA.

We pay Jagotec, exclusive of any value added tax or similar governmental charges, a price for RAYOS/LODOTRA representing a negotiated mark-up over manufacturing costs. After a short initial period, the price will be adjusted annually to reflect changes in both manufacturing and materials costs as measured by the Ensemble price index. If Jagotec makes a major capital expenditure during the contract term to fulfill increased orders forecast by us, the price per unit will increase if the actual order falls short of the forecast.

The agreement term extends until the end of the fifth year after the first launch of RAYOS/LODOTRA and automatically extends on a yearly basis unless terminated by either party upon prior written notice. Either party may also terminate the agreement in the event of insolvency, liquidation or bankruptcy of the other party or upon an uncured breach by the other party. We have the right to receive a continuing supply of RAYOS/LODOTRA from Jagotec for a period of 24 months after termination by Jagotec, regardless of the reason for termination.

Pursuant to a letter agreement between Jagotec and us, Jagotec agreed to allow us to give Bayer the right to manufacture, test and release quantities of RAYOS/LODOTRA in order to establish and maintain Bayer as a manufacturer of RAYOS/LODOTRA. Under certain circumstances, we may also purchase shortfall quantities of RAYOS/LODOTRA from Bayer to the extent Jagotec is unable to supply us. In March 2013, we entered into an agreement with Bayer to allow us to purchase quantities of RAYOS/LODOTRA.
for these purposes. After our manufacturing license from Jagotec becomes effective, we may also purchase quantities of RAYOS/LODOTRA from Bayer pursuant to our agreement with Bayer.

Manufacturing and Supply Agreement with sanofi-aventis U.S. LLC

In May 2011, we entered into a manufacturing and supply agreement with sanofi-aventis U.S. LLC. Pursuant to the agreement, sanofi-aventis U.S. is obligated to manufacture and supply DUEXIS to us in final, packaged form, and we are obligated to purchase DUEXIS exclusively from sanofi-aventis U.S. for our commercial requirements of DUEXIS in North America and certain countries and territories in Europe, including the European Union member states and Scandinavia, and South America. Sanofi-aventis U.S. is obligated to acquire the components necessary to manufacture DUEXIS, including the APIs DC85, which is ibuprofen in a direct compression blend, and famotidine, and is obligated to acquire all DC85 under the terms of any agreements we may have with suppliers for the supply of DC85. We expect that sanofi-aventis U.S. will obtain DC85 from BASF Corporation through our sales contract with BASF and will enter into a separate supply agreement for famotidine with another third-party supplier. In order to allow sanofi-aventis U.S. to perform its obligations under the agreement, we granted sanofi-aventis U.S. a non-exclusive license to our related intellectual property. In November 2011, the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. As a result of the FDA approval of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec, sanofi-aventis U.S. is the exclusive commercial manufacturer and supplier of DUEXIS. In December 2011, Valeant acquired Demik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. The price for DUEXIS under the agreement varies depending on the configuration and volume of DUEXIS we purchase and is subject to annual adjustments to reflect changes in costs as measured by the Producer Price Index published by the U.S. Department of Labor, Bureau of Labor Statistics and certain other changes and events set forth in the agreement. We have paid for the purchase and installation of equipment necessary to manufacture DUEXIS tablets, and sanofi-aventis U.S. is obligated to pay the costs of routine maintenance of the equipment. Upon expiration or termination of the agreement we may also be obligated to reimburse sanofi-aventis U.S. for the depreciated net book value of any other equipment purchased by sanofi-aventis U.S. in order to fulfill its obligations under the agreement.

The agreement term extends until the eighth anniversary of the first commercial sale of DUEXIS in any country in the territory and automatically extends for successive two year terms unless terminated by either party upon two years prior written notice. Either party may terminate the agreement upon 30 days’ prior written notice to the other party in the event of breach by the other party that is not cured within 30 days of notice (which notice period may be longer in certain, limited situations) or in the event we lose regulatory approval to market DUEXIS in all countries within the territory, and either party may terminate the agreement without cause upon two years prior written notice to the other party at any time after the third anniversary of the first commercial sale of DUEXIS in any country in the territory.

Temmler Supply Agreement

We have entered into an agreement with Temmler Werke GmbH, or Temmler, for the packaging and assembling of RAYOS/LODOTRA. Pursuant to the agreement, we may order RAYOS/LODOTRA according to specified rolling forecasts. Subject to early termination, the agreement will remain in effect until December 21, 2015. Thereafter, the agreement automatically renews for additional one year periods unless either party provides notice to the other party at least twelve months prior to the expiration of the then-current period. Either party may also terminate the agreement at any time for an uncured material breach. There are no minimum purchase requirements under the agreement and we may enter into agreements with other third-party packagers for RAYOS/LODOTRA. In December 2012, Temmler was acquired by the Aenova Group.
**BASF Sales Contract**

In July 2010, we entered into a sales contract with BASF Corporation, or BASF, for the purchase of DC85, the active ingredient in DUEXIS. The agreement provides for an initial pre-purchase credit in the hundreds of thousands of dollars to be used as payment for DC85. Pursuant to the agreement, we are obligated to purchase a significant majority of our commercial demand for DC85 from BASF.

The sales contract expires in December 2017. Thereafter, the agreement automatically renews for successive renewal terms of three years each until terminated by either party giving specified prior written notice to the other party. Either party may also terminate the agreement in the event of uncured breach by the other party. If the agreement terminates for any reason before a specified date and we have not purchased requisite amounts of DC85, BASF has the right to withhold from the pre-purchase credit an amount based upon the total amount of DC85 purchased throughout the life of the agreement.

**Mallinckrodt Agreement**

In June 2012, we entered into a co-promotion agreement with Mallinckrodt, pursuant to which we engaged Mallinckrodt on a non-exclusive basis to promote DUEXIS in the United States, excluding Puerto Rico and any other territories or possessions. Under the terms of the Mallinckrodt agreement, Mallinckrodt agreed to use commercially reasonable efforts to promote DUEXIS to an agreed list of physician promotion targets. Mallinckrodt was required to achieve minimum levels of prescriptions from targeted physicians on a quarterly basis during the term of the agreement, and we agreed not to grant to any third party the right to co-promote DUEXIS to those targeted physicians in the agreed upon territory during the term, other than an existing third party agreement that has since been terminated. Under the terms of the Mallinckrodt agreement, we were responsible for the manufacture, supply and distribution of DUEXIS. Each party could terminate the agreement early upon certain failures to achieve minimum levels of prescriptions for a specified period of time. In June 2013, we provided written notice to Mallinckrodt of the termination of the Mallinckrodt agreement, effective 30 days after the date of such notice. The Mallinckrodt agreement was terminated as a result of Mallinckrodt not achieving minimum levels of prescriptions from targeted physicians for two consecutive quarters during the period prior to September 30, 2013.

**Sales and Marketing**

Subsequent to the April 2011 FDA approval of DUEXIS we hired our initial commercial organization of approximately 80 field sales representatives and completed sales force training. We began detailing DUEXIS to physicians in December 2011 and held our launch meeting for DUEXIS in the United States in January 2012. In June 2012, to increase the number of called-on physicians for DUEXIS and in anticipation of the potential FDA approval of RAYOS, we began expanding our commercial organization and in early October 2012, we announced the expansion to approximately 150 field sales representatives was completed. In December 2013, as a result of the acquisition of U.S. rights to VIMOVO from AstraZeneca, we began the expansion of our sales force to approximately 250 primary care representatives and 40 rheumatology sales specialists. We announced the availability of Horizon-labeled VIMOVO on January 2, 2014. We completed the hiring and training of our expanded sales force in January 2014 and began selling VIMOVO in early February 2014. We have, and expect to continue to, entered into agreements with third parties for commercialization of our products outside the United States.

**Intellectual Property**

Our policy is to patent the technology, inventions and improvements that we consider important to the development of our business. We have a portfolio of patents and applications based on clinical and pharmacokinetic/pharmacodynamic modeling discoveries, and our novel formulations. In addition, we have an exclusive license to pending United States and foreign patent applications from SkyePharma. We also have
licenses to United States patents and patent applications and trademarks covering VIMOVO from Pozen and AstraZeneca. We intend to continue filing patent applications seeking intellectual property protection as we generate anticipated formulation refinements, new methods of manufacturing and clinical trial results.

We will only be able to protect our technologies and products from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. As such, our commercial success will depend in part on receiving and maintaining patent protection and trade secret protection of our technologies and products as well as successfully defending these patents against third-party challenges.

With respect to RAYOS/LODOTRA, there are five issued U.S. patents listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Three of those patents were in-licensed from SkyePharma, U.S. 8,168,218 (listed for the 5 mg dosage form only), U.S. 8,309,124, and U.S. 8,394,407, each of which expires between 2024 and 2028. In addition, we purchased from a third party two issued U.S. patents, which are listed for the 1 mg and 2 mg dosage forms and which are anticipated to expire in 2020 (U.S. 6,488,960 and U.S. 6,667,326).

Prosecution is ongoing for our own pending patent applications in the United States and those in-licensed from SkyePharma to obtain broader patent coverage on RAYOS. We have filed our own patent applications related to delayed release corticosteroid treatment of RA and delayed release treatment of asthma. Related patent applications have been filed in the following jurisdictions: Algeria, Argentina, Australia, Brazil, Canada, China, Egypt, Eurasian Patent Organization, European Patent Office, Gulf Cooperation Council, Hong Kong, India, Indonesia, Israel, Japan, Libya, Malaysia, Mexico, Monaco, Norway, Singapore, South Africa, South Korea, Syria, Taiwan, Tunisia, Ukraine and United Arab Emirates. If granted, and not otherwise invalidated, the patents are anticipated to protect the related subject matters until between 2027 and 2030. We have also in-licensed pending patent applications pending from SkyePharma for its proprietary drug delivery technology, GeoClock™, which cover tablet geometry and design.

On March 13, 2013, we received purported Notice Letters that a Paragraph IV Patent Certification had been filed by Alvogen Pine Brook, Inc., or Alvogen, advising that Alvogen had filed an Abbreviated New Drug Application, or ANDA, with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. In the Notice Letters, Alvogen noted that as of March 13, 2013, the FDA had not accepted the ANDA for review. Alvogen has agreed that their Notice Letters do not constitute Notice as described in 21 U.S.C. 355(j)(2)(B).

On or about August 12, 2013, we received a Notice of Opposition to a European patent covering LODOTRA, EP 2049123, filed by Laboratorios Liconsa, S.A. In the European Union, the grant of a patent may be opposed by one or more private parties.

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc. — Florida, or Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc., or collectively WLF. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Par Pharmaceutical, Inc. has not advised us as to the timing or status of the
FDA’s review of its filing. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., or collectively Par. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

With regard to DUEXIS, there are six issued U.S. patents listed in the FDA’s Orange Book, U.S. 8,067,451, U.S. 8,067,033, U.S. 8,309,127, U.S. 8,318,202, U.S. 8,449,910, and U.S. 8,501,228, all of which expire on July 18, 2026. Further, DUEXIS is protected in Europe by EP 2043637, which was granted on January 4, 2012. Patents covering DUEXIS have also issued/granted in Australia, China, South Africa, and New Zealand.

We are also seeking to expand the patent position of DUEXIS. We have filed multiple patent applications claiming the product and methods for its use in the United States, as well as related applications in Australia, Canada, China, Europe, Israel, New Zealand, South Africa, Brazil, India, and Japan. If granted, and not otherwise invalidated, the patents are anticipated to expire between 2026 and 2028. Our patent strategy for DUEXIS aims at providing protection specific to DUEXIS for three times daily administration and is intended to prevent direct product copying as well as the use of any other ibuprofen-famotidine single dose products for three times daily use to treat patients.

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par’s ANDA and/or preventing Par from selling a generic version of DUEXIS. In January 2013, we filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par’s ANDA and/or preventing Par from selling a generic version of DUEXIS.

On August 21, 2013, we entered into a settlement agreement, or Par settlement agreement, and license agreement, or Par license agreement, with Par relating to our patent infringement litigation. Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par’s generic version of DUEXIS in the United States after the generic entry date and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par’s generic version of DUEXIS prior to the generic entry date. The generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. If any of the events that permit Par to enter the market with its generic version of DUEXIS prior to January 1, 2023 were to occur, we will likely face generic competition from Par shortly after the event, and our sales of DUEXIS would be substantially harmed. Also, despite our Par settlement agreement and Par license agreement, additional third parties may file ANDAs with the FDA for their own generic versions of DUEXIS and we may not be successful in preventing any other generic products from entering the market.

On November 18, 2013 we entered into an asset purchase agreement with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs in the United States.
With respect to VIMOVO, there are eight issued VIMOVO U.S. patents listed in the FDA’s Orange Book: U.S. 5,714,504, U.S. 5,900,424, U.S. 6,369,085, U.S. 6,875,872, U.S. 6,926,907, U.S. 7,411,070, U.S. 7,745,466, and U.S. 8,557,285. These patents expire between May 2014 and February 2023. There are also five issued U.S. patents, although not allowed to be listed in the Orange Book, that are directed to manufacturing processes of VIMOVO. Furthermore, there are currently three pending U.S. applications directed to further patent coverage of VIMOVO.

In connection with our acquisition of the U.S. rights to VIMOVO, we received the benefit of a covenant not to sue under AstraZeneca’s patent portfolio with respect to Nexium (esomeprazole), which will automatically become a license under such patent portfolio if and when AstraZeneca reacquires control of such patent portfolio from Merck Sharp & Dohme Corp. and certain of its affiliates. AstraZeneca also assigned the Pozen license agreement to us, under which AstraZeneca had in-licensed exclusive rights under certain of Pozen’s patents with respect to VIMOVO, and assigned to us AstraZeneca’s ownership interest in certain U.S. patents covering VIMOVO that are jointly owned with Pozen.

Currently, patent litigation is pending against five generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the District of New Jersey and are grouped in three sets: (i) Dr. Reddy’s Laboratories, Inc., or Dr. Reddy’s; Lupin Pharmaceuticals Inc., or Lupin; Anchen Pharmaceuticals Inc., or Anchen, or collectively, the DRL cases; (ii) Mylan Laboratories Limited, or collectively, the Mylan cases; and (iii) Watson Pharma, Inc., or collectively, the Watson cases. We understand that Dr. Reddy’s has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy’s will not be able to commercialize VIMOVO under AstraZeneca’s Nexium patent rights until May 28, 2014. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The DRL cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy’s notice letters were dated March 11, 2011 and November 12, 2012; the Lupin notice letter was dated June 10, 2011; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order. The DRL cases do not have a trial date set. We understand Anchen has recertified under Paragraph III and has filed a motion to dismiss on that basis.

The Watson cases were filed on May 10, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a March 29, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date for the Watson cases.

The Mylan cases were filed on June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a May 16, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date for the Mylan cases.

In the United States, in addition to any patent protection, DUEXIS, VIMOVO and RAYOS have been granted three years of marketing exclusivity as a Section 505(b)(2)NDA. This marketing exclusivity period for each product began upon marketing approval of such product and runs in parallel with any patents that have issued or we expect to be issued protecting such product. In the European Union, LODOTRA has received 10 years of marketing exclusivity protection, beginning with its March 2009 marketing authorization in Germany. We anticipate that DUEXIS will also receive 10 years of marketing exclusivity upon European approval, on a country by country basis.
The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies’ patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example:

- we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents;
- our issued patents and the issued patents of our licensors may not provide a basis for commercially viable drugs, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;
- we may not be successful in any patent litigation to enforce our patent rights, including our pending patent litigation regarding VIMOVO;
- we may not develop additional proprietary technologies or product candidates that are patentable; or
- the patents of others may have an adverse effect on our business.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies and generic drug companies such as Par, although we are not currently aware of any other delayed release prednisone drug or ibuprofen/famotidine combination drug in development. We believe that the key competitive factors that will affect the commercial success of DUEXIS, VIMOVO and RAYOS LODOTRA, as well as future drug candidates that we may develop, are efficacy, safety and tolerability profile, convenience in dosing, price and reimbursement.

DUEXIS and VIMOVO

DUEXIS and VIMOVO compete with other branded NSAIDs, including Celebrex, marketed by Pfizer Inc. Celebrex is an NSAID that selectively inhibits the COX-2 enzyme and is an effective anti-arthritic agent that reduces the risk of ulceration compared to traditional NSAIDs such as ibuprofen. However, two other COX-2 inhibitors, Vioxx and Bextra, have been withdrawn from the market due to safety concerns.

In general, DUEXIS and VIMOVO will also face competition from the separate use of NSAIDs for pain relief and ulcer medications to address the risk of NSAID-induced ulcers. Use of these therapies separately in generic form may be cheaper than DUEXIS and VIMOVO. In addition, physicians could begin to prescribe both an NSAID and a GI protectant to be taken together but in separate pills. We expect to compete with the separate use of NSAIDs and ulcer medications primarily through DUEXIS’ and VIMOVO’s advantages in dosing convenience and patient compliance, and by educating physicians about such advantages, including through funding we have provided for the American Gastroenterology Association to help physicians and patients better understand and manage NSAID risks. We expect DUEXIS will be the only product containing a histamine-2 receptor antagonist with an indication to reduce the risk of NSAID-induced upper GI ulcers and that VIMOVO will be the only product containing a PPI with an indication to reduce the risk of NSAID-induced ulcers.
RAYOS/LODOTRA

RAYOS/LODOTRA competes in Europe and in the United States with a number of products on the market to treat RA, including corticosteroids, such as prednisone, traditional DMARDs, such as methotrexate and biologic agents, such as HUMIRA and Enbrel. The majority of RA patients, however, are treated with DMARDs. DMARDs, such as methotrexate, are typically used as initial therapy in patients with RA whereas biologic agents are typically added to DMARDs as combination therapy. It is common for an RA patient to take a combination of a DMARD, an oral glucocorticoid, an NSAID and/or a biologic agent.

Manufacturing

DUEXIS

The DUEXIS manufacturing process is well-established and we validated the process in accordance with regulatory requirements prior to commercialization in the United States. We have contracted with internationally recognized pharmaceutical companies with operations in North America and Europe for contract manufacturing and packaging. In May 2011, we entered into a long-term supply and manufacturing agreement with sanofi-aventis U.S. for the manufacture of DUEXIS. In November 2011, the FDA approved the use of the sanofi-aventis Canada Inc. manufacturing site in Laval, Quebec to manufacture DUEXIS. In December 2011, Valeant acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. All of the facilities contracted by us are registered with the FDA, European Medicines Agency, or EMA, and other internationally recognized regulatory authorities. In addition, these facilities have been audited by these agencies to confirm compliance. We do not plan to build manufacturing facilities and plan to scale our operations using our contract manufacturers.

The first API in DUEXIS is ibuprofen in a direct compression blend called DC85, which is manufactured by BASF in Bishop, Texas. DC85 is a proprietary blend of ibuprofen and manufacturing capacity and batch quantities are currently sufficient to meet our forecasted commercial requirements. DC85 is manufactured in compliance with the FDA’s current good manufacturing practices regulations for pharmaceuticals, or cGMPs. The second API in DUEXIS is famotidine, which is readily available from a number of international suppliers. We purchase famotidine manufactured by Dr. Reddy’s in India. Dr. Reddy’s has been audited by the FDA and found to be compliant in all aspects of the product. Our personnel have also completed audits of each supplier location and did not identify any critical cGMP deficiencies. We currently receive both APIs in powder form and each is blended with a number of United States Pharmacopeia inactive ingredients. We purchase DUEXIS in final, packaged form exclusively from sanofi-aventis U.S. for our commercial requirements for DUEXIS in North America and certain countries and territories in Europe, including the European Union member states and Scandinavia, and South America.

VIMOVO

In November 2013, in connection with our asset purchase agreement with AstraZeneca for VIMOVO, we entered into a transitional supply agreement with AstraZeneca for commercialization in the United States through December 31, 2014. AstraZeneca relies on well-established third party manufacturers for the manufacture of VIMOVO, with the exception of final packaging which AstraZeneca does internally. We are transitioning the supply chain to these third parties (including the packaging) during the transition period.

As part of this transition, in November 2013, we entered into the Patheon manufacturing agreement with Patheon, who is AstraZeneca’s contract bulk supply manufacturer of VIMOVO, pursuant to which Patheon will manufacture and package VIMOVO for us from the end of the AstraZeneca supply agreement through December 31, 2019.
The APIs in VIMOVO are manufactured by Patheon into finished tablets for AstraZeneca and will be manufactured into finished packaged products for us after the transition from AstraZeneca. The first API in VIMOVO is naproxen, which is supplied to AstraZeneca by Divis Laboratories Limited in India. The second API in VIMOVO is esomeprazole magnesium trihydrate and is supplied to AstraZeneca by Minakem Holding SAS in France. We plan to continue to purchase APIs from these companies after the transition from AstraZeneca and we are currently negotiating long-term supply agreements with them, although we cannot guarantee that we will reach definitive agreements on acceptable terms.

**RAYOS/LODOTRA**

We rely on well-established third-party manufacturers for the manufacture of RAYOS/LODOTRA. In Europe, we retain quality responsibility for RAYOS/LODOTRA by controlling the final release of products. We purchase the primary active ingredients for RAYOS/LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and from Sanofi Chimie SA in France.

We have contracted with Jagotec for the production of RAYOS/LODOTRA tablets. Jagotec produces RAYOS/LODOTRA operating through its affiliate SkyPharma. The SkyPharma production site in Lyon, France, complies with cGMP requirements and has been audited by the FDA for the production of several sustained release tablets employing SkyPharma’s GeoMatrix technology. In August 2011, SkyPharma leased their entire pharmaceutical manufacturing business to Aenova, and Aenova is now a subcontractor for Jagotec for the manufacture of RAYOS/LODOTRA, with our consent. We consider Aenova an experienced and reliable contract manufacturer dedicated largely to advanced oral dosage forms. The commercial scale production of RAYOS/LODOTRA tablets was implemented prior to the launch of LODOTRA in Europe in 2009. Under our manufacturing and supply agreement, we are required to purchase RAYOS/LODOTRA exclusively from Jagotec through April 2014, after which we will be able to purchase RAYOS/LODOTRA from other manufacturers if we choose.

Pursuant to a letter agreement between Jagotec and us, Jagotec agreed to allow us to give Bayer the right to manufacture, test and release quantities of RAYOS/LODOTRA in order to establish and maintain Bayer as a manufacturer of RAYOS/LODOTRA. Under certain circumstances, we may also purchase shortfall quantities of RAYOS/LODOTRA from Bayer to the extent Jagotec is unable to supply us. In March 2013, we entered into an agreement with Bayer to allow us to purchase quantities of RAYOS/LODOTRA for these purposes. After our manufacturing license from Jagotec becomes effective, we may also purchase quantities of RAYOS/LODOTRA from Bayer pursuant to our agreement with Bayer.

Analytical testing of RAYOS/LODOTRA is conducted by PHAST GmbH, a German provider of contract analytical services. The packaging of RAYOS/LODOTRA tablets is conducted by Temmler in Munich, Germany. Temmler was acquired by the Aenova Group in December 2012. Catalent Pharma Solutions, or Catalent, in Schorndorf, Germany is registered as a second site for Europe supplies. A CBE 30 has been submitted to the FDA notifying the FDA of our intent to include Catalent as the second packaging site for RAYOS in the United States.

All sites involved in the manufacturing and control of RAYOS/LODOTRA have been inspected by us and audited by national and international authorities in Europe. In addition, all sites have been audited by authorities in the United States, including the FDA.

**Distribution**

Finished tablets for DUEXIS, VIMOVO and RAYOS are shipped to a central third-party logistics FDA-compliant warehouse for storage and distribution into the supply chain. Our third-party logistics providers specialize in integrated operations that include warehousing and transportation services that can be scaled and customized to our needs based on market conditions and the demands and delivery service requirements for our products and materials. Their services eliminate the need to build dedicated internal infrastructures that would be difficult to scale without significant capital investment. Our third-party logistics provider warehouses all finished product in controlled FDA-registered facilities. Incoming orders are prepared and shipped through an order entry system to ensure just in time delivery of the products throughout the United States and Europe.
Third-Party Coverage and Reimbursement

In both U.S. and foreign markets, our ability to commercialize our products successfully depends in significant part on the availability of coverage and adequate reimbursement to healthcare providers from third-party payers, including, in the United States, government payers such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third-party payers are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. This is especially true in markets where over the counter and generic options exist. Even if coverage is made available by a third-party payer, the reimbursement rates paid for covered products might not be adequate. For example, third-party payers may use tiered coverage and may adversely affect demand for our products by not covering our products or by placing them in a more expensive formulary tier relative to competitive products (where patients have to pay relatively more out of pocket than for products in a lower tier). We cannot be certain that our products will be covered by third-party payers or that such coverage, where available, will be adequate, or that our products will successfully be placed on the list of drugs covered by particular health plan formularies. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. The industry competition to be included on such formularies and preferred drug lists often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other therapeutic alternative is available. In addition, because each third-party payer individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payer separately with no assurance that approval would be obtained, and we may need to conduct pharmacoeconomic studies to demonstrate the cost effectiveness of our products for formulary coverage and reimbursement. Even with studies, our products may be considered less safe, less effective or less cost-effective than competitive products, and third-party payers may not provide coverage and adequate reimbursement for our products or our product candidates. These pricing and reimbursement pressures may create negative perceptions to any product price increases, or limit the amount we may be able to increase our product prices, which may adversely affect our product sales and results of operations. Where coverage and reimbursement are not adequate, physicians may limit how much or under what circumstances they will prescribe or administer such products, and patients may decline to purchase them. This, in turn, could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

The U.S. market has seen a trend in which retail pharmacies have become increasingly involved in determining which prescriptions will be filled with the requested product or a substitute product, based on a number of factors, including potentially perceived product costs and benefits, as well as payer substitution policies. Many states have in place requirements for prescribers to indicate in writing on their prescriptions if they do not want pharmacies to make substitutions; these requirements are varied and not consistent across states. We may need to increasingly spend time and resources to ensure the prescriptions written for our products are filled as written, where appropriate.

Coverage policies, third-party reimbursement rates and product pricing regulation may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose extensive requirements upon the clinical development, pre-market approval, manufacture, labeling, marketing, promotion, pricing, storage and distribution of pharmaceutical products. These agencies and other regulatory agencies regulate research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, advertising and promotion of drugs. Failure to
comply with applicable FDA or foreign regulatory agency requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

• submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;
• completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA’s Good Laboratory Practice, or GLP, regulations;
• performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
• submission to the FDA of an NDA after completion of all pivotal clinical trials;
• a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
• satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the API and finished drug product are produced and tested to assess compliance with cGMP regulations; and
• FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the U.S. IND are required in the EEA and other jurisdictions in which we may conduct clinical trials. Investigator-sponsored or investigator-initiated clinical trials are studies for which the investigator holds the IND, or equivalent regulatory filing in foreign jurisdictions, and is responsible for compliance with both the investigator and sponsor requirements under applicable law.

Clinical Trials. For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

• Phase 1 Clinical Trials: Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism, and excretion, typically in healthy humans, but in some cases in patients.
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- **Phase 2 Clinical Trials.** Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- **Phase 3 Clinical Trials.** These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.

- **Phase 4 Clinical Trials.** The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a postmarketing commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

**New Drug Applications.** The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee. Once the submission has been accepted for filing, the FDA’s goal is to review applications within 12 months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, eight months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. The FDA may deny approval of an NDA by issuing a Complete Response Letter if the applicable regulatory criteria are not satisfied. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may occur with Risk Evaluation and Mitigation Strategies, or REMS, which limit the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

The DUEXIS, VIMOVO and RAYOS NDAs were submitted under Section 505(b)(2) of the FFDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA’s findings of safety and effectiveness for previously approved products, such as ibuprofen, famotidine and prednisone.

DUEXIS, VIMOVO and RAYOS have obtained, and any other products of ours approved by the FDA could obtain, three years of Hatch-Waxman marketing exclusivity, based upon our conducting or sponsoring new clinical investigations that are essential to approval of the respective NDA. Under this form of exclusivity, the FDA would be precluded from approving a generic drug application or, in some cases, another 505(b)(2) application for a drug product for the protected conditions of approval (for example, a product that incorporates the change or innovation represented by our product) for a period of three years, although the FDA may accept and commence review of such applications at any time. However, this form of exclusivity would not prevent the FDA from approving an NDA that relies on its own clinical data to support the change or innovation. Further, if
another company obtains approval for either product candidate for the same indication we are studying before we do, our approval could be blocked until the other company’s Hatch-Waxman marketing exclusivity expires.

Other Regulatory Requirements. Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review, payment of product and manufacturing establishment fees and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Our products may be subject to REMS requirements that affect labeling, distribution or post market reporting. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA requires us to recall a drug from distribution or withdraw approval of the NDA for that drug.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available drugs for uses that are not described in the product’s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers’ communications regarding off-label use. If our promotional activities, including any promotional activities that a contracted sales force may perform on our behalf, fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business. Thus, we may only market DUEXIS, VIMOVO and RAYOS for their approved indications and we could otherwise be subject to enforcement action for off-label marketing.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution, including a drug pedigree which tracks the distribution of prescription drugs.
Outside the U.S., our partners’ ability to market a product is contingent upon obtaining marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country.

In the EMA (which is comprised of the 27 Member States of the European Union, plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining an MA. There are three types of marketing authorizations:

• the Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

• Decentralized Procedure (DCP) MAs are available for products not falling within the mandatory scope of the Centralized Procedure. An identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States, or CMS, for their approval. If the CMS raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all of the selected Member States (i.e. in the RMS and the selected CMS). Where a product has already been authorized for marketing in a Member State of the EEA, this DCP approval can be recognized in other Member States through the Mutual Recognition Procedure, or MRP.

• National Procedure MAs, which are issued by a single competent authority of the Member States of the EEA and only covers their respective territory, are also available for products not falling within the mandatory scope of the Centralized Procedure. Once a product has been authorized for marketing in a Member State of the EEA through the National Procedure, this National MA can also be recognized in other Member States through the MRP.

Under the procedures described above, before granting the MA, the EMA or the competent authority(ies) of the Member State(s) of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Under Regulation (EC) No 726/2004/EC and Directive 2001/83/EC (each as amended), the European Union has adopted a harmonized approach to data and marketing exclusivity (known as the 8 + 2 + 1 formula). The approach permits eight years of data exclusivity and 10 years of marketing exclusivity. An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

The data exclusivity period begins on the date of the product’s first MA in the European Union and prevents generics from relying on the marketing authorization holder’s pharmacological, toxicological, and clinical data for a period of eight years. After eight years, a generic product application may be submitted and generic companies may rely on the marketing authorization holder’s data. However, a generic cannot launch until two years later (or a total of 10 years after the first marketing authorization in the European Union of the innovator product), or three years later (or a total of 11 years after the first MA in the European Union of the innovator product) if the MA holder obtains marketing authorization for a new indication with significant clinical benefit within the eight-year data exclusivity period.
The 8 + 2 + 1 exclusivity scheme applies to products that have been authorized in the European Union by either the EMA through the Centralized Procedure or the competent authorities of the Member States of the EEA (under the Decentralized, or Mutual Recognition procedures).

The holder of a Community MA or National MA is subject to various obligations under applicable EEA regulations, such as pharmacovigilance obligations, requiring it to, among other things, report and maintain detailed records of adverse reactions, and to submit periodic safety update reports to the competent authorities. The holder must also ensure that the manufacturing and batch release of its product is in compliance with the applicable requirements. The MA holder is further obligated to ensure that the advertising and promotion of its products complies with applicable laws, which can differ from Member State to Member State of the EEA.

Healthcare Fraud and Abuse Laws. As a pharmaceutical company, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients’ rights are and will be applicable to our business. We may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the FDA, such as us, and hospitals, physicians and other potential purchasers of such products.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute may have been violated, and enforcement will depend on the relevant facts and circumstances. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute to state that a person or entity needs not have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The federal Anti-Kickback Statute is broad, and despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. In addition, where such activities involve foreign government officials, they may also potentially be subject to the Foreign Corrupt Practices Act. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including our activities pursuant to partnerships with other companies and pursuant to contracts with contract research organizations, could be subject to challenge under one or more of such laws.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any
request or demand” for money or property presented to the U.S. government. In addition, the PPACA specified that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. The federal False Claims Act has been the basis for numerous enforcement actions and settlements by pharmaceutical and other healthcare companies in connection with various alleged financial relationships with customers. In addition, a number of pharmaceutical manufacturers have reached substantial financial settlements in connection with allegedly causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses. Certain marketing practices, including off-label promotion, may also violate false claims laws, as might violations of the federal physician self-referral laws, such as the Stark laws, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician’s family member has a financial interest and prohibit submission of a claim for reimbursement pursuant to a prohibited referral. The “qui tam” provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted similar fraud and abuse statutes or regulations, including, without limitation, false claims laws analogous to the False Claims Act, and laws analogous to the federal Anti-Kickback Statute, that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

Separately, there are a number of other fraud and abuse laws that pharmaceutical manufacturers must be mindful of, particularly after a product candidate has been approved for marketing in the United States. For example, a federal criminal law enacted as part of, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Healthcare Privacy and Security Laws. We may be subject to, or our marketing activities may be limited by, HIPAA, as amended by the Health Information Technology and Clinical Health Act and their respective implementing regulations, which established uniform standards for certain “covered entities” (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. Among other things, HIPAA’s privacy and security standards are directly applicable to “business associates” — independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. In addition to possible civil and criminal penalties for violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

“Sunshine” and Marketing Disclosure Laws. There are an increasing number of state “sunshine” laws that require pharmaceutical manufacturers to make reports to states on pricing and marketing information. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, and make periodic public disclosures on sales and marketing activities, and prohibiting certain other sales and marketing practices. In addition, a similar recently implemented federal requirement requires manufacturers, including pharmaceutical manufacturers, to track and report to the federal government certain payments and other transfers of value made to physicians and other healthcare professionals and teaching hospitals and ownership or investment interests held by physicians and their immediate family members. The federal government will disclose the reported information on a publicly available website beginning in 2014. These laws may adversely affect our sales, marketing, and other activities with respect to our products in the United States by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.
Government Price Reporting. For those marketed products which are covered in the United States by the Medicaid programs, we have various obligations, including government price reporting and rebate requirements, which generally require products be offered at substantial rebates/discounts to Medicaid and certain purchasers (including “covered entities” purchasing under the 340B Drug Discount Program). We are also required to discount such products to authorized users of the Federal Supply Schedule of the General Services Administration, under which additional laws and requirements apply. These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial penalties.

In General. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities, in the U.S., could be subject to challenge under one or more of such laws. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in U.S. federal or state healthcare programs, and the curtailment or restructuring of our operations. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, sunshine, government price reporting, and fraud laws may prove costly.

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

The United States and some foreign jurisdictions are considering or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, the PPACA. The PPACA, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial new provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, and impose additional health policy reforms, any or all of which may affect our business. A significant number of provisions are not yet, or have only recently become, effective, but the PPACA is likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Other legislative changes have also been proposed and adopted since the PPACA was

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enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws may result in additional reductions in Medicare and other healthcare funding. In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Employees

As of December 31, 2013, we had 304 full-time employees. Of our employees as of December 31, 2013, 28 were engaged in development, regulatory and manufacturing activities, 244 were engaged in sales and marketing and 32 were engaged in administration, including business development, finance, information systems, facilities and human resources. None of our employees is subject to a collective bargaining agreement. We consider our employee relations to be satisfactory.

Available Information

We make available free of charge on or through our internet website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. Our internet address is www.horizonpharma.com. Information is also available through the Securities and Exchange Commission’s website at www.sec.gov, or is available at the Securities and Exchange Commission’s Public Reference Room located at 100 F Street, NE, Washington DC, 20549. Information on the operation of the Public Reference Room is available by calling the Securities and Exchange Commission at 800-SEC-0330.

Item 1A. Risk Factors

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

Risks Related to Our Business and Industry

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

DUEXIS, VIMOVO and RAYOS/LODOTRA, and other product candidates that we may develop, acquire, or in-license, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. In the U.S. market, we began selling DUEXIS in December 2011. We began commercial sales of RAYOS, which was approved by the U.S. Food and Drug Administration, or FDA, in July 2012, to a subset of rheumatologists in the fourth quarter of 2012 with the full launch to the majority of U.S. rheumatologists and key primary care physicians in late January 2013. Outside the United States, LODOTRA has been sold in a limited number of countries and sales may not grow to expected levels, in part because we depend on our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for commercialization outside the United States. With respect to DUEXIS, we have only received marketing approval in the United Kingdom, or UK, thus far, and even if it is approved in other European countries, we do not expect the opportunity in Europe
to be material to our business given the current state of the market in Europe for pain products and the revenue being generated by existing branded non-
steroidal anti-inflammatory drugs, or NSAIDs, in Europe. There have been no sales of DUEXIS in the UK thus far. VIMOVO was launched in the U.S. market
in the fourth quarter of 2010 by AstraZeneca AB, or AstraZeneca, under its license from Pozen Inc., or Pozen. Following our acquisition of the U.S. rights to
VIMOVO in November 2013, we began selling VIMOVO in the first quarter of 2014 and have completed the expansion of our sales force to approximately
250 primary care representatives and approximately 40 rheumatology sales specialists. We believe that the degree of market acceptance and our ability to
generate revenues from our products will depend on a number of factors, including:

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

With respect to DUEXIS and VIMOVO, studies indicate that physicians do not commonly co-prescribe gastrointestinal, or GI, protective agents to
high-risk patients taking NSAIDs. We believe this is due in part to a lack of awareness among physicians prescribing NSAIDs of the risk of NSAID-induced
upper GI ulcers, in addition to the inconvenience of prescribing two separate medications and patient compliance issues associated with multiple
prescriptions. If physicians remain unaware of, or do not otherwise believe in, the benefits of combining GI protective agents with NSAIDs, our market
opportunity for DUEXIS and VIMOVO will be limited. Some physicians may also be reluctant to prescribe DUEXIS or VIMOVO due to the inability to vary
the dose of ibuprofen and naproxen, respectively, or if they believe treatment with NSAIDs or GI protective agents other than those contained in DUEXIS and
VIMOVO, including those of our competitors, would be more effective for their patients. With respect to each of DUEXIS, VIMOVO and RAYOS/LODOTRA,
their higher cost compared to the generic or branded forms of their active ingredients alone may limit adoption by physicians, patients and healthcare payers.
If DUEXIS, VIMOVO, RAYOS/LODOTRA or any other product that we may seek approval for, acquire or in-license fail to attain market acceptance, we may
not be able to generate significant revenue to achieve or sustain profitability, which would have a material adverse effect on our business, results of
operations, financial condition and prospects.
Our current business plan is highly dependent upon our ability to successfully execute on our sales and marketing strategy for the commercialization of DUEXIS, VIMOVO and RAYOS/LODOTRA. If we are unable to successfully execute on our sales and marketing strategy, we may not be able to generate significant product revenues or execute on our business plan.

Our strategy is to build a fully-integrated U.S.-focused biopharmaceutical company to successfully execute the commercialization of DUEXIS, VIMOVO and RAYOS in the U.S. market. We may not be able to successfully commercialize DUEXIS, VIMOVO or RAYOS in the United States. Prior to our commercial launch of DUEXIS in the United States in December 2011, we did not have any experience commercializing pharmaceutical products on our own. LODOTRA was commercially launched in Europe by our exclusive distribution partners Merck Serono and Mundipharma. In order to commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Although we have expanded our sales force to approximately 290 sales representatives in connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market these products and any additional products we may acquire or in-license will be expensive and time-consuming and could delay any product launch or our success in assuming commercialization for VIMOVO in the United States. Nor can we be certain that we will be able to continue to successfully develop this capability. As a result of the evolving role of various constituents in the prescription decision making process, we adjusted the profile of the sales representatives we hire from those with traditional pharmaceutical sales experience to those with successful business to business experience. For example, we have faced challenges due to pharmacists increasingly switching a patient’s intended prescription from DUEXIS to a generic or over the counter brand. We have faced similar challenges for RAYOS with respect to generic brands and expect to face similar challenges with respect to VIMOVO. While we believe the new profile of our representatives is better suited for this evolving environment, we cannot be certain that our representatives will be able to successfully protect DUEXIS, VIMOVO and RAYOS prescriptions or that we will be able to continue attracting and retaining sales representatives with our desired profile and skills. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain commercial personnel. To the extent we rely on additional third parties to commercialize any approved products, we may receive less revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of any third parties involved in our commercialization efforts. In the event we are unable to successfully develop and maintain our own commercial organization or collaborate with a third-party sales and marketing organization, we would not be able to commercialize our product candidates and execute on our business plan. If we are unable to sufficiently implement our commercial plans and drive adoption by patients and physicians of any approved products through our sales, marketing and commercialization efforts, or if our partners fail to successfully commercialize our products, then we will not be able to generate sustainable revenues from product sales which will have a material adverse effect on our business and prospects.

Our future prospects are highly dependent on the success of DUEXIS, VIMOVO and RAYOS/LODOTRA, and we may not be able to successfully commercialize these products. Failure to do so would adversely impact our financial condition and prospects.

A substantial majority of our resources are focused on the commercialization of DUEXIS and RAYOS in the United States and we expect to devote significant additional resources to the commercialization of VIMOVO in the United States. Our ability to generate significant product revenues and to achieve commercial success in the near term will initially depend almost entirely on our ability to successfully commercialize DUEXIS, VIMOVO and RAYOS in the United States. DUEXIS has been approved for marketing in the UK but is not yet approved in any other countries in Europe and therefore, unless we obtain regulatory approval in other countries, DUEXIS may not be commercialized to any significant extent outside of the United States. Even if DUEXIS is approved in other European countries, we do not expect the opportunity in Europe to be material to our business given the current state of the market in Europe for pain products and the revenue being generated by existing branded NSAIDs in Europe. Following our acquisition of the U.S. rights to VIMOVO in November 2013, we
began selling VIMOVO in the first quarter of 2014. Our strategy with respect to VIMOVO included bringing its pricing in-line with DUEXIS and thereby significantly increasing the value realized per prescription. While we have recently employed a similar strategy for DUEXIS, we cannot guarantee a similar result for VIMOVO, including due to the past declines in VIMOVO prescriptions and our need to re-negotiate managed care contracts for VIMOVO. Our initial strategy for RAYOS is to solely focus on the rheumatology indications approved for RAYOS where our Phase 3 clinical trial data supports our commercial plans. We initially launched RAYOS in the United States to a subset of rheumatologists in the fourth quarter of 2012, and the full launch to the majority of U.S. rheumatologists and key primary care physicians occurred in late January 2013. Although LODOTRA is approved for marketing in more than 30 countries outside the United States, to date it has only been marketed in a limited number of countries. While we anticipate that LODOTRA will be marketed in additional countries as our distribution partner, Mundipharma, formulates its reimbursement strategy, the ability to market LODOTRA in additional countries will depend on Mundipharma’s ability to obtain reimbursement approvals in these countries. Even if we obtain additional marketing and reimbursement approvals, our product revenues in Europe are entirely dependent upon the marketing efforts of our exclusive distribution partner, over which we have no control. Before we can market and sell these products in a particular jurisdiction, we need to obtain necessary regulatory approvals (from the FDA in the United States and from similar foreign regulatory agencies in other jurisdictions) and in some jurisdictions, reimbursement authorization. There are no guarantees that we or our commercialization partners will obtain any additional regulatory approvals for our products. Even if we or our commercialization partners obtain additional regulatory approvals, we may never generate significant revenues from any commercial sales of our products. If we fail to successfully commercialize DUEXIS, VIMOVO or RAYOS, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be adversely affected.

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

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

Our products are subject to extensive regulation, and we may not obtain additional regulatory approvals for our products.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution and other possible activities relating to our product candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions.
To market any drugs outside of the United States, we and current or future collaborators must comply with numerous and varying regulatory and compliance related requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

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

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

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

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

Following our acquisition of the U.S. rights to VIMOVO in November 2013, we have three products approved in the United States, one product with broad approval for commercial sale in Europe, and another product approved only for commercial sale in the UK thus far. RAYOS/LODOTRA has been approved in the United States and over 30 other countries, including Australia, Korea, Israel and select countries within Europe. However, we have a limited history of marketing LODOTRA through our distribution partners, and LODOTRA is not yet marketed in all of the countries where it has been approved. DUEXIS was approved in the United States on April 23, 2011, and in March 2013 we announced we were granted marketing authorization for DUEXIS in the UK, and we have generated limited revenues for DUEXIS to date. We began the commercial sale of RAYOS in the United States in the fourth quarter of 2012 and the commercial sale of VIMOVO in the United States in the first quarter of 2014. We face considerable risks and difficulties as a company with limited commercial operating history, particularly as a consolidated entity with operating subsidiaries that also have limited operating histories. If we do not successfully address these risks, our business, prospects, operating results and financial condition will be materially and adversely harmed. Our limited commercial operating history and our lack of any history commercializing VIMOVO makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. For example, we may underestimate the resources we will require to successfully commercialize VIMOVO or not realize the benefits we expect to derive from the acquisition.

We only have U.S. rights to VIMOVO and have no control over the activities of AstraZeneca to commercialize VIMOVO outside of the United States, which could adversely impact commercialization of VIMOVO in the United States.

AstraZeneca has retained its existing rights to VIMOVO in territories outside of the United States, including the right to use the VIMOVO name and related trademark. We have little or no control over AstraZeneca’s activities with respect to VIMOVO outside of the United States, even though those activities could impact our ability to successfully commercialize VIMOVO in the United States. For example, AstraZeneca or its assignees can make statements or use promotional materials with respect to VIMOVO outside of the United States that are inconsistent with our positioning of the product in the United States, and can sell VIMOVO in foreign countries, including Canada, at prices that are dramatically lower than the prices we expect to charge in the United States. These activities and decisions, while occurring outside of the United States, could harm our commercialization strategy in the United States, in particular because AstraZeneca is continuing to market the product outside the United States under the same VIMOVO brand name that we are using in the United States. In addition, product recalls or safety issues with VIMOVO outside of the United States, even if not related to the commercial product we sell in the United States, could result in serious damage to the brand in the United States and impair our ability to successfully market VIMOVO. We also rely on AstraZeneca to provide us with timely and accurate safety information regarding the use of VIMOVO outside of the United States, as we have limited access to this information ourselves.

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

The facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities. We do not control the manufacturing processes of third-party manufacturers and are currently completely dependent on our third-party manufacturing partners sanofi-aventis U.S. LLC, or sanofi-aventis U.S., operating through Valeant Pharmaceuticals International, Inc., or
Although we have entered into supply agreements for the manufacture of our products, our manufacturers may not perform as agreed or may terminate their agreements with us. Under our manufacturing and supply agreement with sanofi-aventis U.S., operating through Valeant, either we or sanofi-aventis U.S. may terminate the agreement upon an uncured breach by the other party or without cause upon two years prior written notice, so long as such notice is given after the third anniversary of the first commercial sale of DUEXIS. Under our master manufacturing services and product agreement with Patheon for finished VIMOVO product, either we or Patheon may terminate the agreement for uncured material breach by the other party or upon the other party’s bankruptcy or insolvency, we may terminate the agreement if any regulatory authority takes any action or raises any objection that prevents us from commercializing the VIMOVO product and Patheon may terminate the agreement if we assign our rights or obligations under the agreement to a competitor of Patheon or to a party that, in the reasonable opinion of Patheon, is not a credit worthy substitute for us, or in certain other circumstances where we assign the agreement without Patheon’s consent. Under our manufacturing and supply agreement with
Jagotec, either we or Jagotec may terminate the agreement in the event of an insolvency, liquidation or bankruptcy of the other party or upon an uncured breach by the other party. While we have the right to receive a continuing supply of RAYOS/LODOTRA from Jagotec for a period of 24 months after termination, we would need to move our manufacturing to our alternate supplier of RAYOS/LODOTRA, Bayer Pharma AG, in such an event and we would have to qualify a new back-up manufacturer.

In addition, we do not have the capability to package DUEXIS, VIMOVO, RAYOS/LODOTRA or any other product candidates for distribution. Consequently, we have entered into an agreement with Temmler Werke GmbH, or Temmler, for packaging of RAYOS/LODOTRA in certain European countries, Israel and in the United States, as well as any additional countries as may be agreed to by the parties. We intend to sell drug product finished and packaged by either Temmler or an alternate packager. At the end of 2012, Temmler was acquired by the Aenova Group. Valeant manufactures and supplies DUEXIS to us in final, packaged form for the United States as well as any additional countries as may be agreed to by the parties. During 2014, AstraZeneca is obligated to supply us VIMOVO in final, packaged form under a transition agreement and will work with us to transfer product packaging to Patheon. After 2014, we expect that Patheon will supply final, packaged VIMOVO product pursuant to the master manufacturing services and product agreement we executed in connection with our acquisition of the U.S. rights to VIMOVO.

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

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

We have experienced recent growth and have expanded the size of our organization substantially in connection with our acquisition of the U.S. rights to VIMOVO in November 2013, and we may experience difficulties in managing this growth.

As of December 31, 2010, we employed 41 full-time employees as a consolidated entity. In anticipation of the commercial launch of DUEXIS, we hired 80 sales representatives during the period from September 2011 through October 2011. As of December 31, 2012 and December 31, 2013, we employed 247 and 304 full-time employees, respectively, as a consolidated entity. In connection with our acquisition of the U.S. rights to VIMOVO, we hired approximately 115 additional employees as part of our commercial organization, and as of February 28, 2014, we employed 401 employees. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire in connection with the commercialization of our products, requiring us to hire and train new sales representatives. Our management,
personnel, systems and facilities currently in place may not be adequate to support this recent and anticipated growth, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses.

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

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

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

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize our products in the United States will be harmed.

As DUEXIS and RAYOS were not fully commercially launched in the United States until January 2012 and January 2013, respectively, and we did not begin commercializing VIMOVO in the United States until the first quarter of 2014, the members of our sales force have limited experience promoting any of our products. As a result, we are required to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense our products. In addition, we must train our sales force to ensure that a consistent and appropriate message about our products is being delivered to our potential customers. Our sales representatives may also experience challenges promoting multiple products when they call on physicians and their office staff, and our representatives may also be distracted from selling DUEXIS and RAYOS now that we are commercializing VIMOVO. This is particularly true with respect to DUEXIS, since VIMOVO is approved for similar indications and prescribed to similar patients, and our sale representatives have previously been incentivized to increase DUEXIS market share at the expense of VIMOVO. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire, requiring us to train new sales representatives. As a result of the managed care environment and pharmacies switching patient’s prescriptions to a generic or over the counter brand, we have had to adjust the profile of the sales representatives we hire from the traditional pharmaceutical representative to a representative with business to business experience that is focused on the total office call in order to protect the prescription the physician has written and ensure the patient receives what their doctor ordered. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of our products and their proper administration and label indication, our efforts to successfully commercialize our products 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 United States and international markets, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors and we will have to find new ways to compete and may have to potentially merge with or acquire other businesses to stay competitive. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or in-licensing on an exclusive basis, products that are more effective and/or less costly than our products.

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

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an Abbreviated New Drug Application, or ANDA, with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., or collectively Par, for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par’s ANDA and/or prevent Par from selling a generic version of DUEXIS. In January 2013, we filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par’s ANDA and/or prevent Par from selling a generic version of DUEXIS.

On August 21, 2013, we entered into a settlement agreement, or Par settlement agreement, and license agreement, or Par license agreement, with Par relating to our patent infringement litigation. Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par’s generic version of DUEXIS in the United States after the generic entry date and to take steps necessary to develop inventory of and obtain regulatory approval for, but not commercialize, Par’s generic version of DUEXIS prior to the generic entry date. The generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. If any of the events that permit Par to enter the market with its generic version of DUEXIS prior to January 1, 2023 were to occur, we
will likely face generic competition from Par shortly after the event, and our sales of DUEXIS would be substantially harmed. Also, despite our Par settlement agreement and Par license agreement with Par, additional third parties may file ANDAs with the FDA for their own generic versions of DUEXIS and we may not be successful in preventing any other generic products from entering the market.

Currently, patent litigation is pending against five generic companies intending to market VIMOVO before the expiration of patents listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. These cases are in the District of New Jersey and are grouped in three sets: (i) Dr. Reddy’s Laboratories, Inc., or Dr. Reddy’s; Lupin Pharmaceuticals Inc., or Lupin; Anchen Pharmaceuticals Inc., or Anchen, or collectively, the DRL cases; (ii) Mylan Laboratories Limited or collectively, the Mylan cases; and (iii) Watson Pharma, Inc., or collectively, the Watson cases. We understand that Dr. Reddy’s has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy’s will not be able to commercialize VIMOVO under AstraZeneca’s Nexium patent rights until May 28, 2014. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The DRL cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy’s notice letters were dated March 11, 2011 and November 12, 2012; the Lupin notice letter was dated June 10, 2011; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order. The DRL cases do not have pretrial deadlines or a trial date set. We understand Anchen has recertified under Paragraph III and has filed a motion to dismiss on that basis.

The Watson cases were filed on May 10, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a March 29, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Watson cases.

The Mylan cases were filed on June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a May 16, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Mylan cases.

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

On March 13, 2013, we received purported Notice Letters that a Paragraph IV Patent Certification had been filed by Alvogen Pine Brook, Inc., or Alvogen, advising that Alvogen had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. In the Notice Letters, Alvogen noted that as of March 13, 2013, the FDA had not accepted the ANDA for review. Alvogen has agreed that their Notice Letters do not constitute Notice as described in 21 U.S.C. 355(j)(2)(B).
On July 15, 2013, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc. — Florida, or Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc., or collectively WLF. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

On or about August 12, 2013, we received a Notice of Opposition to a European patent covering LODOTRA, EP 2049123, filed by Laboratorios Liconsa, S.A. In the European Union, the grant of a patent may be opposed by one or more private parties.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Par Pharmaceutical, Inc. has not advised us as to the timing or status of the FDA’s review of its filing. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par. The lawsuit alleges that Par has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

If we are unsuccessful in any of the on-going patent litigations, we will likely face generic competition with respect to VIMOVO and/or RAYOS and our sales of VIMOVO and/or RAYOS will be substantially harmed.

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

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

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

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

A variety of risks associated with operating our business and marketing our products internationally could materially adversely affect our business.

In addition to our U.S. operations, we have operations in Switzerland and Germany. Moreover, LODOTRA is currently being marketed in a limited number of countries outside the United States, and Mundipharma is in the process of obtaining pricing and reimbursement approval for, and preparing to market, LODOTRA in other European countries, as well as in certain Asian, Latin American, Middle Eastern and African countries. Also, Grünenthal S.A. is in the registration process for the commercialization of DUEXIS in Latin America. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for our products;
- compliance with Swiss laws with respect to our Horizon Pharma AG subsidiary, including laws requiring maintenance of cash in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities;
- difficulties in staffing and managing foreign operations;
- in certain circumstances, including with respect to the commercialization of LODOTRA in Europe and certain Asian, Latin American, Middle Eastern and African countries, and commercialization of DUEXIS in Latin America, increased dependence on the commercialization efforts and regulatory compliance of our distributors or strategic partners;
- compliance with German laws with respect to our Horizon Pharma GmbH subsidiary through which Horizon Pharma AG conducts most of its European operations;
- foreign government taxes, regulations and permit requirements;
- United States and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.
These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

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

A key element of our strategy is to develop, acquire or in-license and commercialize a portfolio of other product candidates in addition to DUEXIS and RAYOS/LODOTRA, such as our November 2013 acquisition of the U.S. rights to VIMOVO. Because we do not have proprietary drug discovery technology, the success of this strategy depends in large part upon the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license clinically enabled product candidates for the treatment of pain-related diseases, or for therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring, licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management’s time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects will be limited.

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

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

Our November 2013 acquisition of the U.S. rights to VIMOVO and any other strategic transactions that we may pursue in the future could have a variety of negative consequences, and we may not realize the benefits of such transactions or attempts to engage in such transactions.

We acquired the U.S. rights to VIMOVO in November 2013 and from time to time, we may seek to engage in additional strategic transactions with third parties, such as acquisitions of companies or divisions of companies, asset purchases or in-licensing of product candidates or technologies that we believe will complement or augment our existing business. We may also consider a variety of other business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and other investments. Any such transaction may require us to incur non-recurring and other charges, increase our near and long-term expenditures, pose significant integration challenges, create additional tax, legal, accounting and operational complexities in our business, require additional expertise, result in dilution to our existing stockholders and disrupt our management and business, which could harm our operations and financial results. For example, in connection with our acquisition of the U.S. rights to VIMOVO, we assumed primary responsibility for the existing patent infringement litigation with respect to VIMOVO, and have also agreed to reimburse certain legal expenses of Pozen with respect to its continued involvement in such litigation, and we expect that this will result in substantial on-going expenses and potential distractions to our management team. Because VIMOVO is approved for similar indications and prescribed to similar patients compared to DUEXIS, we may also experience lower prescriptions of DUEXIS as we seek to commercialize VIMOVO, particularly from the approximately 30% of physicians that currently prescribe both products. Moreover, we face significant competition in seeking appropriate strategic partners and transactions, and the
negotiation process for any strategic transaction can be time-consuming and complex. In addition, we may not be successful in our efforts to engage in certain strategic transactions because our financial resources and research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential. We may not be able to expand our business or realize our strategic goals if we do not have sufficient funding or cannot borrow or raise additional capital. There is no assurance that following our acquisition of the U.S. rights to VIMOVO or any other strategic transaction, we will achieve the anticipated revenues or net income that we believe to justify such transaction. Any failures or delays in entering into strategic transactions could also delay or negatively impact the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. In addition, any failures or delays in entering into strategic transactions anticipated by analysts or the investment community could result in a decline in our stock price.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, sales and marketing and scientific and medical personnel, including our Chairman, President and Chief Executive Officer, Timothy P. Walbert; our Executive Vice President and Chief Financial Officer, Robert J. De Vaere; our Executive Vice President, Development, Manufacturing and Regulatory Affairs and Chief Medical Officer, Jeffrey W. Sherman, M.D.; and our Executive Vice President and Chief Commercial Officer, Todd Smith. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide incentive stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

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

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

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

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

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

Any regulatory approvals that we obtain for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMPs, good clinical practices, or GCPs, international conference on harmonization regulations, or ICH regulations, and good laboratory practices, or GLPs, which are regulations and guidelines enforced by the FDA for all of our products in clinical development, for any clinical trials that we conduct post-approval. For example, as post-marketing requirements for DUEXIS, we are required by the FDA to develop a pediatric formulation for DUEXIS and conduct two clinical studies of the drug product for pediatric populations. In addition, in connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we assumed responsibility for completing an ongoing Pediatric Research Equity Act post-marketing requirement study in children 12 years to 16 years and 11 months of age with Juvenile RA for which the FDA recently granted an extension with a final report due date of December 2015. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.
Coverage and reimbursement may not be available, or reimbursement may be available at only limited levels, for our products, which could make it difficult for us to sell our products profitably or to successfully execute planned product price increases.

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

Outside of the United States, the success of our products, including LODOTRA and, if widely approved, DUEXIS, will depend largely on obtaining and maintaining government coverage, because in many countries patients are unlikely to use prescription drugs that are not covered by their government healthcare programs. To date, LODOTRA is approved in over 30 countries outside the United States, and reimbursement for LODOTRA has been obtained in Germany, Italy, Sweden and Switzerland. Mundipharma is seeking coverage for LODOTRA in a number of countries and currently sells LODOTRA without coverage in a limited number of countries. Negotiating coverage and reimbursement with governmental authorities can delay commercialization by 12 months or more. Coverage and reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and we expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceutical products, which we believe has impacted the reimbursement rates and timing to launch for LODOTRA to date, and we expect these discounts to continue as countries attempt to manage healthcare expenditures, especially in light of current economic conditions. For example, legislation was recently enacted in Germany that will increase the rebate on prescription pharmaceuticals and likely lower the revenues from the sale of LODOTRA in Germany that we would otherwise receive. As a result of these pricing practices, it may become difficult to achieve profitability or expected rates of growth in revenue or results of operations. Any shortfalls in revenue could adversely affect our business, financial condition and results of operations.

In light of such policies and the uncertainty surrounding proposed regulations and changes in the coverage and reimbursement policies of governments and third-party payers, we cannot be sure that coverage and reimbursement will be available for DUEXIS or LODOTRA in any additional markets or for any other product candidates that we may develop. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If coverage and reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products.
We expect to experience pricing pressures in connection with the sale of our products, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. There may be additional pressure by payers and healthcare providers to use generic drugs that contain the active ingredients found in DUEXIS, VIMOVO and RAYOS/LODOTRA or any other product candidates that we may develop, acquire or in-license. If we fail to successfully secure and maintain coverage and adequate reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and expected revenue and profitability which would have a material adverse effect on our business, results of operations, financial condition and prospects. We may also experience pressure from payers concerning certain promotional approaches that we may implement such as co-pay programs whereby we assist patients to achieve an acceptable co-pay for our product, which may be contrary to payers’ financial interests. If we are unsuccessful with our co-pay initiatives, we would be at a competitive disadvantage in terms of pricing versus preferred branded and generic competitors.

We are subject to federal, state and foreign healthcare laws and regulations and implementation or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to regulate and to change the healthcare system in ways that could affect our ability to sell our products profitably, described in greater detail in the Government Regulation Section of this report. In the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to civil and/or criminal penalties, damages, fines, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management’s attention away from the operation of our business.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. An expansion in the government’s role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using our products, reduce product utilization and adversely affect our business and results of operations. It is unclear whether and to what extent, if at all, other anticipated developments resulting from the federal healthcare reform legislation, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us additional revenue to offset the annual excise tax (on certain drug product sales) enacted under the PPACA, subject to limited exceptions. It is possible that the tax burden, if we are not excepted, would adversely affect our financial performance, which in turn could cause the price of our stock to decline. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our current products and/or those for which we may receive regulatory approval in the future.

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

In the United States, we are subject directly, or indirectly through our customers, to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims
Act, federal and state privacy and security laws, sunshine laws, government price reporting laws, and other fraud laws, as described in greater detail in the Government Regulation Section of this report. These laws may impact, among other things, our proposed sales, marketing and educational programs, as well as other possible relationships with customers, payers, and patients.

Compliance with these laws, including the development of a comprehensive compliance program, is difficult, costly and time consuming and companies that do not comply with these state laws face civil penalties. Even if we structure our programs with the intent of compliance with such laws, there can be no certainty that we would not need to defend our business activities against enforcement or litigation, in light of the fact that there is significant enforcement interest in pharmaceutical companies in the United States, and some of the applicable laws are quite broad in scope with very narrow exceptions.

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

Our products or any other product candidate that we develop may cause undesirable side effects or have other properties that could delay or prevent regulatory approval or commercialization, result in product re-labeling or withdrawal from the market or have a significant impact on customer demand.

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

In addition, if we or others identify undesirable side effects caused by our products or any other product candidate that we may develop that receives marketing approval, or if there is a perception that the product is associated with undesirable side effects:

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

If any of these events occurred with respect to our products, our ability to generate significant revenues from the sale of these products would be significantly harmed.
We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or if they experience regulatory compliance issues, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

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

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

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

In addition, pursuant to a March 2011 letter agreement and in connection with our waiver of certain milestone payments, Mundipharma initiated a separate Phase 3 clinical trial for LODOTRA for the potential treatment of polymyalgia rheumatica, or PMR. We had limited control over the timing and implementation of the planned clinical trial and in February 2014, Mundipharma informed us that they had terminated the clinical trial primarily due to recruitment difficulties based on the inclusion criteria and as a result of the cessation of production of the comparator product Decortin® 1mg.

We also, as part of the April 23, 2011 FDA approval of DUEXIS, have a commitment under the Pediatric Research Equity Act to conduct an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients. In addition, in connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we assumed responsibility for completing an ongoing Pediatric Research Equity Act post-marketing requirement study in children 12 years to 16 years and 11 months of age with Juvenile RA for which the FDA recently granted an extension with a final report due date of December 2015. Although we are committed to carrying out these commitments, there are challenges in conducting studies in pediatric patients including availability of study sites, patients, and obtaining parental informed consent.
Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

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

To the extent that we are required to conduct additional clinical development of DUEXIS, VIMOVO or RAYOS/LODOTRA or we conduct clinical development of earlier stage product candidates or for additional indications for RAYOS/LODOTRA, we may experience delays in these clinical trials. While we are currently not focusing any resources on internal development of new product candidates, we do not know whether any additional clinical trials will be initiated in the future, begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

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

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

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

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

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

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

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

- decreased demand for our products or product candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or product candidates; and
- a decline in our stock price.
Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies and commercial product sales in the amount of $20 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the on-going commercialization of DUEXIS, VIMOVO and RAYOS in the United States and/or the potential commercial launches of DUEXIS and LODOTRA in additional markets, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

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

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

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

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

We have a limited operating history. We have financed our operations primarily through equity and debt financings and have incurred significant operating losses since our inception. We had net losses of $149.0 million, $87.8 million and $113.3 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of $457.1 million. We do not know whether or when we will become profitable. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. Our losses have resulted principally from costs incurred in our development activities for our products and product candidates, commercialization activities related to our product launches and costs associated with derivative liability accounting. We anticipate that we will continue to incur operating losses until such time as the revenues we generate from the sale of our products are sufficient to cover our operating expenses.

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

Our ability to become profitable depends upon our ability to generate revenues from sales of our products. DUEXIS was approved by the FDA on April 23, 2011, and we began generating revenues from sales of DUEXIS in late 2011 following the commercial launch in the United States. LODOTRA is approved for marketing in over 30 countries outside the United States, and to date we have generated only limited revenues from sales of LODOTRA. RAYOS was approved by the FDA on July 26, 2012, and we began marketing it in the United States through our full field sales force in late January 2013. Following our November 2013 acquisition of the U.S. rights to VIMOVO, we began commercialization efforts in the United States in the first quarter of 2014. We may never be able to successfully commercialize DUEXIS, VIMOVO or RAYOS or develop or commercialize other products in the United States, which we believe represents our most significant commercial opportunity, or sell DUEXIS in Europe, where we do not consider it to be material to our business. Our ability to generate future revenues depends heavily on our success in:

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

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

We may need to obtain additional financing to successfully commercialize or further develop DUEXIS, VIMOVO and RAYOS/LODOTRA, or to develop, acquire or in-license other products.

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

- commercialize DUEXIS, VIMOVO and RAYOS in the United States, including the substantial expansion of our sales force in connection with our November 2013 acquisition of the U.S. rights to VIMOVO;
- complete the regulatory approval process, and any future required clinical development related thereto, for DUEXIS, VIMOVO and RAYOS/LODOTRA;
conduct clinical trials with respect to RAYOS/LODOTRA to generate clinical data in diseases beyond RA, such as PMR; and

potentially acquire or in-license additional complementary products or products that augment our current therapeutic areas of focus.

While we believe that our existing cash and cash equivalents at December 31, 2013, of $80.5 million, together with interest thereon, will be sufficient to fund our operations to the point of generating positive cash flow based on our current expectations of continued revenue growth, we may need to raise additional funds if we choose to expand our commercialization or development efforts more rapidly than we presently anticipate, if we develop, acquire or in-license additional products or acquire companies, or if our revenues do not meet expectations.

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

seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or

relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Even if we obtain additional financing, our Horizon Pharma AG subsidiary is subject to Swiss laws regarding overindebtedness that require Horizon Pharma AG to maintain assets in excess of its liabilities. As of December 31, 2013, our Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. We will continue to monitor and review steps to address any overindebtedness, until such time as our Swiss subsidiary may generate positive income at a statutory level, which could require us to have cash at our Swiss subsidiary in excess of its near term operating needs and could affect our ability to have sufficient cash at our U.S. subsidiary to meet its near term operating needs.

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

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

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

In August 2012, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may sell our common stock through Cowen in at-the-market, or ATM, offerings. Subject to the terms
and conditions of the sales agreement, Cowen may sell the shares by methods deemed to be an ATM offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including sales made through The NASDAQ Global Market, on any other existing trading market for our common stock or to or through a market maker. The sale of additional shares of our common stock pursuant to the sales agreement will have a dilutive impact on our existing stockholders and could cause the market price of our common stock to be lower than it would otherwise be absent sales activities by Cowen. Sales of our common stock under the sales agreement, or the perception that such sales will occur, could also encourage short sales by third parties, which could contribute to a decline of our stock price.

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

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. In September 2012, the sale of our common stock and warrants to purchase shares of our common stock in a public equity offering triggered an “ownership change” limitation and, as a result, we will be subject to annual limits on our ability to utilize net operating loss carryforwards. We estimate that these annual limits will be a cumulative carryforward of $49.9 million in 2014, and at a minimum, $22.0 million for each of 2015 and 2016 assuming only the carryforward limitation. The net operating loss carryforward limitation is cumulative such that any use of the carryforwards below the limitation in one year will result in a corresponding increase in the limitation for the subsequent tax year. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including potentially as a result of our debt and equity financings. Any limitation on our ability to use our net operating loss carryforwards will likely increase the taxes we would otherwise pay in future years if we were not subject to such limitations.

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

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

At December 31, 2013, we had $80.5 million of cash and cash equivalents consisting of cash and money market funds. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, 2013, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities owned by us.

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

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

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

In November 2013, we issued $150.0 million aggregate principal amount of 5.00% Convertible Senior Notes due 2018, or the Convertible Senior Notes, to investors pursuant to note purchase agreements with such investors. As of March 13, 2014, all $150.0 million principal amount of the Convertible Senior Notes remained outstanding. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Convertible Senior Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Risks Related to Our Intellectual Property

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

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

Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. On March 13, 2013, we received purported Notice Letters that a Paragraph IV Patent Certification had been filed by Alvogen, advising that Alvogen had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. In the Notice Letters, Alvogen noted that as of March 13, 2013, the FDA had not accepted the ANDA for review. Alvogen has agreed that their Notice Letters do not constitute Notice as described in 21 U.S.C. 355(j)(2)(B).

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against WLF. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Par Pharmaceutical, Inc. has not advised us as to the timing or status of the FDA’s review of its filing. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

Currently there are patent litigations pending against five generics intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the District of New Jersey and are grouped in three sets: (i) the DRL cases; (ii) the Mylan cases; and (iii) the Watson cases. We understand that Dr. Reddy’s has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy’s will not be able to commercialize VIMOVO under AstraZeneca’s Nexium patent rights until May 28, 2014. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The DRL cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy’s notice letters were dated March 11, 2011 and November 12, 2012; the Lupin notice letter was dated June 10, 2011; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order. The case does not have pretrial deadlines or a trial date set. We understand Anchen has recertified under Paragraph III and has filed a motion to dismiss on that basis.
The Watson cases were filed on May 10, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a March 29, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Watson cases.

The Mylan cases were filed on June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a May 16, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Mylan cases.

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

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on
September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or U.S. PTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the U.S. PTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States and Canada. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

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

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

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

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

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

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

In connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we (i) received the benefit of a covenant not to sue under AstraZeneca’s patent portfolio with respect to Nexium (which shall automatically become a license under such patent portfolio if and when AstraZeneca reacquires control of such patent portfolio from Merck Sharp & Dohme Corp. and certain of its affiliates), (ii) were assigned AstraZeneca’s amended and restated collaboration and license agreement for the United States with Pozen under which AstraZeneca has in-licensed exclusive rights under certain of Pozen’s patents with respect to VIMOVO, and (iii) acquired AstraZeneca’s co-ownership rights with Pozen with respect to certain joint patents covering VIMOVO, all for the commercialization of VIMOVO in the United States. If we fail to comply with our obligations under our agreements with AstraZeneca or if we fail to comply with our obligations under our agreements with Pozen as we take over AstraZeneca’s agreements with Pozen, our rights to commercialize VIMOVO in the United States may be adversely affected or terminated by AstraZeneca or Pozen.

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.
Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

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

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

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

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

Risks Related to Ownership of our Common Stock

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

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

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

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

- our failure to successfully execute our commercialization strategy with respect to our approved products, particularly our commercialization of DUEXIS, VIMOVO and RAYOS in the United States;
- disputes or other developments relating to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products and product candidates;
- unanticipated serious safety concerns related to the use of our products;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our products or product candidates, including but not limited to clinical trial requirements for approvals;
- inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;
- developments concerning our commercial partners, including but not limited to those with our sources of manufacturing supply;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse results or delays in clinical trials;
- our failure to successfully develop, acquire, and/or in-license additional product candidates;
- introduction of new products or services offered by us or our competitors;
- our inability to effectively manage our growth;
- overall performance of the equity markets and general political and economic conditions;
- failure to meet or exceed revenue and financial projections we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- our inability to successfully enter new markets;
- the termination of a collaboration or the inability to establish additional collaborations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our inability to maintain an adequate rate of growth;
- ineffectiveness of our internal controls or our inability to otherwise comply with financial reporting requirements;
- adverse U.S. and foreign tax exposure;
• additions or departures of key management, commercial or regulatory personnel;
• issuances of debt or equity securities;
• significant lawsuits, including patent or stockholder litigation;
• changes in the market valuations of similar companies;
• sales of our common stock by us or our stockholders in the future;
• trading volume of our common stock;
• effects of natural or man-made catastrophic events or other business interruptions; and
• other events or factors, many of which are beyond our control.

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

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

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the increase, if any, of our stock price.

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

Our officers, directors and funds affiliated with our directors held in the aggregate approximately 17% of our outstanding voting stock as of December 31, 2013. Therefore, these stockholders have the ability to influence us through this ownership position, including through matters requiring stockholder approval. For example, these stockholders may be able to influence the elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

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

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

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

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

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

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

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

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

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

In August 2012, we entered into a sales agreement with Cowen pursuant to which we may sell common stock in ATM offerings under our registration statement on Form S-3, which became effective on August 9, 2012. As of December 31, 2013, Cowen had sold a cumulative total of 2,448,575 shares of our common stock with gross proceeds to us of $6.2 million.

Pursuant to our 2011 equity incentive plan, or 2011 EIP, our board of directors is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under our 2011 EIP automatically increases on January 1 of each year by an amount equal to the lesser of 5% of our capital stock outstanding as of December 31 of the preceding calendar year or 1,474,304 shares, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. In addition, our board of directors may grant or provide for the grant of rights to purchase shares of our common stock pursuant to the terms of the 2011 employee stock purchase plan, or 2011 ESPP. The number of shares of our common stock reserved for issuance automatically increases on January 1 of each year by an amount equal to the lesser of 4% of our capital stock outstanding as of December 31 of the preceding calendar year or 1,053,074, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. On December 5, 2013, pursuant to the terms of our 2011 EIP and 2011 ESPP, our board of directors approved increases in the number of shares available for issuance under the 2011 EIP and the 2011 ESPP of 1,474,304 shares and 1,053,074 shares, respectively, effective January 1, 2014.

In addition, (i) on November 7, 2013, November 16, 2013 and March 3, 2014, our board of directors approved amendments to the 2011 EIP to reserve an additional 200,000 shares, 800,000 shares and 730,000 shares, respectively, of our common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of ours (or following a bona fide period of non-employment with us), as an inducement material to the individual’s entry into employment with us within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules and (ii) on January 10, 2014, our board of directors approved an amendment to the 2011 EIP to increase the number of shares available for issuance under the 2011 EIP by 703,400 shares, or the January 2014 amendment, with such increase to the number of shares available for issuance under the 2011 EIP subject to stockholder approval of the January 2014 amendment.

In November 2013, we issued $150.0 million aggregate principal amount of the Convertible Senior Notes. The Convertible Senior Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding August 15, 2018 only under certain conditions. On or after August 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date for the Convertible Senior Notes, holders will be able to convert their Convertible Senior Notes at their option at the conversion rate then in effect at any time, regardless of these conditions. Subject to certain limitations, we may settle conversions of the Convertible Senior Notes by paying or delivering, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

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

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

- authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
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 or incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could depress the market price of our common stock.

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

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

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

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

Item 1B. Unresolved Staff Comments
None.

Item 2. Properties
We occupy approximately 34,460 square feet of space in our headquarters in Deerfield, Illinois under lease agreements that expire on June 30, 2018. We also occupy approximately 5,000 square feet of office space in Mannheim, Germany under a lease that expires on December 31, 2014 and approximately 3,200 square feet of
office space in Reinach, Switzerland under a lease that expires on May 31, 2015. We have no laboratory, research or manufacturing facilities. We believe that our current facilities are adequate for our needs and that, should it be needed, suitable additional space or renewal of our existing leases will be available to accommodate expansion of our operations on commercially reasonable terms.

Item 3. Legal Proceedings

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an Abbreviated New Drug Application, or ANDA, with the U.S. Food and Drug Administration, or FDA, for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., or collectively Par, for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par’s ANDA and/or prevent Par from selling a generic version of DUEXIS. In January 2013, we filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par’s ANDA and/or prevent Par from selling a generic version of DUEXIS.

On August 21, 2013, we entered into a settlement agreement, or Par settlement agreement, and license agreement, or Par license agreement, with Par relating to our patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both us and Par of all claims that were or could have been asserted in the litigation and that arise out of the specific patent issues that were the subject of the litigation, including all resulting damages or other remedies.

Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par’s generic version of DUEXIS in the United States after the generic entry date (as defined below) and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par’s generic version of DUEXIS prior to the generic entry date, or collectively the license. The license covers all patents owned or controlled by us during the term of the Par license agreement that would, absent the license, be infringed by the manufacture, use, sale, offer for sale, or importation of Par’s generic version of DUEXIS in the United States. Unless terminated sooner pursuant to the terms of the Par license agreement, the license will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. Only in the event that Par enters the DUEXIS market due to the specified changes in DUEXIS market conditions will the license become royalty-bearing, with the royalty obligations ceasing upon the occurrence of one of the other events that would have allowed Par to enter the DUEXIS market.

Under the Par license agreement, we also agreed not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by us during the term of the Par license agreement based on the manufacture, use, sale, offer for sale, or importation of Par’s generic version of DUEXIS in the United States.

The Par license agreement may be terminated by us if Par commits a material breach of the agreement that is not cured or curable within 30 days after we provide notice of the breach. We may also terminate the Par license agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the Par license agreement will terminate automatically upon termination of the Par settlement agreement.
On March 13, 2013, we received purported Notice Letters that a Paragraph IV Patent Certification had been filed by Alvogen Pine Brook, Inc., or Alvogen, advising that Alvogen had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. In the Notice Letters, Alvogen noted that as of March 13, 2013, the FDA had not accepted the ANDA for review. Alvogen has agreed that their Notice Letters do not constitute Notice as described in 21 U.S.C. 355(j)(2)(B).

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc.—Florida, or Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA’s review of its filing. On August 26, 2013, we, together with Jagotec AG, or Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Actavis Corp., and Actavis, Inc., or collectively WLF, seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

On or about August 12, 2013, we received a Notice of Opposition to a European patent covering LODOTRA, EP 2049123, filed by Laboratorios Liconsa, S.A. In the European Union, the grant of a patent may be opposed by one or more private parties.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Par Pharmaceutical, Inc. has not advised us as to the timing or status of the FDA’s review of its filing. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

Currently there are patent litigations pending against five generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the District of New Jersey and are grouped in three sets: (i) Dr. Reddy’s Laboratories, Inc., or Dr. Reddy’s; Lupin Pharmaceuticals Inc., or Lupin; Anchen Pharmaceuticals Inc., or Anchen, or collectively, the DRL cases; (ii) Mylan Laboratories Limited, or collectively, the Mylan cases; and (iii) Watson Pharma, Inc., or collectively, the Watson cases. These cases seek an injunction preventing any infringing activity until the expiration of the patents. We understand that Dr. Reddy’s has entered into a settlement with AstraZeneca AB, or AstraZeneca, with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy’s will not be able to commercialize VIMOVO under AstraZeneca’s Nexium patent rights until May 28, 2014. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The DRL cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We
understand the Dr. Reddy’s notice letters were dated March 11, 2011 and November 12, 2012; the Lupin notice letter was dated June 10, 2011; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order. The DRL cases do not have pretrial deadlines or a trial date set. We understand Anchen has recertified under Paragraph III and has filed a motion to dismiss on that basis.

The Watson cases were filed on May 10, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a March 29, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Watson cases.

The Mylan cases were filed on June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from a May 16, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Mylan cases.

Item 4. Mine Safety Disclosures

None.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock began trading on The NASDAQ Global Market on July 28, 2011 under the symbol “HZNP.” Prior to such time, there was no public market for our common stock. The following table sets forth the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market for the periods indicated.

<table>
<thead>
<tr>
<th></th>
<th>High</th>
<th>Low</th>
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</thead>
<tbody>
<tr>
<td><strong>2013</strong></td>
<td></td>
<td></td>
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<tr>
<td>First quarter</td>
<td>$2.95</td>
<td>$1.97</td>
</tr>
<tr>
<td>Second quarter</td>
<td>2.75</td>
<td>2.23</td>
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<tr>
<td>Third quarter</td>
<td>3.55</td>
<td>2.11</td>
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<tr>
<td>Fourth quarter</td>
<td>7.80</td>
<td>3.21</td>
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<tr>
<td><strong>2012</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First quarter</td>
<td>$4.96</td>
<td>$3.05</td>
</tr>
<tr>
<td>Second quarter</td>
<td>7.47</td>
<td>3.50</td>
</tr>
<tr>
<td>Third quarter</td>
<td>8.72</td>
<td>3.29</td>
</tr>
<tr>
<td>Fourth quarter</td>
<td>3.50</td>
<td>2.03</td>
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Holders of Record

The closing price of our common stock on March 11, 2014 was $13.33. As of March 11, 2014, there were approximately 68 holders of record of our common stock.
Performance Graph

The following graph shows a comparison from July 28, 2011 (the date our common stock commenced trading on The NASDAQ Global Market) through December 31, 2013, of the cumulative total return for our common stock, the NASDAQ US Index and the NASDAQ Pharmaceutical Index. The graph assumes an initial investment of $100 on July 28, 2011. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.

The foregoing graph and table are furnished solely with this report, and are not filed with this report, and shall not be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Securities Act, or the Securities Exchange Act of 1934, as amended, whether made by us before or after the date hereof, regardless of any general incorporation language in any such filing, except to the extent we specifically incorporate this material by reference into any such filing.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors.
Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K regarding information about securities authorized for issuance under our equity compensation plans.

Issuer Repurchases of Equity Securities

None.

Item 6. Selected Financial Data

The selected statement of operations data for the years ended December 31, 2013, 2012 and 2011, and the balance sheet data as of December 31, 2013 and 2012 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statement of operations data for the years ended December 31, 2010 and 2009, and the balance sheet data as of December 31, 2011, 2010 and 2009 have been derived from audited financial statements which are not included in this Annual Report on Form 10-K.
The following selected financial data also reflects the 1-for-2.374 reverse stock split of our outstanding common stock effected in July 2011.

Our historical results are not necessarily indicative of future results. The selected financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K (amounts in thousands, except per share data).

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Gross sales</td>
<td>$102,995</td>
<td>$22,978</td>
<td>$6,939</td>
<td>$2,376</td>
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<td>Sales discounts and allowances (1)</td>
<td>(28,979)</td>
<td>(4,134)</td>
<td>(12)</td>
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<td>—</td>
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<tr>
<td>Net sales</td>
<td>74,016</td>
<td>18,844</td>
<td>6,927</td>
<td>2,376</td>
<td>—</td>
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<td>Cost of goods sold (1)</td>
<td>14,625</td>
<td>11,875</td>
<td>7,267</td>
<td>4,263</td>
<td>—</td>
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<tr>
<td>Gross profit (loss)</td>
<td>59,391</td>
<td>6,969</td>
<td>(340)</td>
<td>(1,887)</td>
<td>—</td>
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<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Research and development</td>
<td>10,084</td>
<td>16,837</td>
<td>15,358</td>
<td>17,697</td>
<td>10,894</td>
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<td>Sales and marketing</td>
<td>68,595</td>
<td>49,561</td>
<td>20,314</td>
<td>5,558</td>
<td>2,072</td>
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<td>General and administrative</td>
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<td>19,444</td>
<td>15,008</td>
<td>18,612</td>
<td>5,823</td>
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<td>Intangible impairment charge</td>
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<td>—</td>
<td>69,621</td>
<td>—</td>
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<td>Total operating expenses</td>
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<td>85,842</td>
<td>120,301</td>
<td>41,867</td>
<td>18,789</td>
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<td>Loss from operations</td>
<td>(42,854)</td>
<td>(78,873)</td>
<td>(120,641)</td>
<td>(43,754)</td>
<td>(18,789)</td>
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<td>Other (expense) income, net:</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(39,178)</td>
<td>(14,525)</td>
<td>(6,284)</td>
<td>(3,024)</td>
<td>(2,189)</td>
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<tr>
<td>Loss on derivative revaluation</td>
<td>(69,300)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<tr>
<td>Bargain purchase gain</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>19,326</td>
<td>—</td>
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<td>Foreign exchange gain (loss)</td>
<td>1,206</td>
<td>489</td>
<td>(1,023)</td>
<td>(273)</td>
<td>—</td>
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<td>Other (expense) income</td>
<td>—</td>
<td>(56)</td>
<td>—</td>
<td>—</td>
<td>478</td>
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<td>Loss before income tax benefit</td>
<td>(150,126)</td>
<td>(92,965)</td>
<td>(127,948)</td>
<td>(27,725)</td>
<td>(20,500)</td>
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<td>Income tax benefit</td>
<td>(1,121)</td>
<td>(5,171)</td>
<td>(14,683)</td>
<td>(660)</td>
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<td>Net loss</td>
<td>(149,005)</td>
<td>(87,794)</td>
<td>(113,265)</td>
<td>(27,065)</td>
<td>(20,500)</td>
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<td>Capital contribution</td>
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<td>Net loss attributable to common stockholders</td>
<td>$ (149,005)</td>
<td>$ (87,794)</td>
<td>$ (113,265)</td>
<td>$ (27,065)</td>
<td>$ (17,011)</td>
</tr>
<tr>
<td>Net loss per share—basic and diluted</td>
<td>$ (2.34)</td>
<td>$ (2.26)</td>
<td>$ (12.56)</td>
<td>$ (21.16)</td>
<td>$ (40.65)</td>
</tr>
<tr>
<td>Weighted average shares outstanding—basic and diluted</td>
<td>63,657,924</td>
<td>38,871,422</td>
<td>9,014,968</td>
<td>1,279,133</td>
<td>418,520</td>
</tr>
</tbody>
</table>

(1) For the year ended December 31, 2012, the reported amount for sales discounts and allowances has been revised from ($3.3) million to ($4.1) million, the reported amount for net sales has been revised from $19.6 million to $18.8 million, and the reported amount for cost of goods sold has been revised from $12.7 million to $11.9 million, reflecting reclassification of wholesaler service fees from cost of goods sold to sales discounts and allowances. See Note 1 “The Company” in the notes to our consolidated financial statements included in this Annual Report on Form 10-K.
## Table of Contents

As of December 31,

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Assets:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$80,480</td>
<td>$104,087</td>
<td>$17,966</td>
<td>$5,384</td>
<td>$7,160</td>
</tr>
<tr>
<td>Working capital (deficit)</td>
<td>67,455</td>
<td>79,983</td>
<td>1,065</td>
<td>(17,944)</td>
<td>(905)</td>
</tr>
<tr>
<td>Total assets</td>
<td>252,596</td>
<td>193,984</td>
<td>101,078</td>
<td>161,685</td>
<td>8,213</td>
</tr>
<tr>
<td>Long-term debt, net of current maturities</td>
<td>150,000</td>
<td>36,866</td>
<td>15,834</td>
<td>10,395</td>
<td>3,133</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(457,116)</td>
<td>(308,111)</td>
<td>(220,317)</td>
<td>(107,052)</td>
<td>(79,987)</td>
</tr>
<tr>
<td>Total stockholders’ (deficit) equity</td>
<td>(49,802)</td>
<td>105,978</td>
<td>45,912</td>
<td>97,056</td>
<td>(3,177)</td>
</tr>
</tbody>
</table>

For the Years Ended December 31,

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Selected Statement of Cash Flows Data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net cash used in operating activities</td>
<td>$ (54,287)</td>
<td>$ (76,641)</td>
<td>$ (41,540)</td>
<td>$ (37,532)</td>
<td>$(18,392)</td>
</tr>
<tr>
<td>Net cash (used in) provided by investing activities</td>
<td>(36,135)</td>
<td>(1,386)</td>
<td>(2,154)</td>
<td>5,575</td>
<td>(357)</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>66,716</td>
<td>164,308</td>
<td>55,152</td>
<td>29,760</td>
<td>11,842</td>
</tr>
</tbody>
</table>
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

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

The discussion below contains “forward-looking statements,” as defined in Section 21E of the Securities Exchange Act of 1934, as amended, that reflect our current expectations regarding our future growth, results of operations, cash flows, performance and business prospects and opportunities, as well as assumptions made by, and information currently available to, our management. We have tried to identify forward-looking statements by using words such as “anticipate,” “believe,” “plan,” “expect,” “intend,” “will,” and similar expressions, but these words are not the exclusive means of identifying forward-looking statements. These statements are based on information currently available to us and are subject to various risks, uncertainties, and other factors, including, but not limited to, those matters discussed in Item 1A. “Risk Factors” in Part I of this Annual Report on Form 10-K, that could cause our actual growth, results of operations, cash flows, performance and business prospects and opportunities to differ materially from those expressed in, or implied by, these statements. Except as expressly required by the federal securities laws, we undertake no obligation to update such factors or to publicly announce the results of any of the forward-looking statements contained herein to reflect future events, developments, or changed circumstances, or for any other reason.

Overview

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

On April 23, 2011, the U.S. Food and Drug Administration, or FDA, approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis, or RA, osteoarthritis, or OA, and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. In the second half of 2011, we hired our initial commercial organization, including approximately 80 sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products. In the third quarter of 2012, we expanded our sales force to approximately 150 representatives, and have subsequently further expanded our sales force to approximately 290 representatives, most recently by adding approximately 115 representatives in connection with our acquisition of the U.S. rights to VIMOVO in November 2013. In March 2013, we announced that the United Kingdom, or UK, Medicines and Healthcare Products Regulatory Agency granted a National Marketing Authorization for DUEXIS in the UK. We will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded non-steroidal anti-inflammatory drugs, or NSAIDs, we do not expect a material level of sales from DUEXIS in European markets.
Our second approved product in the United States, RAYOS, known as LODOTRA outside the United States, is a proprietary delayed-release formulation of low-dose prednisone for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, polymyalgia rheumatic, or PMR, psoriatic arthritis, ankylosing spondylitis, or AS, asthma and chronic obstructive pulmonary disease and a number of other conditions. We are focusing our promotion of RAYOS in the United States on rheumatology indications, including RA and PMR. We began detailing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of U.S. rheumatologists and key primary care physicians. LODOTRA is currently marketed outside the United States by our distribution partner, Mundipharma International Corporation Limited, or Mundipharma.

On November 18, 2013, we entered into agreements with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs in the United States. VIMOVO (naproxen/esomeprazole magnesium) is a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, layer surrounding the core. VIMOVO was originally developed by Pozen Inc., or Pozen, together with AstraZeneca pursuant to an exclusive global collaboration and license agreement under which AstraZeneca and Pozen agreed to co-develop VIMOVO and AstraZeneca obtained exclusive rights to commercialize VIMOVO worldwide. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of OA, RA, and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

Under the asset purchase agreement with AstraZeneca, we acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the investigational new drug application and new drug application for VIMOVO in the United States, AstraZeneca’s interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. In addition, AstraZeneca assigned to us its amended and restated collaboration and license agreement for the United States with Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States.

In December 2013, as a result of the acquisition of the U.S. rights to VIMOVO, we began the expansion of our sales force to approximately 250 primary care representatives and 40 rheumatology sales specialists and recognized revenues under our transition agreement. We announced the availability of Horizon-labeled VIMOVO on January 2, 2014. We completed the hiring and training of our expanded sales force in January 2014 and began selling VIMOVO in early February 2014. Our primary care representatives will promote DUEXIS in a primary position to physician targets who are high branded NSAID prescribers and are also prescribers of DUEXIS and ibuprofen and they will promote VIMOVO in a second position among these target physicians. Our primary care representatives will promote VIMOVO in a primary position to physician targets who are high branded NSAID prescribers and are also prescribers of VIMOVO and naproxen and they will promote DUEXIS in a second position among these target physicians. Our analysis indicates that there is an approximate 30% overlap of physician targets who prescribe both DUEXIS and VIMOVO. In those cases, individual target-by-target promotional plans will be executed and both DUEXIS and VIMOVO will be promoted to these targets. We have also expanded our rheumatology specialty sales force from 25 sales specialists to approximately 40 sales specialists, with these specialist representatives promoting RAYOS and VIMOVO to rheumatologists. We have also included VIMOVO in our Prescriptions-Made-Easy specialty pharmacy program, along with DUEXIS and RAYOS, and offer co-pay assistance for all of our marketed products to ensure patients receive them at a reasonable out-of-pocket cost.
Critical Accounting Policies and Significant Judgments and Estimates

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

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

Revenue Recognition

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

Revenue from product deliveries

We recognize revenue from the delivery of our products when delivery has occurred, title has transferred, the selling price is fixed or determinable, the right of return no longer exists (which is the earlier of product being dispensed through patient prescriptions or the expiration of the right of return) or product returns can be reasonably estimated, collectability is reasonably assured, and we have no further performance obligations. Prior to October 2012, revenue for products sold in the United States to our wholesale pharmaceutical distributors and retail chains was recognized based on the amount of product sold through to the end consumer. Beginning in October 2012, due to our ability to reasonably estimate and determine allowances for product returns, rebates and discounts, we began to recognize DUEXIS and RAYOS revenue at the point of sale to the wholesale pharmaceutical distributors and retail chains. Beginning in 2014, we began to recognize VIMOVO revenue at the point of sale, consistent with our revenue recognition of DUEXIS and RAYOS, given the availability of prior VIMOVO product return data.

Revenue from upfront license fees

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

Revenue from milestone receipts

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

**DUEXIS, VIMOVO and RAYOS Product Sales Discounts and Allowances**

Prior to the fourth quarter of 2012, we recorded DUEXIS sales to wholesale pharmaceutical distributors and retail chains as deferred revenue. Allowances for product returns, rebates and discounts were also deferred at the time of sale to wholesale pharmaceutical distributors and national and regional retail chains. These deferred expenses were recognized to arrive at net product sales at the time the related revenue was recognized. In the fourth quarter of 2012, we began recognizing revenue at the point of sale to our wholesale pharmaceutical distributors and retail chains, at which point the associated allowances for product returns, rebates and allowances were also recognized. We are required to make significant judgments and estimates in determining some of these allowances. If actual results differ from our estimates, we will be required to make adjustments to these allowances in the future. Beginning in 2014, in connection with our marketing of VIMOVO in the United States, we will also recognize VIMOVO revenue at the point of sale to our wholesale pharmaceutical distributors and retail chains.

**Customer Discounts and Rebates**

**Product Launch Discounts**

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

**Customer Rebates**

We participate in certain commercial rebate programs. Under these rebate programs, we pay a rebate to the commercial entity or third-party administrator of the program. We accrue estimated rebates based on contract prices, estimated percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel and record the rebate as a reduction of revenue.

**Distribution Service Fees**

We include distribution service fees paid to our wholesalers for distribution and inventory management services as a reduction to revenue. The estimates are based on contractually determined fees, typically as a percentage of revenue.

**Government Rebates and Chargebacks**

**Government Rebates**

We participate in certain federal government rebate programs, such as Medicare and Medicaid. We accrue estimated rebates based on estimated percentages of product sold to qualified patients, estimated rebate percentages and estimated levels of inventory in the distribution channel that will be sold to qualified patients and record the rebate as a reduction of revenue.

**Government Chargebacks**

We provide discounts to federal government qualified entities with whom we have contracted. These federal entities purchase products from the wholesale pharmaceutical distributors at a discounted price, and the wholesale pharmaceutical distributors then charge back to us the difference between the current retail price and the contracted price that the federal entities paid for the product. We accrue estimated chargebacks based on contract prices and sell-through sales data obtained from third party information and record the chargeback as a reduction of revenue.
Co-Pay Assistance
We offer discount card programs to patients under which the patient receives a discount on his or her prescription. We reimburse pharmacies for this discount through a third-party vendor. We record the total amount of estimated discounts for sales recorded in the period as a reduction of revenue.

Returns and Prompt Pay Allowances
Sales Returns
Consistent with industry practice, we maintain a return policy that allows customers to return product within a specified period prior to and subsequent to the product expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date and up to one year after its expiration date. The right of return expires on the earlier of one year after the product expiration date or the time that the product is dispensed to the patient. The majority of our product returns are the result of product dating, which falls within the range set by our policy, and are settled through the issuance of a credit to the customer. Our estimate of the provision for returns is based upon our historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which our customer may return product. This period is known to us based on the shelf lives of our products at the time of shipment. We record sales returns as an allowance against accounts receivable and a reduction of revenue.

Prompt Pay Discounts
As an incentive for prompt payment, we offer a 2% cash discount to customers. We expect that all customers will comply with the contractual terms to earn the discount. We record the discount as an allowance against accounts receivable and a reduction of revenue.

The following table summarizes our customer-related accruals and allowances as of December 31, 2013 and 2012:

<table>
<thead>
<tr>
<th></th>
<th>Customer Discounts and Rebates</th>
<th>Co-Pay Assistance</th>
<th>Government Rebates and Chargebacks</th>
<th>Returns and Prompt Pay Allowances</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at December 31, 2011</td>
<td>$ 796</td>
<td>$ 4</td>
<td>$ 62</td>
<td>$ 170</td>
<td>$ 1,032</td>
</tr>
<tr>
<td>Current provisions relating to sales in current year</td>
<td>1,773</td>
<td>1,578</td>
<td>418</td>
<td>365</td>
<td>4,134</td>
</tr>
<tr>
<td>Adjustments relating to prior years</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Payments/returns relating to sales in current year</td>
<td>(757)</td>
<td>(1,160)</td>
<td>(159)</td>
<td>(419)</td>
<td>(2,495)</td>
</tr>
<tr>
<td>Payments/returns relating to sales in prior years</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(39)</td>
<td>(39)</td>
</tr>
<tr>
<td>Balance at December 31, 2012</td>
<td>$ 1,812</td>
<td>$ 422</td>
<td>$ 321</td>
<td>$ 77</td>
<td>$ 2,632</td>
</tr>
<tr>
<td>Current provisions relating to sales in current year</td>
<td>8,191</td>
<td>13,609</td>
<td>3,909</td>
<td>3,270</td>
<td>28,979</td>
</tr>
<tr>
<td>Adjustments relating to prior years</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Payments/returns relating to sales in current year</td>
<td>(4,781)</td>
<td>(11,641)</td>
<td>(2,785)</td>
<td>(2,723)</td>
<td>(21,930)</td>
</tr>
<tr>
<td>Payments/returns relating to sales in prior years</td>
<td>(763)</td>
<td>(132)</td>
<td>(38)</td>
<td>(193)</td>
<td>(1,126)</td>
</tr>
<tr>
<td>Balance at December 31, 2013</td>
<td>$ 4,459</td>
<td>$ 2,258</td>
<td>$ 1,407</td>
<td>$ 431</td>
<td>$ 8,555</td>
</tr>
</tbody>
</table>
Cost of Goods Sold

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

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

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

Cost of goods sold for VIMOVO in the fourth quarter of 2013, following our acquisition in November 2013 of certain assets and rights necessary to commercialize VIMOVO in the United States, includes only intangible amortization expense. Beginning in 2014, in connection with our marketing of VIMOVO in the United States, cost of goods sold for VIMOVO will include all costs directly related to the acquisition of product from AstraZeneca and/or the third-party manufacturer.

Inventories

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

Intangible Assets

Our intangible assets consist of developed technology related to three of our approved products: LODOTRA outside the United States, RAYOS in the United States and intellectual property rights related to our acquisition of the U.S. rights to VIMOVO. We amortize LODOTRA and RAYOS intangible assets over twelve years, which is the estimated useful life of the underlying patents, and we amortize the U.S. intellectual property rights of the VIMOVO intangible asset over 61.5 months. We review our intangible assets when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. We measure fair value based on the estimated future discounted cash flows associated with our assets in addition to other assumptions and projections that we deem to be reasonable and supportable.

Fair Value of Financial Instruments

The carrying amounts of our financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities. The estimated fair value of our derivative liability related to the convertible portion of our 5.00% Convertible Senior Notes due 2018, or the Convertible Senior Notes, was derived utilizing the binomial lattice approach for the valuation of convertible instruments. Assumptions used in the calculation included, among others, determining the appropriate credit spread using benchmarking analysis and solving for the implied
credit spread, calculating the fair value of the stock component using a discounted risk free rate and borrowing cost and calculating the fair value of the note component using a discounted credit adjusted discount rate. Based on the assumptions used to determine the fair value of the derivative liability associated with the Convertible Senior Notes, we concluded that these inputs were Level 3 inputs. We will continue to derive the fair value of the derivative liability using the binomial lattice approach and these assumptions in all future reporting periods.

Provision for Income Taxes

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

Stock-Based Compensation

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

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

Year Ended December 31, 2013 Compared to Year Ended December 31, 2012

<table>
<thead>
<tr>
<th></th>
<th>For the Years Ended December 31, 2013</th>
<th>2012 (Revised)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gross sales</strong></td>
<td>$102,995</td>
<td>$22,978</td>
</tr>
<tr>
<td>Sales discounts and allowances (1)</td>
<td>(28,979)</td>
<td>(4,134)</td>
</tr>
<tr>
<td><strong>Net sales</strong></td>
<td>74,016</td>
<td>18,844</td>
</tr>
<tr>
<td><strong>Cost of goods sold (1)</strong></td>
<td>14,625</td>
<td>11,875</td>
</tr>
<tr>
<td><strong>Gross profit</strong></td>
<td>59,391</td>
<td>6,969</td>
</tr>
<tr>
<td>Operating expenses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>10,084</td>
<td>16,837</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>68,595</td>
<td>49,561</td>
</tr>
<tr>
<td>General and administrative</td>
<td>23,566</td>
<td>19,444</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td>102,245</td>
<td>85,842</td>
</tr>
<tr>
<td><strong>Operating loss</strong></td>
<td>(42,854)</td>
<td>(78,873)</td>
</tr>
<tr>
<td>Other income (expense)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(39,178)</td>
<td>(14,525)</td>
</tr>
<tr>
<td>Foreign exchange gain</td>
<td>1,206</td>
<td>489</td>
</tr>
<tr>
<td>Loss on derivative revaluation</td>
<td>(69,300)</td>
<td>—</td>
</tr>
<tr>
<td>Other expense</td>
<td>—</td>
<td>(56)</td>
</tr>
<tr>
<td><strong>Total other expense, net</strong></td>
<td>(107,272)</td>
<td>(14,092)</td>
</tr>
<tr>
<td><strong>Loss before benefit for income taxes</strong></td>
<td>(150,126)</td>
<td>(92,965)</td>
</tr>
<tr>
<td><strong>Benefit for income taxes</strong></td>
<td>(1,121)</td>
<td>(5,171)</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>$(149,005)</td>
<td>$(87,794)</td>
</tr>
</tbody>
</table>

(1) For the year ended December 31, 2012, the reported amount for sales discounts and allowances has been revised from $(3.3) million to $(4.1) million, the reported amount for net sales has been revised from $19.6 million to $18.8 million, and the reported amount for cost of goods sold has been revised from $12.7 million to $11.9 million, reflecting reclassification of wholesaler service fees from cost of goods sold to sales discounts and allowances. See Note 1 “The Company” in our consolidated financial statements included in this Annual Report on Form 10-K.

**Sales.** During the year ended December 31, 2013, gross and net sales were $103.0 million and $74.0 million, respectively, compared to $23.0 million and $18.8 million, respectively, during the year ended December 31, 2012. DUEXIS gross and net sales during the year ended December 31, 2013 were $85.5 million and $59.0 million, respectively, after deducting sales discounts and allowances of $26.5 million, including co-pay assistance costs of $12.8 million, compared to gross and net sales of $13.2 million and $10.3 million, respectively, during the year ended December 31, 2012. The increase in DUEXIS sales during the year ended December 31, 2013 compared to the prior year was primarily the result of product price increases implemented during the course of 2013 and increased volume driven by the expansion of our sales force.

RAYOS gross and net sales were $7.8 million and $5.8 million, respectively, during the year ended December 31, 2013 after deducting sales discounts and allowances of $2.0 million, including co-pay assistance costs of $0.8 million, compared to gross and net sales of $0.8 million and $0.3 million, respectively, during the year ended December 31, 2012. The increase in RAYOS sales during the year ended December 31, 2013 compared to the prior year was primarily attributable to the inclusion of a full year of sales during the year ended December 31, 2013 following the RAYOS launch in December 2012.
LODOTRA gross and net sales during the year ended December 31, 2013 were $8.7 million and $8.2 million, respectively, after deducting trade allowances of $0.5 million, compared to gross and net sales of $9.0 million and $8.2 million, respectively, during the year ended December 31, 2012. The decrease in LODOTRA sales during the year ended December 31, 2013 compared to the prior year was the result of lower product shipments to our European distribution partner, Mundipharma, partially offset by an increase in the recognition of deferred revenues related to product previously shipped and invoiced to Mundipharma at contract minimum prices and where the contractual price adjustment period has passed. LODOTRA sales to Mundipharma occur at the time we ship product to Mundipharma based on its estimated requirements. Accordingly, LODOTRA sales are not linear or tied to Mundipharma sales to the market and can therefore fluctuate from year to year.

VIMOVO net sales during the year ended December 31, 2013 were $1.0 million and represented net profits paid to us by AstraZeneca in the fourth quarter of 2013 under a transition services agreement in connection with our acquisition of certain assets and commercial rights to VIMOVO in the United States on November 18, 2013.

Sales discounts and allowances. During the year ended December 31, 2013, sales discounts and allowances were $29.0 million compared to $4.1 million during the year ended December 31, 2012. As a percentage of gross product sales, sales discounts and allowances increased to 28% during the year ended December 31, 2013 compared to 18% during the year ended December 31, 2012. The increase in sales discounts and allowances was attributable to a significant increase in product sales during the year ended December 31, 2013, which resulted in a corresponding increase in customer discounts and rebates, including distribution service fees and prompt pay allowances. Co-pay assistance costs increased $12.0 million during the year ended December 31, 2013 compared to the prior year as a result of a larger number of prescriptions being filled by patients and product price increases implemented during the course of 2013, which resulted in us increasing the amount of co-pay assistance we would provide to a patient. The following table presents our sales discounts and allowances for the years ended December 31, 2013 and 2012:

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

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

Cost of Goods Sold. Cost of goods sold increased $2.7 million to $14.6 million during the year ended December 31, 2013, from $11.9 million during the year ended December 31, 2012. The increase in cost of goods sold was primarily attributable to a $3.4 million increase in intangible amortization expense. The increase in amortization expense was related to the FDA approval of RAYOS in July 2012, which resulted in the reclassification and subsequent amortization of an indefinite-lived intangible asset to a finite-lived intangible asset, which resulted in additional intangible amortization expense of $2.0 million during the year ended December 31, 2013 as a result of a full year of amortization as compared to 2012. Additionally, as a result of our asset purchase agreement with AstraZeneca, we capitalized $67.7 million in intangible assets related to the VIMOVO intellectual property rights. This intangible asset will be amortized using a straight-line method over its estimated useful life of 61.5 months. During the year ended December 31, 2013, we recorded $1.4 million in intangible amortization expense related to the intellectual property acquired in connection with our acquisition of the U.S. rights to VIMOVO. For the years ended December 31, 2013 and 2012, intangible amortization expense accounted for 56% and 40%, respectively, of total cost of goods sold.
Research and Development Expenses. Research and development expenses during the year ended December 31, 2013 were $10.1 million, a decrease of $6.7 million compared to research and development expenses of $16.8 million during the year ended December 31, 2012. The decrease in research and development expenses during the year ended December 31, 2013 was primarily associated with the classification of $5.0 million in medical affairs expenses to sales and marketing expenses, a $0.9 million reduction in consulting fees and a $0.8 million decrease in regulatory and clinical trial expenses. During the first quarter of 2013, in connection with the full commercial launch of RAYOS, we began to classify our medical affairs expenses, which now consist of expenses related to scientific publications, health outcomes, biostatistics, medical education and information, and medical communications, as sales and marketing expenses. Prior to the full commercial launch of RAYOS in late January 2013, medical affairs expenses were classified as part of research and development expenses.

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

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

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

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

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

Income Tax Benefit. Income tax benefit was $1.1 million during the year ended December 31, 2013, a decrease of $4.1 million compared to an income tax benefit of $5.2 million during the year ended December 31, 2012. The decrease in income benefit during the year ended December 31, 2013 was primarily attributable to the absence of a one-time tax benefit which was recorded during the year ended December 31, 2012. On July 26, 2012, the FDA approved RAYOS, which resulted in the reclassification of the entire asset balance of $35.5 million, from an indefinite-lived intangible asset to a finite-lived intangible asset. The reclassification from an indefinite-lived intangible asset to a finite-lived intangible asset required us to amortize this asset over the useful life of 90 years.
life of the asset, which resulted in a corresponding reduction to our net deferred tax liabilities and the recognition of a one-time net income tax benefit of $4.3 million that was recorded during the third quarter of 2012.

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

<table>
<thead>
<tr>
<th></th>
<th>For the Years Ended December 31,</th>
<th>Increase/ (Decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2012 (Revised)</td>
<td>2011</td>
</tr>
<tr>
<td><strong>Gross sales</strong></td>
<td>$22,978</td>
<td>$6,939</td>
</tr>
<tr>
<td>Sales discounts and allowances (1)</td>
<td>(4,134)</td>
<td>(12)</td>
</tr>
<tr>
<td><strong>Net sales</strong></td>
<td>18,844</td>
<td>6,927</td>
</tr>
<tr>
<td><strong>Cost of goods sold</strong> (1)</td>
<td>11,875</td>
<td>7,267</td>
</tr>
<tr>
<td><strong>Gross profit (loss)</strong></td>
<td>6,969</td>
<td>(340)</td>
</tr>
<tr>
<td><strong>Operating expenses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>16,837</td>
<td>15,358</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>49,561</td>
<td>20,314</td>
</tr>
<tr>
<td>General and administrative</td>
<td>19,444</td>
<td>15,008</td>
</tr>
<tr>
<td>Intangible impairment charge</td>
<td>—</td>
<td>69,621</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td>85,842</td>
<td>120,301</td>
</tr>
<tr>
<td><strong>Operating loss</strong></td>
<td>(78,873)</td>
<td>(120,641)</td>
</tr>
<tr>
<td><strong>Other income (expense)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(14,525)</td>
<td>(6,284)</td>
</tr>
<tr>
<td>Foreign exchange gain (loss)</td>
<td>489</td>
<td>(1,023)</td>
</tr>
<tr>
<td>Other expense</td>
<td>(56)</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total other expense, net</strong></td>
<td>(14,092)</td>
<td>(7,307)</td>
</tr>
<tr>
<td><strong>Loss before benefit for income taxes</strong></td>
<td>(92,965)</td>
<td>(127,948)</td>
</tr>
<tr>
<td><strong>Benefit for income taxes</strong></td>
<td>(5,171)</td>
<td>(14,683)</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>$(87,794)</td>
<td>$(113,265)</td>
</tr>
</tbody>
</table>

(1) For the year ended December 31, 2012, the reported amount for sales discounts and allowances has been revised from ($3.3) million to ($4.1) million, the reported amount for net sales has been revised from $19.6 million to $18.8 million, and the reported amount for cost of goods sold has been revised from $12.7 million to $11.9 million, reflecting reclassification of wholesaler service fees from cost of goods sold to sales discounts and allowances. See Note 1 “The Company” in the notes to our consolidated financial statements included in this Annual Report on Form 10-K.

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

DUEXIS gross sales were $13.2 million during the year ended December 31, 2012, an increase of $13.1 million compared to gross sales of $0.1 million during the year ended December 31, 2011. Net sales of DUEXIS during the year ended December 31, 2012 were $10.3 million, an increase of $10.2 million compared to net sales of $0.1 million during the year ended December 31, 2011. The increase in DUEXIS sales was attributable to the inclusion of a full year of sales during the year ended December 31, 2012 compared to initial launch product sales in the prior year. In addition, during the fourth quarter of 2012, as a result of a change in timing of DUEXIS revenue recognition to when product is sold into the wholesale and pharmacy channel instead of when product is dispensed through patient prescriptions, we recognized gross and net DUEXIS sales of $1.8 million and $1.4 million, respectively, that were previously deferred.
LODOTRA gross sales during the year ended December 31, 2012 were $9.0 million, an increase of $2.2 million compared to gross sales of $6.8 million during the year ended December 31, 2011. Net sales of LODOTRA during the year ended December 31, 2012 were $8.2 million, an increase of $1.4 million compared to net sales of $6.8 million during the year ended December 31, 2011. The increase in LODOTRA sales was attributable to higher product shipments in 2012 in addition to a higher recognition of deferred revenues associated with product sales in prior periods to our distribution partner, Mundipharma.

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

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

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

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

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

Sales and Marketing Expenses. Sales and marketing expenses during the year ended December 31, 2012 were $49.5 million, an increase of $29.2 million compared to $20.3 million during the year ended December 31, 2011. The increase in sales and marketing expenses was primarily attributable to salaries and related expenses for
the full year for our initial 80 field sales representatives hired during the second half of 2011, incremental salaries and related expenses associated with increasing our field sales organization during the course of 2012 to approximately 150 sales representatives, salaries and related expenses associated with staffing the sales support functions to support a 150-person field sales force and an increase in marketing related expenses to launch and commercialize DUEXIS and RAYOS in the U.S. During the year ended December 31, 2012, personnel related costs increased approximately $17.5 million as a result of staffing our sales and marketing organization, expenses associated with marketing efforts for DUEXIS and RAYOS increased $9.0 million, consulting and outside service costs increased $1.9 million and other sales and marketing expenses increased $1.0 million.

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

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

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

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

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

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

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

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

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

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

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

On November 18, 2013, we entered into note purchase agreements with investors to issue $150.0 million aggregate principal amount of Convertible Senior Notes. The note purchase agreements contain customary
representations, warranties, covenants and closing conditions. The Convertible Senior Notes were issued on November 22, 2013. We received net proceeds of $124.9 million from the sale of the Convertible Senior Notes, after deducting fees and expenses of approximately $6.4 million and $18.7 million related to a capped call transaction. The Convertible Senior Notes are governed by an Indenture, dated as of November 22, 2013, between us and U.S. Bank National Association, as trustee. The Convertible Senior Notes bear interest at a rate of 5.00% per year, payable in arrears on May 15 and November 15 of each year, beginning on May 15, 2014. The Convertible Senior Notes will mature on November 15, 2018, unless earlier repurchased or converted. The Convertible Senior Notes were sold at a price equal to 100% of the principal amount thereof and are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding August 15, 2018 only under certain conditions. On or after August 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date for the Convertible Senior Notes, holders will be able to convert their Convertible Senior Notes at their option at the conversion rate then in effect at any time, regardless of these conditions. Subject to certain limitations, we may settle conversions of the Convertible Senior Notes by paying or delivering, as the case may be, cash, shares of common stock or a combination of cash and shares of our common stock, at our election. If we undergo a fundamental change prior to the maturity date of the Convertible Senior Notes, the holders may require us to repurchase for cash all or any portion of their Convertible Senior Notes at a price equal to 100% of the principal amount of the Convertible Senior Notes to be repurchased, plus accrued and unpaid interest.

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

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

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

In August 2012, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may sell common stock in at-the-market, or ATM, offerings under our registration statement on Form S-3, which became effective on August 9, 2012. Subject to the terms and conditions of the sales agreement, Cowen will use its commercially reasonable efforts to sell on our behalf any shares of common stock requested to be sold by us, Cowen and we each have the right, by giving written notice as specified in the sales agreement, to terminate the sales agreement in each party’s sole discretion at any time. The aggregate compensation payable...
to Cowen as sales agent will not exceed 3.0% of the gross sales price of the shares sold through it pursuant to the sales agreement. On March 25, 2013, we requested that Cowen begin to make sales under the sales agreement and provided them both daily volume and minimum price restrictions under which they could sell our common stock. Cowen has not sold shares under the ATM since July 2013 and as of December 31, 2013, Cowen had sold a cumulative total of 2,448,575 shares of our common stock with gross proceeds to us of $6.2 million.

We are required to maintain compliance with applicable Swiss laws with respect to our Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. We review on a regular basis whether our Swiss subsidiary is overindebted. As of December 31, 2013, our Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. We will continue to monitor and review steps to address any overindebtedness until such time as our Swiss subsidiary may generate positive income at a statutory level, which could require us to have cash at our Swiss subsidiary in excess of its near term operating needs and could affect our ability to have sufficient cash at our U.S. subsidiary to meet its near term operating needs. As of December 31, 2013, Horizon Pharma AG had $3.5 million in cash and cash equivalents. Based upon the cash and cash equivalents held by our Swiss subsidiary as of December 31, 2013 and its level of overindebtedness at such time, we do not expect that our financial position or results of operations will be materially affected by any need to address overindebtedness at our Swiss subsidiary. To date, the overindebtedness of our Swiss subsidiary has not resulted in the need to divert material cash resources from our U.S. subsidiary.

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

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

Net Cash Used in Operating Activities

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

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

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

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

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

Net Cash Provided by Financing Activities

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

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

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

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

<table>
<thead>
<tr>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Convertible Senior Notes (1)</td>
<td>$7,372</td>
<td>$7,500</td>
<td>$7,500</td>
<td>$7,500</td>
<td>$157,500</td>
<td>$—</td>
<td>$187,372</td>
</tr>
<tr>
<td>Purchase commitments (2)(3)(4)</td>
<td>12,174</td>
<td>1,151</td>
<td>1,117</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>14,442</td>
</tr>
<tr>
<td>Operating lease obligations (5)</td>
<td>681</td>
<td>662</td>
<td>624</td>
<td>623</td>
<td>341</td>
<td>—</td>
<td>2,931</td>
</tr>
<tr>
<td>Total contractual cash obligations</td>
<td>$20,227</td>
<td>$9,313</td>
<td>$9,241</td>
<td>$8,123</td>
<td>$157,841</td>
<td>$—</td>
<td>$204,745</td>
</tr>
</tbody>
</table>

(1) Represents the minimum contractual obligation due under our $150,000 Convertible Senior Notes, which includes quarterly interest payments beginning in May 2014 and repayment of the Convertible Senior Notes principal in November 2018.

(2) Minimum purchase commitment for RAYOS/LODOTRA tablets from Jagotec through December 31, 2016 (the end of the minimum term), which is the firm commitment term under the contract.

(3) Purchase commitment of $6,614 for final packaged DUEXIS tablets from sanofi-aventis U.S. through February 2014.

(4) Minimum purchase commitment for VIMOVO tablets from AstraZeneca through July 2014.

(5) These amounts reflect payments due under the following operating leases:

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

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

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

Off-Balance Sheet Arrangements

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to various market risks, which include potential losses arising from adverse changes in market rates and prices, such as interest rates and foreign exchange fluctuations. We do not enter into derivatives or other financial instruments for trading or speculative purposes.
Interest Rate Risk. We are subject to interest rate fluctuation exposure through our investment in money market accounts which bear a variable interest rate. The goals of our investment policy are associated with the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market risk, we maintain our excess cash and cash equivalents in money market funds. Because of the short-term maturities of our cash equivalents, we do not believe that a decrease in interest rates would have any material negative impact on the fair value of our cash equivalents.

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

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

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

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

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

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

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

Changes in Internal Control Over Financial Reporting

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

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

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

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

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Directors

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

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

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

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

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

Ronald Pauli. Mr. Pauli has served on our board of directors since September 2011. Mr. Pauli is currently a financial consultant for the pharmaceutical and life science industries. Prior to that, Mr. Pauli held senior positions at a number of biopharmaceutical companies, including chief financial officer at Sagent Pharmaceuticals, Inc. and NeoPharm, Inc. and corporate controller and interim chief financial officer at Abraxis BioScience, Inc. (formerly American Pharmaceutical Partners, Inc.). In addition, Mr. Pauli previously served as corporate controller for Applied Power, Inc. and R.P. Scherer Corporation, held multiple finance positions at Kmart Corporation and began his career at Ernst & Whinney. Mr. Pauli received a B.S. in accounting from Michigan State University and a master's degree in finance from Walsh College. Our board believes that Mr. Pauli’s financial experience at numerous biotechnology and pharmaceutical companies will add valuable expertise in guiding the strategic direction of the company and working with the investment community.
Gino Santini. Mr. Santini has served on our board of directors since March 2012. Mr. Santini currently serves on the boards of directors of AMAG Pharmaceuticals, Inc. and Allena Pharmaceuticals, Inc. Mr. Santini is currently retired from a distinguished career with Eli Lilly and Company that spanned nearly three decades. During his tenure at Lilly, Mr. Santini held various leadership positions of increasing responsibility, including manager of various international regions, president of the women’s health franchise and president of U.S. operations. Mr. Santini capped his career at Lilly as a member of the company’s executive committee and as the senior vice president of corporate strategy and business development. Mr. Santini, fluent in four languages, holds an undergraduate degree in mechanical engineering from the University of Bologna and a master’s in business administration from the University of Rochester. Our board believes that Mr. Santini’s extensive international and domestic commercial and business development experience will bring important insight to our board as we plan Horizon’s future growth.

Executive Officers (other than Mr. Walbert)

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

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

Jeffrey W. Sherman, M.D., FACP. Dr. Sherman has served as our executive vice president, development, manufacturing and regulatory affairs and chief medical officer since June 2011, as our executive vice president, development and regulatory affairs and chief medical officer since our inception in March 2010 and as the executive vice president, development and regulatory affairs and chief medical officer of Horizon Pharma USA since June 2009. From June 2009 to June 2010, Dr. Sherman served as president and board member of the Drug Information Association, or DIA, a nonprofit professional association of members who work in government regulatory, academia, patient advocacy, and the pharmaceutical and medical device industry. Dr. Sherman is now a past president of DIA and serves as DIA liaison to the Clinical Trial Transformation Initiative, a public-private partnership founded by the FDA and Duke University to improve the quality and efficiency of clinical trials. He also serves on the Board of Advisors of the Center for Information and Study on Clinical Research Participation, a nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process. Dr. Sherman is an adjunct assistant professor of Medicine at the Northwestern University Feinberg School of Medicine and is a member of a number of professional societies as well as a diplomat of the National Board of Medical Examiners and the American Board of Internal Medicine. From August 2007 to June 2009, Dr. Sherman served as senior vice president of research and development and chief medical officer at IDM which was acquired by Takeda in 2009. From June 2007 to August 2007, Dr. Sherman served as vice president of clinical science at Takeda, a pharmaceutical research and development center. From September 2000 to June 2007,
Dr. Sherman served as chief medical officer and executive vice president at NeoPharm, Inc., a biopharmaceutical company. From October 1992 to August 2000, Dr. Sherman served as director, senior director and executive director of clinical research and head of oncology global medical operations at Searle/Pharmacia, or Searle, a pharmaceutical company. Prior to joining Searle, Dr. Sherman worked in clinical pharmacology and clinical research at Bristol-Myers Squibb Company, a biopharmaceutical company. Dr. Sherman received his M.D. from the Rosalind Franklin University/Chicago Medical School. Dr. Sherman completed an internal medicine internship, residency and chief medical residency at Northwestern University as well as fellowship training at the University of California, San Francisco, or UCSF. Dr. Sherman was also a research associate at the Howard Hughes Medical Institute at UCSF.

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

Board Composition

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

- Class I, which consists of Mr. Grey and Mr. Pauli, and whose term will expire at our 2015 annual meeting of stockholders;
- Class II, which consists of Dr. Formela and Dr. Himawan, and whose term will expire at our 2016 annual meeting of stockholders; and
- Class III, which consists of Dr. Bird, Mr. Santini and Mr. Walbert, and whose term will expire at our 2014 annual meeting of stockholders.

At each annual meeting of stockholders, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% of our voting stock.
Director Independence
Our board of directors has reviewed the materiality of any relationship that each of our directors has with us, either directly or indirectly. Based on this review, our board has determined that, with the exception of Mr. Walbert, all of the directors are “independent directors” as defined by Rule 5605(a)(2) of the NASDAQ Listing Rules.

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

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

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

- evaluating the performance, independence and qualifications of our independent registered public accounting firm and determining whether to retain our existing independent registered public accounting firm or engage a new independent registered public accounting firm;
- reviewing and approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent registered public accounting firm on our engagement team as required by law;
- reviewing our annual and quarterly financial statements and reports and discussing the statements and reports with our independent registered public accounting firm and management;
- reviewing with our independent registered public accounting firm and management significant issues that arise regarding accounting principles and financial statement presentation, and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
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• preparing the report that the SEC requires in our annual proxy statement;
• reviewing and providing oversight with respect to any related party transactions and monitoring compliance with our code of business conduct and ethics;
• reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;
• reviewing our investment policy on a periodic basis; and
• reviewing and evaluating, at least annually, the performance of the audit committee, including compliance of the audit committee with its charter.

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

Compensation Committee

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

• reviewing and recommending to our board of directors the compensation and other terms of employment of our executive officers;
• reviewing and recommending to our board of directors performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
• evaluating and approving the equity incentive plans, compensation plans and similar programs advisable for us, as well as modification or termination of existing plans and programs;
• evaluating and recommending to our board of directors the type and amount of compensation to be paid or awarded to non-employee board members;
• administering our equity incentive plans;
• establishing policies with respect to equity compensation arrangements;
• reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
• reviewing and recommending to our board of directors the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
• reviewing with management our disclosures under the caption “Compensation Discussion and Analysis” and recommending to the full board its inclusion in our periodic reports to be filed with the SEC;
• preparing the report that the SEC requires in our annual proxy statement;
• reviewing the adequacy of our compensation committee charter on a periodic basis;
reviewing and evaluating, at least annually, the performance of the compensation committee; and

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

Business Development Committee

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

• reviewing proposed product or business acquisitions, licensing, distribution, promotion, collaboration and other commercial agreements and arrangements, joint ventures, and any other business development transactions;
• monitoring negotiations and other communications with third parties in connection with potential business development transactions;
• considering historical and current information regarding our business, prospects, financial condition, operations, capabilities, products, management, advisors, competitive position and industry, and how these factors may affect business development opportunities;
• considering general economic, industry and financial market conditions and trends, and how these factors may affect business development opportunities;
• meeting with management to identify and develop board focus on issues that will further our business development strategy; and
• periodically reviewing and evaluating prior transactions for consistency with, and achievement of, our strategic business goals, objectives or plans.

Nominating and Corporate Governance Committee

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

• identifying, reviewing and evaluating candidates to serve on our board of directors;
• determining the minimum qualifications for service on our board of directors;
• evaluating director performance on the board and applicable committees of the board;
• considering nominations by stockholders of candidates for election to our board;
• considering and assessing the independence of members of our board of directors;
• developing, as appropriate, a set of corporate governance principles, and reviewing and recommending to our board of directors any changes to such principles;
• periodically reviewing our policy statements to determine their adherence to our code of business conduct and ethics and considering any request by our directors or executive officers for a waiver from such code;
• reviewing the adequacy of its charter on an annual basis; and
• evaluating, at least annually, the performance of the nominating and corporate governance committee.
Section 16(a) Beneficial Ownership Reporting Compliance

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

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

Code of Ethics

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

Item 11. Executive Compensation

Compensation Discussion and Analysis

Overview

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

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

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

• Total stockholder return of 227%.
• Total annual net revenues increased from $18.8 to $74.0.
• Total prescriptions for DUEXIS® increased 128% over 2012 to 214,690.
• Total prescriptions for RAYOS® were 8,987 in its first full year of launch.
• Executed the initial launch of RAYOS®.
• We completed the acquisition of the U.S. rights to VIMOVO from AstraZeneca.
• Our cash and cash equivalents at December 31, 2013 were approximately $80.5 million.

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

• No Guaranteed Salary Increases or Bonus Awards. We do not provide our named executive officers with guaranteed salary increases or bonuses. Our named executive officers are employed at-will and are expected to demonstrate strong performance in order to continue serving as members of the executive team.
• No Excessive Perquisites. We do not provide personal lifestyle perquisites, such as country club memberships, vacation units, personal use of aircraft, personal entertainment accounts, or similar perquisites, nor have we provided tax-gross ups for any executive perquisites.
• Responsible Severance and Change in Control Compensation. Our executive employment agreements and our Severance Benefit Plan, in all cases require an involuntary or constructive termination of employment for our named executive officers to be eligible for any non-change of control related severance benefits or change of control related severance benefits. The severance benefits are less than two times the annual base salary of our named executive officers, other than for our chief executive officer, who as a result of changes approved by our board of directors in January 2014 would receive in a change in control related termination two times the sum of his annual base salary and target bonus, plus twelve months of COBRA premiums. We do not provide any tax gross-ups for any severance or change in control benefits.

Compensation Objectives
We believe in providing a competitive total compensation package to our executive management team through a combination of base salary, discretionary annual bonuses, grants under our equity incentive compensation plan and severance and change in control benefits. Our executive compensation programs are designed to achieve the following objectives:

• attract and retain talented and experienced executives to manage our business to meet our long-term objectives;
• motivate and reward executives whose knowledge, skills and performance are critical to our success;
• align the interests of our executive officers and stockholders by motivating executive officers to achieve performance objectives that will increase stockholder value;
• provide a competitive compensation package in which total compensation is determined in part by market factors, key performance objectives and milestones and the achievement level of these performance objectives and milestones by our executive officers; and
• reward the achievement of key corporate and individual performance measures.
Our compensation committee believes that our executive compensation programs should include short- and long-term performance incentive components, including cash and equity-based compensation, and should reward consistent performance that meets or exceeds expectations by increasing base salary levels, awarding cash bonuses and granting additional equity awards, as appropriate. The compensation committee evaluates both performance and compensation to make sure that the total compensation provided to our executives remains competitive relative to compensation paid by companies of similar size, geographic location and stage of development operating in the life sciences industries, taking into account our relative performance and our own strategic objectives.

**Setting Executive Compensation**

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

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

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

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

<table>
<thead>
<tr>
<th>Peer Group</th>
<th>Peer Group</th>
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<tbody>
<tr>
<td>Acorda Therapeutics</td>
<td>Neurocrine Biosciences</td>
</tr>
<tr>
<td>AMAG Pharmaceuticals</td>
<td>Orexigen Therapeutics</td>
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<tr>
<td>Antares Pharma</td>
<td>Pacira Pharmaceuticals</td>
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<tr>
<td>Arena Pharmaceuticals</td>
<td>Progenics Pharmaceutical</td>
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<tr>
<td>Auxillium Pharma</td>
<td>Sangamo Biosciences</td>
</tr>
<tr>
<td>Avanir Pharmaceuticals</td>
<td>Spectrum Pharmaceuticals</td>
</tr>
<tr>
<td>BioDelivery Sciences</td>
<td>Sucampo Pharmaceuticals</td>
</tr>
<tr>
<td>Cadence Pharmaceuticals</td>
<td>Supernus Pharmaceuticals</td>
</tr>
<tr>
<td>Corcept Therapeutics</td>
<td>Synta Pharmaceuticals</td>
</tr>
<tr>
<td>Depomed</td>
<td>Vanda Pharmaceuticals</td>
</tr>
<tr>
<td>Dyax</td>
<td>VIVUS</td>
</tr>
<tr>
<td>INSYS Therapeutics</td>
<td>Zogenix</td>
</tr>
<tr>
<td>Ironwood Pharmaceuticals</td>
<td></td>
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</tbody>
</table>
Compensia Inc. was engaged in 2013 to analyze and present competitive ongoing market base salaries, discretionary annual bonuses, and long-term incentive grant practices provided by these peer group companies with respect to their employees, including executive management.

Benchmarking

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

Independence of Compensation Consultant

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

Role of Chief Executive Officer in Compensation Decisions

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

Elements of Executive Compensation

The compensation program for our executive officers consists principally of base salary, annual cash incentive compensation and long-term compensation in the form of equity awards, as well as severance protection for certain of our executive officers through employment agreements with those executive officers and
our Severance Benefit Plan. As discussed in more detail below, base salary is based primarily on market factors and annual cash incentive compensation is a target percentage of base salary, with the actual amount awarded determined in the compensation committee’s discretion based upon its determination of the level of attainment of performance goals. The amount of cash compensation and the amount of equity awards granted to our executives are both considered in determining total compensation for our executive officers.

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

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

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

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

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

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

In December 2013, our compensation committee recommended increases to the base salaries for our executive officers, effective January 1, 2014, after a review of the 2013 Radford Global Life Sciences survey data for comparable companies and executive officer positions, executive officer salaries at the peer group companies, and individual and company performance. The compensation committee recommended and the board approved a 3.0% increase to the annual base salary of Mr. De Vaere, Dr. Sherman and Mr. Smith, and a 9.3% increase for Mr. Walbert. These increases were approved in order to align their base salaries with the 75% percentile of the peer group companies because our board of directors determined that our named executive officers should be rewarded for our above target performance during 2013 and their individual efforts in contributing to such performance.
The base salaries for each of our named executive officers for 2014, 2013 and 2012 are as follows:

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

(1) Mr. Carey began employment with us on March 5, 2014.
(2) Mr. Adatto terminated employment with us on June 17, 2013.

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

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

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

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

Actual bonus award levels are determined at the compensation committee’s discretion and recommended to the board of directors for approval. At the close of the applicable calendar year, the compensation committee reviews the performance of the executive officers even if the specified corporate performance goals are not met, in recognition of the officer’s efforts throughout the year in meeting other objectives not contemplated at the beginning of the performance period. In making the final recommendation on the amount of bonuses earned, if any, the compensation committee considers the review of the year-end corporate results as well as the performance of the individual executive officers. In sum, the amount of variable compensation that is actually
earned by our named executive officers is a subjective, entirely discretionary, determination made by the compensation committee without the use of pre-determined formulas. The compensation committee believes that maintaining discretion to evaluate our and the executive’s performance at the close of the year based on the totality of the circumstances, and to recommend or fail to recommend bonus compensation without reliance on rote calculations under set formulas, is appropriate in responsibly discharging its duties. Payouts of awarded bonuses, if any, are generally made in the year following the year of performance.

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

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

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

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

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

2014 Cash Incentive Compensation. In December 2013, our compensation committee recommended changes to the target cash bonuses for our executive officers, effective for 2014, after a review of the 2013 Radford Global Life Sciences survey data for comparable companies and executive officer positions, and after reviewing executive officer cash incentive compensation at the peer group companies. The compensation committee recommended and the board of directors approved 2014 target cash bonuses expressed as a percentage
of base salary as reflected in the table below. The board of directors approved these increases in target cash bonus percentages for 2014 in order to bring the executive’s total target cash compensation to the 75th percentile of the peer group.

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

(1) Mr. Carey began employment with us on March 5, 2014.
(2) Mr. Adatto terminated employment with us on June 17, 2013.

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

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

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

Severance and Change in Control Benefits. Our named executive officers are entitled to certain severance and change in control benefits, the terms of which are further described below under “— Potential Payments Upon Termination or Change-in-Control.” We believe these severance and change in control benefits are an essential element of our overall executive compensation package and assist us in recruiting and retaining talented individuals and aligning the executives’ interests with the best interests of the stockholders.
In January 2014, our compensation committee reviewed severance and change of control benefits of the peer group companies and based on that review, recommended, and the board approved changes to certain of the terms of the severance and change of control benefits for our executive officers. Mr. Walbert, Mr. De Vaere, Dr. Sherman and Mr. Smith each have severance benefit protection under the terms of their employment agreements which provide for up to 12 months’ base salary and COBRA health insurance premiums in the event of an involuntary or constructive termination. Mr. Walbert also receives his target annual bonus amount for the preceding year in the event of his involuntary termination. In the event of an involuntary or constructive termination in connection with a change in control, Mr. Walbert has severance benefit protection under the terms of his employment agreements which provide for up to 24 months’ base salary, two years of target bonus and 12 months COBRA health insurance premiums, and Mr. De Vaere, Dr. Sherman, and Mr. Smith have severance benefit protection under the terms of their employment agreements which provide for up to 12 months’ base salary, one year of target bonus and 12 months COBRA health insurance premiums. In addition, stock option and other equity awards are subject to acceleration under the terms of their employment agreements in the event of a qualifying termination within 90 days prior to or within 18 months following a change in control. Each of Mr. Walbert, Mr. De Vaere, Dr. Sherman and Mr. Smith must enter into a non-competition agreement that is to be effective during the period that the severance benefits are payable.

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

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

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

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

Accounting and Tax Considerations. We account for stock-based awards exchanged for employee services in accordance with the Compensation — Stock Compensation topic of the Financial Accounting Standards Board, or FASB, Accounting Standards Codification. In accordance with the topic, we are required to estimate and record an expense for each award of equity compensation over the vesting period of the award. Accounting rules also require us to record cash compensation as an expense over the period during which it is earned.
Section 162(m) of the Internal Revenue Code of 1986, as amended, or the IRC, limits our deduction for federal income tax purposes to not more than $1 million of compensation paid to certain executive officers in a calendar year. Compensation above $1 million may be deducted if it is “performance-based compensation.” To maintain flexibility in compensating our executive officers in a manner designed to promote our objectives, the compensation committee has not adopted a policy that requires all compensation to be deductible. However, the compensation committee intends to evaluate the effects of the compensation limits of Section 162(m) on any compensation it proposes to grant, and the compensation committee intends to provide future compensation in a manner consistent with our best interests and those of our stockholders.

**Summary Compensation Table**

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

<table>
<thead>
<tr>
<th>Name and Principal Position</th>
<th>Year</th>
<th>Salary</th>
<th>Bonus</th>
<th>Option Awards(1)</th>
<th>Stock Awards(2)</th>
<th>Non Equity Incentive Plan</th>
<th>All Other Compensation(3)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timothy P. Walbert</td>
<td>2013</td>
<td>$589,160</td>
<td>$ 0</td>
<td>$257,250</td>
<td>$606,282</td>
<td>$441,870(4)</td>
<td>$ 600</td>
<td>$1,895,162</td>
</tr>
<tr>
<td>Chairman, President and Chief Executive Officer</td>
<td>2012</td>
<td>$572,000</td>
<td>$ 0</td>
<td>$ 0</td>
<td>$588,000</td>
<td>$275,000(4)</td>
<td>$ 1,218</td>
<td>$1,436,218</td>
</tr>
<tr>
<td></td>
<td>2011</td>
<td>$550,000</td>
<td>$ 0</td>
<td>$797,744</td>
<td>$658,883</td>
<td>$363,000(4)</td>
<td>$ 1,218</td>
<td>$2,370,845</td>
</tr>
<tr>
<td>Robert J. De Vaere</td>
<td>2013</td>
<td>$374,920</td>
<td>$ 0</td>
<td>$89,250</td>
<td>$256,667</td>
<td>$187,460(4)</td>
<td>$ 600</td>
<td>$908,897</td>
</tr>
<tr>
<td>Executive Vice President and Chief Financial Officer</td>
<td>2012</td>
<td>$364,000</td>
<td>$ 0</td>
<td>$ 0</td>
<td>$462,000</td>
<td>$120,000(4)</td>
<td>$ 1,156</td>
<td>$947,156</td>
</tr>
<tr>
<td></td>
<td>2011</td>
<td>$350,000</td>
<td>$ 0</td>
<td>$197,170</td>
<td>$162,843</td>
<td>$162,800(4)</td>
<td>$ 1,156</td>
<td>$873,969</td>
</tr>
<tr>
<td>Jeffrey W. Sherman</td>
<td>2013</td>
<td>$396,340</td>
<td>$ 0</td>
<td>$89,250</td>
<td>$231,914</td>
<td>$198,172(5)</td>
<td>$ 600</td>
<td>$916,276</td>
</tr>
<tr>
<td>Executive Vice President, Development, Manufacturing, and Regulatory Affairs, and Chief Medical Officer</td>
<td>2012</td>
<td>$384,800</td>
<td>$ 0</td>
<td>$ 0</td>
<td>$462,000</td>
<td>$142,000(5)</td>
<td>$ 1,070</td>
<td>$898,870</td>
</tr>
<tr>
<td></td>
<td>2011</td>
<td>$370,000</td>
<td>$ 0</td>
<td>$197,170</td>
<td>$162,843</td>
<td>$162,800(5)</td>
<td>$ 1,070</td>
<td>$893,883</td>
</tr>
<tr>
<td>Todd Smith</td>
<td>2013</td>
<td>$375,950</td>
<td>$ 0</td>
<td>$106,750</td>
<td>$255,914</td>
<td>$187,975(6)</td>
<td>$ 600</td>
<td>$927,189</td>
</tr>
<tr>
<td>Executive Vice President and Chief</td>
<td>2012</td>
<td>$332,583</td>
<td>$ 0</td>
<td>$ 0</td>
<td>$315,000</td>
<td>$106,000(6)</td>
<td>$ 824</td>
<td>$754,407</td>
</tr>
<tr>
<td>Commercial Officer</td>
<td>2011</td>
<td>$274,275</td>
<td>$ 0</td>
<td>$80,455</td>
<td>$66,448</td>
<td>$96,250(6)</td>
<td>$ 824</td>
<td>$518,252</td>
</tr>
<tr>
<td>Michael Adatto(7)</td>
<td>2013</td>
<td>$139,719</td>
<td>$ 0</td>
<td>$38,063</td>
<td>$47,520</td>
<td>$ 0</td>
<td>$300</td>
<td>$225,602</td>
</tr>
<tr>
<td>Former Senior Vice President, Managed Care and Commercial Development</td>
<td>2012</td>
<td>$300,000</td>
<td>$ 0</td>
<td>$ 0</td>
<td>$315,000</td>
<td>$37,000(7)</td>
<td>$ 1,331</td>
<td>$653,331</td>
</tr>
<tr>
<td></td>
<td>2011</td>
<td>$274,275</td>
<td>$ 0</td>
<td>$80,455</td>
<td>$66,448</td>
<td>$96,250(7)</td>
<td>$ 1,331</td>
<td>$518,759</td>
</tr>
</tbody>
</table>

(1) Amounts shown in this column do not reflect actual compensation received by our named executive officers. The amounts reflect the grant date fair value of stock option awards and are calculated in accordance with the provisions of FASB Accounting Standards Codification Topic 718, “Compensation—Stock Compensation,” or ASC Topic 718, and assume no forfeiture rate derived in the calculation of the grant date fair value of these awards. Assumptions used in the calculation of these awards are included in Note 17 “Equity Incentive Plans” in the notes to our consolidated financial statements included in this Annual Report on Form 10-K. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.
Amounts shown in this column do not reflect actual compensation received by our named executive officers. The amounts reflect the grant date fair value of restricted stock units issued in accordance with the provisions of ASC Topic 718 and are based on the closing stock price of our common stock on the date of grant and assume no forfeiture rate derived in the calculation of the grant date fair value of these awards. Stock awards granted to our named executive officers during 2013 and 2011 consisted of restricted stock units that vest equally in four annual installments commencing on the anniversary date of the grant. Stock awards granted to our named executive officers during 2013 also included a fully vested deferred issuance of restricted stock units provided as a one-time bonus payment in connection with the completion of our acquisition of the U.S. rights to VIMOVO. Stock awards granted to our named executive officers during 2012 consisted of performance-based restricted stock units and vested only upon the achievement of certain performance objectives during 2012. See Note 17 “Equity Incentive Plans” in the notes to our consolidated financial statements included in this Annual Report on Form 10-K for further information on our restricted stock units.

In December 2011, our board approved Mr. Walbert’s 2011 bonus in the amount of $363,000, but deferred payment until completion of a debt financing, which occurred in February 2012. Mr. Walbert’s target bonus amount for 2012 was $343,200. In December 2012, our board approved Mr. Walbert’s bonus in the amount of $275,000, which was paid in January 2013. Mr. Walbert’s target bonus amount for 2013 was $353,496, or 60% of base salary. In December 2013, our board approved Mr. Walbert’s bonus in the amount of $441,870, which was paid in January 2014.

In December 2011, our board approved Mr. De Vaere’s 2011 bonus in the amount of $162,800, but deferred payment until the completion of the debt financing, which occurred in February 2012. Mr. De Vaere’s target bonus amount for 2012 was $145,600. In December 2012, our board approved Mr. De Vaere’s bonus in the amount of $120,000, which was paid in January 2013. Mr. De Vaere’s target bonus amount for 2013 was $149,968, or 40% of base salary. In December 2013, our board approved Mr. De Vaere’s bonus in the amount of $187,460, which was paid in January 2014.

In December 2011, our board approved Dr. Sherman’s 2011 bonus in the amount of $162,800, but deferred payment until the completion of the debt financing, which occurred in February 2012. Dr. Sherman’s target bonus amount for 2012 was $153,920. In December 2012, our board approved Dr. Sherman’s bonus in the amount of $142,000, which was paid in January 2013. Dr. Sherman’s target bonus amount for 2013 was $158,536, or 40% of base salary. In December 2013, our board approved Dr. Sherman’s bonus in the amount of $198,172, which was paid in January 2014.

In December 2011, our board approved Mr. Smith’s 2011 bonus in the amount of $96,250, but deferred payment until the completion of the debt financing, which occurred in February 2012. Mr. Smith’s target bonus for 2012 was $146,000. In December 2012, our board approved Mr. Smith’s bonus in the amount of $106,000, which was paid in January 2013. Mr. Smith’s target bonus amount for 2013 was $150,380, or 40% of base salary. In December 2013, our board approved Mr. Smith’s bonus in the amount of $187,975, which was paid in January 2014.

In December 2011, our board approved Mr. Adatto’s 2011 bonus in the amount of $96,250, but deferred payment until the completion of the debt financing, which occurred in February 2012. Mr. Adatto’s target bonus amount for 2012 was $105,000. In December 2012, our board approved Mr. Adatto’s bonus in the amount of $37,000, which was paid in January 2013.

On March 14, 2013, our board of directors determined that Mr. Adatto, our Senior Vice President, Managed Care and Commercial Development, would increasingly focus his efforts on managed care activities and, as a result, would no longer retain his prior policy making functions. Accordingly, his status as an executive officer at Horizon ended as of that date. On June 17, 2013, Mr. Adatto terminated his employment with us. Upon termination of his employment, Mr. Adatto was eligible to receive severance benefits under the Severance Benefit Plan, which provided for six months’ base salary and COBRA health insurance premiums. On June 16, 2013, we entered into a three month consulting agreement with Mr. Adatto effective upon his termination of employment.

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

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

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

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

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

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

Releases. All termination-based payments (other than due to death or complete disability) to Mr. Walbert, Mr. De Vaere, Dr. Sherman and Mr. Smith pursuant to their employment agreements are contingent upon (1) the executive’s execution of a standard release of claims in our favor and (2) the executive’s entering into a
non-competition agreement to be effective during the period during which the executive receives severance benefits.

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

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Upon Termination Without Cause or Resignation for Good Reason - No Change of Control</th>
<th>Upon Termination Without Cause or Resignation for Good Reason - Change of Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cash Severance</td>
<td>Continuation of Medical Benefits</td>
</tr>
<tr>
<td>Timothy P. Walbert</td>
<td>$644,100</td>
<td>$19,192</td>
</tr>
<tr>
<td>Robert J. De Vaere</td>
<td>$386,168</td>
<td>$19,252</td>
</tr>
<tr>
<td>Jeffrey W. Sherman</td>
<td>$408,234</td>
<td>$19,252</td>
</tr>
<tr>
<td>Todd N. Smith</td>
<td>$387,229</td>
<td>$19,252</td>
</tr>
<tr>
<td>Michael Adatto(3)</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

(1) Amounts in these columns assume that termination occurs within 90 days immediately preceding or during the 18 months immediately following a change in control.
(2) The value of accelerated vesting is equal to the closing stock price of $7.62 per share on December 31, 2013, multiplied by the number of shares subject to accelerated vesting, less the stock option exercise price, if applicable.
(3) Mr. Adatto terminated employment with us on June 17, 2013.
## Grants of Plan-Based Awards

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

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

(1) Mr. Walbert’s target bonus for 2013 was $353,496 or 60% of his base salary. In December 2013, our compensation committee approved Mr. Walbert’s bonus in the amount of $441,870, or 125% of his target bonus, which was paid in January 2014.

(2) Mr. De Vaere’s target bonus for 2013 was $149,968 or 40% of his base salary. In December 2013, our compensation committee approved Mr. De Vaere’s bonus in the amount of $187,460, or 125% of his target bonus, which was paid in January 2014.

(3) Dr. Sherman’s target bonus for 2013 was $158,536 or 40% of his base salary. In December 2013, our compensation committee approved Dr. Sherman’s bonus in the amount of $198,172, or 125% of his target bonus, which was paid in January 2014.

(4) Mr. Smith’s target bonus for 2013 was $150,380 or 40% of his base salary. In December 2013, our compensation committee approved Mr. Smith’s bonus in the amount of $187,975, or 125% of his target bonus, which was paid in January 2014.

(5) On January 2, 2013, our named executive officers were granted restricted stock units vesting in four equal annual installments beginning on the first anniversary of the grant date.

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

(7) Amounts shown in this column do not reflect dollar amounts actually received by our named executive officers. Instead, these amounts reflect the grant date fair value of such awards and are calculated in accordance with the provisions of ASC Topic 718 and assume no forfeiture rate derived in the calculation of the grant date fair value of these awards. Assumptions used in the calculation of these amounts and further information on our restricted stock units are included in Note 17 “Equity Incentive Plans” in the notes to our consolidated financial statements included in this Annual Report on Form 10-K.
The following table sets forth certain information regarding outstanding stock options and restricted stock units held by our named executive officers on December 31, 2013.

<table>
<thead>
<tr>
<th>Name</th>
<th>Option Awards</th>
<th>Stock Awards</th>
<th>Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that Have Not Vested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Award Grant Date</td>
<td>Number of Securities Underlying Exercisable Options (#)</td>
<td>Number of Securities Underlying Unexercised Options (#)</td>
</tr>
<tr>
<td>Timothy P. Walbert</td>
<td>7/16/2008</td>
<td>121,706(1)(2)</td>
<td>5,373(3)</td>
</tr>
<tr>
<td>2/3/2010</td>
<td>123,564(1)</td>
<td>14,999(5)</td>
<td>$ 12.94</td>
</tr>
<tr>
<td>1/2/2013</td>
<td>33,687(4)</td>
<td>113,313(4)</td>
<td>$ 2.40</td>
</tr>
<tr>
<td>Robert J. De Vaere</td>
<td>10/6/2008</td>
<td>46,335(1)(2)</td>
<td>—</td>
</tr>
<tr>
<td>2/3/2010</td>
<td>45,666(3)</td>
<td>1,986(3)</td>
<td>$ 5.20</td>
</tr>
<tr>
<td>6/16/2010</td>
<td>37,008(3)</td>
<td>5,287(5)</td>
<td>$ 12.94</td>
</tr>
<tr>
<td>12/9/2011</td>
<td>26,810(4)</td>
<td>26,811(4)</td>
<td>$ 4.96</td>
</tr>
<tr>
<td>1/2/2013</td>
<td>11,687(4)</td>
<td>39,313(4)</td>
<td>$ 2.40</td>
</tr>
<tr>
<td>2/3/2010</td>
<td>45,666(3)</td>
<td>1,986(3)</td>
<td>$ 5.20</td>
</tr>
<tr>
<td>6/16/2010</td>
<td>37,008(3)</td>
<td>5,287(5)</td>
<td>$ 12.94</td>
</tr>
<tr>
<td>12/9/2011</td>
<td>26,810(4)</td>
<td>26,811(4)</td>
<td>$ 4.96</td>
</tr>
<tr>
<td>1/2/2013</td>
<td>11,687(4)</td>
<td>39,313(4)</td>
<td>$ 2.40</td>
</tr>
<tr>
<td>Todd Smith</td>
<td>12/2/2010</td>
<td>15,005(2)</td>
<td>3,950(2)</td>
</tr>
<tr>
<td>12/9/2011</td>
<td>10,940(4)</td>
<td>10,940(4)</td>
<td>$ 4.96</td>
</tr>
<tr>
<td>1/2/2013</td>
<td>13,979(4)</td>
<td>47,021(4)</td>
<td>$ 2.40</td>
</tr>
<tr>
<td>12/5/2013</td>
<td>—</td>
<td>—</td>
<td>$ 6.87</td>
</tr>
<tr>
<td>Michael Adatto</td>
<td>—</td>
<td>39,924</td>
<td>61,911</td>
</tr>
</tbody>
</table>

(1) The initial grant for each officer is early exercisable; as such, 100% of the option award is exercisable.
(2) 1/48th of the shares vest one year after the vesting commencement date and 1/48th of the shares vest monthly thereafter over the next three years. The options reflected in the table have the following vesting commencement dates: Mr. Walbert — June 30, 2008, Mr. De Vaere — October 6, 2008, Dr. Sherman — June 29, 2009 and Mr. Smith — October 1, 2010.
(3) 1/48th of the shares vest one year after the vesting commencement date, which is the same date as the grant date, and 1/48th of the shares vest monthly thereafter over the next three years.
(4) 1/48th of the shares vest in equal monthly installments over the four years following the vesting commencement date, which is the grant date.
(5) Stock awards represent restricted stock units granted and vest in four equal annual installments commencing on the anniversary of the grant date.
(6) Represents restricted stock units that are fully vested but are subject to delayed issuance. As of December 31, 2013, the underlying shares had not yet been issued.
(7) The market value of stock awards that have not vested is based on the closing stock price of our common stock of $7.62 per share on December 31, 2013.
(8) Mr. Adatto terminated employment with us on June 17, 2013.
Option Exercises and Stock Vested

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

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

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

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

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

Option Repricings

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

Pension Benefits

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

Nonqualified Deferred Compensation

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

Other Benefits

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

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

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

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

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

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

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

Limitation of Liability and Indemnification

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

- breach of their duty of loyalty to the corporation or its stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- transaction from which the directors derived an improper personal benefit.

Our amended and restated certificate of incorporation does not eliminate a director’s duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, which remain available under Delaware law. These limitations also do not affect a director’s responsibilities under any
other laws, such as the federal securities laws or other state or federal laws. Our amended and restated bylaws provide that we will indemnify our directors and officers, and may indemnify employees and other agents, to the extent not prohibited by law. Our amended and restated bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding and also permit us to secure insurance on behalf of any officer, director, employee or other agent required or permitted to be indemnified by our amended and restated bylaws. We have obtained a policy of directors’ and officers’ liability insurance.

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

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

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

Compensation Committee Interlocks and Insider Participation

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

Compensation Committee Report

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

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

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

Respectively submitted,

The Compensation Committee of the Board of Directors
Jeff Himawan, Ph.D., Chairman
Michael Grey
Ronald Pauli
The following table provides information as of December 31, 2013, with respect to shares of our common stock that may be issued under our existing equity compensation plans:

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

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

2005 Stock Plan. Our board of directors adopted and our stockholders approved our 2005 stock plan, or the 2005 plan, in October 2005 for eligible employees, directors and consultants. The 2005 plan provided for the grant of up to 1,771,289 shares of our common stock as stock awards. The terms of the stock option agreements, including vesting requirements, were determined by our compensation committee, subject to the provisions of the 2005 plan.

Options granted under the 2005 plan generally vest over four years and are exercisable after they have been granted and up to ten years from the date of grant. The exercise price of the incentive stock options must equal at least the fair market value of the stock on the date of grant. Following the signing of the underwriting agreement for our initial public offering and stockholder approval of the 2011 equity incentive plan, or 2011 EIP, all future equity awards will be granted under our 2011 EIP. However, all stock options granted under the 2005 plan prior to the initial public offering will continue to be governed by the terms of the 2005 plan.

2011 Equity Incentive Plan. The 2011 EIP provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of equity compensation, or collectively, stock awards. In addition, the 2011 EIP provides for the grant of performance cash awards. Incentive stock options may be granted only to employees, subject to certain limitations. All other awards may be granted to employees, including officers, as well as directors and consultants. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2011 EIP was 3,366,228 shares, which number is the sum of (1) the number of shares reserved for future issuance under the 2005 plan at the time the 2011 EIP became effective, (2) an additional number of shares, up to 1,317,534, that are subject to outstanding stock awards granted under the 2005 plan that expire or terminate for any reason prior to their exercise or settlement and would otherwise return to the 2005 Plan reserve and (3) an additional 1,600,673 of new shares. Then, the number of shares of our common stock reserved for issuance under the 2011 EIP will automatically increase on January 1 of each year through January 1, 2021, by the least of (a) 5% of the total number of shares of our common stock outstanding on
December 31 of the preceding calendar year, (b) 1,474,304 shares, or (c) such lesser number of shares of common stock as determined by our board of directors. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2011 EIP is 2,106,149 shares plus the number of shares that are added to the 2011 EIP share reserve pursuant to annual evergreen increases or pursuant to outstanding 2005 plan awards that expire or terminate prior to exercise or settlement. The exercise price for an incentive stock option or a non-qualified stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted typically vest over a four-year period and the term can be up to ten years. As of December 31, 2013, there were 78,795 shares available for future grants under the 2011 EIP. On December 5, 2013, pursuant to the terms of our 2011 EIP, our board of directors approved an increase in the number of shares available for issuance under the 2011 EIP of 1,474,304 shares, effective January 1, 2014.

In addition, (i) on November 7, 2013, November 16, 2013 and March 3, 2014, our board of directors approved amendments to our 2011 EIP to reserve an additional 200,000 shares, 800,000 shares and 730,000 shares, respectively, of our common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of ours (or following a bona fide period of non-employment with us), as an inducement material to the individual’s entry into employment with us within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules, or Rule 5635(c)(4) and (ii) on January 10, 2014, our board of directors approved an amendment to the 2011 EIP to increase the number of shares available for issuance under the 2011 EIP by 703,400 shares, or the January 2014 amendment, with such increase to the number of shares available for issuance under the 2011 EIP subject to stockholder approval of the January 2014 amendment. As of December 31, 2013, there were 674,400 shares available for future grants under the 2011 EIP pursuant to Rule 5635(c)(4).

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

Security Ownership of Certain Beneficial Owners and Management
The following table sets forth information regarding the beneficial ownership of our common stock as of March 6, 2014 for:

- each of our Named Executive Officers as defined in Part III — Item 11, “Executive Compensation” of this report;
- each of our directors;
- each person known by us to beneficially own more than 5% of our common stock; and
- all of our Named Executive Officers and directors as a group.
Beneficial ownership is determined in accordance with the rules of the SEC and includes voting and investment power with respect to the securities. Except as indicated by footnote, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. The number of shares of common stock used to calculate the percentage ownership of each listed person includes the shares of common stock underlying options, warrants or other rights held by such persons that are exercisable as of May 5, 2014, which is 60 days after March 6, 2014.

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

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

(1) 30,910 shares of common stock are owned by Gino Santini, husband of one of the Directors.
(2) The name of this entity is subject to change from time to time.
(3) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(4) includes 61,007 shares of common stock issuable upon the exercise of warrants.
(5) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(6) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(7) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(8) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(9) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(10) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(11) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(12) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(13) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(14) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(15) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(16) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(17) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(18) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
(19) includes 10,353,103 shares of common stock that are owned by the member of this entity that is not a named beneficial owner.
* Represents beneficial ownership of less than one percent.

(1) Includes (a) 3,915,400 shares and (b) 2,783,456 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on January 10, 2014 by FMR LLC, which reflects beneficial ownership as of December 31, 2013. FMR LLC reported that it had beneficial ownership of, and sole dispositive power with respect to, 3,915,400 shares of our common stock, including 2,783,456 shares issuable upon exercise of warrants. The Schedule 13G includes shares beneficially owned by Edward C. Johnson, III and family members, Fidelity Management & Research Company, or Fidelity, Fidelity SelectCo, LLC, or SelectCo, and Strategic Advisers, Inc., or Strategic Advisers. Fidelity, SelectCo and Strategic Advisers are all wholly-owned subsidiaries of FMR LLC and are beneficial owners as a result of acting as investment advisers to various registered investment companies, or Fidelity funds. Mr. Johnson is Chairman of FMR LLC. The Schedule 13G states that Mr. Johnson and various family members, through their ownership of FMR LLC common stock and the execution of a stockholders’ voting agreement, may be deemed a controlling group with respect to FMR LLC. The Schedule 13G also states that neither FMR LLC nor Mr. Johnson has the sole power to vote or direct the voting of the shares owned directly by the Fidelity funds, which power resides with the Fidelity funds’ boards of trustees pursuant to established guidelines.

(2) Includes (a) 5,064,731 shares and (b) 751,209 shares issuable upon exercise of warrants. James L. Currie, Jeff Himawan, Martin Sutter, Immanuel Thangaraj and Petri Vainio share voting and investment power over the shares held by Essex Woodlands Health Ventures Fund VII, L.P. and each disclaim beneficial ownership of such shares except to the extent of any pecuniary interest therein.

(3) Includes (a) 4,488,888 shares and (b) 150,000 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on February 14, 2014. The shares are beneficially owned by Deerfield Partners, L.P., Deerfield International Master Fund, L.P., Deerfield Special Situations Fund, L.P. and Deerfield Special Situations International Master Fund, L.P., of which Deerfield Management, L.P. is the general partner.

(4) Includes 4,257,469 shares beneficially owned by Broadfin Capital, LLC, Broadfin Healthcare Master Fund, Ltd. and Kevin Kotler. This information is based on the Schedule 13G filed on February 14, 2014 with the SEC.

(5) Includes 4,174,909 shares held by Discovery Group. This information is based on the Schedule 13D filed with the SEC on March 3, 2014. Discovery Group is the sole general partner of Discovery Equity Partners and has sole discretionary investment authority with respect to Discovery Equity Partners’ investment in the common stock. Messrs. Donoghue and Murphy are the sole managing members of Discovery Group. As a consequence, Discovery Group and Messrs. Donoghue and Murphy may be deemed to share beneficial ownership of all of the shares of common stock owned by both Discovery Group and Discovery Equity Partners, while Discovery Equity Partners shares beneficial ownership with Discovery Group and Messrs. Donoghue and Murphy of only the shares of common stock owned by it.

(6) Includes (a) 3,516,009 shares and (b) 690,369 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on February 14, 2013. Quaker BioVentures Capital II, L.P., the general partner of Quaker BioVentures II, L.P., and Quaker BioVentures Capital II, LLC, the general partner of Quaker BioVentures Capital II, L.P., may be deemed to share voting and investment power with respect to such shares with Quaker BioVentures II, L.P.

(7) Includes (a) 3,595,714 shares and (b) 561,861 shares issuable upon exercise of warrants. This information is based on the Schedule 13G filed with the SEC on February 14, 2014 by Christoph F. Boehringer and CD-Venture GmbH. Mr. Boehringer is the beneficial owner of 4,157,575 shares of our common stock, including 2,357,575 shares of our common stock beneficially owned by CD-Venture.

(8) Includes (a) 3,516,377 shares held by Atlas Venture Fund VI, L.P., or Atlas VI, (b) 64,385 shares held by Atlas Venture Fund VI GmbH & Co. KG, or Atlas GmbH, (c) 107,532 shares held by Atlas Venture Entrepreneurs’ Fund VI, L.P., or Atlas EVC, and (d) 197,456, 3,616, and 6,038 shares issuable upon exercise of warrants held by Atlas VI, Atlas GmbH and Atlas EVC, respectively. These shares are held directly by Atlas VI, Atlas EVC and Atlas GmbH. Atlas Venture Associates VI, L.P., or AVA VI L.P. is the sole general partner of Atlas VI and Atlas EVC and the managing limited partner of Atlas GmbH. Atlas Venture Associates VI, Inc., or AVA VI Inc., is the sole general partner of AVA VI L.P. Jean-Francois Formela, M.D., Jeffrey Fagnan and Kristen Laguerre are each directors of AVA VI Inc. As a result,
each of Dr. Formela, Mr. Fagnan and Ms. Laguerre may be deemed to have beneficial ownership with respect to all shares held by AVA VI Inc. Each of
the foregoing disclaims beneficial ownership of these shares except to the extent of their pecuniary interest therein.

(9) Includes the shares referred to in footnote (2) above. Dr. Himawan disclaims beneficial ownership of these shares, except to the extent of his pecuniary
interest therein.

(10) Includes the shares referred to in footnote (8) above. Dr. Formela disclaims beneficial ownership of these shares, except to the extent of his pecuniary
interest therein.

(11) Includes (a) 99,912 shares held by the Jeffrey W. Bird and Christina R. Bird Trust dated October 31, 2000, or the Bird Trust, of which Dr. Bird is a
trustee, (b) 21,685 shares issuable upon exercise of warrants held by the Bird Trust, (c) 2,096,558 shares held by Sutter Hill Ventures, a California
Limited Partnership, or SHV, (d) 458,902 shares issuable upon exercise of warrants held by SHV, (e) 5,000 shares held by Dr. Bird in a Roth IRA
account, (f) 1,250 shares issuable upon the exercise of warrants held by Dr. Bird in a Roth IRA account, (g) 7,000 shares held by NestEgg Holdings, a
Limited Partnership, (h) 1,750 shares issuable upon exercise of warrants held by NestEgg Holdings and (i) 18,333 shares that Dr. Bird has the right to
acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options. Dr. Bird disclaims beneficial ownership of these shares,
except to the extent of his pecuniary interest therein.

(12) Includes 32,665 shares that Mr. Grey has the right to acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options.

(13) Includes 32,665 shares that Mr. Pauli has the right to acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options.

(14) Includes 30,910 shares that Mr. Santini has the right to acquire from us within 60 days of March 6, 2014 pursuant to the exercise of stock options.

(15) Includes (a) 105,207 shares, (b) 75,465 restricted stock units that are fully vested but are subject to a delayed issuance stock award such that the
underlying shares have not yet been issued and (c) 552,865 shares that Mr. Walbert has the right to acquire from us within 60 days of March 6, 2014
pursuant to the exercise of stock options.

(16) Includes (a) 68,604 shares, (b) 32,890 restricted stock units that are fully vested but are subject to a delayed issuance stock award such that the
underlying shares have not yet been issued and (c) 188,632 shares that Mr. De Vaere has the right to acquire from us within 60 days of March 6, 2014
pursuant to the exercise of stock options.

(17) Includes (a) 73,309 shares, (b) 29,287 restricted stock units that are fully vested but are subject to a delayed issuance stock award such that the
underlying shares have not yet been issued and (c) 188,632 shares that Dr. Sherman has the right to acquire from us within 60 days of March 6, 2014
pursuant to the exercise of stock options.

(18) Includes (a) 22,924 shares, (b) 31,787 restricted stock units that are fully vested but are subject to a delayed issuance stock award such that the
underlying shares have not yet been issued and (c) 55,909 shares that Mr. Smith has the right to acquire from us within 60 days of March 6, 2014
pursuant to the exercise of stock options.

(19) Includes the following held by our executives and directors, in the aggregate: (a) 11,231,539 shares, (b) 169,429 restricted stock units that are fully
vested but are subject to a delayed issuance stock award such that the underlying shares have not yet been issued, (c) 1,100,611 shares that can be
acquired within 60 days of March 6, 2014 pursuant to the exercise of stock options and (d) 1,441,906 shares issuable upon the exercise of warrants.

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

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

• the amounts involved exceeded or will exceed $120,000; and
• a director, executive officer, holder of more than 5% of our common stock or any member of their immediate family had or will have a direct or
indirect material interest.
We also describe below certain other transactions with our directors, executive officers and stockholders. We believe that the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm’s-length transactions.

**Employment Agreements and Change of Control Arrangements**

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

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

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

**Indemnification of Officers and Directors**

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

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

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

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

- the risks, costs and benefits to us;
- the impact on a director’s independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
the terms of the transaction;
the availability of other sources for comparable services or products; and
the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

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

**Director Independence**

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

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

<table>
<thead>
<tr>
<th>Director</th>
<th>Principal Stockholder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jean-François Formela, M.D.</td>
<td>Atlas Venture Fund VI, L.P.</td>
</tr>
<tr>
<td>Jeff Himawan, Ph.D.</td>
<td>Essex Woodlands Health Ventures Fund VII, L.P.</td>
</tr>
</tbody>
</table>

**Item 14. Principal Accounting Fees and Services**

**Audit and All Other Fees**

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

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<thead>
<tr>
<th></th>
<th>2013</th>
<th>2012</th>
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</thead>
<tbody>
<tr>
<td>Audit fees(1)</td>
<td>$1,326,000</td>
<td>$1,021,000</td>
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<tr>
<td>Tax fees(2)</td>
<td>—</td>
<td>13,000</td>
</tr>
<tr>
<td>Total</td>
<td>$1,326,000</td>
<td>$1,034,000</td>
</tr>
</tbody>
</table>

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

(2) Tax fees consist of fees for professional services performed by PricewaterhouseCoopers LLP with respect to tax compliance, tax advice and tax planning.

The audit committee has considered whether the provision of non-audit services is compatible with maintaining the independence of PricewaterhouseCoopers LLP, and has concluded that the provision of such services is compatible with maintaining the independence of our registered public accounting firm.
Audit Committee Policy Regarding Pre-Approval of Audit and Permissible Non-Audit Services of Our Independent Registered Public Accounting Firm

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

PART IV
Item 15. Exhibits, Financial Statement Schedules
(a) Documents filed as part of this report.

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

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

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

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

HORIZON PHARMA, INC.

Dated: March 13, 2014

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

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

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

<table>
<thead>
<tr>
<th>Signature</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>/s/ Timothy P. Walbert</td>
<td>Chairman, President and Chief Executive Officer</td>
<td>March 13, 2014</td>
</tr>
<tr>
<td>Timothy P. Walbert</td>
<td>(Principal Executive Officer)</td>
<td></td>
</tr>
<tr>
<td>/s/ Robert J. De Vaere</td>
<td>Executive Vice President and Chief Financial Officer</td>
<td>March 13, 2014</td>
</tr>
<tr>
<td>Robert J. De Vaere</td>
<td>(Principal Financial and Accounting Officer)</td>
<td></td>
</tr>
<tr>
<td>/s/ Jeffrey Bird, M.D., Ph.D.</td>
<td>Director</td>
<td>March 13, 2014</td>
</tr>
<tr>
<td>Jeffrey Bird, M.D., Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Jean-François Formela, M.D.</td>
<td>Director</td>
<td>March 13, 2014</td>
</tr>
<tr>
<td>Jean-François Formela, M.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Michael Grey</td>
<td>Director</td>
<td>March 13, 2014</td>
</tr>
<tr>
<td>Michael Grey</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Jeff Himawan, Ph.D.</td>
<td>Director</td>
<td>March 13, 2014</td>
</tr>
<tr>
<td>Jeff Himawan, Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Ronald Pauli</td>
<td>Director</td>
<td>March 13, 2014</td>
</tr>
<tr>
<td>Ronald Pauli</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Gino Santini</td>
<td>Director</td>
<td>March 13, 2014</td>
</tr>
<tr>
<td>Gino Santini</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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HORIZON PHARMA, INC.
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Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2013, 2012 and 2011  F-4
Consolidated Statements of Stockholders' Equity (Deficit) for the Years Ended December 31, 2013, 2012 and 2011  F-5
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

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

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

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

/s/ PricewaterhouseCoopers LLP
Chicago, Illinois
March 13, 2014

F-2
# Horizon Pharma, Inc.

## Consolidated Balance Sheets

(In thousands, except share data)

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSETS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CURRENT ASSETS:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$80,480</td>
<td>$104,087</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>738</td>
<td>800</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>15,958</td>
<td>3,463</td>
</tr>
<tr>
<td>Inventories, net</td>
<td>8,701</td>
<td>5,245</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>4,888</td>
<td>3,323</td>
</tr>
<tr>
<td>Total current assets</td>
<td>110,765</td>
<td>116,918</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>3,780</td>
<td>3,725</td>
</tr>
<tr>
<td>Intangible assets, net</td>
<td>131,094</td>
<td>68,892</td>
</tr>
<tr>
<td>Other assets</td>
<td>6,957</td>
<td>4,449</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>$252,596</td>
<td>$193,984</td>
</tr>
<tr>
<td><strong>LIABILITIES AND STOCKHOLDERS' EQUITY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CURRENT LIABILITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts payable</td>
<td>9,921</td>
<td>5,986</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>24,049</td>
<td>16,784</td>
</tr>
<tr>
<td>Accrued royalties</td>
<td>8,010</td>
<td>—</td>
</tr>
<tr>
<td>Deferred revenues—current portion</td>
<td>1,330</td>
<td>2,230</td>
</tr>
<tr>
<td>Notes payable—current portion</td>
<td>—</td>
<td>11,935</td>
</tr>
<tr>
<td>Total current liabilities</td>
<td>43,310</td>
<td>36,935</td>
</tr>
<tr>
<td><strong>LONG-TERM LIABILITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible debt, net</td>
<td>110,762</td>
<td>—</td>
</tr>
<tr>
<td>Derivative liability</td>
<td>109,410</td>
<td>—</td>
</tr>
<tr>
<td>Accrued royalties</td>
<td>24,982</td>
<td>—</td>
</tr>
<tr>
<td>Notes payable, net of current</td>
<td>—</td>
<td>36,866</td>
</tr>
<tr>
<td>Deferred revenues, net of current</td>
<td>9,686</td>
<td>9,554</td>
</tr>
<tr>
<td>Deferred tax liabilities, net</td>
<td>3,362</td>
<td>4,408</td>
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<tr>
<td>Other long term liabilities</td>
<td>166</td>
<td>243</td>
</tr>
<tr>
<td>Total long-term liabilities</td>
<td>258,368</td>
<td>51,071</td>
</tr>
<tr>
<td><strong>COMMITMENTS AND CONTINGENCIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>STOCKHOLDERS' EQUITY:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common stock, $0.00001 par value; 200,000,000 shares authorized; 66,097,417 and 61,722,247 shares issued and outstanding at December 31, 2013 and 2012, respectively</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>410,430</td>
<td>417,455</td>
</tr>
<tr>
<td>Accumulated other comprehensive loss</td>
<td>(2,403)</td>
<td>(3,372)</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(457,116)</td>
<td>(308,111)</td>
</tr>
<tr>
<td>Total stockholders' (deficit) equity</td>
<td>(49,082)</td>
<td>105,978</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</strong></td>
<td>$252,596</td>
<td>$193,984</td>
</tr>
</tbody>
</table>

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

F-3
HORIZON PHARMA, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except share data)

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

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

F-4
HORIZON PHARMA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS’ EQUITY (DEFICIT)
(In thousands, except share data)

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

<table>
<thead>
<tr>
<th>For the Years Ended</th>
<th>December 31</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM OPERATING ACTIVITIES:</strong></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$(149,005)</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash used in operating activities:</td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization expense</td>
<td>9,310</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>5,014</td>
</tr>
<tr>
<td>Loss on derivative revaluation</td>
<td>69,300</td>
</tr>
<tr>
<td>Intangible impairment charge</td>
<td>-</td>
</tr>
<tr>
<td>Paid in kind interest expense</td>
<td>2,225</td>
</tr>
<tr>
<td>Amortization of debt discount, deferred financing costs and debt extinguishment</td>
<td>17,245</td>
</tr>
<tr>
<td>Foreign exchange (gain) loss</td>
<td>(1,206)</td>
</tr>
<tr>
<td>Changes in operating assets and liabilities:</td>
<td></td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>(12,491)</td>
</tr>
<tr>
<td>Inventories</td>
<td>(3,426)</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>(1,240)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>3,908</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>7,942</td>
</tr>
<tr>
<td>Deferred revenues</td>
<td>(1,145)</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>(1,186)</td>
</tr>
<tr>
<td>Other non-current assets and liabilities</td>
<td>468</td>
</tr>
<tr>
<td>Net cash used in operating activities</td>
<td>$(54,287)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM INVESTING ACTIVITIES:</strong></td>
<td></td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td>(1,198)</td>
</tr>
<tr>
<td>Change in restricted cash</td>
<td>63</td>
</tr>
<tr>
<td>VIMOVO asset acquisition</td>
<td>(35,000)</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>(36,135)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM FINANCING ACTIVITIES:</strong></td>
<td></td>
</tr>
<tr>
<td>Proceeds from the issuance of convertible debt, net of issuance costs</td>
<td>143,598</td>
</tr>
<tr>
<td>Proceeds of capped calls</td>
<td>(18,675)</td>
</tr>
<tr>
<td>Proceeds from issuance of common stock under an ATM agreement, net of issuance costs</td>
<td>5,998</td>
</tr>
<tr>
<td>Proceeds from issuance of common stock in initial public offering, net of underwriting fees and issuance costs</td>
<td>-</td>
</tr>
<tr>
<td>Proceeds from issuance of bridge notes payable to related parties</td>
<td>-</td>
</tr>
<tr>
<td>Proceeds from equity finance offerings, net of offering costs</td>
<td>-</td>
</tr>
<tr>
<td>Proceeds from the issuance of notes payable</td>
<td>-</td>
</tr>
<tr>
<td>Repayment of notes payable</td>
<td>(64,844)</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>66,716</td>
</tr>
<tr>
<td><strong>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</strong></td>
<td>64,444</td>
</tr>
<tr>
<td><strong>CASH AND CASH EQUIVALENTS, beginning of the year</strong></td>
<td>104,087</td>
</tr>
<tr>
<td><strong>CASH AND CASH EQUIVALENTS, end of the year</strong></td>
<td>$ 80,480</td>
</tr>
<tr>
<td><strong>Supplemental cash flow information:</strong></td>
<td></td>
</tr>
<tr>
<td>Cash paid for interest</td>
<td>$ 8,573</td>
</tr>
<tr>
<td>Cash paid for income taxes</td>
<td>44</td>
</tr>
<tr>
<td>Cash paid for debt extinguishment interest and penalties</td>
<td>$ 12,152</td>
</tr>
<tr>
<td><strong>Significant non-cash investing activities:</strong></td>
<td></td>
</tr>
<tr>
<td>Contingent liabilities assumed in acquisition</td>
<td>$ 32,992</td>
</tr>
<tr>
<td>Intangible assets acquired in acquisition</td>
<td>$ 67,708</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
NOTE 1 – THE COMPANY

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

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

On April 23, 2011, the U.S. Food and Drug Administration (“FDA”) approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis (“RA”), osteoarthritis (“OA”) and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. In the second half of 2011, the Company hired its initial commercial organization, including approximately 80 sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In June 2012, the Company licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products. In the third quarter of 2012, the Company expanded its sales force to approximately 150 representatives and has subsequently further expanded its sales force to approximately 290 representatives, most recently by adding approximately 115 representatives in connection with the Company’s acquisition of the U.S. rights to VIMOVO in November 2013. In March 2013, the Company announced that the United Kingdom (“UK”) Medicines and Healthcare Products Regulatory Agency granted a National Marketing Authorization for DUEXIS in the UK. The Company will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded non-steroidal anti-inflammatory drugs (“NSAIDs”), the Company does not expect a material level of sales from DUEXIS in European markets.

On April 23, 2011, the U.S. Food and Drug Administration (“FDA”) approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis (“RA”), osteoarthritis (“OA”) and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. In the second half of 2011, the Company hired its initial commercial organization, including approximately 80 sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In June 2012, the Company licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products. In the third quarter of 2012, the Company expanded its sales force to approximately 150 representatives and has subsequently further expanded its sales force to approximately 290 representatives, most recently by adding approximately 115 representatives in connection with the Company’s acquisition of the U.S. rights to VIMOVO in November 2013. In March 2013, the Company announced that the United Kingdom (“UK”) Medicines and Healthcare Products Regulatory Agency granted a National Marketing Authorization for DUEXIS in the UK. The Company will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded non-steroidal anti-inflammatory drugs (“NSAIDs”), the Company does not expect a material level of sales from DUEXIS in European markets.

The Company’s second approved product in the United States, RAYOS, known as LODOTRA outside the United States, is a proprietary delayed-release formulation of low-dose prednisone for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, polymyalgia rheumatica (“PMR”), psoriatic arthritis, ankylosing spondylitis (“AS”), asthma and chronic obstructive pulmonary disease and a number of other conditions. The Company is focusing its promotion of RAYOS in the United States on rheumatology indications, including RA and PMR. The Company began detailing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of U.S. rheumatologists and key primary care physicians. LODOTRA is currently marketed outside the United States by the Company’s distribution partner, Mundipharma International Corporation Limited (“Mundipharma”).
On November 18, 2013, the Company entered into agreements with AstraZeneca pursuant to which the Company acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs in the United States. VIMOVO (naproxen/esomeprazole magnesium) is a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, layer surrounding the core. VIMOVO was originally developed by Pozen Inc. (“Pozen”) together with AstraZeneca pursuant to an exclusive global collaboration and license agreement under which AstraZeneca and Pozen agreed to co-develop VIMOVO and AstraZeneca obtained exclusive rights to commercialize VIMOVO worldwide. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of OA, RA, and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

Under the asset purchase agreement with AstraZeneca, the Company acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the investigational new drug application (“IND”) and new drug application (“NDA”) for VIMOVO in the United States, AstraZeneca’s interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. In addition, AstraZeneca assigned to the Company its amended and restated collaboration and license agreement for the United States with Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States. For accounting purposes, the acquisition of the U.S. rights to VIMOVO was treated as a business combination. Collectively, these transactions are referred to as the “VIMOVO Acquisition.”

In December 2013, as a result of its acquisition of the U.S. rights to VIMOVO, the Company began the expansion of its sales force to approximately 250 primary care representatives and 40 rheumatology sales specialists and recognized revenues under the transition agreement with AstraZeneca. The Company announced the availability of Horizon-labeled VIMOVO on January 2, 2014. The Company completed the hiring and training of its expanded sales force in January 2014 and began selling VIMOVO in early February 2014. The Company’s primary care representatives will promote DUEXIS in a primary position to physician targets who are high branded NSAID prescribers and are also prescribers of DUEXIS and ibuprofen and will promote VIMOVO in a second position among these target physicians. The Company’s primary care representatives will promote VIMOVO in a primary position to physician targets who are high branded NSAID prescribers and are also prescribers of VIMOVO and naproxen, and they will promote DUEXIS in a second position among these target physicians. The Company’s analysis indicates that there is an approximate 30% overlap of physician targets who prescribe both DUEXIS and VIMOVO. In those cases, individual target-by-target promotional plans will be executed and both DUEXIS and VIMOVO will be promoted to these targets. The Company has also expanded its rheumatology specialty sales force from 25 sales specialists to approximately 40 sales specialists, with these specialist representatives promoting RAYOS and VIMOVO to rheumatologists. The Company has also included VIMOVO in its Prescriptions-Made-Easy specialty pharmacy program, along with DUEXIS and RAYOS, and offers co-pay assistance for all of its marketed products to ensure patients receive them at a reasonable out-of-pocket cost.

Revision of Prior Period Financial Statements

In the course of preparing the Company’s Consolidated Statements of Comprehensive Loss for this Annual Report on Form 10-K, the Company determined that there had been a misclassification of certain fees in its financial statements for the previously reported quarters ended March 31, 2012 and 2013, June 30, 2012 and 2013 and September 30, 2012 and 2013, as well as the Company’s annual financial statements for the year ended December 31, 2012 (collectively, the “Affected Financial Statements”).

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

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revenue instead of an increase in cost of goods sold and have revised all identified prior period misclassifications in the periods in which they originated. The revision had no impact on the Company’s reported gross profit, net loss or cash flows.

In evaluating whether the Company’s previously issued consolidated financial statements were materially misstated, the Company considered the guidance in Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 250, Accounting Changes and Error Corrections, ASC Topic 250-10-S99-1, Assessing Materiality, and ASC Topic 250-10-S99-2, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements. The Company concluded that these misstatements were not material, individually or in the aggregate, to any of the prior reporting periods, and therefore, amendments of previously filed reports were not required. As such, the revisions are reflected in the financial information of the applicable prior periods and will be reflected in future filings containing such financial information.
The following table includes selected line items from our financial statements illustrating the effect of the revision:

<table>
<thead>
<tr>
<th>Financial Statement</th>
<th>As Reported (in thousands)</th>
<th>Adjustment (in thousands)</th>
<th>As Revised (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2012</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(384)</td>
<td>(38)</td>
<td>(422)</td>
</tr>
<tr>
<td>Net Sales</td>
<td>2,523</td>
<td>(38)</td>
<td>2,485</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>2,067</td>
<td>(38)</td>
<td>2,029</td>
</tr>
<tr>
<td><strong>Consolidated Statements of Comprehensive Loss for the Three Months Ended June 30, 2012</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(767)</td>
<td>(160)</td>
<td>(927)</td>
</tr>
<tr>
<td>Net Sales</td>
<td>3,841</td>
<td>(160)</td>
<td>3,681</td>
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<tr>
<td>Cost of goods sold</td>
<td>2,855</td>
<td>(160)</td>
<td>2,695</td>
</tr>
<tr>
<td><strong>Consolidated Statements of Comprehensive Loss for the Three Months Ended September 30, 2012</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(790)</td>
<td>(202)</td>
<td>(992)</td>
</tr>
<tr>
<td>Net Sales</td>
<td>6,521</td>
<td>(202)</td>
<td>6,319</td>
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<tr>
<td>Cost of goods sold</td>
<td>3,810</td>
<td>(202)</td>
<td>3,608</td>
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<tr>
<td><strong>Consolidated Statements of Comprehensive Loss for the Three Months Ended December 31, 2012</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(1,405)</td>
<td>(388)</td>
<td>(1,793)</td>
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<tr>
<td>Net Sales</td>
<td>6,747</td>
<td>(388)</td>
<td>6,359</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>3,931</td>
<td>(388)</td>
<td>3,543</td>
</tr>
<tr>
<td><strong>Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2013</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(1,527)</td>
<td>(478)</td>
<td>(2,005)</td>
</tr>
<tr>
<td>Net Sales</td>
<td>9,171</td>
<td>(478)</td>
<td>8,693</td>
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<tr>
<td>Cost of goods sold</td>
<td>4,247</td>
<td>(478)</td>
<td>3,769</td>
</tr>
<tr>
<td><strong>Consolidated Statements of Comprehensive Loss for the Three Months Ended June 30, 2013</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(5,383)</td>
<td>(1,123)</td>
<td>(6,506)</td>
</tr>
<tr>
<td>Net Sales</td>
<td>12,254</td>
<td>(1,123)</td>
<td>11,131</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>3,517</td>
<td>(1,123)</td>
<td>2,394</td>
</tr>
<tr>
<td><strong>Consolidated Statements of Comprehensive Loss for the Six Months Ended June 30, 2013</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(6,910)</td>
<td>(1,601)</td>
<td>(8,511)</td>
</tr>
<tr>
<td>Net Sales</td>
<td>21,425</td>
<td>(1,601)</td>
<td>19,824</td>
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<tr>
<td>Cost of goods sold</td>
<td>7,764</td>
<td>(1,601)</td>
<td>6,163</td>
</tr>
<tr>
<td><strong>Consolidated Statements of Comprehensive Loss for the Three Months Ended September 30, 2013</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(5,306)</td>
<td>(2,106)</td>
<td>(7,412)</td>
</tr>
<tr>
<td>Net Sales</td>
<td>26,218</td>
<td>(2,106)</td>
<td>24,112</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>5,313</td>
<td>(2,106)</td>
<td>3,207</td>
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<tr>
<td><strong>Consolidated Statements of Comprehensive Loss for the Nine Months Ended September 30, 2013</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(12,216)</td>
<td>(3,707)</td>
<td>(15,923)</td>
</tr>
<tr>
<td>Net Sales</td>
<td>47,643</td>
<td>(3,707)</td>
<td>43,936</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>13,077</td>
<td>(3,707)</td>
<td>9,370</td>
</tr>
</tbody>
</table>
The financial statements are prepared on a going concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business. As of December 31, 2013, the Company had cash and cash equivalents totaling $80,480. The Company believes that it has sufficient liquidity and capital resources to reach cash flow positive operations based on the Company’s current expectations of continued revenue growth. However, the Company is highly dependent in the near term on the commercial success of DUEXIS, VIMOVO and RAYOS in the U.S. market. Additionally, the Company has convertible debt which may be required to be settled in cash up to the principal amount upon certain circumstances outside the control of the Company, prior to obtaining stockholder approval to issue enough shares to cover the conversion option in shares of its common stock.

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

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Principles of Consolidation

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

Segment Information

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

Use of Estimates

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

Foreign Currency Translation and Transactions

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

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

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

Revenue Recognition

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

Revenue from upfront license fees

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

Revenue from milestone receipts

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

Revenue from product deliveries

The Company recognizes revenue from the delivery of its products when delivery has occurred, title has transferred, the selling price is fixed or determinable, collectability is reasonably assured and the Company has no further performance obligations. In addition, revenue is only recognized when the right of return no longer exists (which is the earlier of the product being dispensed through patient prescriptions or the expiration of the right of return) or when product returns can be reasonably estimated. Prior to October 2012, revenue from products sold to the Company’s wholesale distributors and retail chains was recognized based on the amount of product sold through to the end consumer. Since October 2012, due to the Company’s ability to reasonably estimate and determine allowances for product returns, rebates and discounts, the Company has been recognizing DUEXIS and RAYOS revenue at the point of sale to wholesale pharmaceutical distributors and retail chains. The Company has been recognizing VIMOVO revenue at the point of sale, consistent with its revenue recognition of DUEXIS and RAYOS, given the availability of prior VIMOVO product return data.
The Company anticipates revenues will continue to result from distribution, marketing, manufacturing and supply agreements with third parties in Europe and certain Asian, Latin American and other countries with respect to LODOTRA.

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

In December 2011, the Company began recognizing revenues from the sale of DUEXIS following its commercial launch in the United States. DUEXIS is currently sold to wholesale pharmaceutical distributors and to several national and regional retail chains. Until the Company could reliably estimate returns, the Company determined that shipment of products to wholesale pharmaceutical distributors and regional retail chains did not meet the criteria for revenue recognition at the time of shipment. The Company therefore deferred DUEXIS revenue recognition until the right of return no longer existed, which was the earlier of DUEXIS being dispensed through patient prescriptions or the expiration of the right of return (twelve months after the expiration date of the product). During the fourth quarter of 2012, the Company changed from recognizing DUEXIS revenue upon product being dispensed through patient prescriptions to recognizing revenue when product is sold into the wholesale pharmaceutical distributor and retail chain channel. This change was based on approximately one year of minimal product return quantities and an enhanced ability and historical experience upon which to monitor DUEXIS inventory levels in the distribution channel and to assess the relative risk of potential product returns. The Company believes it has the ability to reliably estimate returns and therefore recognizes revenue on the sale of DUEXIS, RAYOS and VIMOVO at the point of sale to the wholesaler.

Product Sales Discounts and Allowances

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

Customer Discounts and Rebates

Product Launch Discounts

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

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

Distribution Service Fees

The Company includes distribution service fees paid to its wholesalers for distribution and inventory management services as a reduction to revenue. The estimates are based on contractually determined fees, typically as a percentage of revenue.

Government Rebates and Chargebacks

Government Rebates

The Company participates in certain federal government rebate programs, such as Medicare and Medicaid. The Company accrues estimated rebates based on percentages of product sold to qualified patients, estimated rebate percentages and estimated levels of inventory in the distribution channel that will be sold to qualified patients and records the rebate as a reduction of revenue.

Government Chargebacks

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

Co-Pay Assistance

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

Returns and Prompt Pay Allowances

Sales Returns

Consistent with industry practice, the Company maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the product expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date and up to one year after its expiration date. The right of return expires on the earlier of one year after the product expiration date or the time that the product is dispensed to the patient. The majority of product returns result from product dating, which falls within the range set by the Company’s policy, and are settled through the issuance of a credit to the customer. The estimate of the provision for returns is based upon the Company’s historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which the customer may return product. This period is known to the Company based on the shelf life of products at the time of shipment. The Company records sales returns as an allowance against accounts receivable and a reduction of revenue.
Prompt Pay Discounts

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

Bad Debt Expense

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

Cost of Goods Sold

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

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

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

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

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

Cost of goods sold of VIMOVO in the fourth quarter of 2013, following our acquisition in November 2013 of certain assets and rights necessary to commercialize VIMOVO in the United States, includes only intangible amortization expense. Beginning in 2014, in connection with the Company’s marketing of VIMOVO in the United States, cost of goods sold for VIMOVO will include all costs directly related to the acquisition of product from AstraZeneca and/or the third-party manufacturer.

Inventories

Inventories are stated at the lower of cost or market value. Inventories consist of raw materials, work-in-process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. The Company’s inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs. As of December 31, 2013 and December 31, 2012, the Company had inventories of $8,701 and $5,245, respectively.

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

Preclinical Studies and Clinical Trial Accruals

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

**Net Loss Per Share**

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

**Cash and Cash Equivalents**

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

**Restricted Cash**

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

**Fair Value of Financial Instruments**

The carrying amounts of the Company’s financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities. The estimated fair value of the Company’s derivative liability related to the convertible portion of its 5.00% Convertible Senior Notes due 2018 (the “Convertible Senior Notes”) was derived utilizing the binomial lattice approach for the valuation of convertible instruments. Assumptions used in the calculation included, among others, determining the appropriate credit spread using benchmarking analysis and solving for the implied credit spread, calculating the fair value of the stock component using a discounted risk free rate and borrowing cost and calculating the fair value of the note component using a discounted credit adjusted discount rate. Based on the assumptions used to determine the fair value of the derivative liability associated with the Convertible Senior Notes, the Company concluded that these inputs were Level 3 inputs. The Company will continue to derive the fair value of the derivative liability using the binomial lattice approach and these assumptions in all future reporting periods.

**Business Combinations**

The Company accounts for business combinations in accordance with the pronouncement guidance in ASC 805, *Business Combinations*, in which acquired assets and liabilities are measured at their respective estimated fair values as of the acquisition date. The Company may be required, as in the case of intangible assets, contingent royalties or derivatives, to determine the fair value associated with these amounts by estimating the fair value using an income approach under the discounted cash flow method, which may include revenue projections and other assumptions made by the Company to determine the fair value.
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>Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery and equipment</td>
<td>5-7 years</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>3-5 years</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>3 years</td>
</tr>
<tr>
<td>Software</td>
<td>3 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.

Intangible Assets

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

Research and Development Expenses

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

Sales and Marketing Expenses

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

Concentration of Credit Risk and Other Risks and Uncertainties

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

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

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

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

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

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

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss) ("OCI"). OCI includes certain changes in stockholders' equity that are excluded from net income (loss), which consist of foreign currency translation adjustments. In February 2013, the Company adopted on a prospective
NOTE 3 – BUSINESS ACQUISITION

On November 18, 2013, the Company entered into agreements with AstraZeneca pursuant to which the Company acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs, in the United States. VIMOVO (naproxen/esomeprazole magnesium), a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, layer surrounding the core, was approved by the FDA in 2010 for the relief of the signs and symptoms of OA, RA and AS, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

Pursuant to the transactions contemplated by the asset purchase agreement, the Company acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the IND and NDA for VIMOVO in the United States, AstraZeneca’s interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. The Company will also be entitled to the benefit of a covenant not to sue granted by Merck Sharp & Dohme Corp. and certain of its affiliates (collectively, “Merck”) to AstraZeneca, with respect to certain patents owned by AstraZeneca but exclusively licensed to Merck, that cover the manufacture and commercialization of VIMOVO in the United States. In addition, AstraZeneca assigned to the Company its amended and restated collaboration and license agreement for the United States with Pozen pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States. The terms of the amended and restated collaboration and license agreement for the United States with Pozen (the “Pozen license agreement”) are described below.

In November 2013, in connection with the closing of the transactions contemplated by the asset purchase agreement, the Company also entered into a license agreement with AstraZeneca, a supply agreement with AstraZeneca’s affiliate, AstraZeneca LP, and certain other agreements that are described below. The Company also executed a transition agreement with AstraZeneca pursuant to which AstraZeneca transitioned to the Company regulatory and commercial responsibility for VIMOVO in the United States. From the closing of the transaction until December 31, 2013, AstraZeneca continued to commercialize VIMOVO in the United States under AstraZeneca’s existing pricing and paid to the Company the net profits recognized on sales of VIMOVO in the United States. Beginning January 1, 2014, the Company commenced commercialization of VIMOVO in the United States on its own behalf and under new pricing for VIMOVO. In consideration for the U.S. rights to VIMOVO, the Company paid to AstraZeneca a one-time upfront cash payment of $35,000.

The Company is responsible for and controls matters relating to VIMOVO in the United States, including responsibility for commercialization of VIMOVO in the United States, responsibility for ongoing developmental and regulatory activities with respect to VIMOVO in the United States and responsibility for the current VIMOVO litigation with respect to the patents the Company purchased under the asset purchase agreement and the patents the Company licensed from Pozen under the Pozen license agreement. AstraZeneca will be responsible for and will retain control of VIMOVO outside the United States.
Additionally, in connection with the closing of the transactions contemplated by the asset purchase agreement, the Company entered into a license agreement with AstraZeneca (the “AstraZeneca license agreement”), pursuant to which AstraZeneca granted the Company an exclusive license under certain intellectual property (including patents, know-how, trademarks, copyrights and domain names) of AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States. AstraZeneca also granted the Company a non-exclusive license under certain intellectual property of AstraZeneca and its affiliates to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States. In addition, AstraZeneca granted the Company a non-exclusive right of reference and use under certain regulatory documentation controlled by AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States and to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States.

Under the AstraZeneca license agreement, the Company granted AstraZeneca a non-exclusive sublicense under such licensed intellectual property and a non-exclusive right of reference under certain regulatory documentation controlled by the Company to manufacture, import, export and perform research and development activities with respect to VIMOVO in the United States but solely for purposes of commercializing VIMOVO outside the United States.

Under the AstraZeneca license agreement, the Company and its affiliates are subject to certain limitations and restrictions on its ability to develop, commercialize and seek regulatory approval with respect to VIMOVO or other products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs (excluding DUEXIS). These limitations and restrictions include, among other things, restrictions on indications for which the Company may commercialize VIMOVO or any such other products, restrictions on the Company’s ability to develop or seek regulatory approval with respect to such other products that contain esomeprazole, restrictions on the Company’s ability to develop or seek regulatory approval for VIMOVO for any indications other than the indications for which NSAIDs are indicated, and restrictions on the Company’s marketing activities with respect to VIMOVO and any such other products.

Under the Pozen license agreement, Pozen granted to the Company an exclusive, royalty-bearing license under certain of Pozen’s intellectual property in the United States to manufacture, develop and commercialize VIMOVO and other products controlled by the Company that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs, excluding DUEXIS, in the United States.

Under the Pozen license agreement, the Company is required to pay Pozen a flat 10% royalty on net sales of VIMOVO and such other products sold by the Company, its affiliates or sublicensees during the royalty term, subject to minimum annual royalty obligations of $5.0 million in 2014 and $7.5 million each year thereafter, which minimum royalty obligations will continue for each year during which one of Pozen’s patents covers such products in the United States and there are no competing products in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing products. The Company’s obligation to pay royalties to Pozen will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in the United States. In addition, the Company is obligated to reimburse Pozen for costs, including attorneys’ fees, incurred by Pozen in connection with VIMOVO patent litigation moving forward, subject to agreed caps.

The Company is responsible for and is required to use diligent and reasonable efforts to commercialize VIMOVO or another qualified product in the United States. The Company also owns and maintains all regulatory filings and marketing approvals in the United States for any such products, including all INDs and NDAs for VIMOVO. Pozen has covenanted that it will not at any time prior to the expiration of the royalty term, and will ensure that its affiliates do not, directly or indirectly, develop or commercialize or license any third party to develop or commercialize certain competing products in the United States.
The Pozen license agreement, unless earlier terminated, will expire upon expiration of the royalty term for all such products in the United States. Either party has the right to terminate the agreement upon any uncured material breach by the other party or upon the bankruptcy or similar proceeding of the other party. The Company also has the right to terminate the Pozen license agreement for cause upon certain defined product failures.

In November 2013, in connection with the asset purchase agreement and the Pozen license agreement, the Company, AstraZeneca and Pozen entered into a letter agreement in which Pozen consented to AstraZeneca’s assignment of the Pozen license agreement to the Company and that addresses the rights and responsibilities of the parties in relation to the Pozen license agreement and the amended and restated collaboration and license agreement between Pozen and AstraZeneca for territories outside the United States (the “Pozen-AstraZeneca license agreement”). Under the letter agreement, the Company and AstraZeneca agreed to pay Pozen milestone payments upon the achievement by the Company and AstraZeneca, collectively, of certain annual aggregate global sales thresholds ranging from $550.0 million to $1.25 billion with respect to products licensed by Pozen to the Company under the Pozen license agreement and to AstraZeneca under the Pozen-AstraZeneca license agreement. The aggregate milestone payment amount that may be owed by AstraZeneca and the Company, collectively, under the letter agreement is $260.0 million, with the amount payable by each of the Company and AstraZeneca with respect to each milestone to be based upon the proportional sales achieved by each of the Company and AstraZeneca, respectively, in the applicable year.

The letter agreement will terminate with respect to Pozen and the Company upon the termination of the Pozen license agreement and will terminate with respect to Pozen and AstraZeneca upon the termination of the Pozen-AstraZeneca license agreement.

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

The supply agreement will expire on December 31, 2014, unless terminated earlier as described herein. The supply agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party. Additionally, the Company has the right to terminate the supply agreement at any time upon 120 days prior written notice to AstraZeneca or immediately upon written notice if the existing regulatory approval of VIMOVO is suspended for any reason or if any regulatory authority provides a warning letter or other official documentation expressing major and significant concerns from a regulatory perspective with AstraZeneca’s or its affiliates’ or third party manufacturer’s manufacturing of VIMOVO. Additionally, the supply agreement will automatically terminate upon any termination of the AstraZeneca license agreement.

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

<table>
<thead>
<tr>
<th>Allocation</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples inventory</td>
<td>$287</td>
</tr>
<tr>
<td>VIMOVO intellectual property</td>
<td>$67,705</td>
</tr>
<tr>
<td>Contingent royalty liabilities</td>
<td>(32,992)</td>
</tr>
<tr>
<td>Total cash consideration paid</td>
<td>$35,000</td>
</tr>
</tbody>
</table>

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

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

**Pro Forma Financial Information**

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

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

**NOTE 4 – EARNINGS PER SHARE**

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

<table>
<thead>
<tr>
<th></th>
<th>For the Years Ended December 31,</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>Basic and diluted earnings per share calculation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$(149,005)</td>
<td>$(87,794) $(113,265)</td>
<td></td>
</tr>
<tr>
<td>Weighted average of common shares outstanding</td>
<td>63,657,924</td>
<td>38,871,422</td>
<td>9,014,968</td>
</tr>
<tr>
<td>Basic and diluted net loss per share</td>
<td>$(2.34)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$(2.26) $(12.56)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The following securities were excluded from the computation of diluted earnings per share for the years ended December 31, 2013, 2012 and 2011 due to the anti-dilutive effects resulting from the Company’s net loss for the periods presented:

- Outstanding stock options to purchase an aggregate of 4,411,080, 2,746,918 and 2,532,262 shares of common stock at December 31, 2013, 2012 and 2011, respectively; outstanding and unvested restricted stock units covering an aggregate of 833,001, 232,158 and 304,890 shares of common stock at December 31, 2013, 2012 and 2011, respectively; and 101,004 and 225,000 vested restricted stock units outstanding at December 31, 2013 and 2012, respectively.
- Outstanding common stock warrants to purchase an aggregate of 16,114,746 and 17,480,243 shares of common stock at December 31, 2013, and 2012, respectively.
- The conversion of approximately 13,164,951 shares of the Company’s common stock associated with the conversion feature of the Convertible Senior Notes as the conversion of the Convertible Senior Notes is subject to receiving stockholder approval to issue enough authorized and unissued shares to cover the conversion option and satisfy the NASDAQ share cap rule.

NOTE 5 – INVENTORIES

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

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

<table>
<thead>
<tr>
<th></th>
<th>As of December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
</tr>
<tr>
<td>Raw materials</td>
<td>$ 91</td>
</tr>
<tr>
<td>Work-in-process</td>
<td>522</td>
</tr>
<tr>
<td>Finished goods</td>
<td>8,088</td>
</tr>
<tr>
<td>Net inventories</td>
<td>$8,701</td>
</tr>
</tbody>
</table>

NOTE 6 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

<table>
<thead>
<tr>
<th></th>
<th>As of December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
</tr>
<tr>
<td>Product samples inventory</td>
<td>$1,323</td>
</tr>
<tr>
<td>Prepaid software license fees</td>
<td>855</td>
</tr>
<tr>
<td>Prepaid clinical trial studies</td>
<td>688</td>
</tr>
<tr>
<td>Prepaid co-pay expenses</td>
<td>621</td>
</tr>
<tr>
<td>Prepaid marketing expenses</td>
<td>381</td>
</tr>
<tr>
<td>Prepaid insurance</td>
<td>379</td>
</tr>
<tr>
<td>Prepaid FDA product and manufacturing fees</td>
<td>312</td>
</tr>
<tr>
<td>Other prepaid expenses</td>
<td>329</td>
</tr>
<tr>
<td>Other current assets</td>
<td>—</td>
</tr>
<tr>
<td>Total prepaid and other current assets</td>
<td>$4,888</td>
</tr>
</tbody>
</table>
NOTE 7 – PROPERTY AND EQUIPMENT

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

<table>
<thead>
<tr>
<th></th>
<th>As of December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
</tr>
<tr>
<td>Machinery and equipment</td>
<td>$2,367</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>113</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>2,160</td>
</tr>
<tr>
<td>Software</td>
<td>775</td>
</tr>
<tr>
<td>Trade show equipment</td>
<td>228</td>
</tr>
<tr>
<td>Leasehold improvement</td>
<td>783</td>
</tr>
<tr>
<td></td>
<td>6,426</td>
</tr>
<tr>
<td>Less-accumulated depreciation</td>
<td>(2,646)</td>
</tr>
<tr>
<td>Total property and equipment</td>
<td>$3,780</td>
</tr>
</tbody>
</table>

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

NOTE 8 – INTANGIBLE ASSETS

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

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

On November 18, 2013, the Company entered into an asset purchase agreement with AstraZeneca, pursuant to which the Company acquired from AstraZeneca and its affiliates certain intellectual property with respect to VIMOVO and obtained the rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs in the United States.

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

In connection with the reclassification of IPR&D to developed technology in the third quarter of 2012, the Company conducted a fair value assessment related to the carrying value of this asset. The analysis indicated that the fair value of the developed technology asset exceeded its carrying value, which resulted in no impairment. Developed technology associated with the Company’s approved and/or marketed products is amortized on a straight-line basis over its estimated useful life of twelve years for both RAYOS and LODOTRA.
As of December 31, 2013 and 2012, intangible assets consisted of the following:

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2013</th>
<th></th>
<th>December 31, 2012</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cost</td>
<td>Basis</td>
<td>Accumulated Amortization</td>
<td>Currency Translation</td>
</tr>
<tr>
<td>Developed technology</td>
<td>$ 84,779</td>
<td>$ (17,823)</td>
<td>$ (2,136)</td>
<td>$ 64,820</td>
</tr>
<tr>
<td>VIMOVO intellectual property</td>
<td>67,705</td>
<td>(1,431)</td>
<td>—</td>
<td>66,274</td>
</tr>
<tr>
<td>Total intangible assets</td>
<td>$152,484</td>
<td>$ (19,254)</td>
<td>$ (2,136)</td>
<td>$131,094</td>
</tr>
</tbody>
</table>

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

- 2014: $19,906
- 2015: 19,906
- 2016: 19,906
- 2017: 19,906
- 2018 and thereafter: 51,471
- Total: $131,094

NOTE 9 – OTHER ASSETS

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

- Deferred financing costs
- Long-term clinical study deposits
- Long-term inventory deposits
- Other
- Total other assets

NOTE 10 – ACCRUED LIABILITIES

Accrued liabilities as of December 31, 2013 and 2012, consisted of the following:
The following tables set forth the Company’s financial instruments that are measured at fair value on a recurring basis within the fair value hierarchy. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The standard describes three levels of inputs that may be used to measure fair value:

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

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

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

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Money market funds</td>
<td>$66,817</td>
<td>$0</td>
<td>$0</td>
<td>$66,817</td>
</tr>
<tr>
<td>Total assets at fair value</td>
<td>$66,817</td>
<td>$0</td>
<td>$0</td>
<td>$66,817</td>
</tr>
<tr>
<td><strong>Liabilities:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Derivative liability</td>
<td>$0</td>
<td>$0</td>
<td>$109,410</td>
<td>$109,410</td>
</tr>
<tr>
<td>Total liabilities at fair value</td>
<td>$0</td>
<td>$0</td>
<td>$109,410</td>
<td>$109,410</td>
</tr>
</tbody>
</table>

In accordance with the pronouncement guidance in ASC 815 “Derivatives and Hedging”, the conversion option included within the Convertible Senior Notes was deemed to include an embedded derivative, which required the Company to bifurcate and separately account for the embedded derivative as a separate liability on its consolidated balance sheets. The estimated fair value was derived utilizing the binomial lattice approach for the valuation of convertible instruments. Assumptions used in the calculation included, among others, determining the appropriate credit spread using benchmarking analysis and solving for the implied credit spread, calculating the fair value of the stock component using a discounted risk free rate and borrowing cost and calculating the fair value of the note component using a discounted credit adjusted discount rate. Based on the assumptions used to determine the fair value of the derivative liability associated with the Convertible Senior Notes, the Company concluded that these inputs were Level 3 inputs.
The following table presents the assumptions used by the Company to determine the initial fair value and the fair value as of December 31, 2013 of the conversion option embedded in the Convertible Senior Notes:

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

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

**NOTE 12 – COMMITMENTS AND CONTINGENCIES**

**Lease Obligations**

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

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

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

**Annual Purchase Commitments**

In August 2007, the Company entered into a manufacturing and supply agreement with Jagotec AG (“Jagotec”). Under the agreement, Jagotec or its affiliates are required to manufacture and supply RAYOS/LODOTRA exclusively to the Company in bulk. The Company committed to a minimum purchase of RAYOS/LODOTRA tablets from Jagotec for five years from the date of first launch of RAYOS/LODOTRA in a major country, as defined in the agreement, which was in April 2009. At December 31, 2013, the minimum remaining...
purchase commitment based on tablet pricing in effect under the agreement was $3,351. The agreement automatically renews on a yearly basis until either party provides two years advance written notice of termination. In April 2013, the agreement automatically renewed, and, therefore, the earliest the current agreement can expire according to this advance notice procedure is April 15, 2016.

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

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

**Royalty Agreements**

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

Under the Pozen license agreement, the Company is required to pay Pozen a flat 10% royalty on net sales of VIMOVO and such other products sold by the Company, its affiliates or sublicensees during the royalty term, subject to minimum annual royalty obligations of $5.0 million in 2014 and $7.5 million each year thereafter, which minimum royalty obligations will continue for each year during which one of Pozen’s patents covers such products in the United States and there are no competing products in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing products. The Company’s obligation to pay royalties to Pozen will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in the United States.

**Contingencies**

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

**Indemnification**

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

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

NOTE 13 – LEGAL PROCEEDINGS

On February 15, 2012, the Company received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an Abbreviated New Drug Application (“ANDA”) with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, the Company filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.(collectively, “Par”) for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par’s ANDA and/or prevent Par from selling a generic version of DUEXIS. In January 2013, the Company filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par’s ANDA and/or prevent Par from selling a generic version of DUEXIS.

On August 21, 2013, the Company entered into a settlement agreement (“Par settlement agreement”), and license agreement (“Par license agreement”) with Par relating to its patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both the Company and Par of all claims that were or could have been asserted in the litigation and that arise out of the specific patent issues that were the subject of the litigation, including all resulting damages or other remedies.

Under the Par license agreement, the Company granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par’s generic version of DUEXIS in the United States after the generic entry date and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par’s generic version of DUEXIS prior to the generic entry date (collectively, the “License”). The License covers all patents owned or controlled by us during the term of the Par license agreement that would, absent the License, be infringed by the manufacture, use, sale, offer for sale, or importation of Par’s generic version of DUEXIS in the United States. Unless terminated sooner pursuant to the terms of the Par license agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. Only in the event that Par enters the DUEXIS market due to the specified changes in DUEXIS market conditions will the License become royalty-bearing, with the royalty obligations ceasing upon the occurrence of one of the other events that would have allowed Par to enter the DUEXIS market.
Under the Par license agreement, the Company also agreed not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by the Company during the term of the Par license agreement based on the manufacture, use, sale, offer for sale, or importation of Par’s generic version of DUEXIS in the United States.

The Par license agreement may be terminated by the Company or if Par commits a material breach of the agreement that is not cured or curable within 30 days after the Company provides notice of the breach. The Company may also terminate the Par license agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the Par license agreement will terminate automatically upon termination of the Par settlement agreement.

On March 13, 2013, the Company received purported Notice Letters that a Paragraph IV Patent Certification had been filed by Alvogen Pine Brook, Inc. (“Alvogen”) advising that Alvogen had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. In the Notice Letters, Alvogen noted that as of March 13, 2013, the FDA had not accepted the ANDA for review. Alvogen has agreed that their Notice Letters do not constitute Notice as described in 21 U.S.C. 355(j)(2)(B).

On July 15, 2013, the Company received a Paragraph IV Patent Certification from Watson Laboratories, Inc.—Florida (“Watson”) advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised the Company as to the timing or status of the FDA’s review of its filing. On August 26, 2013, the Company, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc., (collectively “WLF”) seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

On or about August 12, 2013, the Company received a Notice of Opposition to a European patent covering LODOTRA, EP 2049123, filed by Laboratorios Liconsa, S.A. In the European Union, the grant of a patent may be opposed by one or more private parties.

On September 12, 2013, the Company received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. On October 22, 2013, the Company, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA’s Orange Book. On November 20, 2013, the Company was notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, the Company entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

Currently, patent litigation is pending against five generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the District of New Jersey and are grouped in three sets: (i) Dr. Reddy’s Laboratories, Inc. (“Dr. Reddy’s”); Lupin Pharmaceuticals Inc. (“Lupin”); Anchen Pharmaceuticals Inc. (“Anchen”) (collectively, the “DRL cases”); (ii) Mylan Laboratories Limited (collectively the “Mylan cases”); and (iii) Watson Pharma, Inc. (collectively, the “Watson cases”). The Company understands that Dr. Reddy’s has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium.
for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy’s will not be able to commercialize VIMOVO under AstraZeneca’s Nexium patent rights until May 28, 2014. As part of the Company’s acquisition of the U.S. rights to VIMOVO, the Company has taken over and is responsible for the patent litigations that include the Pozen patents licensed to the Company under the Pozen license agreement.

The DRL cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. The Company understands the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The Company understands the Dr. Reddy’s notice letters were dated March 11, 2011 and November 12, 2012; the Lupin notice letter was dated June 10, 2011; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order. The DRL cases do not have pretrial deadlines or a trial date set. The Company understands Anchen has recertified under Paragraph III and has filed a motion to dismiss on that basis.

The Watson cases were filed on May 10, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. The Company understands the cases arise from a March 29, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Watson cases.

The Mylan cases were filed on June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. The Company understands the cases arise from a May 16, 2013 Paragraph IV Notice Letter providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The court has not yet set a trial date or schedule for the Mylan cases.

NOTE 14 – DEBT AGREEMENTS

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

<table>
<thead>
<tr>
<th>Description</th>
<th>As of December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
</tr>
<tr>
<td>Convertible Senior Notes</td>
<td>$150,000</td>
</tr>
<tr>
<td>Senior Secured Loan</td>
<td>—</td>
</tr>
<tr>
<td>Current debt maturities</td>
<td>—</td>
</tr>
<tr>
<td>Debt discount</td>
<td>(39,238)</td>
</tr>
<tr>
<td>Long-term debt, net of current maturities</td>
<td>$110,762</td>
</tr>
</tbody>
</table>

Senior Secured Loan

In February 2012, the Company entered into a $60,000 senior secured loan facility with a group of institutional lenders (the “Senior Secured Loan”). Under the terms of the Senior Secured Loan, the outstanding principal was to accrue interest until maturity in January 2017 at a rate of 17% per annum, payable quarterly unless repaid earlier. The Senior Secured Loan allowed the Company to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt (i.e., payment in kind borrowings). During 2012, the Company elected to pay the 12% interest in cash, and the remaining 5% interest due of $1,842 was added to the principal loan balance as a payment in kind borrowing. During 2013, the Company again elected to pay the 12% interest in cash, and the remaining 5% interest due of $3,001 was added to the principal loan balance as a payment in kind borrowing.
On September 7, 2012, the Company and the lenders entered into an amendment to the Senior Secured Loan (the “Senior Secured Loan Amendment”), whereby certain affirmative covenants under the Senior Secured Loan relating to minimum levels of liquidity and net revenue were modified.

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

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

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

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

**Convertible Senior Notes**

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

The Company used a portion of the proceeds from the Convertible Senior Notes to purchase $18,675 related to a capped call transaction. The capped call transaction is comprised of a net settled purchased call option and a net settled written call option. The Company purchased the call option with an initial strike price of $5.364, which was equal to the initial conversion price, and sold a call option with a strike price of $6.705, which is equal to the cap price. The number of options underlying the capped call is 150,000 or the equivalent to the number of $1,000 Convertible Senior Notes initially issued by the Company.
The Convertible Senior Notes were sold at a price equal to 100% of the principal amount thereof and are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding August 15, 2018 only under certain conditions. Prior to August 15, 2018, the Convertible Senior Notes will be convertible, at the option of the holders thereof, only under the following circumstances:

1. **Conversion upon Satisfaction of Sale Price Condition:** During any fiscal quarter beginning after June 30, 2014, if the closing price of the Company’s common stock for at least 20 trading days during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day.

2. **Conversion upon Satisfaction of Trading Price Condition:** The Convertible Senior Notes can be surrendered for conversion during the five business day period after any five consecutive trading day period in which the trading price per $1,000 principal amount of Convertible Senior Notes was less than 98% of the product of the last reported sale price of the Company’s common stock and the applicable conversion rate on such date.

3. **Conversion upon Specified Distributions:** If the Company elects to:
   i. issue to all or substantially all holders of the Company’s common stock any rights, options or warrants (other than in connection with a stockholder rights plan) entitling them, for a period of not more than 45 calendar days after the declaration date for such issuance, to subscribe for or purchase shares of the Company’s common stock at a price per share that is less than the average of the last reported sale prices of the Company’s common stock for the 10 consecutive trading day period ending on, and including, the trading day immediately preceding the declaration date for such issuance; or
   ii. distribute to all or substantially all holders of the Company’s common stock our assets, securities or rights to purchase our securities, which distribution has a per share value, as reasonably determined by the Company’s board of directors or a committee thereof, exceeding 10% of the last reported sale price of the Company’s common stock on the trading day preceding the date of announcement for such distribution.

4. **Conversion upon Specified Corporate Events:** If (i) a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs or (ii) the Company is party to a consolidation, merger, binding share exchange, or transfer or lease of all or substantially all of its consolidated assets pursuant to which the Company’s common stock would be converted into cash, securities or other assets.

On or after August 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date for the Convertible Senior Notes, holders will be able to convert their Convertible Senior Notes at their option at the conversion rate then in effect at any time, regardless of these conditions.

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

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

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

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

NOTE 15 – STOCKHOLDERS’ EQUITY

In August 2012, the Company entered into a sales agreement with Cowen and Company, LLC (“Cowen”) pursuant to which the Company may sell its common stock through Cowen in at-the-market (“ATM”) offerings. Subject to the terms and conditions of the sales agreement, Cowen may sell the shares by methods deemed to be an ATM offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including sales made through The NASDAQ Global Market, on any other existing trading market for the Company’s common stock or to or through a market maker. On March 25, 2013, the Company requested Cowen to begin making sales under the sales agreement and provided Cowen both daily volume and minimum price restrictions under which Cowen could sell the Company’s common stock. Cowen has not sold shares under the ATM since July 2013. As of December 31, 2013, Cowen had sold a cumulative total of 2,448,575 shares of the Company’s common stock with gross proceeds to the Company of $6,238.

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

NOTE 16 – CO-PROMOTION AGREEMENT

In June 2012, the Company entered into a co-promotion agreement with Mallinckrodt (the “Mallinckrodt Agreement”), pursuant to which the Company engaged Mallinckrodt on a non-exclusive basis to promote DUEXIS in the United States, excluding Puerto Rico and any other territories or possessions. Under the terms of the Mallinckrodt Agreement, Mallinckrodt agreed to use commercially reasonable efforts to promote DUEXIS to an agreed list of physician promotion targets. Mallinckrodt was required to achieve minimum levels of prescriptions from targeted physicians on a quarterly basis during the term of the agreement, and the Company agreed not to grant to any third party the right to co-promote DUEXIS to those targeted physicians in the agreed

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upon territory during the term, other than an existing third party agreement that has since been terminated. Under the terms of the Mallinckrodt Agreement, the Company was responsible for the manufacture, supply and distribution of DUEXIS.

Each party could terminate the agreement early upon certain failures to achieve minimum levels of prescriptions for a specified period of time. On June 1, 2013, the Company provided written notice to Mallinckrodt of termination of the Mallinckrodt Agreement, effective 30 days after the date of such notice. The Mallinckrodt Agreement was terminated as a result of Mallinckrodt not achieving minimum levels of prescriptions from targeted physicians for two consecutive quarters during the period prior to September 30, 2013.

NOTE 17 – EQUITY INCENTIVE PLANS

Employee Stock Purchase Plan

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

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

Stock-Based Compensation Plans

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

In July 2010, the Company’s board of directors adopted the 2011 EIP. In June 2011, the Company’s stockholders approved the 2011 EIP, and it became effective upon the signing of the underwriting agreement related to the Company’s initial public offering on July 28, 2011. The 2011 EIP had an initial reserve of 3,366,228 shares of common stock, including 460,842 shares of common stock previously reserved for future issuance under the 2005 Plan, 1,304,713 shares of common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan as of the 2011 EIP’s effective date and 1,600,673 new shares of common stock reserved. The 2011 EIP provides that an additional number of shares will automatically be added
to the shares authorized for issuance each year on January 1, until 2021. The number of shares added each year will be equal to the least of: (a) 5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (b) 1,474,304 shares of common stock; or (c) a number of shares of common stock that may be determined each year by the Company’s board of directors that is less than (a) and (b). As of December 31, 2013, there were 78,795 shares available for future grants under the 2011 EIP. On December 5, 2013, pursuant to the terms of the Company’s 2011 EIP, the Company’s board of directors approved an increase in the number of shares available for issuance under the 2011 EIP of 1,474,304 shares, effective January 1, 2014.

On November 7, 2013, November 16, 2013 and March 3, 2014, the Company’s board of directors approved amendments to the Company’s 2011 EIP to reserve an additional 200,000 shares, 800,000 shares and 730,000 shares of the Company’s common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company (or following a bona fide period of non-employment with the Company), as an inducement material to the individual’s entry into employment with the Company within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules (“Rule 5635(c)(4)”). On January 10, 2014, the Company’s board of directors approved an amendment to the 2011 EIP to increase the number of shares available for issuance under the 2011 EIP by 703,400 shares (the “January 2014 amendment”), with such increase to the number of shares available for issuance under the 2011 EIP subject to stockholder approval of the January 2014 amendment. As of December 31, 2013, there were 674,400 shares available for future grants under the 2011 EIP pursuant to Rule 5635(c)(4).

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

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

<table>
<thead>
<tr>
<th>Options</th>
<th>Weighted Average Exercise Price</th>
<th>Weighted Average Remaining Contractual Term</th>
<th>Aggregate Intrinsic Value (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2012</td>
<td>2,746,918</td>
<td>$8.85</td>
<td></td>
</tr>
<tr>
<td>Granted</td>
<td>2,158,950</td>
<td>$2.84</td>
<td></td>
</tr>
<tr>
<td>Exercised</td>
<td>(41,820)</td>
<td>$3.88</td>
<td></td>
</tr>
<tr>
<td>Forfeited</td>
<td>(452,968)</td>
<td>$3.88</td>
<td></td>
</tr>
<tr>
<td>Outstanding as of December 31, 2013</td>
<td>4,411,080</td>
<td>$6.47</td>
<td>$13,283</td>
</tr>
<tr>
<td>Exercisable as of December 31, 2013</td>
<td>2,079,728</td>
<td>$9.57</td>
<td>$3,860</td>
</tr>
</tbody>
</table>

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

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dividend yield</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Risk-free interest rate</td>
<td>1.2%</td>
<td>1.0%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Weighted average volatility</td>
<td>86.7%</td>
<td>89.0%</td>
<td>89.3%</td>
</tr>
<tr>
<td>Expected life (in years)</td>
<td>5.98</td>
<td>5.96</td>
<td>6.00</td>
</tr>
<tr>
<td>Weighted average grant date fair value per share of options granted</td>
<td>$2.8</td>
<td>$2.5</td>
<td>$4.2</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.

Forfeitures

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

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

<table>
<thead>
<tr>
<th>Number of Units</th>
<th>Weighted Average Grant-Date Fair Value Per Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2012</td>
<td>232,158</td>
</tr>
<tr>
<td>Granted</td>
<td>831,004</td>
</tr>
<tr>
<td>Vested</td>
<td>(174,213)</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(55,948)</td>
</tr>
<tr>
<td>Outstanding as of December 31, 2013</td>
<td>833,001</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development</td>
<td>$1,054</td>
<td>$1,186</td>
<td>$760</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>1,465</td>
<td>1,090</td>
<td>451</td>
</tr>
<tr>
<td>General and administrative</td>
<td>2,495</td>
<td>2,385</td>
<td>1,319</td>
</tr>
<tr>
<td>Net effect of share-based compensation expense on net loss</td>
<td>$5,014</td>
<td>$4,661</td>
<td>$2,530</td>
</tr>
</tbody>
</table>

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

NOTE 18 – RELATED PARTY TRANSACTIONS

The Company has entered into consulting agreements with three stockholders, two of whom previously served as directors of Horizon Pharma USA. Two of the consulting agreements terminated as of December 31, 2011, while one remains in effect. In addition, the Company’s wholly-owned subsidiary, Horizon Pharma AG, has entered into a consulting agreement with a former owner and majority shareholder of Nitec. For the years ended December 31, 2013, 2012 and 2011, the Company paid $691, $716 and $678, respectively, in consulting fees to the related parties.
NOTE 19 – INCOME TAXES

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

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

<table>
<thead>
<tr>
<th></th>
<th>For the Years Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
</tr>
<tr>
<td><strong>Current provision</strong></td>
<td></td>
</tr>
<tr>
<td>Federal</td>
<td>$ —</td>
</tr>
<tr>
<td>State</td>
<td>4</td>
</tr>
<tr>
<td>Foreign</td>
<td>43</td>
</tr>
<tr>
<td><strong>Total current provision</strong></td>
<td>47</td>
</tr>
<tr>
<td><strong>Deferred benefit</strong></td>
<td></td>
</tr>
<tr>
<td>Federal</td>
<td>—</td>
</tr>
<tr>
<td>State</td>
<td>(1,168)</td>
</tr>
<tr>
<td>Foreign</td>
<td></td>
</tr>
<tr>
<td><strong>Total deferred benefit</strong></td>
<td>(1,168)</td>
</tr>
<tr>
<td><strong>Total benefit for income taxes</strong></td>
<td>$(1,121)</td>
</tr>
</tbody>
</table>

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

During the year ended December 31, 2011, total benefit for income taxes was $14,683. The increase in income tax benefit during this period compared to the year ended December 31, 2010 was associated with a reduction in the Company’s deferred income tax liabilities and a corresponding income tax benefit recorded as a result of intangible asset impairment charge. During the fourth quarter of 2011, the Company performed its annual impairment test related to its indefinite-lived intangible asset and determined that the carrying value of its indefinite-lived in process research and development (“IPR&D”) asset was greater than the fair value of this asset. Accordingly, the Company recorded an intangible asset impairment charge of $69,621 associated with the Company’s IPR&D asset during 2011, which reduced the Company’s deferred income tax liability and increased the income tax benefit for the period.
The Company’s loss before benefit for income taxes by jurisdiction for the years ended December 31, 2013, 2012 and 2011 is as follows:

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>$(139,347)</td>
<td>$ 56,038</td>
<td>$(43,148)</td>
</tr>
<tr>
<td>International</td>
<td>(10,779)</td>
<td>(149,003)</td>
<td>(84,800)</td>
</tr>
<tr>
<td>Loss before benefit for income taxes</td>
<td>$(150,126)</td>
<td>$(92,965)</td>
<td>$(127,948)</td>
</tr>
</tbody>
</table>

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferred tax assets:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net operating loss carryforwards</td>
<td>$ 121,001</td>
<td>$ 97,724</td>
<td>$ 68,689</td>
</tr>
<tr>
<td>Derivative liability</td>
<td>14,799</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Accruals and reserves</td>
<td>7,073</td>
<td>5,144</td>
<td>1,906</td>
</tr>
<tr>
<td>Original issuance discount related to capped call</td>
<td>6,740</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Contingent royalties</td>
<td>3,122</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Research and development credits</td>
<td>2,571</td>
<td>2,445</td>
<td>2,447</td>
</tr>
<tr>
<td>Foreign intangible assets</td>
<td>—</td>
<td>76</td>
<td>90</td>
</tr>
<tr>
<td>Total deferred tax assets</td>
<td>155,269</td>
<td>105,389</td>
<td>73,132</td>
</tr>
<tr>
<td>Valuation allowance</td>
<td>(128,422)</td>
<td>(95,970)</td>
<td>(68,194)</td>
</tr>
<tr>
<td>Deferred tax assets, net of valuation allowance</td>
<td>26,847</td>
<td>9,419</td>
<td>4,938</td>
</tr>
</tbody>
</table>

Deferred tax liabilities:

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Debt discount</td>
<td>$ 14,477</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>In-process research and development</td>
<td>—</td>
<td>—</td>
<td>7,554</td>
</tr>
<tr>
<td>Developed technology</td>
<td>13,009</td>
<td>13,827</td>
<td>7,145</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>2,823</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total deferred tax liabilities</td>
<td>30,309</td>
<td>13,827</td>
<td>14,499</td>
</tr>
</tbody>
</table>

Net deferred income tax liability

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>$ 3,362</td>
<td>$ 4,408</td>
<td>$ 9,561</td>
<td></td>
</tr>
</tbody>
</table>
The increase in the deferred tax valuation allowance was $32,452, $27,776 and $14,213 for the years ended December 31, 2013, 2012 and 2011, respectively. The increase in the deferred tax valuation allowance in 2013 was primarily the result of higher federal and state net operating losses, which were fully reserved for due to the uncertainty surrounding the realization of these assets. A reconciliation of the beginning and ending amounts of the valuation allowance for the years ended December 31, 2013, 2012 and 2011 were as follows:

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>(53,981)</td>
<td>(14,213)</td>
<td>(68,194)</td>
<td>(32,034)</td>
<td>4,258</td>
<td>(128,422)</td>
<td>(32,452)</td>
<td>(128,422)</td>
</tr>
</tbody>
</table>

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

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

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

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

In September 2012, the sale of the Company’s common stock and warrants to purchase shares of the Company’s common stock in a public equity offering triggered an “ownership change” as prescribed by Section 382 of the Internal Revenue Code of 1986, as amended, which generally imposes an annual limitation on the amount of net operating loss carryforwards and associated built-in losses that may be used to offset taxable income when a corporation has undergone certain changes in stock ownership. The Company estimates that these...
annual limits will be a cumulative carryforward of $49,893 in 2014, and at a minimum, $22,001 for each of 2015 and 2016 assuming only the carryforward limitation. The net operating loss carryforward limitation is cumulative such that any use of the carryforwards below the limitation in one year will result in a corresponding increase in the limitation for the subsequent tax year.

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

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

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

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

**NOTE 20 – EMPLOYEE BENEFIT PLANS**

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

The Company’s wholly-owned subsidiary, Horizon Pharma AG, sponsors a defined benefit savings plan covering all of its employees in Switzerland and a defined contribution plan for its employees in Germany. For the years ended December 31, 2013, 2012 and 2011, the Company recognized expenses of $52, $52 and $55, respectively, under these plans.
**NOTE 21 – SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**

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

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First</td>
<td>Second</td>
</tr>
<tr>
<td>Net sales (1)</td>
<td>$8,693</td>
<td>$11,131</td>
</tr>
<tr>
<td>Gross profit</td>
<td>4,924</td>
<td>8,737</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(18,544)</td>
<td>(15,804)</td>
</tr>
<tr>
<td>Net loss</td>
<td>(22,171)</td>
<td>(18,441)</td>
</tr>
<tr>
<td>Net loss per common share-basic and diluted</td>
<td>$ (0.36)</td>
<td>$ (0.29)</td>
</tr>
</tbody>
</table>

(1) The net sales amounts listed above for the First, Second and Third quarters of 2013 have been revised from $9,171, $12,254 and $26,218, respectively, and the net sales amounts listed above for the First, Second, Third and Fourth quarters of 2012 have been revised from $2,523, $3,842, $6,520 and $6,747, respectively, reflecting the reclassification of wholesaler service fees from cost of goods sold to sales discounts and allowances. See Note 1 “The Company” in the notes to the Company’s consolidated financial statements included in this Annual Report on Form 10-K.
<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1(2)</td>
<td>Amended and Restated Certificate of Incorporation.</td>
</tr>
<tr>
<td>3.2(2)</td>
<td>Amended and Restated Bylaws.</td>
</tr>
<tr>
<td>4.1(1)</td>
<td>Form of Common Stock Certificate.</td>
</tr>
<tr>
<td>4.2(1)</td>
<td>Form of Warrant issued by Horizon Pharma, Inc. to bridge financing investors.</td>
</tr>
<tr>
<td>4.3(1)</td>
<td>Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Comerica Bank.</td>
</tr>
<tr>
<td>4.4(1)</td>
<td>Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Hercules Technology Growth Capital, Inc.</td>
</tr>
<tr>
<td>4.5(1)</td>
<td>Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Comerica Bank.</td>
</tr>
<tr>
<td>4.6(1)</td>
<td>Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Hercules Technology Growth Capital, Inc.</td>
</tr>
<tr>
<td>4.7(1)</td>
<td>Warrant issued by Horizon Pharma, Inc. on April 1, 2010 to Silicon Valley Bank.</td>
</tr>
<tr>
<td>4.8(1)</td>
<td>Investors’ Rights Agreement, dated April 1, 2010, by and among Horizon Pharma, Inc. and certain of its stockholders.</td>
</tr>
<tr>
<td>4.9(1)</td>
<td>Form of Warrant issued by Horizon Pharma, Inc. on June 2, 2011 to Oxford Finance LLC.</td>
</tr>
<tr>
<td>4.10(1)</td>
<td>Warrant issued by Horizon Pharma, Inc. on June 2, 2011 to Silicon Valley Bank.</td>
</tr>
<tr>
<td>4.11(1)</td>
<td>Conversion and Amendment Agreement, dated June 16, 2011, by and among Horizon Pharma, Inc. and certain of its stockholders.</td>
</tr>
<tr>
<td>4.12(4)</td>
<td>Form of Warrant issued by Horizon Pharma, Inc. pursuant to the Securities Purchase Agreement, dated February 28, 2012, by and among Horizon Pharma, Inc. and the Purchasers and Warrant Holders listed therein.</td>
</tr>
<tr>
<td>4.14(8)</td>
<td>Form of Warrant issued in Public Offering of Units.</td>
</tr>
<tr>
<td>4.16(15)</td>
<td>Form of 5.00% Convertible Senior Note due 2018.</td>
</tr>
<tr>
<td>10.1(1)</td>
<td>Form of Indemnity Agreement.</td>
</tr>
<tr>
<td>10.2(1)</td>
<td>2005 Stock Plan and Form of Stock Option Agreement thereunder.</td>
</tr>
<tr>
<td>10.3(14)</td>
<td>2011 Equity Incentive Plan, as amended, and Form of Option Agreement and Form of Stock Option Grant Notice thereunder.</td>
</tr>
<tr>
<td>10.5(1)</td>
<td>Development and License Agreement, dated August 20, 2004, by and among Horizon Pharma AG, Jagotec AG and SkyPharma AG.</td>
</tr>
<tr>
<td>10.6(1)</td>
<td>Amendment to Development and License Agreement, dated August 3, 2007, by and among Horizon Pharma AG, Jagotec AG and SkyPharma AG.</td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Document</td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>10.7*(1)</td>
<td>Manufacturing and Supply Agreement, dated August 3, 2007, by and between Horizon Pharma AG and Jagotec AG.</td>
</tr>
<tr>
<td>10.8*(1)</td>
<td>Technology Transfer Agreement, dated August 2, 2004, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck KgAa.</td>
</tr>
<tr>
<td>10.9*(1)</td>
<td>Transfer, License and Supply Agreement, dated December 21, 2006, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH (which was subsequently assigned to Mundipharma Laboratories GmbH in April 2011).</td>
</tr>
<tr>
<td>10.10*(1)</td>
<td>Amendment to Transfer, License and Supply Agreement, dated December 17, 2008, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH (which was subsequently assigned to Mundipharma Laboratories GmbH in April 2011).</td>
</tr>
<tr>
<td>10.11*(1)</td>
<td>Transfer, License and Supply Agreement, dated March 26, 2009, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck GesmbH.</td>
</tr>
<tr>
<td>10.12+(1)</td>
<td>Form of Employee Proprietary Information and Inventions Agreement.</td>
</tr>
<tr>
<td>10.15+(1)</td>
<td>Amendment to Exclusive Distribution Agreement, dated July 7, 2009, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.</td>
</tr>
<tr>
<td>10.18+(1)</td>
<td>Amended and Restated Executive Employment Agreement, dated July 27, 2010, by and between Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D. FACP.</td>
</tr>
<tr>
<td>10.19*(1)</td>
<td>Amendment to Manufacturing and Supply Agreement, dated March 4, 2011, by and between Horizon Pharma AG and Jagotec AG.</td>
</tr>
<tr>
<td>10.20*(1)</td>
<td>Manufacturing and Supply Agreement, dated May 25, 2011, by and between Horizon Pharma USA, Inc. and sanofi-aventis U.S. LLC.</td>
</tr>
<tr>
<td>10.21+(17)</td>
<td>Non-Employee Director Compensation Policy.</td>
</tr>
<tr>
<td>10.22*(1)</td>
<td>Sales Contract, dated July 1, 2010, by and between Horizon Pharma USA, Inc. and BASF Corporation.</td>
</tr>
<tr>
<td>10.23*(1)</td>
<td>Manufacturing and Supply Agreement, dated November 4, 2010 by and between Horizon Pharma AG and Mundipharma Medical Company.</td>
</tr>
<tr>
<td>10.24*(1)</td>
<td>Exclusive Distribution Agreement, dated November 4, 2010 by and between Horizon Pharma AG and Mundipharma International Corporation Limited.</td>
</tr>
<tr>
<td>10.26*(13)</td>
<td>Amendment to Manufacturing and Supply Agreement, effective as of September 25, 2013, by and between Horizon Pharma USA, Inc. and sanofi-aventis U.S. LLC.</td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Document</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>10.30*(5)</td>
<td>Amendment No. 1 to Exclusive Distribution Agreement, dated March 5, 2012, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.</td>
</tr>
<tr>
<td>10.31(5)</td>
<td>Amendment No. 1 to Manufacturing and Supply Agreement, dated March 5, 2012, by and between Horizon Pharma AG and Mundipharma Medical Company.</td>
</tr>
<tr>
<td>10.32+(6)</td>
<td>Form of Restricted Stock Unit Purchase Agreement.</td>
</tr>
<tr>
<td>10.34+(7)</td>
<td>Executive Employment Agreement, dated June 1, 2012, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Todd N. Smith.</td>
</tr>
<tr>
<td>10.35*(9)</td>
<td>First Amendment to Lease, dated July 31, 2012, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.</td>
</tr>
<tr>
<td>10.36*</td>
<td>Second Amendment to Lease, dated December 10, 2013, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.</td>
</tr>
<tr>
<td>10.37(10)</td>
<td>Sales Agreement, dated August 14, 2012, between Horizon Pharma, Inc. and Cowen and Company, LLC.</td>
</tr>
<tr>
<td>10.39*</td>
<td>Amendment No. 2 to Exclusive Distribution Agreement, dated October 25, 2013, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.</td>
</tr>
<tr>
<td>10.40</td>
<td>Amendment No. 2 to Manufacturing and Supply Agreement, dated October 25, 2013, by and between Horizon Pharma AG and Mundipharma Medical Company.</td>
</tr>
<tr>
<td>10.43*</td>
<td>Asset Purchase Agreement, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and AstraZeneca AB.</td>
</tr>
<tr>
<td>10.44*</td>
<td>License Agreement, dated November 22, 2013, by and between Horizon Pharma USA, Inc. and AstraZeneca AB.</td>
</tr>
<tr>
<td>10.45*</td>
<td>Supply Agreement, dated November 22, 2013, by and between Horizon Pharma USA, Inc. and AstraZeneca AB.</td>
</tr>
<tr>
<td>10.46*</td>
<td>Amended and Restated Collaboration and License Agreement for the United States, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and POZEN Inc.</td>
</tr>
<tr>
<td>10.47*</td>
<td>Amendment No. 1 to Amended and Restated Collaboration and License Agreement for the United States, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and POZEN Inc.</td>
</tr>
<tr>
<td>10.48*</td>
<td>Letter Agreement, dated November 18, 2013, by and among Horizon Pharma USA, Inc., AstraZeneca AB and POZEN Inc.</td>
</tr>
<tr>
<td>10.49*</td>
<td>Master Manufacturing Services Agreement, dated October 31, 2013, by and between Horizon Pharma, Inc. and Patheon Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Document</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>10.50(15)</td>
<td>Capped Call Confirmation, dated November 19, 2013, by and between Horizon Pharma, Inc. and Deutsche Bank AG, London Branch.</td>
</tr>
<tr>
<td>10.51(15)</td>
<td>Capped Call Confirmation, dated November 19, 2013, by and between Horizon Pharma, Inc. and Société Générale.</td>
</tr>
<tr>
<td>10.54+(16)</td>
<td>First Amendment to Amended and Restated Executive Employment Agreement, dated January 16, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D., FACP.</td>
</tr>
<tr>
<td>10.56+</td>
<td>Executive Employment Agreement, dated March 5, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Robert F. Carey.</td>
</tr>
<tr>
<td>21.1</td>
<td>Subsidiaries of Horizon Pharma, Inc.</td>
</tr>
<tr>
<td>23.1</td>
<td>Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.</td>
</tr>
<tr>
<td>24.1</td>
<td>Power of Attorney. Reference is made to the signature page hereto.</td>
</tr>
<tr>
<td>31.1</td>
<td>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.</td>
</tr>
<tr>
<td>31.2</td>
<td>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.</td>
</tr>
<tr>
<td>32.1</td>
<td>Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.</td>
</tr>
<tr>
<td>32.2</td>
<td>Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.</td>
</tr>
<tr>
<td>99.1</td>
<td>Unaudited pro forma condensed combined statements of income/(loss) for the year ended December 31, 2013.</td>
</tr>
<tr>
<td>101.INS</td>
<td>XBRL Instance Document</td>
</tr>
<tr>
<td>101.SCH</td>
<td>XBRL Taxonomy Extension Schema Document</td>
</tr>
<tr>
<td>101.CAL</td>
<td>XBRL Taxonomy Extension Calculation Linkbase Document</td>
</tr>
<tr>
<td>101.DEF</td>
<td>XBRL Taxonomy Extension Definition Linkbase Document</td>
</tr>
<tr>
<td>101.LAB</td>
<td>XBRL Taxonomy Extension Label Linkbase Document</td>
</tr>
<tr>
<td>101.PRE</td>
<td>XBRL Taxonomy Extension Presentation Linkbase Document</td>
</tr>
</tbody>
</table>

+ Indicates management contract or compensatory plan.
* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(1) Incorporated by reference to Horizon Pharma, Inc.’s Registration Statement on Form S-1 (No. 333-168504), as amended.
(2) Incorporated by reference to Horizon Pharma, Inc.’s Current Report on Form 8-K, filed on August 2, 2011.
(3) Incorporated by reference to Horizon Pharma, Inc.’s Quarterly Report on Form 10-Q, filed on November 14, 2011.
(7) Incorporated by reference to Horizon Pharma, Inc.’s Quarterly Report on Form 10-Q, filed on August 10, 2012.
(9) Incorporated by reference to Horizon Pharma, Inc.’s Quarterly Report on Form 10-Q, filed on November 13, 2012.
(13) Incorporated by reference to Horizon Pharma, Inc.’s Quarterly Report on Form 10-Q, filed on November 8, 2013.
SECOND AMENDMENT TO LEASE
(Corporate 500 Centre)

THIS SECOND AMENDMENT TO LEASE ("Second Amendment") is made and entered into as of the 10th day of December, 2013, by and between LONG RIDGE OFFICE PORTFOLIO, L.P., a Delaware limited partnership ("Landlord"), and HORIZON PHARMA USA, INC., a Delaware corporation ("Tenant").

RECITALS

A. Landlord and Tenant entered into that certain Standard Office Lease dated as of August 2, 2011 (the "Original Lease"), whereby Tenant leases certain office space located in that certain building located and addressed at 520 Lake Cook Road, Deerfield, Illinois 60015 (the "Building"). The Original Lease was subsequently amended by that certain First Amendment to Lease dated July 31, 2012, by and between Landlord and Tenant (the "First Amendment"). The Original Lease, as amended by the First Amendment, shall be referred to herein as the "Lease."

B. By this Second Amendment, Landlord and Tenant desire that Tenant lease additional space within the Building, and to otherwise modify the Lease as provided herein.

C. Unless otherwise defined herein, capitalized terms shall have the meanings given such terms in the Lease.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

AGREEMENT

1. Existing Premises. Landlord and Tenant hereby acknowledge that Tenant currently leases from Landlord (a) that certain office space located in the Building containing 4,926 rentable square feet located on the third (3rd) floor of the Building and known as Suite 350, and (b) that certain office space in the Building containing 21,182 rentable square feet located on the fifth (5th) floor of the Building and known as Suites 520 and 550 (collectively the "Existing Premises").

2. Second Expansion Space. That certain space located on the third (3rd) floor of the Building known as Suite 375, as outlined on the floor plan attached hereto as EXHIBIT A, shall be referred to herein as the "Second Expansion Space." Landlord and Tenant hereby stipulate that the Second Expansion Space contains 8,352 rentable square feet. Tenant shall commence to pay charges with regard to the Second Expansion Space effective as of May 1, 2014 ("Second Expansion Commencement Date"). The addition of the Second Expansion Space to the Existing Premises shall, effective as of the Second Expansion Commencement Date, increase the number of rentable square feet leased by Tenant in the Building to a total of 34,460 rentable square feet. Effective as of the Second Expansion Commencement Date, all references to the "Premises" shall mean and refer to the Existing Premises as expanded by the Second Expansion Space.

3. Second Expansion Space Term. The Term for Tenant’s lease of the Second Expansion Space ("Second Expansion Space Term") shall commence on the Second Expansion Commencement Date and shall expire co-terminously with Tenant’s lease of the Existing Premises on June 30, 2018 (the "Expiration Date"). Tenant shall have the right to extend the Second Expansion Space Term beyond the Expiration Date under the terms and conditions set forth in Section 31 of the Original Lease and Section 10 below.

Notwithstanding anything to the contrary contained herein, Tenant shall have the right to commence business from the Second Expansion Space during the period (the "Beneficial Occupancy Period") from the date of Landlord’s delivery of possession of the Second Expansion Space to Tenant until the Second Expansion Commencement Date, provided that (i) Tenant shall give Landlord at least ten (10) days prior notice of any such occupancy of the Second Expansion Space, (ii) a certificate of occupancy (or its equivalent) shall have been issued by the appropriate governmental authorities for the Second Expansion Space, and (iii) all of the terms and conditions of the Lease, as amended hereby, shall apply, including Tenant’s obligation to pay parking fees pursuant to Article 9 below, during the Beneficial Occupancy Period (if any), except that Tenant’s obligation to pay monthly Basic Rental and any Direct Costs shall not apply during the Beneficial Occupancy Period.
4. **Basic Rental.** Notwithstanding anything to the contrary in the Lease, during the Second Expansion Space Term, Tenant shall pay, in accordance with the applicable provisions of the Lease and this Section 4, monthly installments of Basic Rental for the Second Expansion Space as follows:

<table>
<thead>
<tr>
<th>Lease Period</th>
<th>Monthly Basic Rental</th>
<th>Annual Basic Rental per Rentable Square Foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 1, 2014 – November 30, 2014</td>
<td>$12,354.00</td>
<td>$17.75</td>
</tr>
<tr>
<td>December 1, 2014 – November 30, 2015</td>
<td>$12,702.00</td>
<td>$18.25</td>
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<tr>
<td>December 1, 2015 – November 30, 2016</td>
<td>$13,050.00</td>
<td>$18.75</td>
</tr>
<tr>
<td>December 1, 2016 – November 30, 2017</td>
<td>$13,398.00</td>
<td>$19.25</td>
</tr>
<tr>
<td>December 1, 2017 – June 30, 2018</td>
<td>$13,746.00</td>
<td>$19.75</td>
</tr>
</tbody>
</table>

*Subject to the terms of Section 5 below, Tenant’s obligation to pay monthly Basic Rental and Tenant’s Proportionate Share of Direct Costs for the Second Expansion Space shall be conditionally abated with respect to each of the full calendar months of June 2014 through and including the month of September 2014.

5. **Conditional Abatement of Basic Rental and Direct Costs.** Notwithstanding anything to the contrary contained in either the Lease or this Second Amendment, provided that Tenant faithfully performs all of the terms and conditions of the Lease, as hereby amended, through the date monthly Basic Rental and Tenant’s Proportionate Share of Direct Costs would otherwise become due for the Second Expansion Space, Landlord hereby agrees to fully abate Tenant’s obligation to pay monthly Basic Rental and Tenant’s Proportionate Share of Direct Costs for the Second Expansion Space for each of the full calendar months of June 2014 through and including the month of September 2014. The total amount of Basic Rental and Direct Costs so abated may be referred to herein as the “**Abatement Amount.**” During such abatement periods, Tenant shall remain responsible for the payment of all of its other monetary obligations under the Lease, as hereby amended. However, in the event of a default by Tenant under the terms of the Lease, as hereby amended, at any subsequent time during the Second Expansion Space Term which results in early termination pursuant to the provisions of Section 20 of the Original Lease, then as a part of the recovery set forth in Section 20 of the Original Lease, Landlord shall be entitled to the then unamortized portion of the Abatement Amount, with such amortization to be calculated on a monthly basis over the period from the May 1, 2014 Second Expansion Commencement Date through the June 30, 2018 Expiration Date.

6. **Tenant’s Proportionate Share for the Second Expansion Space.** Notwithstanding anything to the contrary in the Lease, during the Second Expansion Space Term, Tenant’s Proportionate Share for the Second Expansion Space shall be 1.25%.

7. **Improvements to the Second Expansion Space.** Commencing upon January 1, 2014, Tenant shall cause certain work to be performed in the Second Expansion Space pursuant to the Tenant Work Letter attached hereto as EXHIBIT B, using Building-standard quantities and materials (the “**Improvements**”). Tenant hereby agrees that the construction of the Improvements shall in no way constitute a constructive eviction of Tenant nor entitle Tenant to any abatement of Basic Rental payable pursuant to this Second Amendment. Landlord shall have no responsibility or for any reason be liable to Tenant for any direct or indirect injury to or interference with Tenant’s business arising from the construction of the Improvements, nor shall Tenant be entitled to any compensation or damages from Landlord for loss of the use of the whole or any part of the Existing Premises or the Second Expansion Space resulting from the construction of the Improvements or for any inconvenience or annoyance occasioned by the construction of the Improvements. Except as specifically set forth in this Second Amendment, Tenant hereby agrees to accept the Second Expansion Space in its “as-is” condition and Tenant hereby acknowledges that Landlord shall not be obligated to provide or pay for any improvement work or services related to the improvement of the Second Expansion Space. Tenant also acknowledges that Landlord has made no representation or warranty regarding the condition of the Second Expansion Space.

8. **Letter of Credit.** Landlord and Tenant hereby acknowledge that Landlord is currently holding a Letter of Credit on file in the amount of $[… ***…]. Landlord shall continue to hold such Letter of Credit in accordance with the applicable terms and conditions of Section 4 of the Original Lease.

9. **Parking.** Effective as of the Second Expansion Commencement Date or commencement of the Beneficial Occupancy Period (if earlier) and continuing throughout the Second Expansion Space Term, Tenant shall rent a total of nine (9) unreserved parking passes (i.e., the seven (7) passes referenced in Section 9 of the First Amendment, plus the conversion of one (1) current month-to-month pass to a

***Confidential Treatment Requested***
permanent pass plus one (1) additional pass) for use in the Building’s underground parking facility. Tenant’s rental and use of such parking passes shall continue to be in accordance with, and subject to, all provisions of Section 23 of the Original Lease, and at the prevailing rate charged from time to time.

10. **Option to Extend.** Tenant’s existing option rights shall remain in full force and effect, pursuant to the terms and conditions of Section 31 of the Original Lease; provided however, the Option shall apply to the entirety of the Existing Premises and the Second Expansion Space.

11. **Monument Sign.** Landlord and Tenant acknowledge that Landlord is currently constructing a multi-tenant monument sign at the entrance to Corporate 500 Centre. Tenant shall be entitled to install, at Tenant’s sole cost and expense, the following (collectively, “Tenant’s Signage”): (i) a sign adjacent to the entry to the Second Expansion Space, with the frame of such sign 23” wide by 6” tall, with 1 7/8” capital letters and 1 1/2” lower case letters, and (ii) a strip on such monument sign. The graphics, materials, color, design and the specifications for Tenant’s Signage shall be subject to Landlord’s reasonable approval. Tenant’s Signage shall be personal to the Original Tenant or an Affiliated Assignee (as those terms are defined in Article 31 of the Original Lease) and may not be assigned to any other assignee or sublessee, or any other person or entity. Landlord has the right, but not the obligation, to oversee the installation of Tenant’s Signage. The cost to maintain and operate, if any, Tenant’s Signage shall be paid for by Tenant. Upon the expiration or earlier termination of the Lease (as amended), Tenant shall be responsible for any and all costs associated with the removal of Tenant’s Signage, including, but not limited to, the cost to repair and restore the monument to its original condition, normal wear and tear excepted. Notwithstanding anything to the contrary contained herein, if Landlord grants signage rights on such monument to another tenant leasing a larger number of rentable square feet than Tenant, Landlord may, at Tenant’s expense, remove Tenant’s Signage granted to Tenant under (ii) above from the monument and repair any damage to the monument resulting from such removal.

12. **Brokers.** Each party represents and warrants to the other that no broker, agent or finder, other than Steve Kling and Chris Cummins of Colliers International on behalf of Landlord and Joe Learner of Studley on behalf of Tenant (collectively, the “Brokers”), negotiated or was instrumental in negotiating or consummating this Second Amendment. Each party further agrees to defend, indemnify and hold harmless the other party from and against any claim for commission or finder’s fee by any entity, other than the Brokers, who claims or alleges that they were retained or engaged by or at the request of such party in connection with this Second Amendment.

13. **Payments to Landlord.** Notwithstanding anything to the contrary contained in the Lease, any and all amounts due and payable by Tenant to Landlord shall be in the form of (i) business checks, (ii) wire transfers, (iii) electronic funds transfers, and (iv) automated clearing house payments. Any other forms of payment are not acceptable to Landlord including, without limitation (1) cash or currency, (2) cashier’s checks and money orders, (3) traveler’s checks, (4) payments from credit unions or other non-bank financial institutions, (5) multiple payments for one (1) scheduled payment, and (6) third party checks.

14. **No Further Modification.** Except as set forth in this Second Amendment, all of the terms and provisions of the Lease shall apply during the Second Expansion Space Term and shall remain unmodified and in full force and effect. Effective as of the date hereof, all references to the “Lease” shall refer to the Lease as amended by this Second Amendment.

(Signatures appear on the following page.)
IN WITNESS WHEREOF, this Second Amendment has been executed as of the day and year first above written.

“LANDLORD”

LONG RIDGE OFFICE PORTFOLIO, L.P.,
a Delaware limited partnership

By: M.F. FUNDING, INC.,
a Delaware corporation
   Its: General Partner

   By: /s/ Scott E. Lyle
      Its: Vice President

“TENANT”

HORIZON PHARMA USA, INC.,
a Delaware corporation

By: /s/ Timothy P. Walbert

Print Name: Timothy P. Walbert
Title: Chairman, President & CEO

By:

Print Name:
Title:
EXHIBIT A – Outline of Second Expansion Space

Exhibit A-1
EXHIBIT B – Tenant Work Letter

This Tenant Work Letter shall set forth the terms and conditions relating to the renovation of the tenant improvements in the Second Expansion Space. This Tenant Work Letter is essentially organized chronologically and addresses the issues of the renovation of the Second Expansion Space, in sequence, as such issues will arise.

1. LANDLORD’S INITIAL CONSTRUCTION IN THE SECOND EXPANSION SPACE

Landlord has constructed, at its sole cost and expense, the base, shell and core (i) of the Second Expansion Space, and (ii) of the floor of the Building on which the Second Expansion Space is located (collectively, the "Base, Shell and Core"). Tenant has inspected and hereby approves the condition of the Second Expansion Space and Base, Shell and Core, and agrees that, subject to construction of the Improvements, the Second Expansion Space and the Base, Shell and Core shall be delivered to Tenant in its current "as-is" condition. The improvements to be initially installed in the Second Expansion Space shall be designed and constructed pursuant to this Tenant Work Letter. Any costs of initial design and construction of any improvements to the Second Expansion Space shall be an “Improvement Allowance Item”, as that term is defined in Section 2B of this Tenant Work Letter.

2. IMPROVEMENTS

A. Improvement Allowance. Beginning January 1, 2014, Tenant shall be entitled to a one-time improvement allowance (the “Improvement Allowance”) in the amount of $187,920 for the costs relating to the initial design and construction of Tenant’s improvements which are permanently affixed to the Second Expansion Space (the “Improvements”). In no event shall Landlord be obligated to make disbursements pursuant to this Tenant Work Letter in a total amount which exceeds the Improvement Allowance.

B. Improvement Allowance Items. Except as otherwise set forth in this Tenant Work Letter, the Improvement Allowance shall be disbursed by Landlord (each of which disbursements shall be made pursuant to Landlord’s disbursement process) for costs related to the construction of the Improvements and for the following items and costs (collectively, the “Improvement Allowance Items”): (i) payment of the fees of the “Architect” and the “Engineers,” as those terms are defined in Section 3 of this Tenant Work Letter, and payment of the fees incurred by, and the cost of documents and materials supplied by, Landlord and Landlord’s consultants in connection with the preparation and review of the “Construction Drawings,” as that term is defined in Section 3 of this Tenant Work Letter; (ii) the cost of permits and license fees relating to construction of the Improvements; (iii) the cost of any changes in the Base, Shell and Core required by the Construction Drawings; (iv) the cost of any changes to the Construction Drawings or Improvements required by applicable building codes (the “Code”); (v) the cost of construction of the Improvements, including, without limitation, testing and inspection costs and trash removal costs; and contractors’ fees and general conditions; (vi) sales and use taxes; and (vii) all other costs to be expended by Tenant and reasonably approved Landlord in connection with the construction of the Improvements. However, in no event shall more than three and 50/100 Dollars ($3.50) per rentable square foot of the Improvement Allowance be used for the aggregate cost of items described in (i) and (ii) above; any additional amount incurred as a result of (i) and (ii) above shall be paid for by Tenant as part of the Over-Allowance Amount.

C. Application toward FF&E and/or Rent Credit. Notwithstanding the foregoing, Tenant shall have the right to apply up to $83,520.00 of the Improvement Allowance to reimburse Tenant for costs associated with the purchase and/or installation of furniture, fixtures and equipment (“FF&E”) within the Second Expansion Space and/or as a credit against monthly Basic Rental for the Second Expansion Space; provided, however, Tenant shall be required to provide Landlord with written notice of its election to utilize any portions of the Improvement Allowance toward any FF&E costs and/or monthly Basic Rental credit, with such notice including copies of paid invoices for furniture, fixtures and equipment in the event Tenant elects to use any portion of the Improvement Allowance for reimbursement of FF&E costs. In no event shall Tenant be entitled to any credit for any unused portion of the Improvement Allowance not applied (toward Improvements, FF&E and/or monthly Basic Rental credit) by December 31, 2014.

D. Disbursement of the Improvement Allowance. Landlord shall disburse the Improvement Allowance in interim progress disbursements (“Progress Disbursement”), and one (1) final disbursement (“Final Disbursement”), within thirty (30) days after Tenant submits complete written disbursement requests, as further described below. Landlord may issue checks to fund the Improvement Allowance jointly or separately to Tenant, its general contractor, and any other of “Tenant’s Agents” (as defined in Section 4A below). Without limiting the generality of the provisions below, Landlord may withhold payments of the Improvement Allowance pending inspection of the Improvements theretofore performed to determine that the applicable portions of the Improvements were properly performed in accordance with this Tenant Work Letter and the Approved Working Drawings, and that no substandard work exists.
which adversely affects the mechanical, electrical, plumbing, heating, ventilating and air conditioning, life-safety or other systems of the Building, the curtain wall of the Building, the structure or exterior appearance of the Building, or any other tenant’s use of such other tenant’s leased premises in the Building; provided, such inspections shall not be deemed a warranty by Landlord that such conditions do not exist nor a waiver of Landlord’s rights if such conditions exist and were not reported during such inspection.

(a) **Progress Disbursements.** Each Progress Disbursement shall be paid based on the percentage value of the Improvements theretofore completed ("Completed Work Percentage"), less ten percent (10%) retention ("Retention") to be deferred to the Final Disbursement. Tenant shall not request any Progress Payments more often than monthly. In each Progress Disbursement Request, Tenant shall: (i) state the Completed Work Percentage as of the date of such Progress Disbursement Request (which may include any material actually delivered to the Second Expansion Space as of such date), and show the subtraction of the Retention required herein, (ii) set forth the total estimated cost of the Improvements, and the computation of the Progress Disbursement, (iii) attach a general contractor application for payment on AIA G702 and G703 forms (or such modified version and/or a “sworn statement” or “affidavit of payment” in such form as Landlord may require consistent with Illinois laws and customs to protect against mechanics’ and other liens), respecting the portion of the Improvements covered by such Progress Disbursement Request, duly executed and certified under oath (or sworn under penalty of perjury and notarized as Landlord may require consistent with Illinois laws) by the general contractor and all subcontractors, and which shall include execution and certification by the Architect that all Improvements for which payment is requested have been properly completed in accordance with the Approved Working Drawings, and shall show the names of all parties furnishing material and labor and the amount previously paid and due or to become due to each of them, and shall include invoices and other reasonable supporting documentation, and (iv) include partial lien releases (which may, at Landlord’s sole option, be conditional as to the amount of the current payment requested, but shall in any event be unconditional releases as to prior amounts), by the general contractor and all subcontractors, suppliers, materialmen and persons who have provided any labor, services, material, fixtures, apparatus or machinery (collectively, “Subcontractors”), in such form as Landlord may require consistent with Illinois laws, respecting the portion of the Improvements covered by such Progress Disbursement Request.

(b) **Final Disbursement Request.** Tenant’s Final Disbursement Request shall specify that it is the “Final Disbursement Request,” and shall include: (i) an “Architect’s Certificate of Substantial Completion” on the current AIA form, and an Architect’s certificate for final payment, (ii) a general contractor application for payment on AIA G702 and G703 forms (or such modified version and/or such form of “sworn statement” or “affidavit of payment” as Landlord may require consistent with Illinois laws to protect against mechanics’ and other liens), duly executed and certified under oath (or sworn under penalty of perjury and notarized as Landlord may require consistent with Illinois laws) by the contractor and all Subcontractors, and which shall include execution and certification by the Architect, as further described above respecting Progress Disbursement Requests, (iii) copies of all invoices for the Improvements not previously provided, (iv) a copy of the permanent certificate of occupancy for the Second Expansion Space (if required by law, or otherwise such evidence or government inspections and approvals as may be customary), and (v) final, complete, unconditional lien releases by the general contractor and all Subcontractors in such form as Landlord may require consistent with Illinois laws, and (vi) such other evidence as Landlord may reasonably require that the costs of the Improvements have been paid and that no architect’s, engineer’s mechanic’s, materialmen’s or other liens have been or may be filed against the Building or Second Expansion Space arising out of the design or performance of such Improvements. Notwithstanding anything to the contrary contained herein, to the extent substantial completion has occurred, but any so-called punch-list items or other items remain to be performed, Landlord may defer paying the Final Disbursement or such portion thereof as Landlord may determine, until all such items are fully completed.

(c) **Other Terms.** Landlord shall only be obligated to make disbursements from the Improvement Allowance to the extent costs are incurred by Tenant for Improvement Allowance Items. Except for furniture, fixtures and equipment purchased under Section 2.C above, all Improvement Allowance Items for which the Improvement Allowance has been made available shall be deemed Landlord’s property under the terms of this Second Amendment.

Exhibit B-2
3. CONSTRUCTION DRAWINGS

A. Selection of Architect/Construction Drawings. Tenant shall retain an architect/space planner approved by Landlord (the “Architect”) to prepare the “Construction Drawings,” as that term is defined in this Section 3. Tenant shall also retain the engineering consultants approved by Landlord (the “Engineers”) to prepare all plans and engineering working drawings relating to the structural, mechanical, electrical, plumbing, HVAC and life safety work of the Improvements. The Architect and the Engineers are collectively referred to herein as the “Design Professionals”. The plans and drawings to be prepared by Architect and the Engineers hereunder shall be known collectively as the “Construction Drawings.” All Construction Drawings shall comply with the drawing format and specifications as reasonably determined by Landlord, and shall be subject to Landlord’s reasonable approval. Tenant and Architect shall verify, in the field, the dimensions and conditions as shown on the relevant portions of the base building plans, and Tenant and Architect shall be solely responsible for the same, and Landlord shall have no responsibility in connection therewith. Landlord’s review of the Construction Drawings as set forth in this Section 3, shall be for its sole purpose and shall not imply Landlord’s review of the same, or obligate Landlord to review the same, for quality, design, Code compliance or other like matters. Accordingly, notwithstanding that any Construction Drawings are reviewed by Landlord or its space planner, architect, engineers and consultants, and notwithstanding any advice or assistance which may be rendered to Tenant by Landlord or Landlord’s space planner, architect, engineers, and consultants, Landlord shall have no liability whatsoever in connection therewith and shall not be responsible for any omissions or errors contained in the Construction Drawings. Approval of the Construction Drawings by Landlord is not a representation that the drawings are in compliance with the requirements of governing authorities, and it shall be Tenant’s responsibility to meet and comply with all federal, state, and local code requirements. Landlord’s approval of the “Contract” (as defined in Section 4B(a) below), and Landlord’s designations, lists, recommendations or approvals concerning Design Professionals and Tenant’s Agents, shall not be deemed a warranty as to the quality or adequacy thereof or of the Construction Drawings or the Improvements, or the design thereof, or of compliance with laws, codes and other legal requirements.

B. Approved Working Drawings. Landlord shall approve (or disapprove) working drawings prepared by the Architect within ten (10) days after Landlord receives the final working drawings (the “Approved Working Drawings”). Tenant shall submit the same to the applicable governmental agencies and diligently pursue its receipt of all applicable building permits. Tenant hereby agrees that neither Landlord nor Landlord’s consultants shall be responsible for obtaining any building permit or certificate of occupancy for the Second Expansion Space and that obtaining the same shall be Tenant’s responsibility; provided, however, that Landlord shall cooperate with Tenant in executing permit applications and performing other ministerial acts reasonably necessary to enable Tenant to obtain any such permit or certificate of occupancy. No changes, modifications or alterations in the Approved Working Drawings may be made without the prior written consent of Landlord, which consent may not be unreasonably withheld.

4. CONSTRUCTION OF THE IMPROVEMENTS

A. Contractor and Tenant’s Agents. The contractor which shall construct the Improvements shall be retained by and contract directly with Tenant and shall be a contractor reasonably approved by Landlord. The contractor selected may be referred to herein as the “Contractor”. All subcontractors, laborers, materialmen, and suppliers used by Tenant (such subcontractors, laborers, materialmen, and suppliers, and the Contractor to be known collectively as “Tenant’s Agents”) must be approved in writing by Landlord, which approval shall not be unreasonably withheld or delayed. If Landlord does not approve any of Tenant’s proposed subcontractors, laborers, materialmen or suppliers, Tenant shall submit other proposed subcontractors, laborers, materialmen or suppliers for Landlord’s written approval.

B. Construction of Improvements by Tenant’s Agency.

(a) Construction Contract; Cost Budget. Prior to Tenant’s execution of the construction contract and general conditions with Contractor (the “Contract”), Tenant shall submit the Contract to Landlord for its approval with regard to proper insurance and licensing requirements and any other provisions which may adversely affect Landlord or Landlord’s interest in the Building, and which approval shall not be unreasonably withheld or delayed by more than five (5) business days after Landlord’s receipt of the Contract. Prior to the commencement of the construction of the Improvements, and after Tenant has accepted all bids for the Improvements, Tenant shall provide Landlord with a detailed breakdown, by trade, of the final costs to be incurred or which have been incurred in connection with the design and construction of the Improvements to be performed by or at the direction of Tenant or the Contractor, which costs form a basis for the amount of the Contract (the “Final Costs”). Prior to the commencement of construction of the Improvements, Tenant shall supply Landlord with an amount (the “Over-Allowance Amount”) equal to the difference between the amount of the Final Costs and the amount of the Improvement Allowance (less any portion thereof already disbursed by Landlord, or in the process of being disbursed by Landlord, Exhibit B-3
on or before the commencement of construction of the Improvements). The Over-Allowance Amount shall be disbursed by Landlord prior to the disbursement of any of the then remaining portion of the Improvement Allowance, and such disbursement shall be pursuant to the same procedure as the Improvement Allowance. In the event that, after the Final Costs have been delivered by Tenant to Landlord, the costs relating to the design and construction of the Improvements shall change, any additional costs necessary to such design and construction in excess of the Final Costs, shall be paid by Tenant to Landlord immediately as an addition to the Over-Allowance Amount or at Landlord’s option, Tenant shall make payments for such additional costs out of its own funds, but Tenant shall continue to provide Landlord with the documents described in Section 2D(a) (i), (ii), (iii) and (iv) of this Tenant Work Letter, above, for Landlord’s approval, prior to Tenant paying such costs.

(b) Tenant’s Agents

(i) Landlord’s General Conditions for Tenant’s Agents and Tenant Improvement Work. Tenant’s and Tenant’s Agent’s construction of the Improvements shall comply with the following: (i) the Improvements shall be constructed in strict accordance with the Approved Working Drawings; (ii) Tenant’s Agents shall submit schedules of all work relating to the Improvements to Contractor and Contractor shall, within five (5) business days of receipt thereof, inform Tenant’s Agents of any changes which are necessary thereto, and Tenant’s Agents shall adhere to such corrected schedule; and (iii) Tenant shall abide by all rules made by Landlord’s Project manager with respect to the use of freight, loading dock and service elevators, storage of materials, coordination of work with the contractors of other tenants, and any other matter in connection with this Tenant Work Letter, including, without limitation, the construction of the Improvements.

(ii) Indemnity and Waiver. Tenant’s indemnity of Landlord and waiver of claims against Landlord as set forth in the Lease shall also apply, to the extent not prohibited by applicable Illinois laws, with respect to any and all costs, losses, damages, injuries and liabilities related in any way to any act or omission of Tenant or Tenant’s Agents, or anyone directly or indirectly employed by any of them, or in connection with Tenant’s non-payment of any amount arising out of the Improvements and/or Tenant’s disapproval of all or any portion of any request for payment. Such indemnity by Tenant, as set forth in the Lease, shall also apply, to the extent not prohibited by applicable Illinois laws, with respect to any and all costs, losses, damages, injuries and liabilities related in any way to Landlord’s performance of any ministerial acts reasonably necessary (i) to permit Tenant to complete the Improvements, and (ii) to enable Tenant to obtain any building permit or certificate of occupancy for the Second Expansion Space.

(iii) Requirements of Tenant’s Agents. Each of Tenant’s Agents shall guarantee to Tenant and for the benefit of Landlord that the portion of the Improvements for which it is responsible shall be free from any defects in workmanship and materials for a period of not less than one (1) year from the date of completion thereof. Each of Tenant’s Agents shall be responsible for the replacement or repair, without additional charge, of all work done or furnished in accordance with its contract that shall become defective within one (1) year after the later to occur of (i) completion of the work performed by such contractor or subcontractor and (ii) the Second Expansion Commencement Date. The correction of such work shall include, without additional charge, all additional expenses and damages incurred in connection with such removal or replacement of all or any part of the Improvements, and/or the Building and/or common areas that may be damaged or disturbed thereby. All such warranties or guarantees as to materials or workmanship of or with respect to the Improvements shall be contained in the Contract or subcontract and shall be written such that such guarantees or warranties shall inure to the benefit of both Landlord and Tenant, as their respective interests may appear, and can be directly enforced by either. Tenant covenants to give to Landlord any assignment or other assurances which may be necessary to effect such right of direct enforcement.

Exhibit B-4
(1) **Lien-Free Basis.** Tenant’s Contractor and the other Tenant’s Agents and the Design Professionals shall perform all work and services on a lien-free basis. If a lien is filed or recorded against the Building due to, or in any way associated with, the design, engineering or construction of the Improvements, Tenant agrees to have such lien released of record by recording a lien release bond or otherwise (in a manner and form approved by Landlord) within five (5) days of Landlord’s notice to Tenant regarding same. If Tenant fails to cause the release of such lien within such five (5) day period to Landlord’s satisfaction, Landlord may cause the removal of such lien from Landlord’s title or require a deposit by Tenant as provided under Article 10 (Liens) of the Lease, and Tenant agrees to repay Landlord for all costs and expenses incurred by Landlord to release the lien (including, but not limited to, the payment of the amount stated in the lien, any filing, processing, recording and attorneys’ fees) within ten (10) days of Landlord’s request therefor, and such amount shall be considered Additional Rent due under the Lease. If Tenant fails to pay Landlord as aforesaid, such failure shall be deemed an uncured noticed material default under the Lease, and Landlord may pursue any remedy provided for under the Lease, at law or in equity. Under no circumstances shall Landlord’s approval or payment of a Progress Disbursement, Final Disbursement or any other amount, be deemed a waiver of Tenant’s obligations or Landlord’s rights respecting liens.

(iv) **Insurance Requirements.**

(1) **General Coverages.** All of Tenant’s Agents shall carry worker’s compensation insurance covering all of their respective employees, and shall also carry commercial general liability insurance, including property damage, all with limits, in form and with companies as are required to be carried by Tenant as set forth in the Lease.

(2) **Special Coverages.** Tenant shall carry “Builder’s All Risk” insurance in an amount approved by Landlord covering the construction of the Improvements, and such other insurance as Landlord may require, it being understood and agreed that the Improvements shall be insured by Tenant pursuant to the Lease, as amended by this Second Amendment, during construction and immediately upon completion thereof. Such insurance shall be in amounts and shall include such extended coverage endorsements as may be reasonably required by Landlord including, but not limited to, the requirement that all of Tenant’s Agents shall carry excess liability and Products and Completed Operating Coverage insurance, each in amounts not less than $500,000 for each incident, $1,000,000 in aggregate, and in form and with companies as are required to be carried by Tenant as set forth in the Lease.

(c) **General Terms.** Certificates for all insurance carried pursuant to this Section 4B(c) shall be delivered to Landlord before the commencement of construction of the Improvements and before the Contractor’s equipment is moved onto the site. All such policies of insurance must contain a provision that the company writing said policy will give Landlord thirty (30) days prior written notice of any cancellation or lapse of the effective date or any reduction in the amounts of such insurance. In the event that the Improvements are damaged by any cause during the course of the construction thereof, Tenant shall immediately repair the same at Tenant’s sole cost and expense. Tenant’s Agents shall maintain all of the foregoing insurance coverage in force until the Improvements are fully completed and accepted by Landlord, except for any Products and Completed Operation Coverage insurance required by Landlord, which is to be maintained for ten (10) years following completion of the work and acceptance by Landlord and Tenant. All policies carried under this Section 4B(c) shall insure Landlord and Tenant, as their interests may appear, as well as Contractor and Tenant’s Agents. All insurance maintained by Tenant’s Agents shall preclude subrogation or contribution claims by the insurer against anyone insured thereunder, to the extent not prohibited under applicable Illinois laws. Such insurance shall provide that it is primary insurance as respects

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**Exhibit B-5**
the Landlord and that any other insurance maintained by Landlord is excess and noncontributing with the insurance required hereunder. The requirements for the foregoing insurance shall not derogate from the provisions for indemnification of Landlord by Tenant under Section 4B(b)(ii) of this Tenant Work Letter.

(d) **Governmental Compliance.** The Improvements shall comply in all respects with the following: (i) the Code and other state, federal, city or quasi-governmental laws, codes, ordinances and regulations, as each may apply according to the rulings of the controlling public official, agent or other person; (ii) applicable standards of the American Insurance Association (formerly, the National Board of Fire Underwriters) and the National Electrical Code; and (iii) material and equipment manufacturer’s specifications for the Building and for materials and equipment to be installed as part of the Improvements.

(e) **Inspection by Landlord.** Landlord shall have the right to inspect the Improvements at all times, provided however, that Landlord’s failure to inspect the Improvements shall in no event constitute a waiver of any of Landlord’s rights hereunder nor shall Landlord’s inspection of the Improvements constitute Landlord’s approval of the same. Should Landlord disapprove any portion of the Improvements, Landlord shall notify Tenant in writing of such disapproval and shall specify the items disapproved. Any defects or deviations in, and/or disapproval by Landlord of, the Improvements shall be rectified by Tenant at no expense to Landlord, provided however, that in the event Landlord determines that a defect or deviation exists or disapproves of any matter in connection with any portion of the Improvements and such defect, deviation or matter might adversely affect the mechanical, electrical, plumbing, heating, ventilating and air conditioning or life-safety systems of the Building, the structure or exterior appearance of the Building or any other tenant’s use of such other tenant’s leased premises, Landlord may take such action as Landlord deems necessary, at Tenant’s expense and without incurring any liability on Landlord’s part, to correct any such defect, deviation and/or matter, including, without limitation, causing the cessation of performance of the construction of the Improvements until such time as the defect, deviation and/or matter is corrected to Landlord’s satisfaction.

(f) **Meetings.** Commencing upon the execution of this Second Amendment, Tenant and Landlord shall hold meetings as required at a reasonable time with the Architect and the Contractor regarding the progress of the preparation of Construction Drawings and the construction of the Improvements, which meetings shall be held at a location designated by Landlord, and Landlord and/or its agents shall receive prior notice of, and shall have the right to attend, all such meetings, and, upon Landlord’s request, certain of Tenant’s Agents shall attend such meetings. One such meeting each month shall include the review of Contractor’s current request for payment.

C. **Copy of “As Built” Plans.** At the conclusion of construction, (i) Tenant shall cause the Architect and Contractor (A) to update the Approved Working Drawings as necessary to reflect all changes made to the Approved Working Drawings during the course of construction, (B) to certify to the best of their knowledge that the “record-set” of as-built drawings are true and correct, which certification shall survive the expiration or termination of the Lease, and (C) to deliver to Landlord two (2) sets of copies of such as-built drawings within ninety (90) days following substantial completion of the Improvements, and (ii) Tenant shall deliver to Landlord a copy of all warranties, guaranties, and operating manuals and information relating to the improvements, equipment, and systems in the Second Expansion Space.

5. **MISCELLANEOUS**

A. **Tenant’s Representative.** Tenant has designated Rob Metz as its sole representative with respect to the matters set forth in this Tenant Work Letter, who, until further notice to Landlord, shall have full authority and responsibility to act on behalf of the Tenant as required in this Tenant Work Letter.

B. **Landlord’s Representative.** Prior to commencement of construction of Improvements, Landlord shall designate a representative with respect to the matters set forth in this Tenant Work Letter, who, until further notice to Tenant, shall have full authority and responsibility to act on behalf of the Landlord as required in this Tenant Work Letter.

C. **Time of the Essence.** Time is of the essence with respect to Tenant’s obligations under this Tenant Work Letter. Unless otherwise indicated, all references herein to a “number of days” shall mean and refer to calendar days.

D. **Tenant’s Lease Default.** Notwithstanding any provision to the contrary contained in the Lease, if an event of default as described in the Lease or this Tenant Work Letter has occurred at any time,
then (i) in addition to all other rights and remedies granted to Landlord pursuant to the Lease, Landlord shall have the right to withhold payment of all or any portion of the Improvement Allowance and/or Landlord may cause Contractor to cease the construction of the Second Expansion Space (in which case, Tenant shall be responsible for any delay in the substantial completion of the Second Expansion Space caused by such work stoppage), and (ii) all other obligations of Landlord under the terms of this Tenant Work Letter shall be forgiven until such time as such default is cured pursuant to the terms of the Lease (in which case, Tenant shall be responsible for any delay in the substantial completion of the Second Expansion Space caused by such inaction by Landlord).

E. **Construction Defects.** Landlord shall have no responsibility for the Improvements and Tenant will remedy, at Tenant’s own expense, and be responsible for any and all defects in the Improvements that may appear during or after the completion thereof whether the same shall affect the Improvements in particular or any parts of the Second Expansion Space in general. Tenant shall indemnify, defend, hold harmless and reimburse Landlord for any liabilities, costs or expenses incurred by Landlord by reason of any defect in any portion of the Improvements constructed by Tenant or Tenant’s contractor or subcontractors, or by reason of inadequate cleanup following completion of the Improvements.

F. **Coordination of Labor.** All of Tenant’s contractors, subcontractors, employees, servants and agents must work in harmony with and shall not interfere with any labor employed by Landlord, or Landlord’s contractors or by any other tenant or its contractors with respect to any portion of the Building.

G. **HVAC Systems.** Tenant agrees to be entirely responsible for the maintenance or the balancing of any heating, ventilating or air conditioning system installed by Tenant and/or maintenance of the electrical or plumbing work installed by Tenant and/or for maintenance of lighting fixtures, partitions, doors, hardware or any other installations made by Tenant.

Exhibit B-7
EXCLUSIVE DISTRIBUTION AGREEMENT – AMENDMENT No. 2

THIS AGREEMENT is made the 25th day of October 2013 (the “Effective Date”)

BETWEEN:

(1) HORIZON PHARMA AG a company incorporated in accordance with the laws of Switzerland with its registered office at Kägenstrasse 17, CH-4153 Reinach, Switzerland (the “Principal”); and

(2) MUNDIPHARMA INTERNATIONAL CORPORATION LIMITED a company incorporated in accordance with the laws of Bermuda with its registered office at Canon’s Court, 22 Victoria Street, Hamilton, HM 12 Bermuda (the “Distributor”).

RECITALS:

(A) WHEREAS, the Principal and Distributor concluded an Exclusive Distribution Agreement (“EDA”) on November 4, 2010 to have the Product registered, marketed, sold and distributed by the Distributor in the Field in the Territory (the terms Product, Field and Territory are defined in the EDA); and,

(B) WHEREAS, the Parties amended the EDA, effective March 5, 2012; and

(C) WHEREAS, the Parties wish to further amend the EDA to include additional territories; and

(D) WHEREAS, the Principal has agreed to grant the Distributor an Exclusive licenses and the rights as set out and upon and subject to the terms and conditions in this agreement and the EDA.

IT IS AGREED as follows:

1. DEFINITIONS AND INTERPRETATION
1.1 As used in this Agreement, capitalized words and expressions shall have the meanings defined in the EDA including this AMENDMENT, provided that the following words and phrases shall have the following meanings: In this Agreement, the following terms shall have the following meanings:

“AMENDMENT” means this Agreement between the Parties as set out and described herein.

“COMMENCEMENT DATE” means (1) November 4, 2010 with respect to the following countries in the Territory: Australia, China, Hong Kong, Indonesia, Korea, Malaysia, New Zealand, Philippines, Singapore, South Africa, Taiwan, Thailand, and Vietnam; and (2) March 5, 2012 with respect to the following countries in the Territory: Mexico, Brazil, Argentina, Colombia, Venezuela, Peru, Chile, Ecuador, Dominican Republic, Guatemala, Costa Rica, Uruguay, Bolivia, Panama, Nicaragua, El Salvador and Honduras; and (3) the Effective Date of this AMENDMENT for: Algeria, Angola, Bahrain, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Congo, Cote D’Ivoire, Democratic Republic of the Congo, Djibouti, Egypt, Equitorial Guinea, Eritria, Ethiopia, Gabon, Ghana, Guinea, Iran, Iraq, Jordan, Kenya, Kuwait, Lebanon, Lesotho, Libya, Madagascar, Malawi, Mali, Mauritius, Morocco, Mozambique, Namibia, Nigeria, Oman, Qatar, Rwanda, Saudi Arabia, Senegal, Seychelles, Sierra Leone, Somalia, South Sudan, Sudan, Swaziland, Tanzania, Togo, Tunisia, U.A.E, Uganda, Yemen, Zambia, Zimbabwe.

1.2 Any reference in this AMENDMENT to “writing” or cognate expressions includes a reference to facsimile transmission.

1.3 The headings in this AMENDMENT are for convenience only and shall not affect its interpretation.

1.4 References to “persons” includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships.
1.5 Any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re-enacted.

2. AMENDMENTS TO THE EDA

2.1 Section 2.3.1 is added as follows:

For all countries in the Territory with a Commencement Date that is the Effective Date of this AMENDMENT, Distributor shall, prior to selling, marketing, distributing or otherwise making available or offering Product for sale in such country, obtain, at its sole cost, the Trademark, or if the Trademark is for any reason not available in such country any other trademark of its choice provided that such Trademark is acceptable to the Principal and provided further that the Trademark will upon Principal’s written request, be transferred to the Principal subject to the Principal’s obligation to reimburse the Distributor for all reasonably incurred direct and indirect costs.

2.2 Section 4.8 of the Agreement shall be amended as follows:

The Principal shall (and shall use commercially reasonable efforts to exercise any rights available to the Principal under the Development and License Agreement to require that SkyePharma plc shall), at the Principal’s cost and expense, maintain the Principal Intellectual Property in the Territory which shall include (without limitation) the prosecution, filing, maintenance and renewal of any patents and any reissues or reexaminations of any patents, including the payment of all related fees, with respect to any country in the Territory with a Commencement Date of November 4, 2010.

Before the Commencement Date, the Principal shall have provided the Distributor with a reasonably detailed written report of all material matters concerning the maintenance of the Principal Intellectual Property in the Territory. After the Commencement Date, upon written request by the Distributor (but not more often than on a quarterly basis), the Principal shall provide the Distributor with reasonably detailed written reports on material matters concerning the maintenance of the Principal Intellectual Property in the Territory. The Principal shall (and shall use commercially reasonable efforts to exercise any rights available to the Principal under the Development and License Agreement to require that SkyePharma plc shall) promptly sign all documents and take all other actions as may be necessary or desirable to maintain the Principal Intellectual Property in the Territory. If the Principal decides to cease the prosecution or maintenance of any Principal Intellectual Property in the Territory, then subject to the Development and License Agreement, it shall notify the Distributor in writing sufficiently in advance so that the Distributor may, at its discretion, assume the responsibility for the prosecution or maintenance of such Principal Intellectual Property, at the Distributor’s sole expense.

2.3 Section 5.2.1 is added as follows:

The terms described in Section 5.2 will not apply to any of countries in the Territory with a Commencement Date that is the Effective Date of this AMENDMENT.
2.4 Section 5.22 is added as follows:

Distributor is in compliance, and shall at all times maintain compliance, with all applicable laws and regulations in performing its obligations, including all consumer protection, health, safety, environmental, customs, import/export and all other applicable foreign, federal, state and local laws, regulations, standards and requirements. Distributor will specifically comply with the all applicable anti-corruption laws, including the U.S. Foreign Corrupt Practices Act. Distributor promises that the Products (including any related technical data) will not be exported, sold, or otherwise diverted outside the Territory. Distributor agrees to comply with all applicable import, export, customs, licensing and product registration requirements, including the applicable requirements for a “routed export transaction” and certifies that (a) its export privileges have not been suspended, revoked or denied by the U.S. Bureau of Export Administration; (b) the Products are intended for civilian use; (c) the Products will not be involved in any way with the manufacture or distribution of weapons; (d) no technical data received from Principal will be transferred to any other party without Principal’s prior written consent. Buyer acknowledges U.S. origin items are subject to U.S. Export Administration Regulations. Distributor further represents that it has all necessary licenses or other approvals required to use, possess, prescribe or otherwise distribute the Products as permitted in this Agreement.

2.5 Schedule 1 of the EDA is amended to add the following additional countries:

“Algeria, Angola, Bahrain, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Congo, Cote D’Ivoire, Democratic Republic of the Congo, Djibouti, Egypt, Equitorial Guinea, Eritrea, Ethiopia, Gabon, Ghana, Guinea, Iran, Iraq, Jordan, Kenya, Kuwait, Lebanon, Lesotho, Libya, Madagascar, Malawi, Mali, Mauritius, Morocco, Mozambique, Namibia, Nigeria, Oman, Qatar, Rwanda, Saudi Arabia, Senegal, Seychelles, Sierra Leone, Somalia, South Sudan, Sudan, Swaziland, Tanzania, Togo, Tunisia, U.A.E, Uganda, Yemen, Zambia, Zimbabwe.”

2.6 Schedule 3 of the EDA is amended to add the following Milestone Payments:

<table>
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<tr>
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<th>Milestone Payment</th>
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<tr>
<td>Amount to be paid within five (5) business days of the signature of this AMENDMENT</td>
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</tbody>
</table>

***Confidential Treatment Requested
In WITNESS WHEREOF the PARTIES hereto have caused this AMENDMENT to be executed in duplicate by their duly authorised officers as of the Commencement Date.

HORIZON PHARMA AG

By: /s/ Robert W. Metz
Name: Robert W. Metz
Title: SVP Business Ops

MUNDIPHARMA INTERNATIONAL CORPORATION LIMITED

By: /s/ Douglas Docherty
Name: Douglas Docherty
Title: General Manager

HORIZON PHARMA AG

By: /s/ Timothy P. Walbert
Name: Timothy P. Walbert
Title: Chairman, President and CEO

S:\8613a
MANUFACTURING AND SUPPLY AGREEMENT – AMENDMENT No. 2

THIS AGREEMENT is made the 25th day of October 2013

BETWEEN:

(1) **HORIZON PHARMA AG** a company incorporated in accordance with the laws of Switzerland with its registered office at Kägenstrasse 17, CH-4153 Reinach, Switzerland (“Horizon”); and

(2) **MUNDIPHARMA MEDICAL COMPANY** a partnership organised in accordance with the laws of Bermuda with Registered No. EC – 16260 and with its registered office at Canon’s Court, 22 Victoria Street, Hamilton, HM 12 Bermuda (“Mundipharma”).

RECITALS

(A) The Principal and Distributor concluded a Manufacturing and Supply Agreement (“MSA”) on November 4, 2010 to have Horizon procure the manufacture of the Products and supply the same and have designated Mundipharma to purchase the Products from Horizon for distribution in accordance with the Exclusive Distribution Agreement (“EDA”) between Horizon and MICL concluded on November 4, 2010 and amended on March 5, 2012.

(B) The Principal and Distributor wish to amend the MSA to include additional territories.
NOW IT IS HEREBY AGREED as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 As used in this Agreement, capitalized words and expressions shall have the meanings defined in the MSA, provided that the following words and phrases shall have the following meanings: In this Agreement, the following terms shall have the following meanings:

“AMENDMENT” means this Agreement between the Parties as set out and described herein.

1.2 Any reference in this AMENDMENT to “writing” or cognate expressions includes a reference to facsimile transmission.

1.3 The headings in this AMENDMENT are for convenience only and shall not affect its interpretation.

1.4 References to “persons” includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships.

1.5 Any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re-enacted.

2. AMENDMENTS TO THE MSA

2.1 Schedule 1 of the MSA is amended to add the following additional countries:

“Algeria, Angola, Bahrain, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Congo, Cote D’Ivoire, Democratic Republic of the Congo, Djibouti, Egypt, Equitorial Guinia, Eritria, Ethiopia, Gabon, Ghana, Guinia, Iran, Iraq, Jordan, Kenya, Kuwait, Lebanon, Lesotho, Libya, Madagascar, Malawi, Mali, Mauritius, Morocco, Mozambique, Namibia, Nigeria, Oman, Qatar, Rwanda, Saudi Arabia, Senegal, Seychelles, Sierra Leone, Somalia, South Sudan, Sudan, Swaziland, Tanzania, Togo, Tunisia, U.A.E, Uganda, Yemen, Zambia, Zimbabwe”
In WITNESS WHEREOF the PARTIES hereto have caused this AMENDMENT to be executed in duplicate by their duly authorized officers as of the Commencement Date.

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<th>HORIZON PHARMA AG</th>
<th>MUNDIPHARMA MEDICAL COMPANY</th>
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<tr>
<td>By: /s/ Robert W. Metz</td>
<td>By: /s/ Douglas Docherty</td>
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<tr>
<td>Name: Robert W. Metz</td>
<td>Name: Douglas Docherty</td>
</tr>
<tr>
<td>Title: SVP Business Ops</td>
<td>Title: General Manager</td>
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<tr>
<td>By: /s/ Timothy P. Walbert</td>
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<tr>
<td>Name: Timothy P. Walbert</td>
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<tr>
<td>Title: Chairman, President and CEO</td>
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S:/6798
Exhibit 10.43

***Text Omitted and Filed Separately with the Securities and Exchange Commission. Confidential Treatment Requested Under 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2

Execution Version

CONFIDENTIAL

ASSET PURCHASE AGREEMENT

By and between
AstraZeneca AB

and

Horizon Pharma USA, Inc.

Dated as of November 18, 2013
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This Asset Purchase Agreement (this “Agreement”) is made and executed as of November 18, 2013 (the “Execution Date”), by and between AstraZeneca AB, a Swedish corporation (“AstraZeneca”), and Horizon Pharma USA, Inc., a Delaware corporation (“Horizon”). AstraZeneca and Horizon are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

RECITALS

WHEREAS, AstraZeneca and certain of its Affiliates (as defined below) are engaged in the sourcing and Exploitation (as defined below) of the Product in the Horizon Territory (collectively, the “Product Business”);

WHEREAS, AstraZeneca wishes to sell or grant to Horizon, and Horizon desires to purchase or obtain from AstraZeneca, certain assets and rights associated with the Product Business, upon the terms and conditions hereinafter set forth and set forth in the License Agreement (as defined below);

WHEREAS, at the Closing, AstraZeneca and Horizon intend to enter into the Ancillary Agreements, other than the Guarantee, the Three Party Letter Agreement and the Post-Transition Safety Data Exchange Agreement (each as defined below); and

WHEREAS, concurrently with the execution and delivery of this Agreement, AstraZeneca and Horizon Pharma, Inc., a Delaware corporation and ultimate parent company of Horizon (“Guarantor”), has executed and delivered to AstraZeneca the Guarantee, in which the Guarantor has unconditionally guaranteed all obligations of Horizon under this Agreement and the other Ancillary Agreements.

NOW, THEREFORE, in consideration of the mutual benefits to be derived from this Agreement and of the representations, warranties, conditions, agreements and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE 1
DEFINITIONS

1.1 Certain Defined Terms. As used herein, the following terms shall have the following meanings:

1.1.1 “Accountants” means an accounting firm of national reputation in the United States (excluding each of AstraZeneca’s and Horizon’s respective regular outside accounting firms) as may be mutually acceptable to AstraZeneca and Horizon; provided, however, if AstraZeneca and Horizon are unable to agree on such accounting firm within 10 days or any such mutually selected accounting firm is unwilling or unable to serve, then AstraZeneca shall deliver to Horizon a list of three other accounting firms of national reputation in the United States that have not performed services for AstraZeneca or Horizon in the preceding three-year period, and Horizon shall select one of such three accounting firms.
1.1.2 "Accounts Receivable" means all accounts receivable, notes receivable and other indebtedness due and owed by any Third Party to AstraZeneca or any of its Affiliates arising from sales of the Product by or on behalf of AstraZeneca or its Affiliates in the Horizon Territory prior to the Closing Date.

1.1.3 "Act" means the United States Federal Food, Drug, and Cosmetic Act and the guidelines, guidances and requirements promulgated thereunder.

1.1.4 "Adverse Event" means, with respect to a product, any undesirable, untoward or noxious event or experience associated with the use, or occurring during or following administration, of such product in humans, occurring at any dose, whether expected and whether considered related to or caused by such product, including such an event or experience as occurs in the course of the use of such product in professional practice, in a clinical trial, from overdose, whether accidental or intentional, from abuse, from withdrawal or from a failure of expected pharmacological or biological therapeutic action of such product, and including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32, 314.80 or 600.80, as applicable, or to foreign Governmental Authorities under corresponding applicable Law outside the United States.

1.1.5 "Affiliate" means, with respect to a Person, any other Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such first Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise or (b) the ownership, directly or indirectly, of more than 50% of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.1.6 "Agreement" has the meaning set forth in the preamble hereof.

1.1.7 "Allocation" has the meaning set forth in Section 2.3.2.

1.1.8 "Ancillary Agreements" means the Guarantee, the Supply Agreement, the Bill of Sale, the License Agreement, the Patent Assignment, the Three Party Letter Agreement, the Joint Defense Agreement, the Quality Agreement, the Bailment Agreement, the Patheon Letter, the Vimovo Litigation Records Side Letter, the Transition Agreement, the Post-Transition Safety Data Exchange Agreement and the Transition Safety Data Exchange Agreement.

1.1.9 "APA Licensed Intellectual Property" means the APA Licensed Know-How, the Licensed Copyrights, the Licensed Domain Names, the APA Licensed Trademarks and the APA Manufacturing Technology.

1.1.10 "APA Licensed Know-How" means any data, information and know-how that (a) is not generally known, (b) is Controlled by AstraZeneca or its Affiliates and (c) is used by or on behalf of AstraZeneca or its Affiliates as of the Closing Date for the Exploitation of the Product in the Horizon Territory, but excludes the Merck Know-How and know-how
1.1.11 "APA Licensed Trademarks" means the Trademark VIMOVO and the other Trademarks and logos listed on Schedule 1.1.11.

1.1.12 “APA Manufacturing Technology” means all Patent Rights (including foreign equivalents of the Merck Patents) and all data, information and know-how that (a) with respect to data, information and know-how, are not generally known, (b) are Controlled by AstraZeneca or any of its Affiliates as of the Closing Date and (c) are used by or on behalf of AstraZeneca or its Affiliates for the Manufacture of Products as of the Closing Date, but excludes the Merck Know-How and Merck Patents; provided, that if any data, information or know-how (but not, for clarity, Patent Rights) included in APA Manufacturing Technology becomes publicly disclosed (other than as a result of any disclosure by Horizon in breach of its obligations under Section 5.5 of this Agreement), such data, information or know-how shall no longer be deemed APA Manufacturing Technology.

1.1.13 "Apportioned Obligations" has the meaning set forth in Section 5.9.2(b).

1.1.14 “Arbitration Notice” has the meaning set forth in Section 9.2.2.

1.1.15 “Arbitrators” has the meaning set forth in Section 9.2.2.

1.1.16 “Assumed Liabilities” has the meaning set forth in Section 2.2.1.

1.1.17 “AstraZeneca” has the meaning set forth in the preamble hereto.

1.1.18 “AstraZeneca Confidential Information” has the meaning set forth in Section 5.5.3.

1.1.19 “AstraZeneca FDA Intent Letters” means the letters to the FDA in the form of Exhibit A, indicating AstraZeneca’s intent to transfer the rights to the Purchased Regulatory Approvals to Horizon.

1.1.20 “AstraZeneca FDA Transfer Letters” means the letters to the FDA in the form of Exhibit B, transferring the rights to the Purchased Regulatory Approvals to Horizon.

1.1.21 “AstraZeneca Indemnitees” has the meaning set forth in Section 7.1.2.

1.1.22 “AstraZeneca Marks” means the trade names, corporate names and corporate logos of AstraZeneca or AstraZeneca’s Affiliates that are used by AstraZeneca or any of AstraZeneca’s Affiliates in connection with the Product in the Horizon Territory or the Product Business prior to or as of the Closing Date, but that are also used by AstraZeneca or any of its Affiliates for any other purpose.
1.1.23 “AstraZeneca Permitted Purpose” has the meaning set forth in Section 5.5.2.
1.1.24 “AstraZeneca Territory” means worldwide, excluding the Horizon Territory.
1.1.25 “AstraZeneca’s Knowledge” means the actual knowledge of the individuals listed on Schedule 1.1.25, after reasonable inquiry in the course of performing their respective duties.
1.1.26 “Bailment Agreement” means that certain Bailment Agreement, in substantially the form of Exhibit C.
1.1.27 “Bill of Sale” means that certain Bill of Sale and Assignment and Assumption Agreement, in substantially the form of Exhibit D.
1.1.28 “Business Day” means any day other than Saturday, Sunday or a day on which banking institutions in New York, New York, United States, London, England or Stockholm, Sweden are permitted or obligated by Law to remain closed.
1.1.29 “Calendar Year” means each successive period of 12 calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the this Agreement shall commence on the Closing Date and end on December 31 of the year in which the Closing Date occurs.
1.1.30 “Carve-Out Financial Statements” has the meaning set forth in Section 5.11.
1.1.31 “cGCP” means the ethical, scientific, and quality standards required by FDA for designing, conducting, recording, and reporting trials that involve the participation of human subjects, as set forth in FDA regulations in 21 C.F.R. Parts 50, 54, 56, and 312, and by the International Conference on Harmonization E6: Good Clinical Practices Consolidated Guideline, or as otherwise required by applicable Law.
1.1.32 “cGMP” means standards and methods to be used in, and the facilities or controls to be used for, the Manufacture of a drug, as set forth in FDA regulations in 21 C.F.R. Parts 210 and 211 or otherwise required by applicable Law.
1.1.33 “Claim Notice” has the meaning set forth in Section 7.2.2.
1.1.34 “Closing” has the meaning set forth in Section 2.4.1.
1.1.35 “Closing Date” means the date on which the Closing occurs.
1.1.37 “Confidential Information” has the meaning set forth in Section 5.5.1.
1.1.38 “Confidentiality Agreement” means that certain Confidentiality Agreement, dated March 7, 2013, by and between AstraZeneca LP and Horizon Pharma, Inc.

1.1.39 “Contract” means any contract, agreement, lease, sublease, license, sublicense or other legally binding commitment or arrangement (whether oral or written).

1.1.40 “Control” means, with respect to any Copyright, Domain Name, Patent Right, Trademark, data, information or other item of know-how, Regulatory Approval or Regulatory Documentation, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the licenses and other grants set forth in the License Agreement and before giving effect to the transactions contemplated by this Agreement), to assign or grant a license, sublicense or other right to or under such Copyright, Domain Name, Patent Right, Trademark, data, information or other item of know-how, Regulatory Approval or Regulatory Documentation, as provided for herein or in any Ancillary Agreement.

1.1.41 “Controlling Party” has the meaning set forth in Section 7.2.2.

1.1.42 “Copyright” means copyrights and rights in copyrightable works, copyright registrations, or any application therefor and all extensions, revisions and renewals of any of the foregoing.

1.1.43 “Disclosing Party” has the meaning set forth in Section 5.5.1.

1.1.44 “Disclosure Schedules” means the disclosure schedules of AstraZeneca related to the representations and warranties of AstraZeneca set forth in Section 3.1.

1.1.45 “Dispute” has the meaning set forth in Section 9.2.1.

1.1.46 “Domain Names” means any and all internet or global computing network addresses or locations, including all generic top-level domains (“gTLDs”) and country code top-level domains (“ccTLDs”).

1.1.47 “Duexis” means the pharmaceutical product containing ibuprofen and famotidine in a single fixed combination dosage form, which product is being commercialized as of the Closing Date by Horizon or its Affiliates in the Horizon Territory as Duexis®.

1.1.48 “Encumbrance” means, with respect to any Purchased Asset, any mortgage, lien (including liens for Taxes), license, pledge, security interest or encumbrance.

1.1.49 “End Date” has the meaning set forth in Section 8.1.2.

1.1.50 “Esomeprazole” means that certain pharmaceutical compound with the name (5-methoxy-2-[(S)-(4-methoxy-3,5-dimethylpyridin-2-yl)methyl]sulfanyl]-1H-benzimidazole), including any [...] ***...

*** Confidential Treatment Requested
1.1.51 “Ex-US Licensed Patents” means the Patent Rights that are the foreign equivalents of the Merck Patents, excluding any such Patent Rights included in the APA Manufacturing Technology.

1.1.52 “Excluded Assets” means all assets, property, rights and interests of AstraZeneca and its Affiliates other than the Purchased Assets, including (a) all intellectual property and intellectual property rights of AstraZeneca and its Affiliates other than the Purchased Patents, (b) all rights with respect to the Product in the AstraZeneca Territory, (c) all tangible personal property of AstraZeneca or any of its Affiliates (other than tangible Purchased Assets), (d) all Accounts Receivable, and (e) all Manufacturing-related assets of AstraZeneca or any of its Affiliates.

1.1.53 “Excluded Liabilities” means all Liabilities of AstraZeneca or any of its Affiliates other than the Assumed Liabilities and shall include:

   (a) any product liability, liability for adverse reactions, liability for recalls, liability for product and packaging complaints for any Product sold in the Horizon Territory prior to the Closing (whether direct or as a result of or as a result of successor liability, transferee liability, joint and several liability or contractual liability) or any Liability for Litigation relating to the Product, Purchased Assets, the APA Licensed Intellectual Property, the ex-US Licensed Patents or the Licensed Regulatory Documentation pending or overtly threatened prior to the Closing other than the Vimovo Litigation;

   (b) any Liability (whether direct or as a result of successor liability, transferee liability, joint and several liability or contractual liability) for Taxes in the Pre-Closing Tax Period except to the extent provided in Section 5.9;

   (c) any Liability under or relating to or arising from any Excluded Assets;

   (d) any Liability (whether arising under Contract or otherwise) to Pozen or Merck relating to the Product Business or Purchased Assets, other than Liability under the Pozen US Agreement arising after the Closing;

   (e) any Liability arising out of or resulting from non-compliance with any Law by AstraZeneca or its Affiliates with respect to the Product Business or Purchased Assets prior to the Closing;

   (f) any Liability of AstraZeneca or any of its Affiliates to pay any fees or commissions to any broker, finder or agent with respect to this Agreement or the transactions contemplated hereby; and

   (g) any Liability of AstraZeneca or any of its Affiliates relating to sale of the Product outside the Horizon Territory prior to, on and after the Closing.

   For clarity, the “Excluded Liabilities” do not include any Liability arising out of or relating to any Product or Other Product sold by or on behalf of Horizon; provided, that
each Party’s Liability with respect to Product sold on behalf of Horizon by AstraZeneca or its Affiliate pursuant to the Transition Agreement shall be as set forth in the Transition Agreement.

1.1.54 “Execution Date” has the meaning set forth in the preamble hereto.

1.1.55 “Existing Inventory” means inventory of finished Product (together with any Product packaging materials thereon) owned by AstraZeneca or any of its Affiliates as of Closing that is labeled and held for sale in the Horizon Territory and has not been shipped to a wholesaler or distributor prior to the Closing.

1.1.56 “Exploit” means to make, have made, import, export, use, have used, sell, offer for sale, have sold, research, develop, commercialize, register, hold or keep (whether for disposal or otherwise), transport, distribute, promote, market, or otherwise dispose of, but excludes, to Manufacture or have Manufactured.

1.1.57 “FDA” means the United States Food and Drug Administration and any successor agency thereto.

1.1.58 “Field” means the treatment of human diseases and conditions by means of a pharmaceutical product.

1.1.59 “Financial Information” has the meaning set forth in Section 3.1.13.

1.1.60 “Fundamental Reps” means the representations and warranties set forth in [...***...].

1.1.61 “GAAP” means generally accepted accounting principles in the United States.

1.1.62 “Gastroprotective Agent” means proton pump inhibitors and H2 receptor antagonists for the treatment, prevention or amelioration of injury to the gastrointestinal tract.

1.1.63 “Governmental Authority” means any supranational, international, federal, state or local court, administrative agency or commission or other governmental authority or instrumentality, domestic or foreign, including the FDA and any corresponding foreign agency.

1.1.64 “Guarantee” means the Guarantee, dated the Execution Date, by Guarantor in favor of AstraZeneca.

1.1.65 “Guarantor” has the meaning set forth in the recital hereto.

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

*** Confidential Treatment Requested
1.1.67 “Horizon Confidential Information” has the meaning set forth in Section 5.5.2.
1.1.68 “Horizon FDA Intent Letters” means the letters to the FDA in the form of Exhibit E, indicating Horizon’s intent to accept the transfer of rights to the Purchased Regulatory Approvals from AstraZeneca.
1.1.69 “Horizon FDA Transfer Letters” means the letters to the FDA in the form of Exhibit F, accepting the transfer of rights to the Purchased Regulatory Approvals from AstraZeneca.
1.1.70 “Horizon Indemnitees” has the meaning set forth in Section 7.1.1.
1.1.71 “Horizon Material Adverse Effect” means any event, fact, condition, occurrence, change or effect that prevents or materially impedes or delays the consummation by Horizon of the transactions contemplated by this Agreement or the Ancillary Agreements.
1.1.72 “Horizon Permitted Purpose” has the meaning set forth in Section 5.5.3.
1.1.73 “Horizon Territory” means the United States and its territories and possessions.
1.1.74 “IND” means an Investigational New Drug Application as defined in the Act.
1.1.75 “Indemnification Certificate” has the meaning set forth in Section 7.2.1.
1.1.76 “Indemnified Party” has the meaning set forth in Section 7.2.1.
1.1.77 “Indemnifying Party” has the meaning set forth in Section 7.2.1.
1.1.78 “Joint Defense Agreement” means the certain Joint Defense Agreement executed and delivered by the Parties on the Execution Date.
1.1.79 “Law” means any domestic or foreign, federal, state or local statute, law, treaty, judgment, ordinance, rule, administrative interpretation, regulation, guidance, order or other requirement of any Governmental Authority, in each case, that has the force of law.
1.1.80 “Liabilities” means any debts, liabilities, obligations, commitments, claims or complaints, whether accrued or fixed, known or unknown, fixed or contingent, determined or determinable (including all adverse reactions, recalls, product and packaging complaints and other liabilities) and whether or not the same would be required to be reflected in financial statements or disclosed in the notes thereto.
1.1.81 “License Agreement” means that certain License Agreement, in substantially the form of Exhibit G.
1.1.82 “Licensed Copyrights” means all Copyrights in the Horizon Territory that are Controlled by AstraZeneca and that are used by AstraZeneca or any of AstraZeneca’s Affiliates in connection with the Product Business, including those Copyrights listed on Schedule 1.1.82(a) and excluding the Copyrights listed as excluded on Schedule 1.1.82(b).

1.1.83 “Licensed Domain Names” means the Domain Names listed on Schedule 1.1.83.

1.1.84 “Licensed Regulatory Documentation” means any and all Regulatory Documentation related to the Product or any Other Product, in each case, Controlled by AstraZeneca or any of its Affiliates as of and following the Closing, excluding the Regulatory Documentation included in the Purchased Assets.

1.1.85 “Litigation” means any claim, action, arbitration, mediation, hearing, investigation, proceeding, litigation, suit, warning letter, findings of deficiency or non-compliance, notice of violation or request for recall (whether civil, criminal, administrative, investigative or informal).

1.1.86 “Loss” or “Losses” means any Liabilities, losses, damages, judgments, assessments, levies, fines, penalties, amounts paid in settlement, costs and expenses, including reasonable fees and disbursements of counsel and accountants’, investigators’, and experts’ fees and expenses).

1.1.87 “Manufacture” and “Manufacturing” means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of the Product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.

1.1.88 “Material Adverse Effect” means an event, fact, condition, occurrence, change or effect that is, or would reasonably be expected to (a) be materially adverse to the business, results of operations or condition (financial or otherwise) of the Product Business, the Purchased Assets and the Assumed Liabilities, taken as a whole, or (b) prevent or materially impede or delay the consummation by AstraZeneca of the transactions contemplated by this Agreement and the Ancillary Agreements; provided, however, that, except as provided in clause (vii) below, none of the following, and no events, facts, conditions, occurrences, changes or effects resulting from the following, shall be deemed (individually or in combination) to constitute, or shall be taken into account in determining whether there has been, a “Material Adverse Effect”: (i) political or economic conditions in the Horizon Territory or conditions affecting the capital or financial markets generally; (ii) conditions generally affecting any industry or industry sector in which the Product Business operates or competes or in which the Product is Manufactured or Exploited, including increases in operating costs; (iii) any change in accounting requirements or applicable Law; (iv) any hostility, act of war, sabotage, terrorism or military actions, or any escalation of any of the foregoing; (v) any hurricane, flood, tornado, earthquake or other natural disaster or force majeure event; (vi) the public announcement of the execution or delivery of the Agreement or the pendency of the transactions contemplated hereby; (vii) the failure of the Product Business to achieve any financial projections, predictions or
forecasts (provided, that the underlying causes of such failure shall not be excluded); and (viii) the taking of any action by AstraZeneca or any of its Affiliates that is expressly contemplated by this Agreement or that Horizon has expressly requested be taken; except, in each of clauses (i) through (v), for those conditions that have a disproportionate effect on the Product Business, the Purchased Assets and Assumed Liabilities, taken as a whole, relative to other Persons operating businesses similar to the Product Business in the Horizon Territory.

1.1.89 “Merck Agreements” means any agreement between AstraZeneca or any of its Affiliates, on the one hand, and any Merck Party or any of its Affiliates, on the other hand, with respect to, among other things, Esomeprazole, as amended.

1.1.90 “Merck” means Merck Sharp & Dohme Corp.

1.1.91 “Merck Covenant” has the meaning set forth in Section 2.1.2.

1.1.92 “Merck-Exploitation” means the act of making, having made, manufacturing, having manufactured, developing, using, selling, offering for sale, importing, exporting, marketing or promoting a product.

1.1.93 “Merck Know-How” means any data, information and know-how that (a) is not generally known, (b) is owned or otherwise controlled by a Merck Party pursuant to one or more Merck Agreements and (c) is used by or on behalf of AstraZeneca or its Affiliates as of the Execution Date or the Closing Date, for the Manufacture, having Manufactured or Exploitation of the Product in the Horizon Territory.

1.1.94 “Merck Parties” means Merck, KBI Inc., KBI-E Inc., Merck Holdings, Inc. and KBI Sub Inc.

1.1.95 “Merck Patent Litigation” has the meaning set forth in Section 5.1.3.

1.1.96 “Merck Patents” means the Patent Rights set forth on Schedule 1.1.96.

1.1.97 “Merck Product” means any product that both (a) combines (as the sole active ingredients) Esomeprazole and a therapeutic level of Naproxen in any fixed combination dosage form and (b) is marketed and promoted [***...***] for (x) one or more indications for which [***...***], together with (y) the prevention, treatment or amelioration of, or decrease in the risk of, [***...***] in patients at risk of [***...***], so long as such prevention, treatment or amelioration of, or decrease in the risk of, [***...***] is described or referenced in the product prescribing information.

1.1.98 “Merck-Related Persons” has the meaning set forth in Section 2.1.2.

1.1.99 “Naproxen” means that certain pharmaceutical compound with the chemical name (S)-6-methoxy-(alpha)-methyl-2-naphthaleneacetic acid, including any [***...***].

*** Confidential Treatment Requested
1.1.100 “NDA” means a New Drug Application as defined in the Act.
1.1.101 “NDC” means “National Drug Code,” which is the eleven digit code registered by a company with the FDA with respect to a pharmaceutical product.
1.1.102 “Nexium” means any product containing Esomeprazole as the sole active ingredient in any presentation form that is sold under a Nexium Trademark.
1.1.103 “Nexium Business” means Exploitation activities pertaining to Nexium.
1.1.104 “Nexium Trademark” means the Trademarks and logos listed on Schedule 1.1.104.
1.1.105 “NSAID” means any non-steroidal anti-inflammatory drug, the primary mechanism of action of which is inhibition of cyclooxygenase, but excluding acetyl salicylic acid (including salts and derivatives thereof).
1.1.106 “Non-Controlling Party” has the meaning set forth in Section 7.2.2.
1.1.107 “Notice” has the meaning set forth in Section 9.3.1.
1.1.108 “Other Product” means (a) any product, other than the Product, that combines a Gastroprotective Agent and any NSAID in a single fixed combination dosage form, that would, if made, used, sold, offered for sale, had made, imported or exported without a license from Pozen of the Pozen Patents, infringe one or more Valid Claims of the Pozen Patents and (b) any product, other than the Product and any product described in clause (a), that combines a Gastroprotective Agent and any NSAID in a single fixed combination oral solid dosage form (with or without one or more additional therapeutically active agents) where the right to Exploit such product is owned or Controlled by AstraZeneca or its Affiliates. For the avoidance of doubt, “Other Product” does not include any product containing acetyl salicylic acid (including salts and derivatives thereof) and does not include DUEXIS.
1.1.109 “Owned Registered Product IP” has the meaning set forth in Section 3.1.11(b).
1.1.110 “Party(ies)” has the meaning set forth in the preamble hereto.
1.1.111 “Patent Assignment” means that certain Patent Assignment, in substantially the form of Exhibit H.
1.1.112 “Patent Rights” means: (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisional applications, converted provisional and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications (a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing
patents or patent applications ((a), (b) and (c)); and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.1.113 “Patheon Letter” means that certain Letter, in substantially the form of Exhibit I.

1.1.114 “Payee” has the meaning set forth in Section 5.9.1.

1.1.115 “Payer” has the meaning set forth in Section 5.9.1.

1.1.116 “Payments” has the meaning set forth in Section 5.9.1.

1.1.117 “Permitted Encumbrance” means any (a) Encumbrance for accrued Taxes not yet due or delinquent or for those Taxes being contested in good faith by appropriate proceedings for which an adequate reserve has been taken; (b) Encumbrance caused by Law that does not or would not be reasonably expected to materially detract from the current value of, or materially interfere with, the present use and enjoyment of any Purchased Asset subject thereto or affected thereby in the ordinary course of business of the Product Business; (c) right, title or interest of a licensor or licensee under a license that is reasonably apparent from the text of the applicable license agreement, provided that any such license is disclosed on Schedule 1.1.117 and made available to Horizon prior to the Execution Date and (d) any Encumbrance disclosed on Schedule 1.1.117.

1.1.118 “Person” means any individual, partnership, limited partnership, limited liability company, joint venture, syndicate, sole proprietorship, corporation, unincorporated association, trust, trustee, executor, administrator or other legal personal representative, or any other legal entity, including a Governmental Authority.

1.1.119 “Post-Closing Tax Period” has the meaning set forth in Section 5.9.2(b).

1.1.120 “Post-Transition Safety Data Exchange Agreement” means that certain Safety Data Exchange Agreement, in a form reasonably acceptable to each Party, to be executed by the Parties prior to the transfer of the Purchased Regulatory Approvals to Horizon.

1.1.121 “Pozen” means Pozen Inc.

1.1.122 “Pozen Original Agreement” means that certain Collaboration and License Agreement, dated August 1, 2006, but and between Pozen and AstraZeneca, as amended as of the Execution Date.

1.1.123 “Pozen Patent Litigation” has the meaning set forth in Section 5.1.2.

1.1.124 “Pozen Patents” means the Patent Rights set forth on Schedule 1.1.124.
1.1.125 “Pozen ROW Agreement” means that certain Amended and Restated Collaboration and License Agreement for outside the United States, dated on or prior to the Closing Date, by and between Pozen and AstraZeneca.

1.1.126 “Pozen US Agreement” means that certain Amended and Restated Collaboration and License Agreement for the United States, dated on or prior to the Closing Date, by and between Pozen and AstraZeneca, in substantially the form of Exhibit J.

1.1.127 “Pre-Closing Period” has the meaning set forth in Section 4.1.1.

1.1.128 “Pre-Closing Tax Period” has the meaning set forth in Section 5.9.2(b).

1.1.129 “Product” means the pharmaceutical product(s) containing non-enteric coated Esomeprazole and enteric-coating Naproxen that is the subject of NDA#22-511 in the Horizon Territory, which products are being commercialized by AstraZeneca or its Affiliates as of the Execution Date in the Horizon Territory as VIMOVO™.

1.1.130 “Product Business” has the meaning set forth in the first recital hereto.

1.1.131 “Product Promotional Materials” means all Product materials that have been submitted by or on behalf of AstraZeneca or its Affiliates to the FDA under Form 2253, and the advertising, promotional and media materials, sales training materials (including related quizzes and answers, if any), existing customer lists, co-pay cards, other marketing data and materials, trade show materials (including displays) and videos, including materials containing clinical data, if any, to the extent approved for use by AstraZeneca’s internal promotional review process for the commercialization of the Product in the Horizon Territory until December 31, 2013.

1.1.132 “Product Records” means all books and records relating exclusively to the Product in the Horizon Territory or to the Product Business (other than the Regulatory Documentation) to the extent owned by or maintained by or on behalf of AstraZeneca or any of its Affiliates, but excluding, in all cases, the following books, documents, records and files (a) all books, documents, records and files prepared for the transactions contemplated under this Agreement, including bids received from Third Parties and strategic, financial or Tax analyses relating to the divestiture of the Purchased Assets, the Assumed Liabilities, the Product and the Product Business (b) all books, documents, records and files related solely to the Manufacture of the Product, (c) any attorney work product, attorney client communications and other items protected by established legal privilege, unless the books and records can be transferred without losing such privilege, (d) human resources and any other employee books and records, (e) any financial, Tax and accounting records to the extent not related to the Product in the Horizon Territory, (f) all books and records related to the Merck Patents or the Merck Parties, and (g) any items to the extent applicable Law prohibits their transfer.

1.1.133 “Purchase Price” has the meaning set forth in Section 2.3.1.

1.1.134 “Purchased Assets” has the meaning set forth in Section 2.1.1.

1.1.135 “Purchased Contracts” has the meaning set forth in Section 2.1.1(a).
1.1.136 “Purchased Patents” means the Patent Rights that are listed on Schedule 1.1.136.

1.1.137 “Purchased Regulatory Approvals” has the meaning set forth in Section 2.1.1(b).

1.1.138 “Quality Agreement” means that certain Quality Agreement, dated as of the Closing Date, in substantially the form of Exhibit K.

1.1.139 “Receiving Party” has the meaning set forth in Section 5.5.1.

1.1.140 “Regulatory Approval” means, with respect to the Product or any Other Product, any and all approvals (including NDAs and supplements and amendments thereto and active INDs), licenses, registrations (except manufacturing establishment registrations) or authorizations of any Governmental Authority necessary to commercially distribute, sell or market the Product or such Other Product, as applicable, including, where applicable, (a) pricing or reimbursement approvals, (b) pre- and post-approval marketing authorizations, and (c) labeling approvals.

1.1.141 “Regulatory Authority” means any Governmental Authority that is concerned with the safety, efficacy, reliability, Manufacture, investigation, sale or marketing of pharmaceutical products, medical products, biologics or biopharmaceuticals, including the FDA.

1.1.142 “Regulatory Documentation” means, with respect to the Product or any Other Product, all (a) documentation comprising the Regulatory Approvals, including all submissions, reports and correspondence relating thereto, (b) correspondence and reports necessary to, or otherwise describing the ability to, commercially distribute, sell or market the Product or such Other Product, as applicable, submitted to or received from Governmental Authorities (including minutes and official contact reports relating to any communications with any Governmental Authority) and relevant supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, annual and periodic reports, adverse event files and complaint files and (c) data (including clinical and pre-clinical data and CMC data) contained in any of the foregoing. Regulatory Documentation excludes the Product core data sheet, which shall be retained by AstraZeneca or an Affiliate of AstraZeneca commensurate with continuing safety responsibilities for the Product.

1.1.143 “Representatives” has the meaning set forth in Section 4.1.1.

1.1.144 “Required Actions” has the meaning set forth in Section 3.1.11(b)

1.1.145 “Senior Officer” means, with respect to AstraZeneca, its Vice President, Cornerstone and Commercial Excellence, and with respect to Horizon, its Chief Executive Officer.

1.1.146 “Supply Agreement” means that certain Supply Agreement, in substantially the form attached as Exhibit L.
1.1.147 “Tax Return” means any return, declaration, report, claim for refund, information return or statement relating to Taxes, including any schedule or attachment thereto, filed or maintained, or required to be filed or maintained, in connection with the calculation, determination, assessment or collection of any Tax and includes any amended returns required as a result of examination adjustments made by the Internal Revenue Service or other Tax authority.

1.1.148 “Taxes” means all taxes of any kind, and all charges, fees, customs, levies, duties, imposts, required deposits or other assessments, including all federal, state, local or foreign net income, capital gains, gross income, gross receipt, property, franchise, sales, use, excise, withholding, payroll, employment, social security, worker’s compensation, unemployment, occupation, capital stock, transfer, gains, windfall profits, net worth, asset, transaction and other taxes, and any interest, penalties or additions to tax with respect thereto, imposed upon any Person by any taxing authority or other Governmental Authority under applicable Law.

1.1.149 “Third Party” means any Person other than AstraZeneca, Horizon and their respective Affiliates and permitted successors and assigns.

1.1.150 “Third Party Claim” has the meaning set forth in Section 7.2.2.

1.1.151 “Three Party Letter Agreement” means the letter agreement among AstraZeneca, Horizon and Pozen, dated as of the Execution Date.

1.1.152 “Trademark” means any word, name, symbol, color, product shape, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, product configuration, logo or business symbol, whether or not registered.

1.1.153 “Transfer Taxes” has the meaning set forth in Section 5.9.2(a).

1.1.154 “Transition Agreement” means that certain agreement relating to transition of the Product Business attached as Exhibit M.

1.1.155 “Transition Period” means the period commencing on the Closing Date and ending on the date specified in the Transition Agreement.

1.1.156 “Transition Safety Data Exchange Agreement” means that certain Safety Data Exchange Agreement, in substantially the form attached as Exhibit N.

1.1.157 “Valid Claim” means any claim of any issued and unexpired patent or a patent application that has not been disclaimed or held invalid or unenforceable by judgment or decree entered in any judicial proceeding that is not further reviewable through the exhaustion of all permissible applications for rehearing or review by a superior tribunal, or through the expiration of the time permitted for such applications; provided, that any claim in a pending Patent application that does not issue as a patent claim within [...] years after the earliest priority date of such application will not be a “Valid Claim” until such claim issues as a patent claim.

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1.1.158 “Vimovo Litigation” means any and all Litigation arising out of or related to the submission of Abbreviated New Drug Applications to FDA referencing NDA #22-511 that is described on Schedule 1.1.158.

1.1.159 “Vimovo Litigation Records Side Letter” means that certain Side Letter, in substantially the form attached as Exhibit O.

1.1.160 “[...***...]” has the meaning set forth in Section [...***...].

1.2 Construction. Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including” as used herein does not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party. Unless otherwise specified or where the context otherwise requires, (a) references in this Agreement to any Article, Section, Schedule or Exhibit are references to such Article, Section, Schedule or Exhibit of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; (c) “hereof,” “hereto,” “hereby,” “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (d) references to a Person are also to its permitted successors and assigns; (e) references to a Law include any amendment or modification to such Law and any rules or regulations issued thereunder, in each case, as in effect at the relevant time of reference thereto; (f) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented and in effect at the relevant time of reference thereto; and (g) references to monetary amounts are denominated in United States Dollars.

ARTICLE 2
SALE AND PURCHASE OF ASSETS; LIABILITIES; TRANSITIONAL TRADEMARK LICENSE

2.1 Sale of Purchased Assets.

2.1.1 Purchase and Sale of Purchased Assets. Upon the terms and subject to the conditions of this Agreement and the Ancillary Agreements, at and effective as of the Closing, AstraZeneca shall (or shall cause its applicable Affiliates to) sell, transfer, convey, assign and deliver to Horizon, and Horizon shall purchase and accept from AstraZeneca (or such Affiliates), all right, title and interest in and to the Purchased Assets, free and clear of any and all Encumbrances other than Permitted Encumbrances. As used herein, “Purchased Assets” means all right, title and interest of AstraZeneca (or its Affiliates) in and to the following assets and properties:

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(a) all Contracts listed on Schedule 2.1.1(a), excluding, in each case, all rights to any Accounts Receivable and any other rights, claims or causes of action (including warranty claims) of AstraZeneca or any of its Affiliates thereunder related to Excluded Assets or Excluded Liabilities (the “Purchased Contracts”);

(b) all Regulatory Approvals listed on Schedule 2.1.1(b) from and after the Closing (the “Purchased Regulatory Approvals”);

(c) the documentation comprising the Purchased Regulatory Approvals, including all submissions, reports and correspondence relating thereto, and, to the extent in the possession or Control of AstraZeneca or any of its Affiliates, all other Regulatory Documentation exclusively relating to the Product in the Horizon Territory;

(d) all Product Records;

(e) all Product Promotional Materials; and

(f) the Purchased Patents, including the right to sue and recover for past, present or future infringements, misappropriations, dilution, unauthorized use or disclosure, or other conflict with any of the Purchased Patents.

2.1.2 Merck Covenant. AstraZeneca represents and warrants to Horizon that [***] each of the Merck Parties has agreed that neither it nor any of its Affiliates nor any other Person (to the extent any Merck Party or any Affiliate thereof has the ability (directly or indirectly) to control the actions of such other Person with respect to the matters described in this section) (collectively, the “Merck-Related Persons”) shall institute, pursue, solicit, encourage or assist any action or actions, cause or causes of action (in law or at equity), suits, arbitration proceedings or claims [***] against or adverse to any licensee or sublicensee of either AstraZeneca or Pozen asserting that the Merck-Exploitation of Merck Product infringes any patent application or patent [***] that claims or covers a Merck Product or any components or intermediates thereof or the bulk chemical forms of any compounds [***] (such agreement, the “Merck Covenant”). AstraZeneca agrees that, from and after the Closing Date [***] Horizon shall be entitled to the benefit of the Merck Covenant as provided in this Agreement to the extent that the Manufacture, having Manufactured and Exploitation of any Products and Other Products in the Field in the Horizon Territory by Horizon and its Affiliates, licensees and sublicensees would constitute Merck-Exploitation of a Merck Product. [***] in the event that any Merck-Related Person breaches the Merck Covenant [***]

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2.1.3 Excluded Assets. Horizon shall not acquire pursuant to this Agreement or any Ancillary Agreement, and AstraZeneca shall retain following the Closing Date, the Excluded Assets.

2.1.4 No Rights in the Other Party’s Territory. Horizon acknowledges and agrees that, except for the license and Manufacturing rights granted to Horizon pursuant to the License Agreement and the Supply Agreement, Horizon shall not receive any rights by virtue of this Agreement or any Ancillary Agreement in the AstraZeneca Territory. AstraZeneca acknowledges and agrees that, except for the license rights granted to AstraZeneca pursuant to the License Agreement and the rights retained by AstraZeneca under this Agreement or the License Agreement, AstraZeneca shall not receive any rights to any of Horizon’s intellectual property or Regulatory Documentation by virtue of this Agreement or any Ancillary Agreement in the Horizon Territory.

2.1.5 Retention of Rights. AstraZeneca retains, on behalf of itself and its Affiliates, a non-exclusive right of reference and use under the Purchased Regulatory Approvals and the Regulatory Documentation included in the Purchased Assets, as may be necessary or useful (a) to perform its obligations under the Supply Agreement, the Quality Agreement, the Transition Agreement, the Transition Safety Data Exchange Agreement or the Post-Transition Safety Data Exchange Agreement or (b) to Manufacture or have Manufactured the Product or any Other Product in the Horizon Territory or to perform research and development activities with respect to the Product or any Other Product in the Horizon Territory, in each case solely to support Exploitation of the Product or any Other Product in the AstraZeneca Territory.

2.2 Liabilities.

2.2.1 Assumed Liabilities. Upon the terms and subject to the conditions of this Agreement, at the Closing, AstraZeneca shall assign and Horizon shall unconditionally assume and agree to pay and discharge when due (a) all Liabilities of AstraZeneca and its

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Affiliates under the Purchased Contracts and the Purchased Regulatory Approvals arising on or after the Closing Date, including any Liabilities imposed by applicable Law with respect to obligations under any Purchased Contract or Purchased Regulatory Approval (but other than Liabilities resulting from any breach of or non-compliance with any such Purchased Contract or Purchased Regulatory Approval by AstraZeneca or any of its Affiliates) and (b) all Liabilities arising out of or related to the Vimovo Litigation (excluding any Liabilities for attorneys’, filing and court fees and expenses incurred by AstraZeneca or any of its Affiliates in connection with the Vimovo Litigation), ((a) and (b) together, the “Assumed Liabilities”).

2.2.2 Excluded Liabilities. Horizon shall not assume any Liabilities of AstraZeneca or any of its Affiliates other than the Assumed Liabilities, and the Excluded Liabilities shall remain the sole obligation and responsibility of AstraZeneca and its Affiliates.

2.3 Consideration.

2.3.1 Purchase Price. In consideration of the conveyances contemplated under Section 2.1, the rights granted to Horizon under the License Agreement and the benefit of the Merck Covenant and the Product samples to be supplied to Horizon by AstraZeneca or an Affiliate pursuant to the Transition Agreement, on the Closing Date, Horizon shall pay to AstraZeneca $35,000,000 (the “Purchase Price”), by wire transfer of immediately available funds to the account designated by AstraZeneca by notice to Horizon at least three Business Days prior to the Closing Date.

2.3.2 Allocation of Consideration. Horizon shall allocate the Purchase Price (including the Assumed Liabilities, to the extent properly taken into account under Section 1060 of the Code), among the APA Licensed Intellectual Property, the Ex-US Licensed Patents, the Licensed Regulatory Documentation and the Purchased Assets (the “Allocation”) prior to or within 60 days following the Closing and shall deliver to AstraZeneca a copy of such Allocation (IRS Form 8594) promptly after such determination. AstraZeneca shall have the right to review and raise any objections in writing to the Allocation during the 10-day period after its receipt thereof. If AstraZeneca disagrees with respect to any item in the Allocation, the Parties shall negotiate in good faith to resolve the dispute. If the Parties are unable to agree on the Allocation within 30 days after the commencement of such good faith negotiations (or such longer period as AstraZeneca and Horizon may mutually agree in writing), then the Accountants shall be engaged at that time to review the Allocation, and shall make a determination as to the resolution of such Allocation. The determination of the Accountants regarding the Allocation shall be delivered as soon as practicable following engagement of the Accountants, but in no event more than 60 days thereafter, and shall be final, conclusive and binding upon AstraZeneca and Horizon, and Horizon shall revise the Allocation accordingly. AstraZeneca, on the one hand, and Horizon on the other hand, shall each pay one-half of the cost of the Accountants.

2.4 Closing.

2.4.1 Closing. Pursuant to the terms and subject to the conditions of this Agreement, the closing of the transactions contemplated hereby (the “Closing”) shall take place at the offices of Covington & Burling LLP, 1201 Pennsylvania Avenue, N.W., Washington, D.C. at 10:00 a.m., local time, on the first Business Day on which all conditions (other than those that
by their terms are to be satisfied or taken at the Closing) set forth in Article 6 are satisfied (or, to the extent permitted by applicable Law, waived by the Party entitled to the benefits thereof); provided, that the Closing shall not occur prior to the date that is the earlier of (a) the [...***...] Business Day following the Execution Date and (b) the first Business Day following [...***...], or such other time and place as Horizon and AstraZeneca may agree to in writing. The Closing shall be deemed to have occurred at 12:00 a.m., eastern time, on the Closing Date, such that Horizon shall be deemed the owner of the Purchased Assets on and after the Closing Date.

2.4.2 Closing Deliveries.

(a) Except as otherwise indicated below, at the Closing, AstraZeneca shall deliver the following to Horizon:

(i) each of the Ancillary Agreements to which AstraZeneca is a party, other than the Post-Transition Safety Data Exchange Agreement, the Three Party Letter Agreement and the Guarantee, validly executed by a duly authorized officer of AstraZeneca;

(ii) a receipt acknowledging receipt of the Purchase Price in satisfaction of Horizon’s obligations pursuant to Section 2.3.1, validly executed by a duly authorized representative of AstraZeneca; and

(iii) the Purchased Assets; provided, that (A) with respect to tangible Purchased Assets delivery shall be made as set forth in Schedule 2.4.2(a)(iii), and (B) AstraZeneca may retain one copy of the Product Records included within the Purchased Assets and the Purchased Contracts (and, for clarity, prior to delivering or making available any files, documents, instruments, papers, books and records containing Product Records to Horizon, AstraZeneca shall be entitled to redact from such files, documents, instruments, papers, books and records any information to the extent that it does not relate to the Product Business; provided, that, upon Horizon’s request, AstraZeneca shall provide Horizon with a general description of any such information redacted by AstraZeneca to the extent that AstraZeneca is permitted to do so;

(iv) the Patheon Letter;

(v) the AstraZeneca FDA Intent Letters;

(vi) the AstraZeneca FDA Transfer Letters; and

(vii) the Vimovo Litigation Records Side Letter.

(b) At the Closing, Horizon shall deliver the following to AstraZeneca:

(i) each of the Ancillary Agreements to which Horizon is a party, other than the Post-Transition Safety Data Exchange Agreement and the Three Party Letter Agreement, validly executed by a duly authorized officer of Horizon; and

(ii) the Purchase Price in accordance with Section 2.3.1;

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(iii) the Horizon FDA Intent Letters;
(iv) the Horizon FDA Transfer Letters; and
(v) the Vimovo Litigation Records Side Letter.

(e) Horizon shall conduct a quality and completeness review of the Regulatory Documentation transferred to it pursuant to Section 2.4.2(a)(iii) promptly following such transfer and, as soon as possible, but no later than 60 days after each transfer, shall notify AstraZeneca in writing of any problems or issues experienced by Horizon regarding the completeness, navigation or readability of such transferred Regulatory Documentation that Horizon reasonably and in good faith believes are related to the transfer of such Regulatory Documentation (and not, for example, related to Horizon system capabilities or compatibility). AstraZeneca shall use its commercially reasonable efforts to assist Horizon in remedying any such problems or issues (if any) as soon as reasonably practicable following AstraZeneca’s receipt of Horizon’s notice of the same.

2.5 Transitional Trademark License.

2.5.1 AstraZeneca hereby grants to Horizon and its Affiliates, and Horizon hereby accepts, a non-exclusive, non-transferable, royalty-free, fully paid-up, license in the Horizon Territory to use the AstraZeneca Marks (a) during the period from the Closing Date until all Product samples that contain AstraZeneca’s NDC have been distributed, but in no event later than March 31, 2014, to distribute Product samples in the Horizon Territory and (b) during the period from the Closing Date until December 31, 2013, (i) to use the Product Promotional Materials in the form provided by AstraZeneca at the Closing in connection with the promotion of such Products in the Horizon Territory and (ii) in connection with AstraZeneca’s sale of the Product in the Horizon Territory on behalf of Horizon pursuant to the Transition Agreement.

ARTICLE 3
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of AstraZeneca. AstraZeneca represents and warrants to Horizon as follows, with each such representation and warranty subject to such exceptions, if any, as are set forth in the Disclosure Schedules. Disclosures in any section or paragraph of the Disclosure Schedules shall address only the corresponding section or paragraph of this Agreement, except to the extent that it is reasonably apparent from the face of such disclosure that such disclosure is applicable to other sections or paragraphs of this Agreement.

3.1.1 Entity Status. AstraZeneca is a corporation duly organized, validly existing and in good standing under the Laws of Sweden. AstraZeneca and its Affiliates have all requisite corporate power and authority to own, use and operate the Purchased Assets and to carry on the Product Business as now being conducted.
3.1.2 Authority.

(a) AstraZeneca has the requisite corporate power and authority to enter into this Agreement and the Ancillary Agreements to which it is a party, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and the Ancillary Agreements to which AstraZeneca is a party and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all necessary corporate actions of AstraZeneca. This Agreement constitutes, and each Ancillary Agreement to which it is a party, when executed and delivered by AstraZeneca, will constitute, the valid and legally binding obligation of AstraZeneca, enforceable against AstraZeneca in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity.

(b) Each Affiliate of AstraZeneca that will enter into an Ancillary Agreement has the requisite entity power and authority to perform its obligations under each Ancillary Agreement to which it is a party and to consummate the transactions contemplated thereby. The execution and delivery of the Ancillary Agreements to which any Affiliate of AstraZeneca is a party and the consummation of the transactions contemplated thereby have been duly authorized by all necessary organizational actions of such Affiliate. Each Ancillary Agreement, when executed and delivered by an Affiliate of AstraZeneca that is a party thereto, will constitute the valid and legally binding obligation of such Affiliate, enforceable against such Affiliate in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity.

3.1.3 Non-Contravention. The execution, delivery and performance by AstraZeneca of this Agreement and each Ancillary Agreement to which it is a party and the execution, delivery and performance by each Affiliate of AstraZeneca of each Ancillary Agreement to which such Affiliate is a party do not and will not (a) violate the certificate of incorporation or bylaws or comparable organizational documents of AstraZeneca or such Affiliate, as applicable, (b) violate any Law applicable to AstraZeneca or such Affiliate, as applicable, the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation or (c) subject to obtaining the consents referred to in Section 3.1.5(d), (i) violate, breach or constitute a default under or result in the termination of any Contract to which AstraZeneca or such Affiliate is a party or to which the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation is subject, including any no shop or exclusivity agreement or any option, right of first refusal, right of first offer, right of first negotiation or similar right, (ii) result in the creation of any Encumbrance upon any Purchased Asset other than Permitted Encumbrances or the imposition of any other contractual restrictions on the use of the Purchased Assets or the conduct of the Product Business or (iii) terminate, amend or modify or give any Person the right to terminate, accelerate, amend or modify, abandon or refuse to perform any Purchased Contract (except to the extent that the assignment of a Purchased Contract to Horizon itself constitutes an amendment or modification).
or (iv) violate any order or judgment of a Governmental Authority to which AstraZeneca or any of its Affiliates is subject relating to the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation, except, in the case of the foregoing clauses (b) and (c), for such violations, breaches, defaults, terminations, amendments, modifications, losses of rights, abandonments or refusals to perform that would not reasonably be expected to materially affect the Product Business, taken as a whole.

3.1.4 **No Broker.** There is no broker, finder or financial advisor acting or who has acted on behalf of AstraZeneca or any of its Affiliates, who is entitled to receive any brokerage or finder’s or financial advisory fee from Horizon or any of its Affiliates in connection with the transactions contemplated by this Agreement.

3.1.5 **No Litigation; Consents.**

(a) There is no Litigation (other than any investigation or finding of deficiency or noncompliance, which are addressed in clause (b) below) pending or to AstraZeneca’s Knowledge, threatened, against AstraZeneca or any of its Affiliates before any Governmental Authority relating to the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation or for which the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation is subject.

(b) To AstraZeneca’s Knowledge there is no investigation or finding of deficiency or noncompliance pending or threatened against AstraZeneca or any of its Affiliates before any Governmental Authority relating to the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation or for which the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation is subject.

(c) There is no order or judgment of a Governmental Authority to which AstraZeneca or any of its Affiliates is subject relating to the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation.

(d) Except for (i) consents, permits, authorizations, declarations, filings or registrations that have become applicable solely as a result of the specific regulatory status of Horizon or its Affiliates and (ii) items disclosed in Section 3.1.5(d) of the Disclosure Schedules, no notice to, filing with, permit of, authorization of, exemption by, or consent of, any Governmental Authority or other Person is required for AstraZeneca to consummate the transactions contemplated hereby or by the Ancillary Agreements.

3.1.6 **Purchased Assets; Sufficiency.**

(a) AstraZeneca has, or its Affiliates have, good title to, or valid contract rights in, as applicable, the Purchased Assets, free and clear of all Encumbrances other than Permitted Encumbrances.

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(b) The Purchased Assets, together with the Merck Covenant and rights granted to Horizon under the License Agreement, the Licensed Regulatory Documentation, the APA Manufacturing Technology and any software or other ordinary course and immaterial Third Party licenses that are commercially available (excluding, for clarity, any license of any Patent Rights), constitute all of the intellectual property, Regulatory Approvals and Regulatory Documentation necessary to (i) operate the Product Business, (ii) Manufacture or have Manufactured the Product in the Horizon Territory, and (iii) Manufacture, have Manufactured, research and develop the Product in the AstraZeneca Territory solely for exportation and use of the Product in connection with the Exploitation of Product in the Horizon Territory, in each case ((i) - (iii)) in the same manner that AstraZeneca and its Affiliates are operating the Product Business, Manufacturing or having Manufactured the Product in the Horizon Territory, and Manufacturing, having Manufactured, researching and developing the Product in the AstraZeneca Territory for exportation and use of the Product in connection with the Exploitation of Product in the Horizon Territory, as applicable, as of the Execution Date and as of the Closing. In the event this Section 3.1.6(b) is breached because AstraZeneca has failed to convey any Purchased Assets or to identify and either transfer to Horizon, or grant Horizon a license to or right of reference and use with respect to, as applicable, any intellectual property, Regulatory Approvals or Regulatory Documentation necessary for the representation and warranty in this Section 3.1.6(b) to be true and correct in all respects, such breach shall be deemed cured as of the date AstraZeneca or any of its Affiliates specifically performs its obligation under this Agreement or any Ancillary Agreement to convey title to all Purchased Assets to Horizon or to transfer to Horizon, or grant Horizon a license to or right of reference and use with respect to, as applicable, such intellectual property, Regulatory Approvals or Regulatory Documentation at no additional cost or expense to Horizon; provided that such breach shall not be deemed cured with respect to any Losses incurred by any Horizon Indemnitee prior to such transfer or grant.

3.1.7 Contracts. Each of the Purchased Contracts is in effect and constitutes a legal, valid and binding agreement of AstraZeneca or an Affiliate of AstraZeneca, enforceable in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity. AstraZeneca is not and, to AstraZeneca’s Knowledge, no other party thereto is, in default in the performance, observance or fulfillment of any obligation or covenant contained in any Purchased Contract and no event has occurred that with the passage of time or giving of notice or both would constitute such a breach or default, result in the payment of any damages or penalties or result in the creation of any Encumbrance thereunder or pursuant thereto other than Permitted Encumbrances. AstraZeneca has not received any written notice from a Third Party at any time during the past [...***...] years regarding any actual, alleged or potential violation or breach of, or default under, any of the Purchased Contracts or stating that such Third Party intends to terminate, cancel or make any material change to any Purchased Contract and there are no pending renegotiations of any of the Purchased Contracts. The Product Business as conducted by AstraZeneca and its Affiliates as of the Execution Date does not rely upon or use rights under any Contract that has expired or been terminated. True and complete copies of all Purchased Contracts and the Pozen Original Agreement have been made available to Horizon. To AstraZeneca’s Knowledge, Pozen is not in breach of the Pozen Original Agreement.

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3.1.8 Compliance with Law.

(a) AstraZeneca and its Affiliates, with respect to the operation of the Product Business, are and during the past [...***...] years prior have been in compliance with all applicable Laws in the Horizon Territory, including (i) any applicable Laws governing the approval, Manufacture, sale, marketing, promotion, or distribution of drugs and the purchase or prescription of or reimbursement for drugs by any Governmental Authority, private health plan or entity, or individual, and (ii) the federal Anti-Kickback Statute (42 U.S.C. §1320a-7(b)), the False Claims Act (42 U.S.C. §1320a-7b(a)), the Foreign Corrupt Practices Act of 1977 (15 U.S.C. §78 et seq.) and the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §1320d et. seq.), and any comparable state or local Laws, in each case, except for such noncompliance that would not reasonably be expected to materially affect the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation, each taken as a whole. This Section 3.1.8 does not address regulatory matters, which are the subject of Section 3.1.9. During the past [...***...] years, neither AstraZeneca or its Affiliates has received any written notices of any alleged violations, delinquency or investigations for violation of any Law relating to the Product Business or the Purchased Assets or Assumed Liabilities or to which the any of the Purchased Assets, or business activities relating to the Product Business are subject.

(b) AstraZeneca, or an Affiliate of AstraZeneca, possesses, and is in material compliance with, all material permits (other than Regulatory Approvals, which are the subject of Section 3.1.9(b)) necessary for the conduct of the Product Business as it is currently conducted.

3.1.9 Regulatory Matters.

(a) Neither AstraZeneca, any of its Affiliates nor, to AstraZeneca’s Knowledge, any Merck Party, or any Person on behalf of any of the foregoing, is Exploiting any Other Products in the Horizon Territory.

(b) AstraZeneca, or an Affiliate of AstraZeneca, owns all Regulatory Approvals and Regulatory Documentation necessary to conduct the Product Business in the Horizon Territory as currently conducted and such Regulatory Approvals are in full force and effect. AstraZeneca has the right to grant the right of reference and use under the Licensed Regulatory Documentation to Horizon in accordance with the License Agreement. Neither AstraZeneca nor its Affiliates has received any written communication from any Governmental Authority threatening to withdraw or suspend any such Regulatory Approvals. No proceeding is pending or, to AstraZeneca’s Knowledge, threatened regarding the revocation of any such Regulatory Approval. AstraZeneca and its Affiliates have not voluntarily or involuntarily surrendered, terminated or permitted to lapse or expire any Regulatory Approval used or maintained by them in the conduct of the Product Business, except where any such Regulatory Approval has been not renewed in the ordinary course of business. AstraZeneca or its Affiliates have filed with the applicable Governmental Authority all material filings, declarations, listings, registrations, reports or submissions, including adverse event reports required in connection with the conduct of the Product Business. All such filings, declarations, listings, registrations, reports or submissions were in compliance in all material respects with all applicable Laws when filed.
and no deficiencies have been asserted by any applicable Governmental Authority with respect to any such filings, declarations, listings, registrations, reports or submissions. Neither AstraZeneca nor any of its Affiliates is in violation of the terms of any Regulatory Approval for the Horizon Territory.

(c) There has not been any product recall or market withdrawal or replacement conducted by or on behalf of AstraZeneca concerning the Product in the Horizon Territory or any product recall, market withdrawal or replacement conducted by or on behalf of any Third Party as a result of any alleged defect in the Product in the Horizon Territory. AstraZeneca has made available to Horizon copies of material field alerts, dear doctor letters, complaints and notices of alleged defect or adverse reaction with respect to the Product in the Horizon Territory that have been received in writing by AstraZeneca and its Affiliates.

(d) The Product has been Manufactured in compliance with applicable Law, including cGMP, and applicable Regulatory Approvals. Neither AstraZeneca nor any Affiliate or Third Party engaged by it, in any capacity, in connection with the Manufacture of the Product has received in the past [...***...] years or is currently subject to a Warning Letter (as defined in the Act) with respect to any facility manufacturing Product for Exploitation in the Horizon Territory. Subject to backorders or delays in the ordinary course, AstraZeneca or its Affiliate has fulfilled all purchase orders submitted for the Product in the Horizon Territory.

(e) All studies, tests and preclinical and clinical trials conducted by or on behalf of AstraZeneca or its Affiliates relating to the Product were conducted, and all studies, tests and trials currently being conducted by or on behalf of AstraZeneca or its Affiliates in connection with the clinical trials listed in Section 3.1.9(e) of the Disclosure Schedules are being conducted, in either case in all material respects in accordance with cGCP and other applicable Laws. AstraZeneca has completed all pediatric assessments or postmarketing commitments required by the FDA with respect to the Product in the Horizon Territory. Neither AstraZeneca nor any Affiliate of AstraZeneca has received any written notices or correspondence from any applicable Governmental Authority requiring the termination, suspension, material modification or clinical hold of any clinical trials listed in Section 3.1.9(e) of the Disclosure Schedules.

3.1.10 **Debarred Personnel**. Neither AstraZeneca nor any of its Affiliates, officers, directors, employees, consultants, or, to AstraZeneca’s Knowledge, any of its vendors, contractors, investigators or agents, who has undertaken activities in connection with the Product Business has been debarred or deemed subject to debarment pursuant to Section 306 of the Act nor, to AstraZeneca’s Knowledge, are any such Persons the subject of a conviction described in such section.

3.1.11 **Intellectual Property.**

(a) AstraZeneca or one of its Affiliates owns the Merck Patents and the APA Licensed Intellectual Property, jointly with Pozen owns the Purchased Patents and has the right to use the Pozen Patents and has the right to license the APA Licensed Intellectual Property to Horizon in accordance with the License Agreement. The Purchased Patents are the only Joint Patents (as defined in the Pozen Original Agreement) in the Horizon Territory under the Pozen Original Agreement. There are no Patent Rights in the Horizon Territory claiming any

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AstraZeneca Inventions (as defined in the Pozen Original Agreement) under the Pozen Original Agreement. There are no data, information, know-how or Patent Rights owned or controlled by a Merck Party pursuant to any Merck Agreement that claim or cover any Manufacturing, having Manufactured or Exploitation activities with respect to the Product outside the Horizon Territory.

(b) Section 3.1.11(b)(i) of the Disclosure Schedules sets forth a true and complete list of all APA Licensed Intellectual Property owned by AstraZeneca or one of its Affiliates, other than the Purchased Patents, that has not expired or been abandoned and has issued, been registered or granted or that is the subject of an application for registration, issuance or grant in the Horizon Territory (“Owned Registered Product IP”). Section 3.1.11(b)(ii) of the Disclosure Schedules identifies: (i) each Purchased Patent, (ii) the owner(s) thereof, registration, issuance, grant, serial, and application or other identifying number, filing, registration, issuance, grant, renewal, and expiration date, and title, as applicable; and (iii) any other Person that has an ownership interest in such item of Purchased Patent and the nature of such ownership interest. Section 3.1.11(b)(ii) of the Disclosure Schedule describes each filing, payment, and action that, to AstraZeneca’s Knowledge, must be made or taken on or before the date that is 120 days after the Execution Date in order to file, prosecute and maintain each such Purchased Patent (“Required Actions”). All required maintenance fees, annuity fees or renewal fees for Owned Registered Product IP and the Purchased Patents that are due and payable prior to the Closing Date have been or will be paid (without filing any extension delaying payment to a date after the Closing Date).

(c) To AstraZeneca’s Knowledge, the APA Licensed Intellectual Property, the Merck Patents, the Purchased Patents and the Pozen Patents, are valid and subsisting and have not been denied, rejected or invalidated, lapsed, expired, been cancelled or become abandoned. With respect to the Purchased Patents and to AstraZeneca’s Knowledge, with respect to the Merck Patents and the Pozen Patents, all relevant published patents, patent applications, articles and other prior art references have been disclosed to the relevant patent examiner at the U.S. Patent and Trademark Office. To AstraZeneca’s Knowledge, each Person who has or has had any rights in or to the Merck Patents, the Purchased Patents or the Pozen Patents, has executed an agreement assigning his, her or its entire right, title and interest therein, and the inventions embodied, described or claimed therein, to the stated owner thereof.

(d) To AstraZeneca’s Knowledge, all required maintenance fees, annuity fees or renewal fees for the Merck Patents and the Pozen Patents in the Horizon Territory that are due and payable have been paid, and no applications or registrations therefor have lapsed or become abandoned, been cancelled or expired.

(e) To AstraZeneca’s Knowledge, (i) none of the Purchased Patents or the Pozen Patents is involved in any Litigation, inventorship challenge, reissue, interference, reexamination or opposition and (ii) none of the Merck Patents is involved in any Litigation, inventorship challenge, reissue, interference, reexamination or opposition regarding the Product Business.

(f) None of the Licensed Copyrights, APA Licensed Trademarks or Licensed Domain Names or registrations or applications to use or register such items is involved in any pending action, arbitration, mediation, hearing, litigation, claim, suit, cancellation,
nullification, interference, concurrent use or opposition proceeding or, to AstraZeneca’s Knowledge, any investigation or finding of deficiency or noncompliance.

(g) The conduct of the Product Business as currently conducted does not infringe or misappropriate any Third Party’s intellectual property rights in the Horizon Territory. Except for the Vimovo Litigation, no Litigation is pending or, to AstraZeneca’s Knowledge, threatened (i) based upon, challenging or seeking to deny or restrict the use of any of the APA Licensed Intellectual Property, the Purchased Patents or the Pozen Patents, (ii) alleging that AstraZeneca’s conduct of the Product Business infringes or misappropriates the intellectual property rights of any Third Party in the Horizon Territory, or (iii) asserting a Paragraph IV Notification under 21 U.S.C. 355(j)(2)(B) relative to any Patent Rights listed in NDA #22-511.

(h) (i) AstraZeneca is in compliance in all material respects with its obligations under the Merck Agreements and (ii) to AstraZeneca’s Knowledge, neither Merck nor any Merck Party is in breach of the Merck Agreements in each case ((i) and (ii)), except for any noncompliance or breach that would reasonably be expected to adversely affect Horizon’s rights under this Agreement, including Horizon’s rights with respect to the Merck Covenant, or any Ancillary Agreement.

(i) Other than licenses or sublicenses granted to any Third Party for the Manufacture of the Product on behalf of AstraZeneca or any of its Affiliates, (i) neither AstraZeneca nor any Affiliate of AstraZeneca has granted any licenses, sublicenses or other rights (including any covenant not to sue) in or with respect to the Purchased Patents or the Pozen Patents to any Third Parties in the Horizon Territory and (ii) except for the exclusive license granted to KBI-E Inc. under the Merck Patents pursuant to the Merck Agreements and any license granted to a Third Party in connection with the Vimovo Litigation as described on Schedule 3.1.11(i), neither AstraZeneca nor any Affiliate of AstraZeneca has granted any licenses, sublicenses or other rights in or with respect to the Merck Patents to any Third Parties to Exploit the Product or any Other Product in the Horizon Territory. To AstraZeneca’s Knowledge, no Third Party is engaging in any activity that infringes or misappropriates the Owned Registered Product IP, the Purchased Patents, the Pozen Patents or any other APA Licensed Intellectual Property in the Horizon Territory. Neither AstraZeneca nor any Affiliate of AstraZeneca has received any written notice that any Person is suspected of infringing or misappropriating such intellectual property rights in the Horizon Territory.

(j) Except as set forth in the Pozen US Agreement, there is no royalty or other license payment obligation to any Third Party with respect to the Exploitation of Products or Other Products in the Horizon Territory, other than any amounts that may be payable under any Merck Agreement, which shall be the sole responsibility of AstraZeneca and its Affiliates.

(k) AstraZeneca and, as applicable, AstraZeneca’s Affiliates, have taken reasonable measures to maintain in confidence all APA Licensed Know-How and to protect the secrecy, confidentiality and value of any trade secrets included within the APA Licensed Know-How.
The development of the APA Licensed Intellectual Property and the Purchased Patents has not been funded, in whole or in part, by the United States government.

3.1.12 Existing Inventory. As of the Execution Date, AstraZeneca or its Affiliates own at least [...***...] units of the Product packaged for commercial sale in the Horizon Territory and at least [...***...] units of the Product to be distributed as samples in the Horizon Territory. All Existing Inventory is useable or saleable in the ordinary course of the Product Business. All Existing Inventory has been manufactured in accordance with cGMP and is of good and marketable quality.


3.1.14 Certain Financial Statements. AstraZeneca or an Affiliate of AstraZeneca has made available to Horizon or its Representatives the annual gross sales and net sales (and certain components thereof) for the Product in the Horizon Territory for the past [...***...] completed Calendar Years. Such financial information was prepared from the books and records of Astra Zeneca or an Affiliate of AstraZeneca, as applicable, and fairly presents in all material respects the annual gross sales and net sales for the Product in the Horizon Territory for the periods indicated.

3.2 Representations and Warranties of Horizon. Horizon represents and warrants to AstraZeneca as follows:

3.2.1 Corporate Status. Horizon is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware.

3.2.2 Authority. Horizon has the requisite corporate power and authority to enter into this Agreement and the Ancillary Agreements to which it is a party, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and Ancillary Agreements to which Horizon is a party and the consummation of the transactions contemplated hereby and thereby have been duly authorized by the necessary corporate actions of Horizon. This Agreement constitutes and each Ancillary Agreement to which Horizon is a party, when executed and delivered by Horizon will constitute, the valid and legally binding obligation of Horizon, enforceable against Horizon in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity.

3.2.3 Non-Contravention. The execution, delivery and performance by Horizon of this Agreement and each Ancillary Agreement to which it is a party do not and will not (a) violate the certificate of incorporation or bylaws or comparable organizational documents of Horizon, (b) violate any Law applicable to Horizon, (c) violate, breach or constitute a default under or result in the termination of any material Contract to which Horizon is a party, or (d) *** Confidential Treatment Requested
violate any order or judgment of a Governmental Authority to which Horizon or any of its Affiliates is subject.

3.2.4 No Broker. There is no broker, finder, financial advisor or other Person acting or who has acted on behalf of Horizon or its Affiliates, who is entitled to receive any brokerage or finder’s or financial advisory fee from AstraZeneca or any of its Affiliates in connection with the transactions contemplated by this Agreement.

3.2.5 Litigation; Consents.

(a) To the knowledge of Horizon, there is no (i) Litigation pending or threatened against Horizon or any of its Affiliates before any Governmental Authority, or (ii) order or judgment of a Governmental Authority to which Horizon or any of its Affiliates is subject, except for such Litigation, orders and judgments that would not reasonably be expected to have a Horizon Material Adverse Effect.

(b) Except for consents, permits or authorizations that if not received, or declarations, filings or registrations that if not made, would not reasonably be expected to have a Horizon Material Adverse Effect, no notice to, filing with, permit of, authorization of, exemption by, or consent of, Governmental Authority or other Person is required for Horizon to consummate the transactions contemplated hereby or by the Ancillary Agreements.

3.2.6 Debarred Personnel. Neither Horizon nor any of its employees or consultants has been debarred or deemed subject to debarment pursuant to Section 306 of the Act nor, to the knowledge of Horizon, are any such Persons the subject of a conviction described in such section.

3.2.7 Financial Capacity. Horizon will have on the Closing Date immediately available cash that is sufficient to enable it to complete the transactions contemplated hereby and to perform all of its obligations under this Agreement and the Ancillary Agreements.

3.2.8 Compliance with Applicable Law. Horizon is aware of applicable Law in the Horizon Territory relating to marketing, distribution and sale of the Product, and can legally import, store, market, distribute and sell the Product in the Horizon Territory immediately as of the Closing.

3.3 Exclusivity of Representations.

3.3.1 HORIZON ACKNOWLEDGES AND AGREES THAT, EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES CONTAINED IN SECTION 2.1.2 AND SECTION 3.1 OR MADE BY ASTRAZENECA OR ITS AFFILIATES IN THE LICENSE AGREEMENT OR THE SUPPLY AGREEMENT, (A) ASTRAZENECA HAS MADE NO REPRESENTATION OR WARRANTY WHATSOEVER HEREIN OR OTHERWISE RELATED TO THE TRANSACTIONS CONTEMPLATED HEREBY AND (B) HORIZON HAS NOT RELIED ON ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED IN CONNECTION WITH THE TRANSACTIONS CONTEMPLATED HEREBY.
ARTICLE 4
PRE-CLOSING COVENANTS

4.1 Access and Information.

4.1.1 During the period commencing on the Execution Date and ending on the earlier to occur of (a) the Closing and (b) the termination of this Agreement in accordance with Article 8 (the “Pre-Closing Period”), AstraZeneca shall afford Horizon and its officers, employees, agents, attorneys, consultants, advisors and other representatives (collectively, “Representatives”), continued reasonable access to AstraZeneca employees to discuss the Product Business and full access to the books and records of AstraZeneca, to the extent maintained in connection with the Product Business, shall use its commercially reasonable efforts to provide to Horizon such information, books and records to the extent that they relate to the Product Business, shall not unreasonably disrupt AstraZeneca’s ordinary course operations. Notwithstanding anything to the contrary contained in this Agreement, AstraZeneca shall not be required to disclose any information or provide any such access if such disclosure or access could, in AstraZeneca’s reasonable judgment, (i) violate (A) applicable Law, including applicable antitrust Laws, or (B) any binding agreement entered into prior to the Execution Date (including any confidentiality agreement to which AstraZeneca is a party), (ii) jeopardize any attorney/client privilege or other established legal privilege or (iii) disclose any trade secrets not included in the APA Licensed Intellectual Property or Purchased Assets; provided, that AstraZeneca shall provide Horizon with a general description of the type of any such information withheld by AstraZeneca to the extent that AstraZeneca is permitted to do so.

4.1.2 During the period commencing on the Execution Date and ending on the earlier to occur of (a) the Closing and (b) the termination of this Agreement in accordance with Article 8, Horizon hereby agrees that neither it nor any of its Affiliates or Representatives is authorized to contact, and shall not contact, any licensor, licensee, competitor, supplier, distributor or customer of AstraZeneca with respect to the Product, the Purchased Assets, the APA Licensed Intellectual Property, the Ex-US Licensed Patents, the Licensed Regulatory Documentation, the Merck Patents, the Product Business, this Agreement, the Ancillary...
Agreements or the transactions contemplated hereby or thereby, without the prior written consent of AstraZeneca, which consent may be withheld in
AstraZeneca’s sole discretion. Notwithstanding the foregoing, after the Execution Date Horizon shall be permitted to engage in discussions and negotiations
with (i) Pozen, (ii) any Third Party that is providing any services to AstraZeneca or any of its Affiliates with respect to the study entitled [...***...]
or (iii) Patheon Inc., Patheon Pharmaceuticals Inc., [...***... and [...***... with respect to the Manufacture or Product on behalf of Horizon solely for
Exploitation in the Horizon Territory.

4.2 Ordinary Course of Business. During the Pre-Closing Period, except (a) as set forth in Schedule 4.2 or as otherwise contemplated by this
Agreement or any Ancillary Agreement, (b) as required by applicable Law, (c) as required by the terms of any agreement binding upon AstraZeneca or its
Affiliates as of the Execution Date, (d) for any actions taken by AstraZeneca to (i) perform its obligations under the Transition Agreement, (ii) obtain any
Third Party consents, permits or authorizations in connection with the transactions contemplated by this Agreement or any Ancillary Agreement or (iii) conduct transition planning in preparation for the transfer of the Purchased Assets to Horizon, or (e) as Horizon shall otherwise consent in writing, AstraZeneca shall conduct the Product Business in substantially the same manner as heretofore conducted and in the ordinary course of business and shall
use its commercially reasonable efforts to preserve substantially intact the Product Business, and substantially preserve the current relationships of the
Product Business with customers, suppliers and other Persons with which the Product Business has material business relations. In furtherance of the foregoing and in no way limiting the foregoing, during the Pre-Closing Period, AstraZeneca shall:

(a) promptly take all Required Actions and any other office actions with respect to any Purchased Patents;
(b) keep in full force and effect all material rights relating to the Product Business and not amend or otherwise modify such rights;
(c) not enter into or amend or waive any material rights under any Purchased Contract or permit any of the Purchased Assets to become
subject to any Encumbrance other than Permitted Encumbrances or commit to do any of the foregoing;
(d) not sell Product to wholesalers or distributors in the Horizon Territory in quantities that exceed the average order size from such
wholesalers or distributors during the three month period preceding the Execution Date, except to the extent such increased orders are submitted to
AstraZeneca and its Affiliates by such wholesalers or distributors other than at the direct request of AstraZeneca or its Affiliates, or
(e) not enter into any settlement of any Litigation with any Governmental Authority or other Person relating to the Product Business or any Purchased Assets or any Assumed Liability other than the Merck Patent Litigation or commit to do any of

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the foregoing; and comply with all applicable Laws and orders of Governmental Authorities relating to the Product Business.

4.3 Obligation to Consummate the Transaction. Each of the Parties agrees that, subject to this Section 4.3, it shall use its reasonable best efforts to take, or cause to be taken, all action, and to do, or cause to be done, all things necessary, proper or advisable to the extent permissible under applicable Law, to consummate and make effective the transactions contemplated by this Agreement and to ensure that the conditions set forth in Article 6 are satisfied, insofar as such matters are within the control of either of them. Without limiting the generality of the foregoing, as soon as reasonably practicable after the Execution Date, AstraZeneca shall use its commercially reasonable efforts (not requiring the payment of money) to obtain the consents referred to in Section 3.1.5(d).

4.4 Notice of Litigation/Developments.

4.4.1 Subject to Section 5.5, from and after the Execution Date until the earlier to occur of the Closing and the termination of this Agreement in accordance with Article 8, each Party shall give prompt written notice to the other Party of any Litigation, examination or audit in which such Party is involved as a party that concerns and would reasonably be expected to materially and adversely affect the Product Business, Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation or the other Party’s rights in the same or that would otherwise reasonably be expected to have a Material Adverse Effect or Horizon Material Adverse Effect, as applicable, or that would cause any of the conditions to Closing set forth in Article 6 not to be satisfied.

4.4.2 Between the Execution Date and the date that is [...***...] prior to the Closing Date, AstraZeneca shall have the right to supplement or amend the Disclosure Schedules with respect to any matter that, if existing or occurring prior to the Execution Date, would have been required to be set forth or described in the Disclosure Schedules or that is necessary to correct any information in such Disclosure Schedules that has been rendered inaccurate by an event, condition, fact or circumstance occurring after the Execution Date. Such delivery shall not modify any representation and warranty as of the Execution Date or of as of the Closing Date or otherwise affect any rights of Horizon under this Agreement with respect to any breach of any representation or warranty or covenant of AstraZeneca set forth herein or with respect to any claim for indemnification hereunder.

ARTICLE 5
ADDITIONAL COVENANTS

5.1 Cooperation in Litigation and Investigations.

5.1.1 Subject to Section 5.5 and except as set forth in any Ancillary Agreement, from and after the Closing Date, Horizon and AstraZeneca shall fully cooperate with each other in the defense or prosecution of any Litigation, examination or audit instituted prior to the Closing or that may be instituted thereafter against or by either Party relating to or arising out of the conduct of the Product Business or the Exploitation or Manufacture of the Product in the Horizon Territory prior to or after the Closing (other than Litigation between Horizon and

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AstraZeneca or their respective Affiliates arising out of the transactions contemplated hereby or by the Ancillary Agreements). In connection therewith, and except as set forth in any Ancillary Agreement, from and after the Closing Date, each of AstraZeneca and Horizon shall make available to the other during normal business hours and upon reasonable prior written notice, but without unreasonably disrupting its business, all records to the extent relating to the Purchased Assets, the APA Licensed Intellectual Property, the Licensed Regulatory Documentation, the Assumed Liabilities and the Excluded Liabilities held by it and reasonably necessary to permit the defense or investigation of any such Litigation, examination or audit (other than Litigation between Horizon and AstraZeneca or their respective Affiliates arising out of the transactions contemplated hereby or by the Ancillary Agreements, with respect to which applicable rules of discovery shall apply), and shall preserve and retain all such records for the length of time contemplated by its standard record retention policies and schedules. The Party requesting such cooperation shall pay the reasonable out-of-pocket costs and expenses of providing such cooperation (including legal fees and disbursements) incurred by the Party providing such cooperation and by its officers, directors, employees and agents, and any applicable Taxes in connection therewith.

5.1.2 From and after the Closing, subject to this Section 5.1.2, Horizon shall, at its cost and expense, control, direct and maintain control over the Vimovo Litigation with respect to the Pozen Patents and the Purchased Patents (the “Pozen Patent Litigation”) with counsel of Horizon’s choosing. Horizon shall keep AstraZeneca reasonably informed with respect to the status of and any material developments in the Pozen Patent Litigation. Horizon may settle or otherwise resolve the Pozen Patent Litigation, in its sole discretion; provided, that Horizon shall notify AstraZeneca of its intent to settle the Pozen Patent Litigation and consider in good faith AstraZeneca’s comments with respect thereto.

5.1.3 From and after the Closing, subject to this Section 5.1.3, AstraZeneca shall, at its cost and expense, control, direct and maintain control over the Vimovo Litigation with respect to the Merck Patents (the “Merck Patent Litigation”) with counsel of AstraZeneca’s choosing. AstraZeneca shall keep Horizon reasonably informed with respect to the status of and any material developments in the Merck Patent Litigation. AstraZeneca may settle or otherwise resolve the Merck Patent Litigation, in its sole discretion, including [...***...]; provided, that AstraZeneca shall notify Horizon of its intent to settle the Merck Patent Litigation and consider in good faith Horizon’s comments with respect thereto.

5.2 Further Assurances. Each of AstraZeneca and Horizon shall, at any time or from time to time after the Closing, at the request of the other, execute and deliver to the other all such instruments and documents or further assurances as the other may reasonably request in order to (a) vest in Horizon all of AstraZeneca’s right, title and interest in and to the Purchased Assets as contemplated hereby, (b) effectuate Horizon’s assumption of the Assumed Liabilities and (c) grant to each Party all rights contemplated herein to be granted to such Party under the

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Ancillary Agreements; provided, however, that after the Closing, apart from such customary further assurances, neither AstraZeneca nor Horizon shall have any other obligations except as specifically set forth and described herein or in the Ancillary Agreements. Without limitation of the foregoing, except as expressly set forth in the Ancillary Agreements, neither AstraZeneca nor Horizon shall have any obligation to assist or otherwise participate in the amendment or supplementation of the Purchased Regulatory Approvals or otherwise to participate in any filings or other activities relating to the Purchased Regulatory Approvals other than as necessary to effect the assignment thereof to Horizon in connection with the Closing pursuant to this Agreement.

5.3 Transition Agreement. During the Transition Period, AstraZeneca and Horizon shall cooperate to transition the Exploitation of the Product in the Horizon Territory, and related administrative activities, from AstraZeneca to Horizon and to ensure that Horizon commences the performance of such activities hereunder with the least disruption to customers, in each case, in accordance with and to the extent provided for in the Transition Agreement.

5.4 Publicity. No public announcement related to this Agreement or the transactions contemplated herein will be issued without the joint approval of AstraZeneca and Horizon, which approval shall not be unreasonably withheld, conditioned or delayed, except in any public disclosure which either AstraZeneca or Horizon, in its good faith judgment, believes is required by applicable Law or by any stock exchange on which its securities or those of its Affiliates are listed. If either Party, in its good faith judgment, believes such disclosure is required, such Party will use its commercially reasonable efforts to consult with the other Party and its Representatives, and to consider in good faith any revisions proposed by the other Party or its Representatives, as applicable, prior to making (or prior to any of its Affiliates making) such disclosure, and shall limit such disclosure to only that information which is legally required to be disclosed.

5.5 Confidentiality.

5.5.1 All Confidential Information provided by one Party (or its Representatives or Affiliates) (collectively, the “Disclosing Party”) to the other Party (or its Representatives or Affiliates) (collectively, the “Receiving Party”) shall be subject to and treated in accordance with the terms of this Section 5.5. As used in this Section 5.5, “Confidential Information” means (a) all information disclosed to the Receiving Party by the Disclosing Party in connection with this Agreement but not any Ancillary Agreement, including all information with respect to the Disclosing Party’s licensors, licensees or Affiliates, (b) all information disclosed to the Receiving Party by the Disclosing Party under the Confidentiality Agreement, and (c) all memoranda, notes, analyses, compilations, studies and other materials prepared by or for the Receiving Party to the extent containing or reflecting the information in the preceding clause (a) or (b). Notwithstanding the foregoing, Confidential Information shall not include information that, in each case as demonstrated by competent written documentation:

(i) was already known to the Receiving Party or its Affiliates, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;
(ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party other than through any act or omission of the Receiving Party in breach of this Agreement or the Confidentiality Agreement;

(iv) is subsequently disclosed to the Receiving Party by a Third Party without obligations of confidentiality with respect thereto; or

(v) is subsequently independently discovered or developed by the Receiving Party without the aid, application or use of Confidential Information or Ancillary Confidential Information (as defined in the License Agreement).

5.5.2 All Confidential Information obtained by AstraZeneca (or its Affiliates or Representatives) from Horizon (or its Affiliates or Representatives) and all Confidential Information relating solely to the Product Business (other than Confidential Information relating to (x) the APA Licensed Intellectual Property, the Ex-US Licensed Patents or the Licensed Regulatory Documentation, (y) the Pozen Original Agreement or the Pozen ROW Agreement or (z) the Merck Parties or the Merck Patents), the Purchased Assets and the Assumed Liabilities (the “Horizon Confidential Information”) shall be deemed to be Confidential Information disclosed by Horizon to AstraZeneca for purposes of this Section 5.5 and shall be used by AstraZeneca solely as required to (a) perform its obligations or exercise or enforce its rights under this Agreement, any Ancillary Agreement (including for purposes of engaging in pharmacovigilance tasks, including maintaining the global safety database for the Product), the Pozen ROW Agreement or any Contract related to the Product pursuant to which AstraZeneca or any of its Affiliates obtains rights to the APA Licensed Intellectual Property, the Ex-US Licensed Patents or the Merck Patents, (b) undertake Manufacturing activities in support of Horizon’s operations in the Horizon Territory, or (c) comply with applicable Law (each of (a) through (c), an “AstraZeneca Permitted Purpose”), and for no other purpose. For a period of 10 years after the Execution Date, AstraZeneca shall not disclose, or permit the disclosure of, any of the Horizon Confidential Information to any Person except (x)
those Persons to whom such disclosure is necessary in connection with a Horizon Permitted Purpose or (y) in connection with any due diligence or disclosure obligations under any financing arrangement or equity offering pursuant to obligations of confidentiality and non-use no less stringent than those set forth in this Section 5.5. Horizon shall treat, and will cause its Affiliates and the Representatives of Horizon or any of its Affiliates to treat, AstraZeneca Confidential Information as confidential, using the same degree of care as Horizon normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care.

5.5.4 In the event either Party is requested pursuant to, or required by, applicable Law to disclose any of the other Party’s Confidential Information (i.e., AstraZeneca Confidential Information or Horizon Confidential Information, as applicable), it will notify the other Party in a timely manner so that such Party may seek a protective order or other appropriate remedy or, in such Party’s sole discretion, waive compliance with the confidentiality provisions of this Agreement. Each Party will cooperate in all reasonable respects in connection with any reasonable actions to be taken for the foregoing purpose. In any event, the Party requested or required to disclose such Confidential Information may furnish it as requested or required pursuant to applicable Law (subject to any such protective order or other appropriate remedy) without liability hereunder, provided that such Party furnishes only that portion of the Confidential Information which such Party is advised by an opinion of its counsel is legally required and such Party exercises reasonable efforts to obtain reliable assurances that confidential treatment will be accorded such Confidential Information.

5.5.5 Nothing in this Section 5.5 shall be construed as preventing or in any way inhibiting either Party from complying with applicable Law governing activities and obligations undertaken pursuant to this Agreement or any Ancillary Agreement in any manner which it reasonably deems appropriate.

5.6 FDA Letters. Horizon and AstraZeneca shall file the Horizon FDA Intent Letters and the AstraZeneca FDA Intent Letters, respectively, with the FDA within one Business Day after the Closing Date. Horizon and AstraZeneca shall file the Horizon FDA Transfer Letters and the AstraZeneca FDA Transfer Letters, respectively, with the FDA pursuant to the Transition Agreement. Transfer of title to the NDA and the INDs for the Product shall be effective as of the Closing.

5.7 Regulatory Responsibilities. Except as set forth in the Transition Agreement or as required by a Party to comply with applicable Law or to exercise its rights and obligations hereunder or under any Ancillary Agreement, (a) as of the Closing Date, Horizon shall have the sole right and responsibility for preparing, obtaining and maintaining all Regulatory Approvals necessary for continuing the Product Business after Closing, and for conducting communications with Governmental Authorities of competent jurisdiction, for the Product and any Other Product in the Horizon Territory, and (b) AstraZeneca (on its own behalf or through AstraZeneca’s licensees, sublicensees or distributors, as applicable) shall have the sole right and responsibility for preparing, obtaining and maintaining all Regulatory Approvals, and for conducting communications with Governmental Authorities of competent jurisdiction, for the Product or any Other Product in the AstraZeneca Territory. Without limitation of the foregoing, promptly
following the Closing, Horizon shall obtain such FDA approvals as are necessary for Horizon’s own Product labeling and shall comply with such FDA approvals upon receipt thereof.

5.8 Commercialization. Except to the extent otherwise provided in the Transition Agreement or the License Agreement, from and after the Closing Date, (a) Horizon, at its own cost and expense, shall be responsible for and have sole discretion over the commercialization, marketing strategy, promotion, distribution and sale of the Product and any Other Product in the Horizon Territory and shall independently determine and set prices for the Product and any Other Product in the Horizon Territory, including the selling price, volume discounts, rebates and similar matters; (b) Horizon shall be responsible, at its own cost and expense, for all marketing, advertising and promotional materials in the Horizon Territory related to the Product and any Other Product; and (c) Horizon or its Affiliates shall be responsible for receiving and processing all orders, undertaking all invoicing, collection and receivables, and providing all customer service related to the sale of the Product and any Other Product in the Horizon Territory.

5.9 Certain Tax Matters.

5.9.1 Withholding Taxes. The amounts payable by one party (the “Payer”) to another Party (the “Payee”) pursuant to this Agreement (“Payments”) shall not be reduced on account of any Taxes unless required by applicable Law. The Payee alone shall be responsible for paying any and all Taxes (other than withholding Taxes required to be paid by the Payer) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The Payer shall deduct or withhold from the Payments any Taxes that it is required by applicable Law to deduct or withhold. Notwithstanding the foregoing, if the Payee is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding Tax, it may deliver to the Payer or the appropriate Govermnmental Authority (with the assistance of the Payer to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the Payer of its obligation to withhold Tax, and the Payer shall apply the reduced rate of withholding, or dispense with the withholding, as the case may be, provided that the Payer has received evidence, in a form reasonably satisfactory to the Payer, of the Payee's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least 15 days prior to the time that the Payments are due. If, in accordance with the foregoing, the Payer withholds any amount, it shall pay to the Payee the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to the Payee proof of such payment within 60 days following that payment.

5.9.2 Transfer Taxes and Apportioned Obligations.

(a) All amounts payable hereunder or under any Ancillary Agreement are exclusive of all recordation, transfer, documentary, excise, sales, value added, use, stamp, conveyance or other similar Taxes, duties or governmental charges, and all recording or filing fees or similar costs, imposed or levied by reason of, in connection with or attributable to this Agreement and the Ancillary Agreements or the transactions contemplated hereby and thereby (collectively, “Transfer Taxes”). Horizon shall be solely responsible for the payment of all Transfer Taxes, and shall pay all amounts due and owing in respect of any Transfer Taxes, these
amounts in addition to the sums otherwise payable, at the rate in force at the due time for payment or such other time as is stipulated under applicable Law.

(b) All personal property and similar ad valorem obligations levied with respect to the Purchased Assets for a taxable period which includes (but does not end on) the Closing Date (collectively, the “Apportioned Obligations”) shall be apportioned between AstraZeneca and Horizon based on the number of days of such taxable period ending on the day prior to the Closing Date (such portion of such taxable period, the “Pre-Closing Tax Period”) and the number of days of such taxable period on and after the Closing Date (such portion of such taxable period, the “Post-Closing Tax Period”). AstraZeneca shall be liable for the proportionate amount of such Apportioned Obligations that is attributable to the Pre-Closing Tax Period, and Horizon shall be liable for the proportionate amount of such Apportioned Obligations that is attributable to the Post-Closing Tax Period.

(c) Apportioned Obligations and Transfer Taxes shall be timely paid, and all applicable filings, reports and returns shall be filed, as provided by applicable Law. The paying Party shall be entitled to reimbursement from the non-paying Party in accordance with Section 5.9.2(a) or Section 5.9.2(b), as the case may be. Upon payment of any such Apportioned Obligation or Transfer Tax, the paying Party shall present a statement to the non-paying Party setting forth the amount of reimbursement to which the paying Party is entitled under Section 5.9.2(a) or Section 5.9.2(b), as the case may be, together with such supporting evidence as is reasonably necessary to calculate the amount to be reimbursed. The non-paying Party shall make such reimbursement promptly but in no event later than 10 days after the presentation of such statement.

5.9.3 Cooperation and Exchange of Information. Each of AstraZeneca and Horizon shall (a) provide the other with such assistance as may reasonably be requested by the other in connection with the preparation of any Tax Return, audit or other examination by any taxing authority or judicial or administrative proceeding relating to Liability for Taxes in connection with the Product Business or the Purchased Assets, (b) retain and provide the other with any records or other information that may be relevant to such Tax Return, audit or examination, proceeding or determination and (c) inform the other of any final determination of any such audit or examination, proceeding or determination that affects any amount required to be shown on any Tax Return of the other for any period.

5.9.4 Survival of Covenants. The covenants contained in this Section 5.9 shall survive until 30 days after the expiration of the applicable statute of limitations (including extensions thereof).

5.10 Accounts Receivable and Payable.

5.10.1 Accounts Receivable. The Parties acknowledge and agree that all Accounts Receivable outstanding on the Closing Date shall remain the property of AstraZeneca or its Affiliates and shall be collected by AstraZeneca or its Affiliates subsequent to the Closing. In the event that, subsequent to the Closing, Horizon or an Affiliate of Horizon receives any payments from any obligor with respect to an Account Receivable, then Horizon shall, within 30 days of receipt of such payment, remit the full amount of such payment to AstraZeneca. In the
case of the receipt by Horizon of any payment from any obligor of both AstraZeneca and Horizon then, unless otherwise specified by such obligor, such payment shall be applied first to amounts owed to Horizon with the excess, if any, remitted to AstraZeneca. In the event that, subsequent to the Closing, AstraZeneca or any of its Affiliates receives any payments from any obligor with respect to an account receivable of Horizon for any period after the Closing Date, then AstraZeneca shall, within 30 days of receipt of such payment, remit the full amount of such payment to Horizon. In the case of the receipt by AstraZeneca of any payment from any obligor of both AstraZeneca and Horizon then, unless otherwise specified by such obligor, such payment shall be applied first to amounts owed to AstraZeneca with the excess, if any, remitted to Horizon.

5.10.2 Accounts Payable. In the event that, subsequent to the Closing, Horizon or an Affiliate of Horizon receives any invoices from any Third Party with respect to any account payable of the Product Business outstanding prior to the Closing, then Horizon shall, within 30 days of receipt of such invoice, provide such invoice to AstraZeneca. In the event that, subsequent to the Closing, AstraZeneca or any of its Affiliates receives any invoices from any Third Party with respect to any account payable of Horizon or any of its Affiliates for any period after the Closing, then AstraZeneca shall, within 30 days of receipt of such invoice, provide such invoice to Horizon.

5.11 Financial Information. Within [***] following the Closing Date and continuing until such time as Horizon files the Carve-Out Financial Statements with the Securities and Exchange Commission, AstraZeneca shall cause its auditors to provide to Horizon audited and unaudited financial statements for the Product Business as of the dates and for the periods as are jointly agreed to by AstraZeneca and Horizon and their respective auditors (the “Carve-Out Financial Statements”), and, if applicable, AstraZeneca shall provide and shall use its commercially reasonable efforts to cause its Affiliates and Representatives to provide, information requested by Horizon and reasonably necessary to prepare any applicable pro forma financial information required to be filed by Horizon with the Securities and Exchange Commission in connection with the transactions contemplated by this Agreement. The Carve-Out Financial Statements will be derived from AstraZeneca’s historical financial statements, will be prepared in accordance with GAAP throughout the periods covered thereby, comply as to form in all material respects with the published rules and regulations of the Securities and Exchange Commission applicable to the presentation of acquired company financial statements [***], and accurately present in all material respects the financial position of the Product Business as of the dates thereof and the results of operations of the Product Business for the periods covered thereby. Horizon shall be solely responsible for any information it files with or furnishes to the Securities and Exchange Commission and shall promptly reimburse AstraZeneca for all out-of-pocket costs and expenses reasonably incurred by AstraZeneca and its Affiliates in connection with complying with this Section 5.11.

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ARTICLE 6
CONDITIONS PRECEDENT

6.1 Conditions to Obligations of Horizon and AstraZeneca. The obligations of Horizon and AstraZeneca to complete the transactions contemplated by this Agreement are subject to the satisfaction at or prior to the Closing of the following conditions:

6.1.1 No Adverse Law; No Injunction. No Law shall have been enacted, entered, promulgated or enforced by any Governmental Authority that prohibits the consummation of all or any part of the transactions contemplated by this Agreement or the Ancillary Agreements, and no order by any Governmental Authority restraining, enjoining or otherwise preventing the consummation of the transactions contemplated hereby shall be in effect; and

6.1.2 Governmental Approvals. All required consents of, notifications to and filings with any Governmental Authority shall have been made and any waiting periods applicable to the transactions contemplated hereby pursuant to any applicable Law shall have expired or been terminated.

6.2 Conditions to Obligations of Horizon. The obligation of Horizon to complete the transactions contemplated by this Agreement is subject to the satisfaction or waiver by Horizon at or prior to the Closing of the following additional conditions:

6.2.1 Representations and Warranties. The representations and warranties of AstraZeneca contained in Section 3.1 other than the Fundamental Reps included in Section 3.1 shall be true and correct (disregarding any materiality or Material Adverse Effect qualifications within the representation and warranty) in all respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date), except for breaches of such representations and warranties that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, and each Fundamental Rep included in Section 3.1 shall be true and correct in all respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date);

6.2.2 Covenants. AstraZeneca shall have performed and complied in all material respects with all covenants, agreements and obligations required to be performed or complied with on or prior to the Closing Date;

6.2.3 No Material Adverse Effect. Since the Execution Date, no Material Adverse Effect shall have occurred; and

6.2.4 Closing Deliveries. AstraZeneca shall have delivered to Horizon each of the items listed in Section 2.4.2(a).

6.3 Conditions to Obligations of AstraZeneca. The obligation of AstraZeneca to complete the transactions contemplated by this Agreement is subject to the satisfaction or waiver by AstraZeneca at or prior to the Closing of the following additional conditions:
6.3.1 **Representations and Warranties.** The representations and warranties of Horizon contained in Section 3.2 other than the Fundamental Reps included in Section 3.2 shall be true and correct (disregarding any materiality or Horizon Material Adverse Effect qualifications within the representation and warranty) in all respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date), except for breaches of such representations and warranties that would not, individually or in the aggregate, reasonably be expected to have a Horizon Material Adverse Effect, and each Fundamental Rep included in Section 3.2 shall be true and correct in all respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date);

6.3.2 **Covenants.** Horizon shall have performed and complied in all material respects with all covenants, agreements and obligations required to be performed or complied with on or prior to the Closing Date; and

6.3.3 **Closing Deliveries.** Horizon shall have delivered to AstraZeneca each of the items listed in Section 2.4.2(b).

6.4 **Frustration of Closing Conditions.** With respect to the conditions to Horizon’s and AstraZeneca’s respective obligations to consummate the transactions contemplated by this Agreement as provided hereunder and each such Party’s right to terminate this Agreement as provided in Section 8.1, neither Horizon nor AstraZeneca may rely on the failure of any condition set forth in this Article 6 to be satisfied if such failure was caused by such Party’s failure to act in good faith or to use its reasonable best efforts to cause the condition to be satisfied to the extent required by Section 4.3.

**ARTICLE 7**

**INDEMNIFICATION**

7.1 **Indemnification.**

7.1.1 **Indemnification by AstraZeneca.** Following the Closing, but subject to the provisions of this Article 7, AstraZeneca shall indemnify, defend and hold harmless Horizon and its Affiliates, and their respective officers, directors, and employees (collectively, “Horizon Indemnitees”) from and against any and all Losses incurred by any Horizon Indemnitee arising out of or related to:

(a) any breach by AstraZeneca of any of the representations or warranties made by AstraZeneca in this Agreement as of the Execution Date and as of the Closing as if the representations and warranties are given as of the Closing Date;

(b) any failure of AstraZeneca to perform or any breach by AstraZeneca of any of its covenants, agreements or obligations contained in this Agreement;

(c) any Excluded Liability; or
7.1.2 Indemnification by Horizon. Following the Closing, but subject to the provisions of this Article 7, Horizon shall indemnify and hold harmless AstraZeneca and its Affiliates, and their respective officers, directors, and employees (collectively, “AstraZeneca Indemnitees”) from and against any and all Losses incurred by any AstraZeneca Indemnitee arising out of or related to:

(a) any breach by Horizon of any of the representations or warranties made by Horizon in this Agreement as of the Execution Date and as of the Closing as if the representations and warranties are given as of the Closing Date;

(b) any failure of Horizon to perform or any breach by Horizon of any of its covenants, agreements or obligations contained in this Agreement;

(c) any Assumed Liability;

(d) any failure of Horizon to pay Withholding Taxes under Section 5.9.1; or

(e) any failure of Horizon to pay Transfer Taxes or Apportioned Obligations allocated to Horizon under Section 5.9.2.

7.2 Claim Procedure.

7.2.1 Indemnification Claim Procedure. Except as provided in Section 7.2.2 with respect to Third Party claims, in the event of a claim made by a Horizon Indemnitee or a AstraZeneca Indemnitee (the “Indemnified Party”), the Indemnified Party shall give reasonably prompt written notice to the other Party (the “Indemnifying Party”), which notice (an “Indemnification Certificate”) shall: (a) state that the Indemnified Party has paid or properly accrued or reasonably anticipates that it will have to pay or accrue Losses that are subject to indemnification by the Indemnifying Party pursuant to Section 7.1.1 or Section 7.1.2, as applicable, and (b) specify in reasonable detail the individual items and amounts of such Losses, the date each such item was paid or properly accrued, or the basis for such anticipated Liability, and a description of the basis of such Indemnified Party’s claim for indemnification; provided, however, that the failure to give reasonably prompt notice shall not relieve the applicable Indemnifying Party of its indemnification obligations under this Agreement except to the extent that the Indemnifying Party is materially prejudiced by any delay in receiving such notice. In the event that the Indemnifying Party agrees to or is determined to have an obligation to reimburse the Indemnified Party for Losses as provided in this Article 7, the Indemnifying Party shall, subject to the provisions of Section 7.3, promptly (but in any event, within 30 days) pay such amount to the Indemnified Party by wire transfer of immediately available funds to the account specified in writing by the Indemnified Party. The Indemnifying Party may defer making such payment if it objects in a written statement to the claim made in the Indemnification Certificate and delivers such statement to the Indemnifying Party prior to the expiration of such 30-day period. An Indemnifying Party’s failure to object within such 30-day period to any claim set forth in an Indemnification Certificate shall be deemed to be the Indemnifying Party’s
If an Indemnifying Party shall so object in writing to any claim or claims made in any Indemnification Certificate, the Indemnifying Party and the Indemnified Party shall attempt in good faith for a period of 20 days following the Indemnified Party’s receipt of such objection notice to agree upon the respective rights of the parties with respect to each of such claims. If no such agreement can be reached after such 20-day period of good faith negotiation, either the Indemnifying Party or the Indemnified Party may pursue dispute resolution pursuant to Section 9.2.

7.2.2 Third Party Claim Procedure. In the event an Indemnified Party becomes aware of a claim made by a Third Party (including any action or proceeding commenced or threatened to be commenced by any Third Party) that such Indemnified Party reasonably believes may result in an indemnification claim pursuant to Section 7.1, such Indemnified Party shall promptly (and in any event within three Business Days after becoming aware of such claim) notify the Indemnifying Party in writing of such claim (such notice, the “Claim Notice” and such claim, a “Third Party Claim”). The Claim Notice shall be accompanied by reasonable supporting documentation submitted by the Third Party making such claim and shall describe in reasonable detail (to the extent known by the Indemnified Party) the facts constituting the basis for such Third Party Claim and the amount of the claimed damages; provided, however, that no delay or failure on the part of the Indemnified Party in delivering a Claim Notice shall relieve the Indemnifying Party from any Liability hereunder except to the extent of any damage or Liability caused by or arising out of such delay or failure. Within 30 days after receipt of any Claim Notice, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of the Third Party Claim referred to therein at the Indemnifying Party’s sole cost and expense (which shall be subject to Section 7.3) with counsel reasonably satisfactory to the Indemnified Party; provided, however, that the Indemnifying Party shall not have the right to assume the defense to the extent the Third Party Claim seeks an injunction or equitable relief or involves a criminal act alleged against the Indemnified Party. If the Indemnifying Party does not so assume control of the defense of such Third Party Claim, the Indemnified Party shall control the defense of such claim. The Party not controlling the defense of such Third Party Claim (the “Non-Controlling Party”) may participate therein at its own expense; provided, however, that if the Indemnifying Party assumes control of the defense of such Third Party Claim and the Indemnifying Party and the Indemnified Party have materially conflicting interests or different defenses available with respect to such Third Party Claim that cause the Indemnified Party to hire its own separate counsel with respect to such proceeding, the reasonable fees and expenses of a single counsel to the Indemnified Party shall be considered “Losses” for purposes of this Agreement (to the extent that the claim is subject to indemnification hereunder). The Party controlling the defense of such Third Party Claim (the “Controlling Party”) shall keep the Non-Controlling Party reasonably advised of the status of such Third Party Claim and the defense thereof and shall consider in good faith recommendations made by the Non-Controlling Party with respect thereto. The Non-Controlling Party shall furnish the Controlling Party with such information as it may have with respect to such Third Party Claim (including copies of any summons, complaint or other pleading that may have been served on such party and any written claim, demand, invoice, billing or other document evidencing or asserting the same) and shall otherwise cooperate with and assist the Controlling Party in the defense of such claim. Neither the Indemnified Party nor the Indemnifying Party shall agree to any settlement of, or the entry of any judgment arising from, any such Third Party Claim without the prior written consent of the other Party, which consent
shall not be unreasonably withheld, conditioned or delayed; provided, however, that the consent of the Indemnified Party shall not be required with respect to any such settlement or judgment if the Indemnifying Party agrees in writing to pay or cause to be paid any amounts payable pursuant to such settlement or judgment (net of the applicable deductible amount specified in Section 7.3.1) and such settlement or judgment includes no admission of liability by or other obligation on the part of the Indemnified Party and includes a complete release of the Indemnified Party from further Liability.

7.3 Limitations on Indemnification.

7.3.1 For purposes of computing the amount of any Losses incurred by any Indemnified Party pursuant to Article 7, any materiality, Material Adverse Effect, or Horizon Material Adverse Effect qualification contained in any representation and warranty or covenant giving rise to the claim for indemnity hereunder shall be disregarded, but for clarity, the foregoing shall not apply with respect to determining whether there has been a breach of any representation and warranty.

7.3.2 The provisions for indemnity under Section 7.1.1(a) or Section 7.1.2(a) shall be effective only when the aggregate amount of all Losses for claims (and series of related claims arising from the same circumstances) exceeds [...***...], in which case the Indemnified Party shall be entitled to indemnification of the Indemnified Party’s Losses in excess thereof. In no event shall any Indemnifying Party have liability for indemnification under Section 7.1.1(a) or Section 7.1.2(a), as applicable, for any amount exceeding, in the aggregate, [...***...]; provided, however, that the limitations on indemnification under this Section 7.3.1 shall not apply to breaches of any Fundamental Rep.

7.3.3 The amount of Losses recovered by an Indemnified Party under Section 7.1.1 or Section 7.1.2, as applicable, shall be reduced by (a) any amounts actually recovered by the Indemnified Party from a Third Party in connection with such claim and (b) the amount of any insurance proceeds paid to the Indemnified Party relating to such claim, both in the case of clause (a) and clause (b) net of any costs of recovery or increases in insurance premiums resulting from such claim. If any amounts referenced in the preceding clauses (a) and (b) are received after payment by the Indemnifying Party of the full amount otherwise required to be paid to an Indemnified Party pursuant to this Article 7, the Indemnified Party shall repay to the Indemnifying Party, promptly after such receipt, any amount that the Indemnifying Party would not have had to pay pursuant to this Article 7 had such amounts been received prior to such payment.

7.3.4 If the Indemnified Party receives any payment from an Indemnifying Party in respect of any Losses pursuant to Section 7.1.1 or Section 7.1.2 and the Indemnified Party could have recovered all or a part of such Losses from a Third Party based on the underlying claim asserted against the Indemnifying Party, the Indemnified Party shall assign such of its rights to proceed against such Third Party as are necessary to permit the Indemnifying Party to recover from the Third Party the amount of such payment.

7.3.5 The representations and warranties of AstraZeneca and Horizon contained in this Agreement shall survive the Closing and continue in full force and effect

*** Confidential Treatment Requested
thereafter through and including the date that is [...***...] after the Closing Date; provided, that the Fundamental Reps shall remain in full force and effect and shall survive indefinitely or, if applicable, until 60 days following the expiration of the applicable statute of limitations. None of the covenants or agreements contained in this Agreement shall survive the Closing other than those that by their terms expressly contemplate performance after the Closing Date and such surviving covenants and agreements shall survive the Closing until fully performed.

7.3.6 [...***...]

7.4 Tax Treatment of Indemnification Payments. All payments made pursuant to this Article 7 shall be treated as adjustments to the Purchase Price for all Tax purposes, unless otherwise required by applicable Law.

7.5 Exclusive Remedy. Except as expressly provided otherwise in this Agreement and subject to Section 9.10, each Party acknowledges and agrees that, following the Closing, the remedies provided for in this Article 7 shall be the sole and exclusive remedies for claims and damages available to the Parties and their respective Affiliates arising out of or relating to this Agreement, except that nothing herein shall limit the Liability of either Party for common law fraud or willful misconduct. This Section 7.5 shall not effect either Party’s ability to exercise any rights or remedies available to such Party under any Ancillary Agreement with respect to claims arising under such Ancillary Agreement.

7.6 Setoff Rights. Neither Party shall have any right of setoff of any amounts due and payable, or any Liabilities arising, under this Agreement against any other amounts due and payable under this Agreement or any amounts due and payable, or any Liabilities arising, under any Ancillary Agreement. The payment obligations under each of this Agreement and the Ancillary Agreements remain independent obligations of each Party, irrespective of any amounts owed to any other Party under this Agreement or the respective Ancillary Agreements.

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8.1 Termination. Prior to the Closing, this Agreement shall terminate on the earliest to occur of any of the following events:

8.1.1 the mutual written agreement of Horizon and AstraZeneca;

8.1.2 by written notice delivered by either Horizon or AstraZeneca to the other, if the Closing shall not have occurred on or prior to December 31, 2013 (the “End Date”) (other than due to a breach of any representation or warranty hereunder of the Party seeking to terminate this Agreement or as a result of the failure on the part of such Party to comply with or perform any of its covenants, agreements or obligations under this Agreement);

8.1.3 by written notice delivered by Horizon to AstraZeneca, if (a) there has been a material misrepresentation or material breach by AstraZeneca of a representation or warranty of AstraZeneca contained in this Agreement or (b) there shall be a material breach by AstraZeneca of any covenant, agreement or obligation of AstraZeneca in this Agreement, and such failure or breach described in clause (a) or (b) would result in the failure of a condition set forth in Section 6.2.1 or Section 6.2.2 that has not been waived by Horizon, or in the case of a breach of any covenant or agreement, is not cured upon the earlier to occur of (i) the 30th day after written notice thereof is given by Horizon to AstraZeneca and (ii) the day that is five Business Days prior to the End Date; provided, that Horizon may not terminate this Agreement pursuant to this Section 8.1.3 if Horizon is in material breach of this Agreement; or

8.1.4 by written notice delivered by AstraZeneca to Horizon, if (a) there has been a material misrepresentation or material breach by Horizon of a representation or warranty of Horizon contained in this Agreement or (b) there shall be a material breach by Horizon of any covenant, agreement or obligation of Horizon in this Agreement, and such failure or breach described in clause (a) or clause (b) would result in the failure of a condition set forth in Section 6.3.1 or Section 6.3.2 and has not been waived by AstraZeneca, or in the case of a breach of any covenant or agreement, is not cured upon the earlier to occur of (i) the 30th day after written notice thereof is given by AstraZeneca to Horizon and (ii) the day that is five Business Days prior to the End Date; provided, that AstraZeneca may not terminate this Agreement pursuant to this Section 8.1.4 if AstraZeneca is in material breach of this Agreement.

8.2 Procedure and Effect of Termination.

8.2.1 Notice of Termination. Termination of this Agreement by either Horizon or AstraZeneca shall be by delivery of a written notice to the other. Such notice shall state the termination provision in this Agreement that such terminating Party is claiming provides a basis for termination of this Agreement. Termination of this Agreement pursuant to the provisions of Section 8.1 shall be effective upon and as of the date of delivery of such written notice as determined pursuant to Section 9.2.

8.2.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 8.1 by Horizon or AstraZeneca, this Agreement shall be terminated and have no further effect, and there shall be no liability hereunder on the part of AstraZeneca, Horizon or
any of their respective Affiliates, except that Sections 5.4 (Publicity), 5.5 (Confidentiality), 8.2.2 (Effect of Termination), 8.2.3 (Withdrawal of Certain Filings) and Article 9 (Miscellaneous) shall survive any termination of this Agreement. For clarity, in the event of termination of this Agreement pursuant to Section 8.1, the Parties shall not enter into any of the Ancillary Agreements not entered into on the Execution Date or have any obligations thereunder. Nothing in this Section 8.2.2 shall relieve either Party of liability for fraud, willful misconduct, intentional misrepresentation or any breach of this Agreement prior to the termination hereof.

8.2.3 Withdrawal of Certain Filings. As soon as practicable following a termination of this Agreement for any reason, but in no event less than 30 days after such termination, Horizon or AstraZeneca shall, to the extent practicable, withdraw all filings, applications and other submissions relating to the transactions contemplated by this Agreement filed or submitted by or on behalf of such Party, any Governmental Authority or other Person.

ARTICLE 9
MISCELLANEOUS

9.1 Governing Law, Jurisdiction, Venue and Service.

9.1.1 Governing Law. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, excluding any conflicts or choice of Law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive Law of another jurisdiction.

9.1.2 Jurisdiction. Subject to Section 9.2 and 9.10, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial.

9.1.3 Venue. Subject to Section 9.2 and 9.10, the Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or in the United States District Court for the Southern District of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

9.1.4 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 9.3 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any court.

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9.2 Dispute Resolution.

9.2.1 Except as provided in Section 9.10, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a “Dispute”), then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of 10 Business Days. Any final decision mutually agreed to by the Senior Officers in writing shall be conclusive and binding on the Parties.

9.2.2 If such Senior Officers are unable to resolve any such Dispute within such 10-Business Day period, either Party shall be free to institute binding arbitration in accordance with this Section 9.2.2 upon written notice to the other Party (an “Arbitration Notice”) and seek such remedies as may be available. Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three experts with relevant industry experience (the “Arbitrators”). Each of Horizon and AstraZeneca shall promptly select one Arbitrator, which selections shall in no event be made later than 30 days after the notice of initiation of arbitration. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Horizon and the Arbitrator chosen by AstraZeneca, but in no event later than 30 days after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery; provided that the Arbitrators shall permit such discovery as they deem necessary to permit an equitable resolution of the Dispute. The arbitration shall be administered by the American Arbitration Association (“AAA”) (or its successor entity) in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Agreement. The arbitration shall be held in New York, New York, USA, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The Arbitrators shall, within 15 days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with Applicable Law in the State of New York or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.

9.2.3 Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Section 9.2, and shall pay an equal share of the fees and costs of the Arbitrators and all other general fees related to any arbitration described in Section 9.2.3; provided, however, the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges, or travel expenses) or the fees and costs of the Arbitrators. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Section 9.2.3 is pending under this Agreement, the Parties shall continue to comply with all terms and provisions of this Agreement. All arbitration
proceedings and decisions of the Arbitrator under this 9.2 shall be deemed Confidential Information of both Parties under Section 5.5 of this Agreement. For clarity, nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding.

9.3 Notices.

9.3.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement (each, a “Notice”) shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 9.3.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party at least 5 days’ prior to such address taking effect in accordance with this Section 9.3. Such Notice shall be deemed to have been given as of the date delivered by hand or internationally recognized overnight delivery service or confirmed that it was received by facsimile (with receipt confirmed by telephone or email). Any Notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter.

9.3.2 Address for Notice.

If to AstraZeneca, to:
AstraZeneca AB
Pepparredsleden 1
S-431 83 Mölndal
Attention: President
Facsimile: +46 31 7763871

with a copy (which shall not constitute notice) to:
AstraZeneca AB
Pepparredsleden 1
S-431 83 Mölndal
Attention: Senior Counsel and Lead, Legal Dept.
Facsimile: +46 31 7763871

and to:
Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
Facsimile: (202) 662-6291
Attention: John Hurvitz
9.4 **No Benefit to Third Parties.** The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and, except for the rights of Horizon Indemnitees and AstraZeneca Indemnitees under Article 9, they shall not be construed as conferring any rights on any other Persons.

9.5 **Waiver and Non-Exclusion of Remedies.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

9.6 **Expenses.** Except as otherwise specified herein, and whether or not the Closing takes place, each Party shall bear any costs and expenses incurred by it with respect to the transactions contemplated herein.

9.7 **Assignment.** Except as expressly set forth in this Agreement, neither Party shall have the right or the power to assign, in whole or in part, any of its rights, or delegate the performance of any of its obligations, under this Agreement without the prior written authorization of the other Party, which authorization shall not be unreasonably withheld, conditioned or delayed, and any assignment or delegation of this Agreement or any of such rights or obligations without such authorization shall be void and of no effect; provided, however, that either Party may assign the Agreement, in whole or in part, to an Affiliate without the prior written authorization of the other Party; and provided, further, that either Party shall have the right to assign this Agreement, in whole or in part, in connection with a merger or other
acquisition of the capital stock or all or substantially all of its assets, without the prior written authorization of the other Party. Any permitted assignment or delegation hereunder by a Party shall not relieve such Party of any of its obligations under this Agreement (whether by operation of law or otherwise), unless, with respect an assignment to a Third Party, such assignee agrees in writing to assume such Party’s obligations under this Agreement, in which case such Party shall be relieved of its obligations hereunder from and after the effective date of such assignment and assumption. Subject to the foregoing, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns.

9.8 Amendment. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by both Parties.

9.9 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

9.10 Equitable Relief. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in any court of the United States or any state having jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity. Each Party hereby waives (a) any requirement that the other Party post a bond or other security as a condition for obtaining any such relief, and (b) any defenses in any action for specific performance, including the defense that a remedy at law would be adequate.

9.11 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

9.12 Bulk Sales Statutes. Horizon hereby waives compliance by AstraZeneca with any applicable bulk sales statutes in any jurisdiction in connection with the transactions under this Agreement.

9.13 Counterparts. This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of
a signature page of this Agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

9.14 Entire Agreement. This Agreement, together with the Schedules and Exhibits expressly contemplated hereby and attached hereto, the Disclosure Schedules, the Ancillary Agreements and the other agreements, certificates and documents delivered in connection herewith or therewith or otherwise in connection with the transactions contemplated hereby and thereby, contain the entire agreement between the Parties with respect to the transactions contemplated hereby or thereby and supersede all prior agreements, understandings, promises and representations, whether written or oral, between the Parties with respect to the subject matter hereof and thereof. In the event of any inconsistency between any such Schedules and Exhibits and this Agreement, the terms of this Agreement shall govern.

[Signature Page Follows]
IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Execution Date.

AstraZeneca AB

By: /s/ Jan-Olof Jacke
   Name: Jan-Olof Jacke
   Title: President

Horizon Pharma USA, Inc.

By: /s/ Timothy P. Walbert
   Name: Timothy P. Walbert
   Title: President and Chief Executive Officer
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Schedule 1.1.25
AstraZeneca’s Knowledge

[...***...]

*** Confidential Treatment Requested
Schedule 1.1.82(a)

Licensed Copyrights

Copyrights with respect to the following:

- Product Promotional Materials
- All labels and other written, printed or graphic matter upon a container, wrapper or any package insert utilized with the Product
- The prescribing information for the Product
- Any website associated with any of Licensed Domain Names
Schedule 1.1.82(b)

Excluded Copyrights

None.
vimovo.com
vimovosavingscard.com
vimovofreetrial.com
saveonvimovo.com
learnaboutvimovo.com
vimovosavings.com
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*** Confidential Treatment Requested
Word marks
[...***...]
  • In each case, including any derivatives, translations, transliterations or stylized forms of any of the foregoing word marks

Design marks
[...***...]

*** Confidential Treatment Requested
[...***...]

Color mark
[...***...]

*** Confidential Treatment Requested
None.
**Schedule 1.1.124**

**Pozen Patents**

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### Schedule 1.1.136

## Purchased Patents

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*** Confidential Treatment Requested
## Schedule 1.1.158

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Schedule 2.1.1(a)

Purchased Contracts

Amended and Restated Collaboration and License Agreement for the United States by and between Pozen Inc. and AstraZeneca AB, dated as of November 18, 2013.
Schedule 2.1.1(b)

Purchased Regulatory Approvals

NDA # 22-511
IND # 76301
Schedule 2.4.2(a)(iii)
Delivery Schedule of Tangible Purchased Assets

Purchased Regulatory Approvals and Regulatory Documentation included in Purchased Assets that are addressed in the Transition Agreement to be transferred to Horizon as provided therein. Any remaining Regulatory Documentation included in the Purchased Assets to be transferred to Horizon within [...] days after December 16, 2013.

Product Promotional Materials to be transferred as provided in the Transition Plan.

Product Records to be transferred to Horizon no later than December 31, 2013.

*** Confidential Treatment Requested
Schedule 4.2
Ordinary Course of Business Exceptions

[...***...]

*** Confidential Treatment Requested
LICENSE AGREEMENT

By and between

AstraZeneca AB

and

Horizon Pharma USA, Inc.

Dated as of November 22, 2013
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LICENSE AGREEMENT

This License Agreement (this “Agreement”) is made and entered into effective as of November 22, 2013 (the “Effective Date”) by and between AstraZeneca AB, a Swedish corporation (“AstraZeneca”), and Horizon Pharma USA, Inc., a corporation organized and existing under the Laws of the State of Delaware (“Horizon”). AstraZeneca and Horizon are sometimes referred herein individually as a “Party” and collectively as the “Parties.”

RECITALS

WHEREAS, AstraZeneca and Horizon are parties to that certain Asset Purchase Agreement, dated as of November 18, 2013 (the “Asset Purchase Agreement”), pursuant to which, effective as of the Closing, Horizon is purchasing from AstraZeneca certain assets related to the Product (as defined in the Asset Purchase Agreement) in the Horizon Territory (as defined in the Asset Purchase Agreement) and AstraZeneca is required to grant a license or right of reference and use to Horizon, and Horizon is required to take a license or right of reference and use, under certain intellectual property, regulatory data and approvals, to Exploit the Product and Other Products in the Horizon Territory; and

WHEREAS, following the Closing, Horizon will Control certain regulatory data and approvals with respect to the Product and is required to grant a right of reference and use to AstraZeneca, and AstraZeneca is required to take a right of reference, under such regulatory data and approvals with respect to the Product, to Exploit the Product and Other Products in the AstraZeneca Territory.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth and set forth in the Asset Purchase Agreement, the other Ancillary Agreements, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the meanings set forth in this Article 1 and capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed thereto in the Asset Purchase Agreement.

1.1 “AAA” has the meaning set forth in Section 13.2.2.
1.2 “Agreement” has the meaning set forth in the preamble hereto.
1.3 “Alliance Manager” has the meaning set forth in Section 2.8.
1.4 “Ancillary AstraZeneca Confidential Information” has the meaning set forth in Section 9.1.3.
1.5 “Ancillary Confidential Information” has the meaning set forth in Section 9.1.1.
1.6 “Ancillary Disclosing Party” has the meaning set forth in Section 9.1.1.
1.7 “Ancillary Horizon Confidential Information” has the meaning set forth in Section 9.1.2.
1.8 “Ancillary Receiving Party” has the meaning set forth in Section 9.1.1.
1.10 “Arbitration Notice” has the meaning set forth in Section 13.2.2.
1.11 “Arbitrators” has the meaning set forth in Section 13.2.2.
1.12 “Asset Purchase Agreement” has the meaning set forth in the recitals hereto.
1.13 “AstraZeneca” has the meaning set forth in the preamble hereto.
1.14 “AstraZeneca Indemnitees” has the meaning set forth in Section 11.1.
1.15 “AstraZeneca Patents” has the meaning set forth in Section 6.1.
1.16 “Breaching Party” has the meaning set forth in Section 12.2.
1.17 “CCP” has the meaning set forth in Section 4.1.2.
1.18 “Dispute” has the meaning set forth in Section 13.2.1.
1.19 “Effective Date” has the meaning set forth in the preamble hereto.
1.20 “Ex-US Licensed Patents” means the Patent Rights that are the foreign equivalents of the Merck Patents, excluding any such Patent Rights included in the Manufacturing Technology.
1.21 “Existing Pediatric Study” means that certain study entitled [...***...].
1.22 “Government Official” means (a) any Person employed by or acting on behalf of a government, government-controlled agency or entity or public international organization, (b) any political party, party official or candidate, (c) any Person who holds or performs the duties of a public-sector appointment, office or position created by custom or convention or (d) any Person who holds himself out to be the authorized intermediary of any of the foregoing.

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

1.24 “Horizon Indemnitees” has the meaning set forth in Section 11.2.

1.25 “Horizon Regulatory Documentation” means any and all Regulatory Documentation related to the Product or any Other Product, in each case, Controlled by Horizon or any of its Affiliates effective at any time as of or following the Closing, including the Purchased Regulatory Approvals and any other Regulatory Documentation included in the Purchased Assets.

1.26 “Licensed Intellectual Property” means the US Licensed Patents, the Ex-US Licensed Patents, the Licensed Know-How, the Licensed Copyrights, the Licensed Trademarks, the Licensed Domain Names and the Manufacturing Technology.

1.27 “Licensed Know-How” means (a) as of the Effective Date, any data, information and know-how that (i) is not generally known, (ii) is Controlled by AstraZeneca or its Affiliates and (iii) is used by or on behalf of AstraZeneca or its Affiliates as of the Effective Date for the Exploitation of the Product in the Horizon Territory or the research or development of the Product in the AstraZeneca Territory, excluding the Merck Know-How and (b) as of the date, if any, that AstraZeneca or any of its Affiliates may grant a license to Horizon under the Merck Know-How without violating the terms of any Merck Agreement, (i) the data, information and know-how described in clause (a) and (ii) the Merck Know-How used by or on behalf of AstraZeneca or its Affiliates as of the Effective Date for the Exploitation of the Product in the Horizon Territory; provided, that in either case ((a) or (b)), if such data, information or know-how becomes publicly disclosed (other than as a result of any disclosure by Horizon in breach of its obligations under Section 9.1), such data, information or know-how shall no longer be deemed Licensed Know-How, but excluding in either case ((a) or (b)) any data, information and know-how included in the Manufacturing Technology.

1.28 “Licensed Regulatory Documentation” means any and all Regulatory Documentation related to the Product or any Other Product, in each case, Controlled by AstraZeneca or any of its Affiliates as of and following the Closing, excluding the Regulatory Documentation included in the Purchased Assets.

1.29 “Licensed Trademarks” means (a) the Trademark VIMOVO and the other Trademarks and logos listed on Schedule 1.29 and (b) any variation or derivation of any of the Trademarks set forth in the foregoing clause (a) that are approved by AstraZeneca in accordance with the procedures set forth in Section 7.2.1 for use on or in connection with the Exploitation of the Product or any Other Product in the Horizon Territory.

1.30 “Manufacturing Technology” means (a) as of the Effective Date, all Patent Rights (including foreign equivalents of the Merck Patents) and all data, information and know-how that (i) with respect to data, information and know-how, is not generally known, (ii) are Controlled by AstraZeneca or any of its Affiliates as of the Effective Date and (iii) are used
by or on behalf of AstraZeneca or its Affiliates for the Manufacture of Products or Other Products as of the Effective Date, excluding the Merck Patents and
Merck Know-How and (b) as of the date, if any, that AstraZeneca or any of its Affiliates may grant a license to Horizon under the Merck Patents and Merck
Know-How without violating the terms of any Merck Agreement, the Patent Rights, data, information and know-how described in clause (a) and any Merck
Patents and Merck Know-How that are used by or on behalf of AstraZeneca or its Affiliates for the Manufacture of Products or Other Products as of the
Effective Date; provided, that in either case ((a) or (b)), if any data, information or know-how (but not, for clarity, Patent Rights) included in Manufacturing
Technology becomes publicly disclosed (other than as a result of any disclosure by Horizon in breach of its obligations under Section 9.1), such data,
information or know-how shall no longer be deemed Manufacturing Technology.

1.31 “Merck Net Sales” means, for any period of time, the total amount required to be recorded for such period by Horizon or any of its Affiliates
or Sublicensees on its or their respective books and records in accordance with GAAP with respect to sales of Merck Product in the Horizon Territory for any
use (whether in human medicine or otherwise) to its non-Affiliates after deducting (if not already deducted in the amount recorded) trade discounts, rebates,
returns and allowances, retroactive price reductions or adjustments, and [...***...] of the amount recorded to cover cash discounts ("fast pay"), sales or excise
taxes, transportation, and insurance charges.

1.32 “Notice” has the meaning set forth in Section 13.3.1.

1.33 “Notice Period” has the meaning set forth in Section 12.2.

1.34 “Other Esomeprazole Product” means any Other Product that contains Esomeprazole as an active ingredient.

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

1.36 “Payment” has the meaning set forth in Section 3.4.1(b).

1.37 “Primary Licensed Domain Name” means vimovo.com.

1.38 “Product Label” means, with respect to the Product or any Other Product in the Horizon Territory, (a) the Regulatory Authority-approved
full prescribing information for the Product or any Other Product, as applicable, including any required patient information and (b) all labels and other
written, printed or graphic matter upon a container, wrapper or any package insert utilized with or for the Product or any Other Product, as applicable.

1.39 “Product Websites” has the meaning set forth in Section 8.3.

1.40 “Recipients” means, with respect to a Party, such Party’s and its Affiliates’ respective officers, employees, agents, attorneys, consultants,
contractors, advisors and other representatives.
1.41 “Representatives” has the meaning set forth in Section 3.4.1(b).
1.42 “Secondary Licensed Domain Names” means any Licensed Domain Name other than the Primary Domain Name.
1.43 “Senior Officer” means, with respect to AstraZeneca, its Vice President, Cornerstone and Commercial Excellence and with respect to Horizon, its Chief Executive Officer.
1.44 “Sublicensee” means a Third Party that is granted a sublicense (or further rights of reference and use) by Horizon under the grant in Section 2.1 or by AstraZeneca under the grant in Section 2.3, in either case, in accordance with Section 2.2.
1.45 “Term” has the meaning set forth in Section 12.1.
1.46 “Terminable Rights and Provisions” means (a) the licenses granted by AstraZeneca to Horizon under Section 2.1 with respect to the Licensed Trademarks and Licensed Domain Names only (but not, for clarity, with respect to any other Licensed Intellectual Property or Licensed Regulatory Documentation), (b) Article 7 and (c) Article 8.
1.47 “Third Party Claims” has the meaning set forth in Section 11.1.
1.48 “US Licensed Patents” means as of the date, if any, that AstraZeneca or any of its Affiliates may grant a license to Horizon under the Merck Patents without violating the terms of any Merck Agreement, the Merck Patents, excluding any Merck Patents included in the Manufacturing Technology.

ARTICLE 2
GRANT OF RIGHTS; ALLIANCE MANAGEMENT

2.1 Grants to Horizon. Subject to Section 2.4 and the other terms and conditions of the Asset Purchase Agreement and this Agreement, AstraZeneca (on behalf of itself and its Affiliates), in consideration of the amounts due under the Asset Purchase Agreement, hereby grants to Horizon and its Affiliates:

2.1.1 an exclusive (even as to AstraZeneca and its Affiliates), royalty-free, non-transferable (except as provided in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Licensed Copyrights, Licensed Trademarks, Licensed Domain Names, US Licensed Patents, and Licensed Know-How to Exploit the Product or any Other Product in the Field in the Horizon Territory;

2.1.2 an exclusive (even as to AstraZeneca and its Affiliates), royalty-free, non-transferable (except as provided in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Manufacturing Technology, the Licensed Trademarks and the Licensed Copyrights to Manufacture or have Manufactured the Product or any Other Product in the Field in the Horizon Territory;

2.1.3 a non-exclusive, royalty-free, non-transferable (except as provided
in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Manufacturing Technology, the Licensed Trademarks and the Licensed Copyrights to Manufacture and have Manufactured the Product or any Other Product in the AstraZeneca Territory but solely for the exportation and use of such Product or Other Product in connection with the Exploitation of the Product or any Other Product in the Field in the Horizon Territory;

2.1.4 a non-exclusive, royalty-free, non-transferable (except as provided in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Licensed Copyrights, Ex-US Licensed Patents, and Licensed Know-How to (a) perform research and development activities with respect to the Product or any Other Product in the AstraZeneca Territory solely in connection with the Manufacture and Exploitation of the Product or any Other Product in the Horizon Territory, and (b) to export or import the Product or any Other Product in the AstraZeneca Territory solely in connection with the Manufacture and Exploitation of the Product or any Other Product in the Horizon Territory; and

2.1.5 a non-exclusive, royalty-free, non-transferable (except as provided in Section 13.7) right of reference and use, with the right to grant further rights of reference and use in accordance with Section 2.2, under the Licensed Regulatory Documentation to (a) Manufacture, have Manufactured or Exploit the Product or any Other Product in the Field in the Horizon Territory, (b) Manufacture and have Manufactured the Product or any Other Product in the AstraZeneca Territory but solely for the exportation and use of such Product or Other Product in connection with the Manufacture and Exploitation of the Product or any Other Product in the Horizon Territory, and (c) perform research and development activities with respect to, and export and import, the Product or any Other Product in the AstraZeneca Territory solely in connection with the Manufacture and Exploitation of the Product or any Other Product in the Horizon Territory.

All licenses granted under this Section 2.1 shall be perpetual and irrevocable except as otherwise provided in Article 12 with respect to the termination of the Terminable Rights and Provisions.

2.2 Sublicenses. Horizon shall have the right to grant sublicenses (or further rights of reference and use) under the licenses and rights of reference and use granted in Section 2.1, through multiple tiers of Sublicensees, and AstraZeneca shall have the right to grant sublicenses (or further rights of reference and use) under the licenses and rights of reference and use granted in Section 2.3, through multiple tiers of Sublicensees; provided, however, that any such sublicense granted by Horizon with respect to any Manufacturing Technology related to Esomeprazole under Section 2.1.2 or Section 2.1.3 shall be subject to AstraZeneca’s prior written consent, which consent may be granted or withheld in its sole discretion; provided, further, that AstraZeneca shall not condition, withhold or delay its consent to any such sublicense to be granted by Horizon or any of its Affiliates to any Third Party if, at the time of such proposed sublicense, such Third Party is supplying Esomeprazole to AstraZeneca or any of its Affiliates or any of its or their respective licensees or sublicensees. Notwithstanding the foregoing, AstraZeneca acknowledges and agrees that Horizon intends to grant [...***...] a non-exclusive, sublicense (or further rights of reference and use) under the licenses and rights of reference and use granted in Section 2.1.2 or 2.1.3 solely for the purposes of [...***...] supplying Esomeprazole to Horizon for use in the Manufacture of the Product for Exploitation in

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the Horizon Territory, and AstraZeneca hereby consents to such sublicense. AstraZeneca agrees that neither AstraZeneca nor any of its Affiliates shall claim (or assist a Third Party in claiming) that the further formulation or other processing of Esomeprazole by or on behalf of Horizon or its Affiliates or any Sublicensor in connection with the Manufacture of the Product or any Other Product in the Horizon Territory or in the AstraZeneca Territory but solely for the exportation and use of such Product or Other Product in accordance with this Agreement, infringes or misappropriates any Patent Rights, information, data or know-how that are part of the Manufacturing Technology and that Horizon or its Affiliates or any Sublicensor shall have the right to formulate or otherwise process, or have a Third Party formulate or otherwise process on their behalf, any Esomeprazole from [...] or any other Third Party to whom Horizon or any of its Affiliates grants a sublicense to any Manufacturing Technology related to Esomeprazole with AstraZeneca’s consent in connection with the Manufacture of the Product or any Other Product in the Horizon Territory or in the AstraZeneca Territory but solely for the exportation and use of such Product or Other Product in accordance with this Agreement. Further, if AstraZeneca or any of its Affiliates assigns or transfers any Patent Rights that are part of the Manufacturing Technology, AstraZeneca or such Affiliate shall cause such assignee or transferee to be bound by the covenant set forth in the immediately foregoing sentence. Each Party granting a sublicense pursuant to this Section 2.2 shall (a) remain jointly and severally liable for the performance or non-performance of any such Sublicensor, and (b) provide to the other Party within 14 days after execution by the parties thereto a written notice setting forth in reasonable detail the nature of such sublicense and the identity of the Sublicensor, which written notice shall include a copy of such executed sublicense agreement; provided that the financial terms and any other commercially sensitive terms of any such sublicense agreement may be redacted to the extent not pertinent to an understanding of either Party’s obligations or benefits under this Agreement. The grant of any such sublicense shall not relieve the sublicensing Party of its obligations under this Agreement, except to the extent such obligations are performed by any such Affiliate or Sublicensor. Notwithstanding anything to the contrary herein, neither Party shall be responsible or liable for the other Party’s or its Affiliates’ (or their respective sub-sublicensees’) performance or exercise of any sublicense granted by the first Party to such other Party or its Affiliates under Section 2.1 or Section 2.3, as applicable.

2.3 Grants to AstraZeneca. Subject to the terms and conditions of this Agreement, Horizon (on behalf of itself and its Affiliates and sublicensees) hereby grants to AstraZeneca and its Affiliates:

2.3.1 a non-exclusive, royalty-free, non-transferable (except as provided in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Manufacturing Technology, the Licensed Trademarks and the Licensed Copyrights to Manufacture or have Manufactured the Product or any Other Product in the Horizon Territory but solely for the exportation and use of such Product or Other Product in connection with the Exploitation of the Product or any Other Product in the AstraZeneca Territory;

2.3.2 a non-exclusive, royalty-free, non-transferable (except as provided in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Licensed Copyrights, US Licensed Patents, and Licensed Know-How to (a) perform research and development activities with respect to the Product or any Other Product in the Horizon Territory.
Territory solely in connection with the Exploitation of the Product or any Other Product in the AstraZeneca Territory; and (b) to export or import the Product or any Other Product in the Horizon Territory solely in connection with the Exploitation of the Product or any Other Product in the AstraZeneca Territory; and

2.3.3 a non-exclusive, royalty-free, non-transferable (except as provided in Section 13.7) right of reference and use, with the right to grant further rights of reference and use in accordance with Section 2.2, under the Horizon Regulatory Documentation to (a) Manufacture, have Manufactured or Exploit the Product or any Other Product in the Field in the AstraZeneca Territory, (b) Manufacture and have Manufactured the Product or any Other Product in the Horizon Territory but solely for the exportation and use of such Product or Other Product in connection with the Manufacture and Exploitation of the Product or any Other Product in the Field in the AstraZeneca Territory, and (c) perform research and development activities with respect to, and export and import, the Product or any Other Product in the Horizon Territory solely in connection with the Manufacture and Exploitation of the Product or any Other Product in the AstraZeneca Territory.

2.4 Retention of Rights.

2.4.1 Except for the rights and licenses expressly granted to Horizon and Affiliates in this Agreement or in any other Ancillary Agreement, AstraZeneca, on behalf of itself and its Affiliates, retains all rights under the Licensed Intellectual Property and the Licensed Regulatory Documentation.

2.4.2 Except for the rights and licenses expressly granted to AstraZeneca and Affiliates in this Agreement or in any other Ancillary Agreement, (a) Horizon, on behalf of itself and its Affiliates, retains all rights under Horizon Regulatory Documentation and (b) Horizon, on behalf of its and its Affiliates, retains the exclusive right under (i) the Licensed Copyrights, Licensed Trademarks, Licensed Domain Names, US Licensed Patents, and Licensed Know-How to Exploit the Product or any Other Product in the Field in the Horizon Territory and (ii) the Manufacturing Technology, the Licensed Trademarks and the Licensed Copyrights to Manufacture or have Manufactured the Product or any Other Product in the Field in the Horizon Territory.

2.4.3 No rights shall be deemed granted by either Party to the other Party by implication, estoppel or otherwise with respect thereto.

2.4.4 In addition, AstraZeneca, on behalf of itself and its Affiliates, retains the non-exclusive right in the Horizon Territory under the Licensed Intellectual Property and Licensed Regulatory Documentation to perform its obligations under this Agreement, the Supply Agreement or Section 5.3 of the Asset Purchase Agreement.

2.4.5 Except as expressly granted herein, in the Asset Purchase Agreement or in any other Ancillary Agreement, (a) neither Party grants any right or license to any assets or rights, including intellectual property rights, of such Party and its Affiliates and (b) [***] or [***].

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2.5 No Implied Rights. For the avoidance of doubt, (a) Horizon and its Affiliates shall have no right, express or implied, except as expressly provided in Section 2.1 and elsewhere in this Agreement, the Asset Purchase Agreement, and the Ancillary Agreements with respect to (i) the Licensed Intellectual Property or the Licensed Regulatory Documentation, and (ii) [...] and (b) AstraZeneca and its Affiliates shall have no right, express or implied, with respect to the Horizon Regulatory Documentation, except as expressly provided in Section 2.3 and elsewhere in this Agreement and in Section 2.3.3 of the Supply Agreement. For clarity, except for the licenses granted to Horizon and its Affiliates under the Licensed Trademarks and Licensed Domain Names, nothing herein grants either Party or any of its Affiliates the right to use or to register any Domain Name (including both gTLDs and ccTLDs) or any social media name, tag or handle or similar identifier that incorporates in whole or in part any of the trade names, corporate names and corporate logos of the other Party or the other Party’s Affiliates that are used by the other Party or any of the other Party’s Affiliates.

2.6 Restrictions.

2.6.1 Horizon shall not, and shall cause its Affiliates and Sublicensees not to, Exploit the Product or any Other Product for any indication other than (a) one or more indications for which NSAIDs alone are indicated, together with (b) the prevention, treatment or amelioration of, or decrease in the risk of, gastrointestinal side effects of NSAIDs in patients at risk of developing side effects associated with NSAID use, so long as such prevention, treatment or amelioration of, or decrease in the risk of, gastrointestinal side effects is described or referenced in the product prescribing information.

2.6.2 Without limiting the generality of Section 2.6.1, without the prior written consent of AstraZeneca (which consent may be granted or withheld in its sole discretion), Horizon shall not, and shall cause its Affiliates and Sublicensees not to:

(a) conduct any pre-clinical or clinical studies or any epidemiological, health economic or other similar studies with respect to any Other Esomeprazole Product;

(b) develop or seek Regulatory Approval for any Other Esomeprazole Product;

(c) develop or seek Regulatory Approval for the Product outside of the Field;

(d) refer to, or make any comparisons to, Nexium, any Nexium Trademark or the Nexium Business in advertising or promotional materials or otherwise (including any internet or social media campaigns);

(e) use any advertising or promotional campaign elements or phrases, logos, slogans or branding that are the same as or confusingly similar to those used with respect to Nexium anywhere in the world;

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(f) use the color purple or any phrase that includes the term “purple” to identify the Product or any Other Product;
(g) use any Trademark that is confusingly similar to any Nexium Trademark; or
(h) use any purple packaging or other trade dress with a purple color scheme with respect to the Product or any Other Product, including the physical appearance of the Product or any Other Product.

2.6.3 In the event that a Party intends to conduct any pre-clinical or clinical studies or any epidemiological, health economic or other similar studies with respect to the Product, other than the Existing Pediatric Study, such Party shall notify the other Party in writing of its intent to carry out such study and shall consider in good faith the other Party’s comments with respect to such proposed study.

2.7 Horizon Control in Horizon Territory. Subject to the terms of this Agreement, the Asset Purchase Agreement and the Supply Agreement, from and after the Effective Date, Horizon shall have the sole right and responsibility with respect to the Manufacture and Exploitation of Products and Other Products in the Horizon Territory.

2.8 Alliance Management. The Parties each acknowledge and agree that it would be beneficial to each to have a representative to act as an alliance manager (“Alliance Manager”) and shall appoint such a person promptly after the Effective Date. The Alliance Managers shall serve as a single point of contact within each Party and shall coordinate as necessary with respect to the Products and the Other Products from time to time. If a Party needs to access any information or documentation of the other Party or any of its Affiliates that is related to any Product or Other Product in order to comply with applicable Law or any Regulatory Authority requirement, to the extent such access is not otherwise provided under this Agreement or the Asset Purchase Agreement, the Alliance Managers shall coordinate to provide such first Party appropriate access to such information or documents to the extent necessary for such first Party or its Affiliate to comply with applicable Law or any Regulatory Authority requirement.

ARTICLE 3
TERRITORIAL RESTRICTIONS; COMPLIANCE

3.1 Horizon Restrictions. Horizon (a) shall, and shall cause its Affiliates and its and their respective Sublicensees and distributors to, distribute, market, promote, offer for sale and sell the Product and the Other Products only in the Horizon Territory, and (b) shall not, and shall not permit its Affiliates and its and their respective Sublicensees or distributors to, distribute, market, promote, offer for sale or sell the Product or any Other Product directly or indirectly to any Person for use in the AstraZeneca Territory. If Horizon or any of its Affiliates receives or becomes aware of the receipt by a Sublicensee or distributor of any orders for the Product or any Other Product in the AstraZeneca Territory, such Person shall refer such orders to AstraZeneca. Horizon shall cause its Affiliates and its and their respective Sublicensees and distributors to notify Horizon of any receipt of any orders for the Product or any Other Product in
3.2 **AstraZeneca Restrictions.** AstraZeneca (a) shall, and shall cause its Affiliates and its and their respective licensees, sublicensees and distributors to, distribute, market, promote, offer for sale and sell the Product and the Other Products only in the AstraZeneca Territory, and (b) shall not, and shall not permit its Affiliates and its and their respective licensees, sublicensees or distributors to, distribute, market, promote, offer for sale or sell the Product or any Other Product directly or indirectly to any Person for use in the Horizon Territory. If AstraZeneca or any of its Affiliates receives or becomes aware of the receipt by a licensee, sublicensee or distributor of any orders for the Product or any Other Product in the Horizon Territory, such Person shall refer such orders to Horizon. AstraZeneca shall cause its Affiliates and its and their respective licensees, sublicensees and distributors to notify AstraZeneca of any receipt of any orders for the Product or any Other Product in the Horizon Territory.

3.3 **Compliance with Legal Requirements.** Horizon shall conduct, and shall cause its Affiliates, Sublicensees, and Third Party subcontractors and distributors to conduct, all activities concerning the Product, any Other Product, the Licensed Intellectual Property and the Licensed Regulatory Documentation in compliance with all applicable Laws. AstraZeneca shall conduct, and shall cause its Affiliates, licensees, sublicensees, and Third Party subcontractors and distributors to conduct, all activities concerning the Product and any Other Product in compliance with all applicable Laws. In addition, each Party hereby certifies that it has not employed or otherwise used in any capacity, and will not employ or otherwise use in any capacity, the services of any Person debarred under United States Law, including 21 U.S.C. Section 335a (or any foreign equivalent thereof) or who is the subject of a conviction described in such section (or any foreign equivalent thereof), in connection with the Manufacture or Exploitation of the Product or any Other Product or the performance of any portion of its activities hereunder or pursuant hereto. Each Party shall notify the other Party in writing immediately if any such debarment or conviction occurs or comes to its attention or if any Litigation is pending or, to such Party’s knowledge, is threatened, relating to the debarment or conviction of such Party or any such Person, and shall, with respect to any Person so debarred or convicted promptly remove such Person from performing any activities in connection with the Exploitation of the Product or any Other Product or the performance of any portion of such Party’s activities hereunder or pursuant hereto.

3.4 **Compliance with Ethical Business Practices.**

3.4.1 **Anti-Bribery and Anti-Corruption Compliance.**

(a) Each Party acknowledges that the other Party’s corporate policy requires that such other Party’s business must be conducted within the letter and the spirit of the Law and consistent with good business ethics. By signing this Agreement, each Party agrees to conduct its activities under this Agreement (including, in the case of AstraZeneca, Manufacture, research, development, import and export of Products and Other Products in the Horizon Territory, and the Manufacture and Exploitation of Products and Other Products in the AstraZeneca Territory) in a manner that is consistent with Law, including Anti-Corruption Law, and good business ethics.
(b) Neither Party shall, or permit its Affiliates to, and each Party shall use its commercially reasonable efforts to not permit its Sublicensees, agents, contractors and other representatives to, pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give, or authorize the giving of anything of value (collectively, a “Payment”) to any Government Official in connection with the Manufacture or Exploitation of Products or Other Products where such Payment would constitute a violation of any Anti-Corruption Law. In addition, regardless of legality, neither Party shall make any Payment, directly or indirectly, to any Government Official in connection with the Manufacture or Exploitation of Products or Other Products if such Payment is for the purpose of influencing decisions or actions in connection with the Manufacture or Exploitation of Products or Other Products. Each Party acknowledges and agrees that none of the other Party, or any of its Affiliates or its or their respective officers, directors, employees, agents and representatives (collectively, “Representatives”) is authorized to waive compliance with the provisions of this Section 3.4.1(b) and that it shall be solely responsible for its compliance with the provisions of this Section 3.4.1(b) and the Anti-Corruption Laws irrespective of any act or omission of the other Party or any of its Affiliates or its or their respective Representatives.

3.4.2 Exclusions List. Horizon shall not use (and shall cause its Affiliates not to use) any Person (including any employee, officer, director, Sublicensee or Third Party contractor or distributor) who is (or has been) on the Exclusions List of the Office of Inspector General, U.S. Department of Health & Human Services, or who is (or has been) in violation of the terms hereof in connection with the Manufacture or Exploitation of Products or Other Products. Horizon certifies to AstraZeneca that, as of the Effective Date, Horizon has screened itself, and its officers and directors (and its Affiliates, Sublicensees and Third Party contractors and distributors and their respective officers and directors) against the Exclusions List of the Office of Inspector General, U.S. Department of Health & Human Services and that it has informed AstraZeneca whether Horizon, or any of its officers or directors (or any of its Affiliates, Sublicensees or Third Party contractors or distributors or any of their respective officers and directors) has been in violation of the terms hereof in connection with the performance of any activities hereunder. After the execution of this Agreement, Horizon shall promptly notify AstraZeneca in writing if any such violation comes to its attention.

ARTICLE 4
REGULATORY

4.1 Regulatory Responsibilities.

4.1.1 Notification of Label Changes.

(a) Horizon shall notify AstraZeneca in writing of any revisions to the Product Label for the Product or any Other Product in the Horizon Territory whether initiated by Horizon or requested by FDA within 10 days after such revision is initiated by Horizon or requested by FDA, as applicable. Horizon shall also notify AstraZeneca in writing of any revision to the Product Label for the Product or any Other Product in the Horizon Territory within 10 days after such revision is approved by FDA, and such notice shall include the exact revised language for the applicable Product Label.
(b) AstraZeneca shall notify Horizon in writing of any revisions whether initiated by AstraZeneca or requested by any Regulatory Authority to (i) the Regulatory Authority approved full prescribing information for the Product or any Other Product in the AstraZeneca Territory, including any required patient information and all labels and other written, printed or graphic matter upon a container, wrapper or any package insert utilized with or for the Product or any Other Product in the AstraZeneca Territory or (ii) the Regulatory Authority approved full prescribing information for Nexium anywhere in the world, including any required patient information and all labels and other written, printed or graphic matter upon a container, wrapper or any package insert utilized with or for Nexium anywhere in the world, in either case (i) or (ii) that would reasonably be expected to impact the Product Label for the Product or any Other Product in the Horizon Territory within 10 days after such revision is initiated by AstraZeneca or requested by the applicable Regulatory Authority, as applicable. AstraZeneca shall also notify Horizon in writing of any such revisions within 10 days after such revision is approved by the applicable Regulatory Authority, and such notice shall include the exact revised language for the application revision.

(c) The Party notifying the other Party of any revisions to any Regulatory Authority-approved full prescribing information, including any required patient information or any labels and other written, printed or graphic matter upon a container, wrapper or any package insert pursuant to this Section 4.1.1, shall use commercially reasonable efforts to answer the other Party’s questions with respect to any such revision.

(d) For clarity, the Parties obligations under this Section 4.1.1 are in addition to any other notification obligations either Party has under the Transition Safety Data Exchange Agreement or the Post-Transition Safety Data Exchange Agreement.

4.1.2 If a legalized Certificate of Pharmaceutical Product (“CPP”) is required to renew any Regulatory Approval for a Product or Other Product in any country in the AstraZeneca Territory, upon AstraZeneca’s reasonable request with respect to timing, Horizon shall use commercially reasonable efforts to assist AstraZeneca in obtaining such CPP. AstraZeneca shall provide Horizon with reasonable advance notice of the need for any such CPP and such notice shall contain sufficient information and instructions as to minimize impact into Horizon’s normal business activities. The Alliance Managers shall coordinate with respect to any request for a CPP by AstraZeneca to ensure that such request is handled promptly and with reasonable care. Upon AstraZeneca’s request for any CPP, the Parties shall agree upon the process cost and timelines with respect thereto. AstraZeneca shall reimburse Horizon for all reasonable and documented or otherwise verifiable external and internal costs incurred in connection with processing or otherwise assisting AstraZeneca in obtaining any requested CPP, including the full time equivalent costs of the employees of Horizon involved in processing any requested CPP or otherwise assisting AstraZeneca in obtaining any requested CPP (which shall be calculated at a rate to be agreed to by the Parties), to the extent such costs do not exceed the costs agreed to by the Parties pursuant to the immediately preceding sentence. AstraZeneca shall reimburse Horizon for such costs within 45 days after receipt of an invoice and reasonable supporting documentation with respect to such costs.

4.1.3 Notwithstanding anything to the contrary in this Agreement, if Horizon is required by applicable Law to provide a Regulatory Authority any communication...
4.2 Access to Regulatory Approvals and Documentation

4.2.1 Upon Horizon’s reasonable request with respect to timing of delivery, AstraZeneca promptly shall (a) provide to Horizon, at Horizon’s cost and expense, copies of the Licensed Regulatory Documentation solely for purposes of exercising Horizon’s and its Affiliates’ rights under the grants in Section 2.1 and (b) provide to Horizon and to any specified Governmental Authority in the Horizon Territory a letter, in the form reasonably requested by Horizon, acknowledging that Horizon has the right of reference and use to any Licensed Regulatory Documentation as described under Section 2.1.5. Notwithstanding anything to the contrary contained in this Agreement, AstraZeneca shall not be required to disclose any information contained in the Licensed Regulatory Documentation or provide any such access to such information if such disclosure or access would, in AstraZeneca’s reasonable discretion, (x) violate (i) applicable Law or (ii) any binding agreement entered into by AstraZeneca prior to the Effective Date, including any confidentiality agreement to which AstraZeneca is a party (provided, that AstraZeneca shall use commercially reasonable efforts to obtain consent from any Third Party to any such binding agreement to enable AstraZeneca to disclose such information), (y) jeopardize any attorney/client privilege or other established legal privilege or (z) disclose any trade secrets; provided, that AstraZeneca shall provide Horizon with a general description of the type of any such information redacted or withheld by AstraZeneca to the extent that AstraZeneca is permitted to do so and keep Horizon informed of all efforts undertaken by AstraZeneca to enable AstraZeneca to disclose such redacted or withheld information to Horizon.

4.2.2 Upon AstraZeneca’s reasonable request with respect to timing of delivery, Horizon promptly shall (a) provide to AstraZeneca, at AstraZeneca’s cost and expense, copies of the Horizon Regulatory Documentation solely for purposes of exercising AstraZeneca’s and its Affiliates’ rights under the grants in Section 2.3 and (b) provide to AstraZeneca and to any specified Governmental Authority in the AstraZeneca Territory a letter, in the form reasonably requested by AstraZeneca, acknowledging that AstraZeneca has the right of reference to any Horizon Regulatory Documentation as described under Section 2.3.3. Notwithstanding anything to the contrary contained in this Agreement, Horizon shall not be required to disclose any information contained in the Horizon Regulatory Documentation or provide any such access to such information if such disclosure or access would, in Horizon’s reasonable discretion, (x) violate (i) applicable Law or (ii) any binding agreement entered into by Horizon prior to the Effective Date, including any confidentiality agreement to which Horizon is a party (provided, that Horizon shall use commercially reasonable efforts to obtain consent from any Third Party to any such binding agreement to enable Horizon to disclose such information), (y) jeopardize any attorney/client privilege or other established legal privilege or (z) disclose any

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4.3 Pharmacovigilance Obligations.

4.3.1 Safety Data Exchange Agreement. Each Party shall duly and punctually perform all of its obligations under the Safety Data Exchange Agreement.

4.3.2 Safety Database. AstraZeneca shall set up, hold, and maintain (at AstraZeneca’s sole cost and expense) the global safety database for the Product and the Other Products. Each Party shall use commercially reasonable efforts to provide the other Party with information in its possession and control as necessary for each Party to comply with its pharmacovigilance responsibilities under this Agreement or the Safety Data Exchange Agreement, including, as applicable, any Adverse Events, from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical studies, and commercial experiences with the Product or any Other Product in the format specified in the Safety Data Exchange Agreement.

4.3.3 Esomeprazole Safety Data. Notwithstanding anything to the contrary in this Agreement, if Horizon is required by applicable Law to make any statements in an Adverse Event report or serious Adverse Event report pertaining to [...***...], [...***...], and [...***...], the [...***...].

4.3.4 Medical and Other Inquiries. Except to the extent otherwise provided in this Agreement, the Asset Purchase Agreement (including the Transition Plan) or the Supply Agreement, from and after the Effective Date, Horizon (a) shall be responsible for, and shall handle and respond to, all customer complaints and inquiries (including medical and non-medical inquiries) related to the Product or any Other Product used, marketed, distributed or sold in the Horizon Territory, and (b) shall be responsible for, and shall conduct, all correspondence and communication with physicians and other health care professionals in the Horizon Territory relating to the Product or any Other Product.

4.4 Post-Closing Responsibility for Product. [...***...] shall not [...***...] without the prior written consent of [...***...], such consent not to be unreasonably conditioned, withheld or delayed, if [...***...] in the [...***...].

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ARTICLE 5
RECORDS

5.1 **Records.** Horizon shall, and shall cause its Affiliates and its and their respective Sublicensees to, keep complete and accurate financial books and records pertaining to the commercialization of Merck Products in the Horizon Territory, including books and records of Merck Net Sales of Merck Products, in sufficient detail to determine, calculate and verify Merck Net Sales of Merck Products in the Horizon Territory and the net present value of the projected Merck Net Sales of Merck Products in the Horizon Territory, in each case, from the Effective Date until AstraZeneca provides Horizon written notice that Horizon is no longer obligated to maintain such books and records. From and after the date set forth in such written notice, Horizon shall no longer be obligated to maintain financial books and records pertaining to the commercialization of Merck Products pursuant to this Section 5.1 and AstraZeneca (or its designee) shall no longer have the right to audit and examine Horizon’s financial books and records pursuant to Section 5.2. Horizon shall and shall cause its Affiliates and its and their respective Sublicensees to, retain such books and records under this Section 5.1 until the date AstraZeneca provides written notice that Horizon is no longer obligated to maintain such books and record. In the event that AstraZeneca no longer has any record keeping or reporting obligations to any Merck Party with respect to sales of Merck Products in the Horizon Territory, AstraZeneca shall promptly notify Horizon in writing, and Horizon’s obligations under this Section 5.1 shall automatically terminate effective upon the termination of such obligations of AstraZeneca to the Merck Parties.

5.2 **Review of Horizon Financial Records.** At the request of AstraZeneca, Horizon shall, and shall cause its Affiliates and its and their respective Sublicensees to, permit AstraZeneca (or its designee) or an independent auditor designated by AstraZeneca (or its designee), at reasonable times and upon reasonable notice, to audit and examine, and make copies or extracts of and from, the books, records and accounts of Horizon maintained pursuant to Section 5.1 for the purposes set forth in Section 5.1. As between the Parties, the cost of any such review or audit shall be borne by AstraZeneca. In the event that a Merck Party no longer has any right to audit, and AstraZeneca no longer has any obligation to audit, the books, records and accounts of Horizon maintained pursuant to Section 5.1, AstraZeneca shall promptly notify Horizon in writing, and AstraZeneca’s (including its designees and its or their independent auditors’) rights, and Horizon’s obligations, under this Section 5.2 shall automatically terminate, in each case, effective upon the termination of such rights of the Merck Parties or obligations of AstraZeneca to the Merck Parties.

ARTICLE 6
ASTRAZENECA PATENTS

6.1 **Maintenance and Prosecution of AstraZeneca Patents.** AstraZeneca shall have the sole right, but not the obligation, to prepare, file, prosecute and maintain (including with respect to related interference, re-issuance, re-examination, patent term extensions and opposition proceedings) the Merck Patents, the Ex-US Licensed Patents and any other Patent Rights included in the Manufacturing Technology (the “AstraZeneca Patents”), at AstraZeneca’s sole cost and expense. Horizon shall have no right to prepare, file, prosecute or maintain any AstraZeneca Patents. Horizon shall assist and cooperate with AstraZeneca as
AstraZeneca may reasonably request from time to time in connection with its activities set forth in this Section 6.1, at AstraZeneca’s sole cost and expense. Neither AstraZeneca nor any of its Representatives shall be liable to Horizon in respect of any act, omission, default or neglect on the part of any such Representative in connection with obtaining, prosecuting or maintaining an AstraZeneca Patent or otherwise exercising its rights under this Section 6.1. AstraZeneca will keep Horizon promptly informed of progress with regard to the preparation, filing, prosecution and maintenance of AstraZeneca Patents in the Horizon Territory.

6.2 Enforcement of AstraZeneca Patents.

6.2.1 Notice. If any AstraZeneca Patent is allegedly or actually infringed by a Third Party in a manner relating to the Product or any Other Product, the Party first having knowledge of such infringement shall promptly notify the other in writing, which notice shall set forth the facts of that infringement in reasonable detail.

6.2.2 AstraZeneca Patents. Subject to this Section 6.2.2, AstraZeneca shall have the sole right, but not the obligation, through counsel of its choosing, to control the prosecution of any infringement described in Section 6.2.1 relating to the AstraZeneca Patents hereunder, AstraZeneca shall notify Horizon of its intent to commence such prosecution, and if Horizon in good faith believes that the prosecution of any such infringement of the AstraZeneca Patents by AstraZeneca could have a material adverse effect on the AstraZeneca Patents in the Horizon Territory or Horizon’s rights thereunder, Horizon shall promptly notify AstraZeneca after receiving such notice of intent and the Parties shall discuss in good faith the appropriate actions to be taken in response to such infringement; provided, however, that if the Parties are unable to come to a mutually acceptable resolution, then AstraZeneca shall be entitled to undertake such prosecution in its sole discretion, taking Horizon’s concerns into good faith consideration. Horizon shall have no right to prosecute any infringement of any AstraZeneca Patents.

6.2.3 Enforcement Procedure; Costs and Recovery. If AstraZeneca brings an infringement action in accordance with this Section 6.2, Horizon shall cooperate fully with AstraZeneca in connection therewith, including furnishing powers of attorney, being joined as a party plaintiff in such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours, at AstraZeneca’s sole cost and expense. If AstraZeneca pursues such an infringement action, it shall consider in good faith any comments from Horizon and shall keep Horizon reasonably informed of any steps taken to preclude such infringement. Each Party shall bear its own costs and expenses relating to any enforcement action commenced pursuant to this Section 6.2. Any damages or other amounts collected shall be first allocated to reimburse the Parties for their costs and expenses in enforcing

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the AstraZeneca Patents in order to make such recovery, which amounts shall be allocated pro rata based on the relative costs and expenses incurred by the Parties in connection with such enforcement if insufficient to cover the totality of such expenses. Any amount of recovery remaining after such reimbursement is made shall be retained by AstraZeneca.

6.3 Infringement Claims by Third Parties.

6.3.1 Defense of Third Party Claims. If a Third Party asserts that a Patent Rights or other intellectual property right (other than Trademarks or Domain Names, which shall be governed by Sections 7.4 and 8.5, respectively) owned or controlled by it is infringed by the Manufacture or Exploitation of the Product or any Other Product, the Party first obtaining knowledge of such a claim shall immediately provide the other Party notice of such claim along with the related facts in reasonable detail.

6.3.2 Horizon Territory. Horizon shall have the first right, but not the obligation, to control the defense of any claim described in Section 6.3.1 to the extent it relates to the Manufacture or Exploitation of the Product or any Other Product in the Horizon Territory; provided that Horizon shall not be entitled to assert a claim or counterclaim against such Third Party based on the AstraZeneca Patents in connection therewith without AstraZeneca’s prior written consent, in its sole discretion; and, provided, further, that prior to commencing any such claim or counterclaim hereunder, Horizon shall notify AstraZeneca of its intent to commence such claim or counterclaim, and if AstraZeneca in good faith believes that the assertion of any such claim or counterclaim by Horizon could have a material adverse effect on the AstraZeneca Patents in the AstraZeneca Territory or AstraZeneca’s rights thereunder or the Nexium Business, AstraZeneca shall promptly notify Horizon after receipt of such notice of intent and the Parties shall discuss in good faith the appropriate actions to be taken in response to such claim.

6.3.3 AstraZeneca Territory. AstraZeneca shall have the sole right, but not the obligation, to control the defense of any claim described in Section 6.3.1 to the extent it relates to the Manufacture or Exploitation of the Product or any Other Product in the AstraZeneca Territory.

6.3.4 Defense Procedure. The Party that does not control the defense of a claim under this Section 6.3 shall cooperate with the controlling Party, at the controlling Party’s reasonable request and expense, in any such defense and shall have the right, at its own expense, to be represented separately by counsel of its own choice in any such proceeding. If a Party is entitled to and brings a claim or counterclaim in accordance with this Section 6.3, the other Party shall cooperate fully with the claiming Party in connection therewith, including furnishing powers of attorney, being joined as a party plaintiff in such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours. In connection with any such defense or claim or counterclaim, the controlling Party shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken in connection with such defense, claim or counterclaim.

6.3.5 Settlement of Third Party Claims. The Party that controls the defense of a given claim pursuant to Section 6.3.2 or 6.3.3 also shall have the right to control
settlement of such claim; provided, however, that (a) no settlement shall be entered into without the prior written consent of the other Party if such settlement would adversely affect or diminish the rights and benefits of the other Party under this Agreement, or impose any new obligations or adversely affect any obligations of the other Party under this Agreement and (b) in connection with any such settlement, if Horizon is the controlling Party, unless otherwise agreed in writing by AstraZeneca, Horizon shall only be entitled to grant a license or covenant not to sue under or with respect to the AstraZeneca Patents or Licensed Know-How, as applicable, to the extent provided in Section 2.2.

6.3.6 Allocation of Costs. All costs and expenses relating to any defense, settlement and judgments in Litigation commenced pursuant to this Section 6.3 with respect to (a) the Horizon Territory shall be borne by the Party controlling such Litigation in accordance with this Article 6 and (b) in the AstraZeneca Territory shall be borne by AstraZeneca. Any damages or other amounts collected shall be first allocated to reimburse the financially responsible Party (as set forth in the immediately preceding sentence) for its costs and expenses in making such recovery. Any amount of recovery remaining after such reimbursement is made shall be retained by the controlling Party under this Section 6.3.

6.4 Invalidity or Unenforceability Defenses or Actions. If a Third Party asserts, as a defense or as a counterclaim in any infringement action under Section 6.2 or claim or counterclaim asserted under Section 6.3, or in a declaratory judgment action or similar action or claim filed by such Third Party, in any such case, that any AstraZeneca Patent is invalid or unenforceable, then the Party pursuing such infringement action, or the Party first obtaining knowledge of such declaratory judgment action, as the case may be, shall promptly give written notice to the other Party. AstraZeneca shall have the sole right, but not the obligation, through counsel of its choosing, to defend against such action or claim. If AstraZeneca defends such action or claim, all costs and expenses of defending such action or claim shall be borne by AstraZeneca. Horizon shall assist and cooperate with AstraZeneca as AstraZeneca may reasonably request from time to time in connection with its activities set forth in this Section 6.4, including by providing access to relevant documents and other evidence and making its employees available at reasonable business hours, at AstraZeneca’s sole cost and expense. In connection with any such defense or claim or counterclaim, AstraZeneca shall consider in good faith any comments from Horizon and shall keep Horizon reasonably informed of any steps taken, and shall provide copies of all documents filed, in connection with such defense, claim or counterclaim.

6.5 Statements or Actions Pertaining to Esomeprazole or Nexium. Notwithstanding anything to the contrary in this Article 6, [...***...] of [...***...] or [...***...] of its [...***...] or [...***...] of the [...***...].

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ARTICLE 7
LICENSED TRADEMARKS

7.1 Use of Licensed Trademarks.

7.1.1 Horizon hereby acknowledges AstraZeneca’s exclusive right, title and interest in and to the Licensed Trademarks, together with all goodwill associated therewith and all registrations and registration applications therefor, on a worldwide basis and acknowledges that nothing herein shall be construed to accord to Horizon or its Affiliates any rights in the Licensed Trademarks except for the license rights expressly conferred by this Agreement. Horizon shall not, and shall cause its Affiliates, Sublicensees and distributors not to, use in their respective businesses, any Trademark that is confusingly similar to or a colorable imitation of, misleading or deceptive with respect to or that dilutes any (or any part) of the Licensed Trademarks.

7.1.2 Horizon shall, and shall cause its Affiliates, Sublicensees and distributors to, (a) comply with all trademark usage guidelines, quality standards, business practices, methodology, policies and procedures and technical and operational specifications as may be reasonably specified by AstraZeneca from time to time or as may be imposed by applicable Law with respect to the manner of use of the Licensed Trademarks[...***...], (b) promptly make any changes to any Product Label, packaging with respect to any Product or any Other Product, Product (or any Other Product) inserts and advertising, marketing, promotional or other materials bearing any of the Licensed Trademarks as AstraZeneca may reasonably request to achieve compliance with clause (a), and (c) refrain from taking any action that endangers, destroys or similarly affects, in any material respect, the Licensed Trademarks or the value of the goodwill associated with the Licensed Trademarks.

7.1.3 Horizon shall not, and shall cause its Affiliates, Sublicensees and distributors not to, (a) directly or indirectly, at any time challenge AstraZeneca’s rights, title or interest in and to the Licensed Trademarks or in any registration or registration application therefor in any jurisdiction, (b) do or cause to be done or fail to do anything, the doing, causing or failure of which would contest or impair or in any way tend to impair the rights of AstraZeneca in and to the Licensed Trademarks or in any registrations or registration applications therefor in any jurisdiction, (c) represent to any Third Party that it has, in any jurisdiction, any ownership rights in or to the Licensed Trademarks or in any registration or registration application therefor or any other rights in the Licensed Trademarks other than the specific license rights conferred by this Agreement, or (d) register or attempt to register the Licensed Trademarks or any confusingly similar Trademark (including any translation or transliteration of any of the Licensed Trademarks or any colorable imitation thereof) as a Trademark with any Governmental Authority in its own name or in the name of any of its Affiliate or any Third Party in any jurisdiction.

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7.1.4 Horizon acknowledges and agrees that no ownership rights are vested or created in the Licensed Trademarks anywhere in the world by the licenses and other rights granted in this Agreement (including, for clarity, under Section 2.1 of this Agreement) and that all goodwill generated in connection with the use of the Licensed Trademarks by Horizon, its Affiliates, Sublicensees, and distributors shall inure solely for and to the benefit of AstraZeneca.

7.2 Approval Procedures.

7.2.1 During the Term, if Horizon desires to use any variation or derivative of an existing Licensed Trademark on, or in connection with the Exploitation of, the Product or any Other Product in the Horizon Territory, Horizon shall submit such variation or derivation to AstraZeneca for its approval, which approval may be granted or withheld in AstraZeneca’s sole discretion. If AstraZeneca approves such variation or derivation, then upon such approval by AstraZeneca, such variation or derivation shall be deemed a Licensed Trademark and subject to the terms hereof. AstraZeneca shall respond to each such submission within [...] after AstraZeneca’s receipt of each such request for approval. With respect to any variation or derivation of any existing Licensed Trademark that Horizon submits to AstraZeneca, Horizon shall be responsible for conducting a commercially reasonable trademark clearance search and assessing the availability of any such variation or derivation for use on, and registration for, the Product or any Other Product in the Horizon Territory and shall submit the results of such search and assessment to AstraZeneca when it submits such variation or derivation to AstraZeneca for its approval.

7.2.2 At AstraZeneca’s reasonable request with respect to timing of delivery, Horizon shall, and shall cause its Affiliates, Sublicensees and distributors to, furnish to AstraZeneca representative samples of all goods and all Product Labeling, Product packaging, Product inserts and advertising, marketing, promotional or other materials bearing any of the Licensed Trademarks for registration, renewal and quality control purposes, including web pages, brochures and stationery.

7.3 Clearance, Registration, Prosecution and Maintenance of Licensed Trademarks.

7.3.1 AstraZeneca shall be responsible for the registration, prosecution and maintenance of the Licensed Trademarks in the Horizon Territory. All registrations and applications therefor shall be filed, prosecuted, registered and maintained in the name, and for the benefit, of AstraZeneca. All costs and expenses of clearing, registering, prosecuting and maintaining the Licensed Trademarks in the Horizon Territory shall be borne solely by AstraZeneca. AstraZeneca shall (a) provide Horizon from time to time [...] a written report summarizing the current status of all applications and registrations for the Licensed Trademarks in the Horizon Territory; (b) notify Horizon promptly of, and consult with Horizon with respect to, any material, substantive issue or any opposition, cancellation, invalidity or other proceeding that may be raised or asserted against any application or registration for any Licensed Trademark within the Horizon Territory prior to taking any action in response thereto; and (c) consult with Horizon at least [...] prior to (i) taking any action to abandon or withdraw any application for any Licensed Trademark, or (ii) *** Confidential Treatment Requested

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permitting any registration for any Licensed Trademark to lapse, expire or be cancelled.

7.3.2 If AstraZeneca plans to cease, or ceases, the registration, prosecution and maintenance of a Licensed Trademark in the Horizon Territory, AstraZeneca shall notify Horizon in writing at least [...***...] in advance of the due date of any action that is required with respect thereto and, in such event, Horizon may elect (but shall not be obligated), on written notice to AstraZeneca, at its sole cost and expense, to assume responsibility for and control over such registration, prosecution and maintenance in the name of Horizon. All registrations and applications therefor shall be filed, prosecuted, registered and maintained in the name, and for the benefit, of Horizon. AstraZeneca shall execute such powers of attorney or other instruments and shall take such other actions as Horizon may reasonably request to permit Horizon to file and prosecute any registration application and to maintain, renew, enforce and defend any registration for any such Licensed Trademarks in the Horizon Territory.

7.4 Enforcement and Defense of Licensed Trademarks. Horizon shall have the first right, but not the obligation, to enforce and defend the Licensed Trademarks in the Horizon Territory, including (a) after consultation with AstraZeneca, defending against any alleged, threatened or actual claim by a Third Party that the use of the Licensed Trademarks in the Horizon Territory infringes, dilutes, misappropriates or otherwise violates any Trademark or copyright of that Third Party or constitutes unfair trade practices or any other like offense, or any other claims as may be brought by a Third Party against a Party in connection with the use of or relating to the Licensed Trademarks with respect to the Product or any Other Product in the Horizon Territory and (b) taking such action as Horizon, after consultation with AstraZeneca, deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of, or unfair trade practices or any other like offense relating to, the Licensed Trademarks by a Third Party in the Horizon Territory; provided that if Horizon plans to cease, or ceases, any action with respect to the enforcement or defense of any of the Licensed Trademarks in the Horizon Territory, Horizon shall notify AstraZeneca in writing at least [...***...] in advance of the due date of any action that is required with respect thereto and, in such event, AstraZeneca may elect (but shall not be obligated), on written notice to Horizon, to assume responsibility for and control over such enforcement or defense or to take any such action in its own name or in the name of Horizon. Notwithstanding the foregoing, as long as Horizon is Exploiting the Product or any Other Product under the Licensed Trademarks, if Horizon reasonably determines that initiating a suit or taking other action to enforce or defend any of the Licensed Trademarks in the Horizon Territory pursuant to this Section 7.4 is not in the best interests of the Licensed Trademarks in the Horizon Territory and Horizon so notifies AstraZeneca in writing (which notice shall include a reasonably detailed description of Horizon’s reasons for not initiating suit or taking other action to enforce or defend any of the Licensed Trademarks in the Horizon Territory pursuant to this Section 7.4), then AstraZeneca may not enforce or defend any such Licensed Trademarks pursuant to this Section 7.4. Each enforcing or defending Party shall bear its own costs and expenses relating to any enforcement action or defense commenced pursuant to this Section 7.4 and any settlements and judgments with respect thereto. Any damages or other amounts recovered in any such proceeding shall be retained by the Party controlling such proceeding. Each Party shall provide to the other Party all reasonable assistance requested by the other Party in connection with any such action, defense, claim or suit under this Section 7.4, at such other Party’s cost and expense. Horizon shall obtain

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AstraZeneca’s written consent before entering into any compromise, settlement or stipulation with respect to any such action, defense, claim or suit (such consent not to be unreasonably withheld or delayed). In no event shall Horizon take any position or submit any argument with respect to such action, defense, claim or suit that would be reasonably expected to materially endanger, lessen, impair or undermine the Licensed Trademarks or AstraZeneca’s rights therein or AstraZeneca’s corresponding Trademark rights outside the Horizon Territory. Each Party, at the other Party’s cost and expense, shall execute such powers of attorney or other instruments and shall take such other actions as the other Party may reasonably request as necessary to permit the other Party to assume responsibility for and control over the enforcement or defense of the Licensed Trademarks as permitted hereunder.

7.5 No Implied Rights. Except as expressly provided in this Article 7, Horizon shall have no right to register, maintain, prosecute, enforce or defend the Licensed Trademarks.

7.6 Other Trademarks. Horizon shall have the right to Exploit the Product and any Other Product in the Horizon Territory under a Trademark that is not a Licensed Trademark; provided, that such other Trademark is not confusingly similar to any Licensed Trademark (including any translation or transliteration of any Licensed Trademark or any colorable imitation of any Licensed Trademark).

ARTICLE 8
LICENSED DOMAIN NAMES

8.1 Ownership and Goodwill. Horizon acknowledges that it acquires no right, title or interest in the Licensed Domain Names other than the rights expressly set forth in this Agreement. Horizon shall not at any time do or suffer to be done any act that would materially impair AstraZeneca’s proprietary rights in or to the Licensed Domain Names, and Horizon agrees not to directly or indirectly contest or aid in contesting the ownership of the Licensed Domain Names, or to take any action whatsoever in derogation of AstraZeneca’s claimed rights therein. Horizon agrees and acknowledges that any and all rights and goodwill arising from use of the Licensed Domain Names by Horizon or its Affiliates or permitted sublicensees shall inure exclusively to the benefit of AstraZeneca.

8.2 Registration and Maintenance. AstraZeneca shall (a) at its own expense, maintain the Primary Licensed Domain Name and (b) if requested in writing by Horizon and at Horizon’s expense, maintain the Secondary Licensed Domain Names. Neither Party shall intentionally take, or fail to take, any action that may reasonably be expected to jeopardize the use, value, validity, or enforceability of any Licensed Domain Name; provided, that unless Horizon requests in writing that AstraZeneca maintain a Secondary Licensed Domain Name at Horizon’s expense, AstraZeneca may allow the registration for such Secondary Licensed Domain Name to lapse.

8.3 Control of Licensed Domain Name Websites. AstraZeneca hereby grants Horizon the sole right to administer, manage and control the content of any website associated with, and use, the Licensed Domain Names (the “Product Websites”) under the terms of this Agreement. At Horizon’s request, AstraZeneca shall use the technical contact and
server information provided by Horizon for the Licensed Domain Names. Horizon may ask from time to time that such information be further revised or updated, and AstraZeneca shall, within a reasonable amount of time, contact the domain name registrar and revise the information accordingly. AstraZeneca shall not change the technical contact or server information for the Licensed Domain Names or take any action to direct Internet traffic to any of the Licensed Domain Names to any servers or IP addresses other than those identified by Horizon. AstraZeneca may, from time to time, change the registrar with whom AstraZeneca has contracted to manage its domain name portfolio. Horizon shall assist and cooperate with AstraZeneca, the old registrar or the new registrar in any way necessary to effectuate such a change of registrar. Horizon shall be responsible for the content of the Product Websites and shall ensure that all Product Websites comply with all applicable Law.

8.4 Country-Specific Traffic.

8.4.1 Horizon shall use commercially reasonable efforts to cause traffic to the Licensed Domain Names that originates within a country outside the Horizon Territory, to be re-directed to such ccTLD as AstraZeneca may designate in writing.

8.4.2 AstraZeneca shall use commercially reasonable efforts to cause traffic to vimovoglobal.com, or any other Domain Name used by or on behalf of AstraZeneca or its Affiliates in connection with Exploitation of the Products in more than one country of the AstraZeneca Territory, that originates within a country outside the AstraZeneca Territory, to be re-directed to such ccTLD as Horizon may designate in writing.

8.4.3 Among other techniques that the Parties may mutually agree for re-directing traffic is the placement of a hyperlink on the homepage of the generic "*.com" top-level Licensed Domain Names or other domain names noted in Section 8.4.2, as applicable, which hyperlink shall be placed in a manner, form and style mutually agreeable to the Parties.

8.5 Enforcement. If Horizon becomes aware of any use, trafficking, or registration of a Licensed Domain Name other than by or on behalf of Horizon or its Affiliates or Sublicensees pursuant to this Agreement or of any use, trafficking, or registration a confusingly similar domain name, Horizon shall promptly notify AstraZeneca of such use or traffic or registration. AstraZeneca may take any action and institute legal, administrative or other proceedings relating to the use, trafficking, or registration of such Licensed Domain Names as AstraZeneca, in its sole discretion, deems fit. Horizon shall execute any and all documents and to do such acts as may be reasonably necessary to carry out such proceeding or Litigation, including becoming a nominal party to any legal action. If AstraZeneca fails to take any action within [...***...] days after notification of such use, trafficking or registration, or notifies Horizon that it will not take any action, then Horizon may take any action and institute legal, administrative or other proceedings relating to such use, trafficking or registration as Horizon, in its sole discretion, deems appropriate. AstraZeneca agrees to execute any and all documents and to do such acts as may be reasonably necessary to carry out such proceeding or Litigation, including becoming a nominal party to any legal action. Each Party shall bear its own costs and expenses relating to any enforcement action commenced pursuant to this Section 8.5 and any settlements and judgments with respect thereto.

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ARTICLE 9
CONFIDENTIALITY AND NON-DISCLOSURE

9.1 General.

9.1.1 All Ancillary Confidential Information provided by one Party (or its Recipients or Affiliates) (collectively, the “Ancillary Disclosing Party”) to the other Party (or its Recipients or Affiliates) (collectively, the “Ancillary Receiving Party”) shall be subject to and treated in accordance with the terms of this Section 9.1. As used in this Section 9.1, “Ancillary Confidential Information” means (a) all information disclosed to the Ancillary Receiving Party by the Ancillary Disclosing Party in connection with any Ancillary Agreement, including all information with respect to the Ancillary Disclosing Party’s licensors, licensees or Affiliates and (b) all memoranda, notes, analyses, compilations, studies and other materials prepared by or for the Ancillary Receiving Party to the extent containing or reflecting the information in the preceding clause (a). Notwithstanding the foregoing, Ancillary Confidential Information shall not include information that, in each case as demonstrated by competent written documentation:

(a) was already known to the Ancillary Receiving Party or its Affiliates, other than under an obligation of confidentiality, at the time of disclosure by the Ancillary Disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Ancillary Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure to the Ancillary Receiving Party other than through any act or omission of the Ancillary Receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the Ancillary Receiving Party by a Third Party without obligations of confidentiality with respect thereto; or

(e) is subsequently independently discovered or developed by the Ancillary Receiving Party without the aid, application or use of Confidential Information or Ancillary Confidential Information.

9.1.2 All Ancillary Confidential Information obtained by AstraZeneca (or its Affiliates or Recipients) from Horizon (or its Affiliates or Recipients) and all Ancillary Confidential Information relating solely to the Product Business (other than Ancillary Confidential Information relating to (x) the Licensed Intellectual Property, the Ex-US Licensed Patents or the Licensed Regulatory Documentation, (y) the Pozen Original Agreement or the Pozen ROW Agreement or (z) the Merck Parties or the Merck Patents), the Purchased Assets and the Assumed Liabilities (the “Ancillary Horizon Confidential Information”) shall be deemed to be Ancillary Confidential Information disclosed by Horizon to AstraZeneca for purposes of this Section 9.1 and shall be used by AstraZeneca solely as required for any AstraZeneca Permitted Purpose, and for no other purpose. During the Term and for a period of five years thereafter, AstraZeneca shall not disclose, or permit the disclosure of, any of the Ancillary
Horizon Confidential Information to any Person except those Persons to whom such disclosure is necessary in connection with any AstraZeneca Permitted Purpose. AstraZeneca shall treat, and will cause its Affiliates and the Recipients of AstraZeneca or any of its Affiliates to treat, the Ancillary Horizon Confidential Information as confidential, using the same degree of care as AstraZeneca normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care.

9.1.3 All Ancillary Confidential Information obtained by Horizon (or its Affiliates or Recipients) from AstraZeneca (or its Affiliates or Recipients) other than the Ancillary Horizon Confidential Information (the "Ancillary AstraZeneca Confidential Information") shall be used by Horizon solely as required for any Horizon Permitted Purpose, and for no other purpose. During the Term and for a period of five years thereafter, Horizon shall not disclose, or permit the disclosure of, any of the Ancillary AstraZeneca Confidential Information to any Person except (x) those Persons to whom such disclosure is necessary in connection with a Horizon Permitted Purpose or (y) in connection with any due diligence or disclosure obligations under any financing arrangement or equity offering pursuant to obligations of confidentiality and non-use no less stringent than those set forth in this Section 9.1. Horizon shall treat, and will cause its Affiliates and the Recipients of Horizon or any of its Affiliates to treat, Ancillary AstraZeneca Confidential Information as confidential, using the same degree of care as Horizon normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care.

9.1.4 In the event either Party is requested pursuant to, or required by, applicable Law to disclose any of the other Party’s Ancillary Confidential Information (i.e., Ancillary AstraZeneca Confidential Information or Ancillary Horizon Confidential Information, as applicable), it will notify the other Party in a timely manner so that such Party may seek a protective order or other appropriate remedy or, in such Party’s sole discretion, waive compliance with the confidentiality provisions of this Agreement. Each Party will cooperate in all reasonable respects in connection with any reasonable actions to be taken for the foregoing purpose. In any event, the Party requested or required to disclose such Ancillary Confidential Information may furnish it as requested or required pursuant to applicable Law (subject to any such protective order or other appropriate remedy) without liability hereunder, provided that such Party furnishes only that portion of the Ancillary Confidential Information which such Party is advised by an opinion of its counsel is legally required and such Party exercises reasonable efforts to obtain reliable assurances that confidential treatment will be accorded such Ancillary Confidential Information.

9.1.5 Nothing in this Section 9.1 shall be construed as preventing or in any way inhibiting either Party from complying with applicable Law governing activities and obligations undertaken pursuant to this Agreement, the Asset Purchase Agreement or any other Ancillary Agreement in any manner which it reasonably deems appropriate.

9.2 Other Nexium Communications. Except as expressly provided in Sections 4.1.2, 4.3.4 and 9.3 hereof, the Asset Purchase Agreement or any Ancillary Agreement, without [...***...] prior written consent, [...***...] shall not make, and shall prohibit its Affiliates, Sublicensees, Third Party contractors, and agents from [...***...] or [...***...]

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9.3 Certain Permitted Esomeprazole and Nexium Disclosures. Within 30 days after the Effective Date, the Parties shall mutually agree in good faith on a written document specifying [...***...], and the [...***...] to be [...***...] that is not [...***...].

9.4 Press Releases. [...***...] to the [...***...].

ARTICLE 10
DISCLAIMER OF WARRANTIES

EACH PARTY ACKNOWLEDGES AND AGREES THAT, EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES CONTAINED IN THE ASSET PURCHASE AGREEMENT OR THE SUPPLY AGREEMENT, THE OTHER PARTY HAS MADE NO REPRESENTATION OR WARRANTY WHATSOEVER AND SUCH PARTY HAS NOT RELIED ON ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, INCLUDING ANY WARRANTY OF QUALITY, FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, CONDITION OF THE ASSETS, AS TO THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF ANY PERSON OR AS TO ANY OTHER MATTER IN CONNECTION WITH THE TRANSACTIONS CONTEMPLATED HEREBY.

ARTICLE 11
INDEMNITY

11.1 Indemnification of AstraZeneca. Subject to this Article 11, Horizon shall indemnify, defend and hold harmless AstraZeneca and its Affiliates, and their respective officers, directors, employees and agents (collectively, “AstraZeneca Indemnitees”) from and against any and all Losses incurred by them in connection with any and all Litigation by Third Parties (collectively, “Third Party Claims”) arising from or occurring as a result of: (a) any breach by Horizon of any term of this Agreement; (b) the fraud, gross negligence or willful misconduct on the part of any Horizon Indemnitees in the performance of Horizon’s obligations under this Agreement or (c) the Manufacture or Exploitation of the Product or any Other Product by or on behalf of Horizon, its Affiliates and Sublicensees (but excluding the Manufacture or Exploitation of Product or any Other Product by or on behalf of AstraZeneca or its Affiliates pursuant to the Supply Agreement, the Transition Plan (as defined in the Asset Purchase Agreement) or pursuant to any sublicense granted by Horizon to AstraZeneca under the this Agreement or any Ancillary Agreement), except, in each case ((a), (b) and (c)), to the extent of

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11.2 Indemnification of Horizon. Subject to this Article 11, AstraZeneca shall indemnify, defend and hold harmless Horizon and its Affiliates, and their respective officers, directors, employees and agents (collectively, “Horizon Indemnitees”) from and against any and all Losses incurred by them in connection with any and all Third Party Claims arising from or occurring as a result of: (a) any breach by AstraZeneca of any term of this Agreement; (b) the fraud, gross negligence or willful misconduct on the part of any AstraZeneca Indemnitees in the performance of AstraZeneca’s obligations under this Agreement; (c) the Manufacture or Exploitation of the Product or any Other Product by or on behalf of AstraZeneca, its Affiliates and sublicensees (but excluding the Manufacture of Product under the Supply Agreement), except, in each case ((a), (b) and (c)), to the extent of those Losses for which Horizon has an obligation to indemnify any AstraZeneca Indemnitees pursuant to Section 11.1 or pursuant to the Supply Agreement, as to which Losses each Party shall indemnify the other Party and the AstraZeneca Indemnitees or the Horizon Indemnitees, as applicable, to the extent of its liability for such Losses.

11.3 Indemnification Procedures. All indemnification claims in respect of Horizon or any Horizon Indemnitees shall be made solely by Horizon and all indemnification claims in respect of AstraZeneca or any AstraZeneca Indemnitee shall be made solely by AstraZeneca and, in each case, shall be governed by Section 7.2.2 of the Asset Purchase Agreement. Notwithstanding anything herein to the contrary, the Parties’ respective indemnification obligations under this Article 11 shall not apply to any Losses for which such Party is entitled to indemnification under the Asset Purchase Agreement (excluding for this purpose, application of the limitations in Section 7.3 of the Asset Purchase Agreement).

11.4 Limitation on Damages and Liability. [...***...]

11.5 Insurance. As of the Effective Date, Horizon shall have and maintain adequate insurance coverage, which policies shall be in effect during the Term and shall include products liability coverage and comprehensive general liability insurance of not less than [...***...]; provided that if any such policy is held on a claims-made basis, such policy shall be maintained throughout the Term and for a period of [...***... thereafter. All insurers

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providing such policies shall have an AM Best (A-) or higher rating. Horizon shall provide AstraZeneca with certificates of insurance evidencing that the policies required to be maintained by Horizon hereunder are in full force and effect annually and, upon AstraZeneca’s request, copies of such policies shall be provided. Should any of the policies be cancelled, terminated or otherwise materially altered before the expiration date thereof, notice will be delivered in accordance with the policy provisions in writing to AstraZeneca.

ARTICLE 12
TERM AND TERMINATION

12.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until terminated in accordance with this Article 12 (such period, the “Term”).

12.2 Termination for Material Breach. In the event that either Party (the “Breaching Party”) breaches any of its material obligations under Section 2.6, Section 3.3, Section 3.4, Article 7 or Article 8, the other Party may terminate the Terminable Rights and Provisions upon [...] days’ prior written notice (such [...] day, the “Notice Period”) to the Breaching Party, specifying the breach and its claim of right to terminate; provided, that the termination of the Terminable Rights and Provisions shall not become effective at the end of the Notice Period if (a) the Breaching Party cures such breach during the Notice Period or (b) such breach cannot be cured during the Notice Period and the Breaching Party commences and diligently pursues actions to cure such breach within the Notice Period, in which case the Breaching Party shall have an additional [...] day period to cure such breach before such termination becomes effective.

12.3 Mutual Agreement. This Agreement or the Terminable Rights and Provisions may be terminated upon the mutual written agreement of Horizon and AstraZeneca at any time.

12.4 Consequences of Termination.

12.4.1 Termination of Terminable Rights and Provisions. Upon any termination of the Terminable Rights and Provisions pursuant to Section 12.2 or Section 12.3, (a) the licenses granted by AstraZeneca to Horizon under Section 2.1 solely with respect to the Licensed Trademarks and Licensed Domain Names, any sublicenses related thereto entered into by Horizon pursuant to Section 2.2 and Articles 7 and 8, in each case, at AstraZeneca’s option, shall terminate in their entirety and (b) the licenses granted by AstraZeneca to Horizon under Section 2.1 with respect to the US Licensed Patents, Ex-US Licensed Patents, Licensed Know-How, Licensed Regulatory Documentation and the Manufacturing Technology, the licenses granted by Horizon to AstraZeneca under Section 2.3 and all other provisions of this Agreement (other than those provisions referenced in the preceding clause (a)) shall remain in full force and effect.

12.4.2 Termination of Agreement. Upon the termination of this Agreement pursuant to Section 12.3, all of the licenses granted by the Parties under Article 2, and any sublicenses related thereto entered into by either Party as permitted hereunder, and all

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other rights and obligations of this Agreement (subject to those rights and obligations that survive as set forth in Section 12.4.5 of this Agreement), shall terminate in their entirety.

12.4.3 Discontinued Use of Trademarks. Upon any termination described in Section 12.4.1 or Section 12.4.2, Horizon shall, and shall cause its Affiliates, Sublicensees and distributors to discontinue all use of the Licensed Trademarks (including in connection with all Product Labels, packaging with respect to the Product or any Other Product, Product (or any Other Product) inserts and advertising, marketing, promotional or other materials bearing any of the Licensed Trademarks) and Licensed Domain Names promptly, but in any event, within 90 days after any such termination.

12.4.4 Accrued Rights. The termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination. Such termination shall not relieve a Party from obligations that are expressly indicated to survive the termination of this Agreement.

12.4.5 Survival. Without limiting the foregoing, Sections 2.4, 2.5, 5.1 (to the extent required under the Merck Agreements), 5.2 (to the extent required under the Merck Agreements), this Section 12.4 and ARTICLE 9, ARTICLE 10, ARTICLE 11 (provided that Section 11.5 survives only for as long as provided in Section 11.5), and ARTICLE 13 shall survive the termination of this Agreement for any reason.

ARTICLE 13
MISCELLANEOUS

13.1 Governing Law, Jurisdiction, Venue and Service.

13.1.1 Governing Law. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, excluding any conflicts or choice of Law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive Law of another jurisdiction.

13.1.2 Jurisdiction. Subject to Section 13.2 and 13.12, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial.

13.1.3 Venue. Subject to Section 13.2 and 13.12, the Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or in the United States District Court for the Southern District of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.
13.1.4 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 13.3.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

13.2 Dispute Resolution.

13.2.1 Except as provided in Section 13.12, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a “Dispute”), then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of 10 Business Days. Any final decision mutually agreed to by the Senior Officers in writing shall be conclusive and binding on the Parties.

13.2.2 If such Senior Officers are unable to resolve any such Dispute within such 10-Business Day period, either Party shall be free to institute binding arbitration in accordance with this Section 13.2.2 upon written notice to the other Party (an “Arbitration Notice”) and seek such remedies as may be available. Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three experts with relevant industry experience (the “Arbitrators”). Each of Horizon and AstraZeneca shall promptly select one Arbitrator, which selections shall in no event be made later than 30 days after the notice of initiation of arbitration. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Horizon and the Arbitrator chosen by AstraZeneca, but in no event later than 30 days after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery, provided that the Arbitrators shall permit such discovery as they deem necessary to permit an equitable resolution of the Dispute. The arbitration shall be administered by the American Arbitration Association (“AAA”) (or its successor entity) in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Agreement. The arbitration shall be held in New York, New York, USA, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The Arbitrators shall, within 15 days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with applicable Law in the State of New York or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.

13.2.3 Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Section 13.2, and shall pay an equal share of the fees and costs of the Arbitrators and all other general fees related to any arbitration described in Section 13.2.3; provided, however, the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that
prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges, or travel expenses) or the fees and costs of the Arbitrators. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Section 13.2.3 is pending under this Agreement, the Parties shall continue to comply with all terms and provisions of this Agreement. All arbitration proceedings and decisions of the Arbitrator under this 13.2 shall be deemed Confidential Information of both Parties under Section 5 of the Asset Purchase Agreement. For clarity, nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding.

13.3 Notices.

13.3.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement (each, a “Notice”) shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 13.3.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party at least 10 days’ prior to such address taking effect in accordance with this Section 13.3. Such Notice shall be deemed to have been given as of the date delivered by hand or internationally recognized overnight delivery service or confirmed that it was received by facsimile (with receipt confirmed by telephone or email). Any Notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter.

13.3.2 Address for Notice.

If to AstraZeneca, to:

AstraZeneca AB
Pepparredsleden 1
S-431 83 Mölndal
Attention: President
Facsimile: +46 31 7763871

with a copy (which shall not constitute notice) to:

AstraZeneca AB
Pepparredsleden 1
S-431 83 Mölndal
Attention: Senior Counsel and Lead, Legal Dept.
Facsimile: +46 31 7763871
13.4 **No Benefit to Third Parties.** The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and, except for the rights of Horizon Indemnitees and AstraZeneca Indemnitees under Article 11, they shall not be construed as conferring any rights on any other Persons.

13.5 **Waiver and Non-Exclusion of Remedies.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by any Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable Law or otherwise available except as expressly set forth herein.

13.6 **Expenses.** Except as otherwise specified herein or in the Asset Purchase Agreement or in any other Ancillary Agreement, each Party shall bear any costs and expenses incurred by it with respect to the transactions contemplated herein.
13.7 Assignment. Except as expressly set forth in this Agreement, neither Party shall have the right or the power to assign, in whole or in part, any of its rights, or delegate the performance of any of its obligations, under this Agreement without the prior written authorization of the other Party, which authorization shall not be unreasonably withheld, conditioned or delayed, and any assignment or delegation of this Agreement or any of such rights or obligations without such authorization shall be void and of no effect; provided, however, that either Party may assign the Agreement, in whole or in part, to an Affiliate without the prior written authorization of the other Party; and provided, further, that either Party shall have the right to assign this Agreement, in whole or in part, in connection with a merger or other acquisition of the capital stock or all or substantially all of the assets of such assigning Party, without the prior written authorization of the other Party, subject to providing the other Party with written notice thereof within 30 days after such assignment or delegation. Any permitted assignment or delegation hereunder by a Party shall not relieve such Party of any of its obligations under this Agreement (whether by operation of law or otherwise), unless, with respect an assignment to a Third Party, such assignee agrees in writing to assume such Party’s obligations under this Agreement, in which case such Party shall be relieved of its obligations hereunder from and after the effective date of such assignment and assumption. Subject to the foregoing, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns.

13.8 Use of Affiliates, Third Party Subcontractors. Either Party shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates, or to subcontract any of its rights or obligations under this Agreement to any Third Party, without authorization of the other Party. For clarity this shall not limit the provisions of Section 2.2 with respect to Sublicensees.

13.9 Amendment. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by both Parties.

13.10 Independent Contractors. In the exercise of their respective rights, and the performance of their respective obligations, under this Agreement, the Parties are, and shall remain, independent contractors. Nothing in this Agreement shall be construed to constitute the Parties as partners, joint venturers, or participants in a joint enterprise or undertaking, or to constitute either of the Parties as the agent of the other Party for any purpose whatsoever. Neither Party shall bind, or attempt to bind, the other Party hereto to any contract or the performance of any other obligation, or represent to any Third Party that it is authorized to enter into any contract or binding obligation on behalf of the other Party hereto.

13.11 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this
Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

13.12 **Equitable Relief.** The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in any court of the United States or any state having jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity. Each Party hereby waives (a) any requirement that the other Party post a bond or other security as a condition for obtaining any such relief, and (b) any defenses in any action for specific performance, including the defense that a remedy at law would be adequate.

13.13 **English Language.** This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

13.14 **Counterparts.** This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

13.15 **Entire Agreement.** This Agreement, together with the Schedules and Exhibits expressly contemplated hereby and attached hereto, the Asset Purchase Agreement and the other Ancillary Agreements, contain the entire agreement between the Parties with respect to the transactions contemplated hereby and supersedes all prior agreements, understandings, promises and representations, whether written or oral, between the Parties with respect to the subject matter hereof. In the event of any inconsistency between any such Schedules and Exhibits and this Agreement, the terms of this Agreement shall govern.

13.16 **Construction.** Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including” as used herein does not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party. Unless otherwise specified or where the context otherwise requires, (a) references in this Agreement to any Article, Section, Schedule or Exhibit are references to such Article, Section, Schedule or Exhibit of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; (c) “hereof,” “hereto,” “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (d) references to a Person are also to its permitted
successors and assigns; (e) references to a Law include any amendment or modification to such Law and any rules or regulations issued thereunder, in each case, as in effect at the relevant time of reference thereto; (f) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto; and (g) references to monetary amounts are denominated in United States Dollars.

[Signature page follows]

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

ASTRAZENECA AB

By: /s/ Jan-Olof Jacke
Name: Jan-Olof Jacke
Title: President

HORIZON PHARMA USA, INC.

By: /s/ Timothy P. Walbert
Name: Timothy P. Walbert
Title: President and Chief Executive Officer

[SIGNATURE PAGE TO LICENSE AGREEMENT]
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<th>App No / Reg No</th>
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<td>(Class 5) pharmaceutical preparations and substances for the treatment of pain and inflammation</td>
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<td>App 77670350  / Reg 3941225</td>
<td>(Class 5) pharmaceutical preparations and substances for the treatment of pain and inflammation</td>
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SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT ("Agreement") is made and entered into effective as of November 22, 2013 (the "Effective Date"), by and between ASTRazeneca LP, a Delaware limited partnership ("AstraZeneca"), having offices at 1800 Concord Pike, Wilmington, Delaware 19803, and Horizon Pharma USA, Inc., a Delaware corporation ("Horizon"), having an office at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015. AstraZeneca and Horizon each may be referred to herein individually as a "Party," or collectively as the "Parties."

RECITALS

A. AstraZeneca controls certain patents and other intellectual property pertaining to pharmaceutical products having gastroprotective agents in single fixed combination oral solid dosage form with non-steroidal anti-inflammatory drugs.

B. Horizon and AstraZeneca AB, an Affiliate of AstraZeneca, are parties to that certain (i) Asset Purchase Agreement dated as of November 18, 2013 (as may be amended, the "Asset Purchase Agreement") under which, among other things, effective as of the Closing (as defined in the Asset Purchase Agreement), Horizon is purchasing from AstraZeneca AB certain assets relating to Products (as defined in the Asset Purchase Agreement) in the Field (as defined in the Asset Purchase Agreement) in the Horizon Territory (as defined in the Asset Purchase Agreement) and (ii) License Agreement of even date herewith (as may be amended, the "License Agreement"), under which, among other things, effective as of the Closing (as defined in the Asset Purchase Agreement), Horizon is obtaining an exclusive license to certain of AstraZeneca AB’s intellectual property for the purpose of manufacturing, developing and commercializing Products in the Field in the Horizon Territory.

C. AstraZeneca desires to supply to Horizon, and Horizon desires to obtain from AstraZeneca, on a transitional basis the Supplied Products (as defined herein) on the terms and conditions set forth herein.

In consideration of the foregoing premises, the mutual promises and covenants set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, AstraZeneca and Horizon hereby agree as follows:

AGREEMENT

1. Definitions

When used in this Agreement, capitalized terms have the meanings as defined below and throughout this Agreement and capitalized terms used but not otherwise defined herein have the respective meanings ascribed thereto in the Asset Purchase Agreement.

1.1 "AAA" has the meaning assigned to it in Section 14.3.2.

1.2 "Agreement" has the meaning assigned to it in the preamble hereto.
1.3 “API” means micronized Esomeprazole magnesium trihydrate and Naproxen as further described in the applicable Product Specifications.

1.4 “Arbitration Notice” has the meaning assigned to it in Section 14.3.2.

1.5 “Arbitrators” has the meaning assigned to it in Section 14.3.2.

1.6 “Asset Purchase Agreement” has the meaning assigned to it in the recitals.

1.7 “AstraZeneca” has the meaning assigned to it in the preamble hereto.

1.8 “AstraZeneca Indemnitee” has the meaning assigned to it in Section 12.2 (Indemnification by Horizon).

1.9 “Bailment Agreement” means that certain Bailment Agreement executed and delivered by the Parties on the Effective Date.

1.10 “Bailment Product” means any Supplied Product delivered to Horizon prior to the Bailment Product Transfer Date.

1.11 “Bailment Product Transfer Date” has the meaning set forth in the Bailment Agreement.

1.12 “Breaching Party” has the meaning as defined in Section 11.2 (Termination for Material Breach).

1.13 “Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.14 “Dispute” has the meaning assigned to it in Section 14.3.1.

1.15 “Commercialization” means all activities relating to the marketing, promotion, advertising, selling and distribution of Supplied Product in the Horizon Territory, including preparing advertising and promotional materials, sales force training and all interactions and activities regarding the commercialization of Supplied Product and the maintenance of Regulatory Approvals.

1.16 “Effective Date” has the meaning assigned to it in the preamble hereto.

1.17 “EMA” means the European Medicines Agency, or any successor agency thereto.

1.18 “Existing Regulatory Approval” means NDA# 22-511.

1.19 “Existing Product” means that certain product containing non-enteric coated Esomeprazole and enteric-coated Naproxen that is the subject of the Existing Regulatory Approval in the Horizon Territory, which product is currently known as VIMOVO™ including all dosage strengths thereof.

1.20 “Firm Forecast” has the meaning assigned to it in Section 3.1.3.
1.21 “Forecast” has the meaning assigned to it in Section 3.1.2.

1.22 “Force Majeure Event” has the meaning assigned to it in Section 14.5.

1.23 “Horizon” has the meaning assigned to it in the preamble hereto.

1.24 “Horizon Indemnitee” has the meaning assigned to it in Section 12.1 (Indemnification by AstraZeneca).

1.25 “Horizon Intellectual Property” means (a) any data, information and know-how that (i) is not generally known, (ii) is Controlled by Horizon or its Affiliates as of the Effective Date or during the Term and (iii) is necessary or useful for AstraZeneca to Manufacture the Supplied Products hereunder; (b) any Patent Right that (i) is Controlled by Horizon or its Affiliates as of the Effective Date or during the Term and (ii) is necessary or useful for AstraZeneca to Manufacture the Supplied Products hereunder; (c) any Horizon Marks; and (d) any Licensed Trademark.

1.26 “Horizon Marks” means the trade names, corporate names and corporate logos of Horizon or Horizon’s Affiliates that are used by Horizon or any of Horizon’s Affiliates in connection with the Supplied Product.

1.27 “Horizon Regulatory Documentation” has the meaning assigned to it in the License Agreement.

1.28 “Initial Forecast” has the meaning assigned to it in Section 3.1.1.

1.29 “Initial Purchase Orders” has the meaning assigned to it in Section 3.2.1.

1.30 “Indirect Taxes” has the meaning assigned to it in Section 4.3.2 (Indirect Taxes).

1.31 “License Agreement” has the meaning assigned to it in the preamble hereto.

1.32 “Licensed Trademarks” has the meaning assigned to it in the License Agreement.

1.33 “Manufacturing Process” has the meaning assigned to it in Section 7.3 (Manufacturing Process).

1.34 “Manufacture” and “Manufacturing” means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of the Supplied Product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.

1.35 “Manufacturing Technology” means (a) as of the Effective Date, all Patent Rights and all data, information and know-how that (i) with respect to data, information and know-how, is not generally known, (ii) are Controlled by AstraZeneca or any of its Affiliates as
of the Effective Date and (iii) are used by or on behalf of AstraZeneca or its Affiliates for the Manufacture of Supplied Products as of the Effective Date and (b) as of the date, if any, that AstraZeneca or any of its Affiliates may grant a license to Horizon under the Merck Patents and Merck Know-How without violating the terms of any Merck Agreement, the Patent Rights, data, information and know-how described in clause (a) and any Merck Patents and Merck Know-How that are used by or on behalf of AstraZeneca or its Affiliates for the Manufacture of Supplied Products as of the Effective Date; provided, that in either case (a) or (b), if any data, information or know-how (but not, for clarity, Patent Rights) included in Manufacturing Technology becomes publicly disclosed (other than as a result of any disclosure by Horizon in breach of its obligations under Section 5.5 of the Asset Purchase Agreement), such data, information or know-how shall no longer be deemed Manufacturing Technology.

1.36 “Minimum Batch Quantity” means (a) with respect to the Supplied Product in the form of 500/20mg tablets in 60-count bottles, [...***... bottles; (b) with respect to the Supplied Product in the form of 375/20mg tablets in 60-count bottles, [...***... bottles; and (c) with respect to the Supplied Product in the form of 500/20mg tablets in 6-count bottles, [...***... bottles.

1.37 “Non-Breaching Party” has the meaning assigned to it in Section 11.2 (Termination for Material Breach).

1.38 “Notice” has the meaning assigned to it in Section 14.4 (Notice Requirements).

1.39 “Notice Period” has the meaning assigned to it in Section 11.2 (Termination for Material Breach).

1.40 “Package” and “Packaging” mean the acts of packaging and labeling the Existing Product in bulk form into Supplied Product.

1.41 “Packaging Technology” means all Manufacturing Technology that is necessary or useful for the packaging and labeling of the Existing Product in bulk form into Supplied Product and set forth on Schedule 1.41.

1.42 “Party” and “Parties” each has the meaning assigned to it in the preamble hereto.

1.43 “Pass-Through Affiliate” means, with respect to a Pass-Through Supply Agreement, any Affiliate of AstraZeneca that is party to such Pass-Through Supply Agreement.

1.44 “Pass-Through Supply Agreements” means those agreements set forth on Schedule 1.44.

1.45 “Pass-Through Supply Vendor” means the party to a Pass-Through Supply Agreement other than AstraZeneca or a Pass-Through Affiliate.

1.46 “Patheon Agreement” means that certain Manufacturing Services Agreement by and between Patheon, Inc., Patheon Pharmaceuticals, Inc. and AstraZeneca LP, dated February 24, 2010.

1.47 “Payments” has the meaning assigned to it in Section 4.3.1 (Payments).
1.48 “Product Labeling” means (a) the full prescribing information for a Supplied Product approved by the applicable Regulatory Authority in the Horizon Territory, and (b) all labels and other written, printed or graphic information included in or placed upon any container, wrapper or package insert used with or for a Supplied Product in the Horizon Territory.

1.49 “Product Specifications” means the specifications for the Supplied Product contained in the applicable Regulatory Approval and any specifications mutually agreed to by the Parties established in connection with the Supplied Product and changes to such specifications made at the request of a Regulatory Authority in the Horizon Territory or by mutual agreement of the Parties from time to time, including the specifications set forth on Schedule 1.49.

1.50 “Purchase Order” has the meaning assigned to it in Section 3.2.3.

1.51 “Quality Agreement” has the meaning assigned to it in Section 6.1 (Quality Agreement).

1.52 “Raw Materials” has the meaning assigned to it in Section 7.1 (Raw Materials).

1.53 “Recall” has the meaning set forth in the Quality Agreement.

1.54 “SKU” means, with respect to any Supplied Product, the stock keeping unit number identifying the individual presentation of such Supplied Product.

1.55 “Sublicensee” means a Third Party that is granted a sublicense by Horizon under the grant in Section 2.1 of the License Agreement, in accordance with Section 2.2 of the License Agreement.

1.56 “Subsequent Purchase Order” has the meaning assigned to it in Section 3.2.3.

1.57 “Supplied Product” means the Existing Product in analyzed, released, final, packaged and labeled form, including all Product Labeling, ready for Commercialization in the Field in the Horizon Territory, as further described in the Product Specifications. The Supplied Product does not include HUD blister packs.

1.58 “Technology Recipient” has the meaning assigned to it in Section 2.3.1 (Technology Transfer).

1.59 “Technology Transfer Notice” has the meaning assigned to it in Section 2.3.1 (Technology Transfer).

1.60 “Term” has the meaning assigned to it in Section 11.1 (Term).

1.61 “Third Party” means any entity other than AstraZeneca, Horizon, or any of their respective Affiliates.

1.62 “Third Party Claim” has the meaning assigned to it in Section 12.1 (Indemnification of AstraZeneca).
"Transfer Price" has the meaning assigned to it in Section 4.1 (Transfer Price).

2. Supply of Supplied Products.

2.1 Supply by AstraZeneca. During the Term, subject to the terms and conditions of this Agreement, AstraZeneca will Manufacture or have Manufactured and supply or have supplied to Horizon such quantities of Supplied Products, including samples, as requested by Horizon for use by Horizon and its Sublicensees in connection with activities with respect to Supplied Products in the Horizon Territory, including Exploitation activities in the Horizon Territory.

2.2 Supply Transition. AstraZeneca or its applicable Pass-Through Affiliate will coordinate with each Pass-Through Supply Vendor to enable such Pass-Through Supply Vendor to supply the Supplied Products, or any component thereof, for the benefit of Horizon solely for use in the Horizon Territory without breaching any of the terms of the applicable Pass-Through Supply Agreement (including by entering into any necessary side letters or amending the applicable Pass-Through Supply Agreement, in each case in accordance with Section 14.1 (AstraZeneca’s Third Party Manufacturers)). Without limiting the foregoing, promptly after the Effective Date, AstraZeneca will cause AstraZeneca AB to deliver a side letter in substantially the form of Exhibit A to Patheon Inc. and Patheon Pharmaceuticals Inc.

2.3 Technology Transfer.

2.3.1 Horizon shall have the right, at any time during the Term, to provide notice to AstraZeneca requesting transfer to Horizon or its designated Third Party manufacturer (the “Technology Recipient”) of all Packaging Technology (the “Technology Transfer Notice”). Promptly following the date of such Technology Transfer Notice, the Parties shall work together to agree to a plan for transitioning the Packaging Technology to the Technology Recipient, and each Party shall use commercially reasonable efforts to perform its obligations under such plan in accordance with the timelines set out therein. Such plan shall provide for the transfer by AstraZeneca to the Technology Recipient, at Horizon’s expense, all Packaging Technology; provided, however, that AstraZeneca shall provide up to [***] of technology transfer services at no cost to Horizon in connection with the transfer of the Packaging Technology to Horizon or the Technology Recipient (and in providing reasonable assistance in connection therewith). In the event that Horizon desires additional technology transfer services with respect to the transfer of the Packaging Technology beyond the [***] of assistance provided above, at Horizon’s reasonable request and upon the payment of [***] to AstraZeneca, AstraZeneca shall provide up to [***] of additional technology transfer services, provided that AstraZeneca’s other Manufacturing operations are not disrupted by the provision of such additional assistance.

2.3.2 In no event shall AstraZeneca be required to transfer the Packaging Technology to more than one Technology Recipient. Horizon (or the Technology Recipient at Horizon’s direction) shall obtain and make available such information, personnel, products, materials, services, facilities and other resources, and take such other actions, as are reasonably necessary or useful to enable AstraZeneca to transfer the Packaging Technology to the Technology Recipient, including those set forth in the technology transfer plan to be agreed to by

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the Parties. Horizon acknowledges that the timely and successful transfer of the Packaging Technology to the Technology Recipient depends on the provision of information, personnel, products, materials, services, facilities and other resources by or on behalf of Horizon or the taking of certain actions by or on behalf of Horizon. Horizon acknowledges and agrees that AstraZeneca provides no assurances or guarantee that the Packaging Technology may be successfully transferred to the Technology Recipient.

2.3.3 Limited License. Horizon, on behalf of itself and its Affiliates, hereby grants to AstraZeneca and its Affiliates a non-exclusive, royalty-free, fully paid-up non-transferable (except as provided in Section 14.8) license under the Horizon Intellectual Property and a right of reference and use under the Horizon Regulatory Documentation, with the right, to grant further licenses and sublicenses or rights of reference and use, in each case, to the extent necessary for AstraZeneca and its Affiliates to perform their obligations hereunder.

3. FORECASTS AND PURCHASE ORDERS.

3.1 Forecasts.

3.1.1 Horizon’s written rolling, non-binding (except as set forth in Section 3.1.3) forecast of its and its Sublicensees’ anticipated requirements for Supplied Product in the Horizon Territory broken out on a month-by-month basis by SKU (in multiples of Minimum Batch Quantities) for the twelve-month period beginning January 1, 2014 (the “Initial Forecast”) is attached as Schedule 3.1.1.

3.1.2 Beginning on December 5, 2013, Horizon shall provide AstraZeneca, on or before the [***] day of each calendar month during the Term, with a written rolling, non-binding (except as set forth in Section 3.1.3) forecast of its and its Sublicensees’ anticipated requirements for Supplied Product in the Horizon Territory broken out on a month-by-month basis by SKU (in multiples of Minimum Batch Quantities), for the shorter of the twelve (12)-month period beginning with such calendar month and the remainder of the Term (each, a “Forecast”, and together with the Initial Forecast, the “Forecasts”).

3.1.3 The first (1st) [***] months of each Forecast shall be binding on Horizon (each, a “Firm Forecast”) and may not be changed without AstraZeneca’s written consent (which may be withheld in its sole discretion). The forecasted quantity of each Supplied Product SKU for each of the [***] months of a given Forecast shall not be more than [***] or less than [***] of the forecasted quantity for such Supplied Product SKU for such month in the immediately preceding Forecast.

3.2 Purchase Orders.

3.2.1 Horizon shall order Supplied Product by submitting written purchase orders to AstraZeneca pursuant to the terms of this Section 3.2.

3.2.2 Horizon’s binding written purchase orders to AstraZeneca specifying the quantities of each Supplied Product SKU ordered by Horizon for delivery during December 2013 and each month during the first Calendar Quarter of 2014 (the “Initial Purchase Orders”) are

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3.2.3 Subject to Section 3.2.2, at least [...***...] prior to the first (1st) day of each calendar month during the Term, Horizon shall submit to AstraZeneca a binding written purchase order to AstraZeneca, in a form reasonably acceptable to AstraZeneca, specifying the quantities of each Supplied Product SKU to be delivered to Horizon and its Sublicensees during such month, which quantities shall be the Minimum Batch Quantity for the applicable Supplied Product SKU, or a multiple thereof (each, a "Subsequent Purchase Order", and together with the Initial Purchase Orders, the "Purchase Orders").

3.2.4 AstraZeneca shall make each delivery of Supplied Product in the quantity and during the applicable month specified for it on Horizon’s Purchase Order[...***...]. In the event that the quantity of Supplied Product delivered by AstraZeneca differs from the quantity requested in the applicable Purchase Order, Horizon shall pay AstraZeneca for the quantity of Supplied Products delivered, rather than the quantity ordered, to the extent that the quantity delivered is not more than [...***...] of the quantity required in the Purchase Order. The quantity of each Supplied Product SKU specified in any Purchase Order submitted by Horizon to AstraZeneca for delivery in the applicable month shall be the quantity of such Supplied Product SKU forecasted by Horizon in the Firm Forecast for such month. Any Purchase Order for Supplied Product submitted by Horizon to AstraZeneca shall reference this Agreement and shall be governed exclusively by the terms contained herein. The Parties hereby agree that the terms and conditions of this Agreement shall supersede any term or condition in any order, confirmation or other document furnished by Horizon or AstraZeneca that is in any way inconsistent with these terms and conditions.

4. TRANSFER PRICE AND TAXATION.

4.1 Transfer Price. Horizon will pay AstraZeneca the transfer price set forth on Schedule 4.1 (the "Transfer Price") for Supplied Products supplied by AstraZeneca to Horizon and its Sublicensees under this Agreement.

4.2 Invoices; Method of Payments.

4.2.1 AstraZeneca shall invoice Horizon for the aggregate Transfer Price of: (a) each delivery of Supplied Products that are not Bailment Products, at the time of such delivery and (b) each delivery of Bailment Products, any time after the Bailment Product Transfer Date.

4.2.2 All payments due hereunder to AstraZeneca shall be paid to AstraZeneca in U.S. Dollars not later than [...***...] days following the date of the applicable invoice but not earlier than the date of delivery, unless such delivery of Supplied Product is rejected in accordance with the provisions of Section 6.2.1 (Rejection of Non-Conforming Supplied Products). All amounts due hereunder will be paid in United States Dollars by check sent to such address as may be designated in writing by AstraZeneca from time to time during the Term.

4.2.3 If AstraZeneca does not receive payment of any sum due to it on or before *** Confidential Treatment Requested

8.
the due date, simple interest will thereafter accrue on the sum due beginning on the [...***...] Business Day after the due date until the date of payment at the per annum rate of the then-current [...***...] quoted by Citibank in New York City plus [...***...] basis points, or the maximum rate allowable by applicable Law, whichever is lower.

4.3 Taxes.

4.3.1 The amounts payable by Horizon to AstraZeneca pursuant to this Agreement ("Payments") shall not be reduced on account of any Taxes unless required by applicable Law. AstraZeneca alone shall be responsible for paying any and all Taxes (other than withholding Taxes required to be paid by Horizon levied on account of, or measured in whole or in part by reference to, any Payments it receives. Horizon shall deduct or withhold from the Payments any Taxes that it is required by applicable Law to deduct or withhold. Notwithstanding the foregoing, if AstraZeneca is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding tax, it may deliver to Horizon or the appropriate Governmental Authority (with the assistance of Horizon to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Horizon of its obligation to withhold Tax, and Horizon shall apply the reduced rate of withholding, or dispense with the withholding, as the case may be, provided that Horizon has received evidence, in a form reasonably satisfactory to Horizon, of AstraZeneca’s delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least fifteen (15) days prior to the time that the Payments are due. If, in accordance with the foregoing, Horizon withholds any amount, it shall pay to AstraZeneca the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to AstraZeneca proof of such payment within sixty (60) days following that payment.

4.3.2 "Indirect Taxes" means value added taxes, sales taxes, consumption taxes and other similar taxes. All Payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any Payments, Horizon shall pay such Indirect Taxes at the applicable rate in respect of any such Payments following the receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by AstraZeneca in respect of those Payments. AstraZeneca shall issue invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes.

5. Delivery. AstraZeneca will deliver Supplied Products to Horizon in such quantities and during the applicable month as are specified in Purchase Orders subject to the terms and conditions of this Agreement. Deliveries shall be made [...***...] (Incoterms 2012) [...***...]. For clarity, [...***...] shall be responsible for the freight and insurance costs of delivery of the Supplied Products [...***...]. Except with respect to the Bailment Product, title and risk of loss for the Supplied Products shall [...***...] in accordance with this Section 5. Title and risk of loss with respect to the Bailment Product shall be governed by the Bailment Agreement.

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6. QUALITY ASSURANCE; ACCEPTANCE.

6.1 Quality Agreement. Concurrently with execution of this Agreement, the Parties will enter into an agreement that details the quality assurance obligations of each Party with respect to the Manufacture and supply of Supplied Products under this Agreement (the “Quality Agreement”). Each Party shall perform its obligations under the Quality Agreement in accordance with the terms and conditions thereof. In the event of a conflict between the terms of the Quality Agreement and the terms of this Agreement, the provisions of the Quality Agreement shall govern.

6.2 Acceptance and Rejection.

6.2.1 Rejection of Non-Conforming Supplied Products. Horizon may reject any delivery (or portion thereof) of Supplied Product pursuant to the terms of the Quality Agreement.

6.2.2 Cost of Replacement of Rejected Product. If any delivery of Supplied Product is rejected by Horizon pursuant to the provisions of the Quality Agreement, [...***...]. If only a portion of a delivery is rejected, [...***...].

6.2.3 Return of Rejected Product. If a delivery or partial delivery is rejected by Horizon pursuant to the provisions of the Quality Agreement and there is a determination pursuant to Section 9.1 of the Quality Agreement that such Supplied Product fails to conform to any warranty set forth in Section 9.1 (Supplied Product Warranty), Horizon shall return to AstraZeneca at AstraZeneca’s request and expense (or, at the election of AstraZeneca, destroy at AstraZeneca’s cost and provide evidence of such destruction to AstraZeneca) any such rejected Supplied Product. AstraZeneca shall (a) credit the original invoice in respect of the rejected Supplied Product, and (b) adjust the invoice to Horizon for any Supplied Product that was not rejected, payment of which is due in accordance with the terms of the original invoice. Except as set forth in Section 12.1 (Indemnification by AstraZeneca), this Section 6.2.3 (Return of Rejected Product) shall be Horizon’s sole remedy if AstraZeneca supplies Horizon Supplied Product that fails to conform to any warranty set forth in Section 9.1 (Supplied Product Warranty).

6.2.4 Supply of Replacement Product. During the pendency of any rejection discussions AstraZeneca shall use commercially reasonable efforts to supply Horizon with additional Supplied Product, which Horizon shall purchase on the same terms as the Supplied Product that is the subject of the rejection discussions.

7. MANUFACTURE OF SUPPLIED PRODUCT.

7.1 Raw Materials. AstraZeneca shall be responsible for obtaining and storing, at no cost to Horizon (subject to Section 4.1 (Transfer Price)), all materials required for the Manufacture of Supplied Products including all API, raw materials, components and other

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ingredients, and all Product Labeling and containers, wrappers and other packaging materials (collectively, "Raw Materials") required for the Manufacture of the Supplied Products hereunder. AstraZeneca shall have the right to change any source of Raw Materials; provided, however, that any change to the source of Raw Materials that would require approval by, or notification to, a Regulatory Authority (other than the annual report to the FDA for the Existing Product) shall be subject to the prior written approval of Horizon, such approval not to be unreasonably conditioned, withheld or delayed.

7.2 Manufacture of Supplied Product. AstraZeneca will Manufacture (to the extent AstraZeneca Manufactures), and will use its commercially reasonable efforts to cause the Pass-Through Supply Vendors to Manufacture, Supplied Products in accordance with the Product Specifications, cGMPs and applicable Law.

7.3 Costs of Changes to Product Specifications and Manufacturing Process. The procedures governing changes to the Product Specifications or the process or procedures used to Manufacture the Supplied Product (the "Manufacturing Process") shall be set forth in the Quality Agreement. If any change to the Product Specifications or Manufacturing Process is proposed by AstraZeneca, then AstraZeneca shall bear any expenses of implementing such change. For changes to the Product Specifications or Manufacturing Process proposed by Horizon (including any change that is required solely by a Regulatory Authority in the Horizon Territory), Horizon promptly shall reimburse AstraZeneca for all reasonable internal and external costs incurred by AstraZeneca or any Pass-Through Affiliate (including any and all costs AstraZeneca or any Pass-Through Affiliate must pay to a Pass-Through Supply Vendor) in connection with the implementation of any such change.

7.4 Shelf Life. Supplied Products will have a remaining shelf life of at least [***] months from the date of delivery, unless otherwise agreed by the Parties in writing, such agreement not to be unreasonably conditioned, withheld or delayed.

7.5 Supplied Product Shortfall. AstraZeneca shall use commercially reasonable efforts to avoid shortfalls in supply of Supplied Products based on the Forecasts provided by Horizon. In the event AstraZeneca is unable to supply to Horizon, in whole or in part, Supplied Products requested for any reason (except to the extent caused by Horizon), then AstraZeneca shall promptly notify Horizon, in writing, of such shortage, or potential shortage, or inability to timely supply Supplied Product and, if possible, the date when AstraZeneca will again be able to supply Supplied Product. AstraZeneca will use commercially reasonable efforts to remedy any shortfall of Supplied Product as soon as practicable and AstraZeneca will allocate its available production capacity at its facility located at [***] for the production of Supplied Product in a manner proportional to the utilization of AstraZeneca and Horizon, respectively, of such capacity in the prior [***] period and will allocate such Supplied Product on a proportional basis with respect to remaining shelf-life as well; provided, that in connection with any such shortfall, AstraZeneca shall not be required to supply Supplied Product from its own inventories or from orders for Supplied Product for the AstraZeneca Territory ordered pursuant to the [***] Agreement or to incur any capital or other expenditures in connection therewith.

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8. REGULATORY

8.1 Regulatory Compliance. AstraZeneca shall comply with all regulatory requirements with respect to Manufacture and supply of Supplied Product imposed by applicable Law upon AstraZeneca as the Manufacturer of the Supplied Product.

8.2 Recall of Supplied Product. The procedures governing Recall of Supplied Product shall be set forth in the Quality Agreement. In the event that any Supplied Product is Recalled in the Horizon Territory, Horizon shall be responsible for all costs and expenses related to such Recall and shall reimburse AstraZeneca or its applicable Pass-Through Affiliate for any out-of-pocket expenses incurred in connection with any such Recall, including any amounts payable to any Pass-Through Supply Vendors with respect thereto. Notwithstanding the foregoing, to the extent a Recall results from the nonconformance of Supplied Product supplied by AstraZeneca hereunder with each warranty set forth in Section 9.1 (Supplied Product Warranty), AstraZeneca shall reimburse Horizon for all out-of-pocket expenses incurred by Horizon with respect to such Recall.

9. REPRESENTATIONS AND WARRANTIES

9.1 Supplied Product Warranty. AstraZeneca represents and warrants that, as of the date of delivery, all Supplied Product delivered hereunder will (a) be Manufactured by AstraZeneca in accordance with all applicable Regulatory Approvals, cGMPs and other applicable Law; (b) conform to the Product Specifications at the time of delivery; (c) have a remaining shelf life of at least [...] months from the date of delivery, unless otherwise agreed by the Parties in writing; (d) at the time of delivery, be free and clear of any pledges, liens, charges, security interests, leases, title retention agreements, mortgages, restrictions, development or similar agreements, easements, rights-of-way, title defects, options, or adverse claims or encumbrances of any kind or character whatsoever, and (e) be supplied in accordance with the Quality Agreement[...***...].

9.2 Other AstraZeneca Representations and Warranties. AstraZeneca represents and warrants to Horizon that (a) Schedule 9.2(a) sets forth all Third Party manufacturers engaged by AstraZeneca and its Affiliates to Manufacture or supply Supplied Products, including API and other Raw Materials used to Manufacture Supplied Products, (b) neither AstraZeneca nor any Affiliate, in any capacity, in connection with the Manufacture of Supplied Products, has been debarred or is subject to debarment or has otherwise been disqualified or suspended from performing scientific or clinical investigations or otherwise subjected to any restrictions or sanctions by the FDA or any other governmental or Regulatory Authority or professional body with respect to the performance of scientific or clinical investigations, and (c) neither AstraZeneca nor any Affiliate, in any capacity, in connection with the Manufacture of the Supplied Product has received in the past [...***...] years or is currently subject to a Warning Letter (as defined in the Act) with respect to any facility Manufacturing Supplied Product. AstraZeneca shall, or shall cause its Pass-Through Affiliates to, provide Horizon with the benefit of any warranties with respect to the subject matter in clauses (b) and (c) that AstraZeneca or its *** Confidential Treatment Requested

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Pass-Through Affiliates obtained from the Pass-Through Supply Vendors with respect to the Manufacture of Supplied Products (or components thereof) under the Pass-Through Supply Agreements, and AstraZeneca shall use commercially reasonable efforts to pursue or cause the applicable Pass-Through Affiliate to use commercially reasonable efforts to pursue all remedies available to AstraZeneca or the applicable Pass-Through Affiliate under the Pass-Through Supply Agreement for any breach of any such warranties.

9.3 Reciprocal Representations and Warranties. Each Party represents and warrants to the other Party that: (a) this Agreement is a legal and valid obligation binding upon its execution and enforceable against it in accordance with its terms and conditions; and (b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all necessary corporate action, and the person executing this Agreement on behalf of such Party has been duly authorized to do so by all requisite corporate actions.

9.4 Disclaimer of Warranties. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES SET FORTH IN SECTIONS 9.1 (ASTRAZENECA WARRANTIES), SECTION 9.2 (RECIPROCAL REPRESENTATIONS AND WARRANTIES) OR IN THE ASSET PURCHASE AGREEMENT, EACH PARTY MAKES NO REPRESENTATIONS AND GRANTS NO WARRANTIES WITH RESPECT TO THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND ASTRAZENECA AND HORIZON EACH SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY OR MERCHANTABILITY, OR ANY WARRANTY AS TO THE VALIDITY OR ENFORCEABILITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

9.5 Other Covenants.

9.5.1 Each Party shall comply with all applicable Law in performing its obligations under this Agreement.

9.5.2 AstraZeneca shall not employ, contract with, or retain any person directly or indirectly to perform any services under this Agreement if such a person (a) is under investigation by the FDA for debarment or is presently debarred by the FDA pursuant to 21 U.S.C. § 335a or its successor provisions, or (b) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 C.F.R. § 312.70 or its successor provisions. If, during the Term, AstraZeneca or any person employed or retained by it to perform under this Agreement (excluding any Pass-Through Supply Vendor) (i) comes under investigation by the FDA for a debarment action or disqualification, (ii) is debarred or disqualified, or (iii) engages in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions, AstraZeneca shall immediately notify Horizon of same; provided AstraZeneca shall use commercially reasonable efforts to require the same or similar obligations from its Pass-Through Supply Vendors and shall provide Horizon with the benefit of any warranties with respect to the subject matter.
9.5.3 AstraZeneca has and will maintain (or, as applicable, will use commercially reasonable efforts to cause the applicable Pass-Through Supply Vendors to maintain) during the Term all government permits, including, health, safety and environmental permits, necessary for the conduct of the activities that it undertakes pursuant to this Agreement.

9.5.4 As between AstraZeneca and Horizon, Horizon shall be responsible for ensuring that the Product Specifications shall comply with all applicable Regulatory Approvals, cGMPs and other applicable Law.

10. CONFIDENTIALITY

10.1 General. The rights and obligations of the Parties with respect to Confidential Information disclosed by or on behalf of one Party to the other Party hereunder shall be governed by the terms of Section 9.1 of the License Agreement.

11. TERM AND TERMINATION

11.1 Term. The term of this Agreement will commence as of the Effective Date and, unless earlier terminated in accordance with this Section 11 (Term and Termination), will expire on December 31, 2014 (the “Term”).

11.2 Termination for Material Breach. In the event that either Party (the “Breaching Party”) is in material default of any of its material obligations under this Agreement, in addition to any other right and remedy the other Party (the “Non-Breaching Party”) may have, the Non-Breaching Party may terminate this Agreement by [* *** *] days’ prior written notice (such [* *** *]-day period, the “Notice Period”) to the Breaching Party, specifying the breach and its claim of right to terminate; provided, that the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach complained about during the Notice Period (or, if such default cannot be cured within such Notice Period, if the Breaching Party commences actions to cure such default within the Notice Period and thereafter diligently continues such actions). [* *** *] If either Party initiates a dispute resolution procedure as permitted under Section 14.3 (Dispute Resolution) to resolve the dispute for which termination is being sought and is diligently pursuing such procedure, including any arbitration following therefrom, the termination shall become effective only if and when such dispute is finally resolved through such dispute resolution procedure. This Section 11.2 (Termination for Material Breach) defines exclusively the Parties’ right to terminate in case of any material breach of this Agreement.

11.3 Other Termination by Horizon. Horizon may terminate this Agreement at any time at will upon one hundred twenty (120) days prior written notice to AstraZeneca. In addition, Horizon may terminate this Agreement immediately upon written notice to AstraZeneca if (a) the Existing Regulatory Approval is suspended for any reason or (b) any Regulatory Authority provides a Warning Letter (as defined in the Act) or other official documentation expressing major and significant concerns from a regulatory perspective with *** Confidential Treatment Requested
11.4 Termination for Insolvency. This Agreement may be terminated by written notice by either Party at any time during the Term upon the declaration by a court of competent jurisdiction that the other Party is bankrupt and, pursuant to the U.S. Bankruptcy Code such other Party’s assets are to be liquidated; upon the filing or institution of bankruptcy, liquidation or receivership proceedings (other than reorganization proceedings under Chapter 11 of the U.S. Bankruptcy Code); or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; or in the event a receiver or custodian is appointed for such Party’s business; provided, however, that in the case of any involuntary proceeding, such right to terminate shall only become effective if the proceeding is not dismissed within sixty (60) days after the filing thereof.

11.5 Termination of License Agreement. This Agreement shall automatically terminate upon expiration or termination of the License Agreement.

11.6 Consequences of Expiration and Termination.

11.6.1 Upon expiration or termination of this Agreement, except as set forth in this Section 11.6 or Section 11.7, all obligations of the Parties under this Agreement will terminate immediately. The use by either Party of a termination right provided for under this Agreement and in accordance with this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other party with respect thereto. Subject to the preceding sentence, termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to upon such termination or for any breach of this Agreement.

11.6.2 Upon expiration or termination of this Agreement (a) all unfilled Purchase Orders shall be cancelled; provided, that if Horizon terminates this Agreement pursuant to Section 11.2, at its option, Horizon may require that all unfilled Purchase Orders be delivered in accordance with the terms of this Agreement and (b) Horizon shall promptly pay to AstraZeneca (i) the cost of AstraZeneca’s then existing inventory of Raw Materials that cannot otherwise be used in the business of AstraZeneca or returned to the vendor without additional costs and the cost that AstraZeneca or any Pass-Through Affiliate is required to pay to a Pass-Through Supply Vendor with respect to such Pass-Through Supply Vendor’s then existing inventory of Raw Materials that cannot otherwise be used in the business of such Pass-Through Supply Vendor or returned to the vendor without additional costs and (ii) the applicable Transfer Price for all work in process and finished Supplied Product Manufactured, but not then delivered by AstraZeneca to Horizon; provided all such Raw Materials, work in process, and finished Supplied Product Manufactured but not then delivered by AstraZeneca to Horizon, shall be delivered to Horizon or its designee within thirty (30) days.

11.7 Surviving Obligations. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. The provisions of Sections 2.3 (Technology Transfer) (only for six (6) months after the end of the Term), 9.4 (Disclaimer of Warranties), 10 (Confidentiality), 11.6 (Consequences of Expiration)
and Termination), 11.7 (Surviving Obligations), 12 (Indemnification and Insurance), 13 (Limitation of Liability) and 14 (Miscellaneous) will survive any expiration or termination of this Agreement.

12. **INDEMNIFICATION AND INSURANCE**

12.1 **Indemnification by AstraZeneca.** Subject to this Article 12, AstraZeneca shall indemnify, defend and hold harmless Horizon and its Affiliates, and its and their respective licensors, licensees, officers, directors, employees and agents (collectively, “Horizon Indemnitees”) from and against any and all Losses incurred by them in connection with any and all Litigation by Third Parties (collectively, “Third Party Claims”) arising from or occurring as a result of: (a) the gross negligence or willful misconduct of any AstraZeneca Indemnitee or (b) the breach by AstraZeneca of any warranty, representation, covenant or agreement made by AstraZeneca in this Agreement, in each case, except to the extent such Losses result from the gross negligence or willful misconduct of any Horizon Indemnitee or the breach by Horizon of any warranty, representation, covenant or agreement made by Horizon in this Agreement, as to which Losses each Party shall indemnify the other Party and the AstraZeneca Indemnitees or the Horizon Indemnitees, as applicable, to the extent of its liability for such Losses.

12.2 **Indemnification by Horizon.** Subject to this Article 12, Horizon shall indemnify, defend and hold harmless AstraZeneca and its Affiliates, and its and their respective officers, directors, employees and agents (collectively, “AstraZeneca Indemnitees”) from and against any and all Losses incurred by them in connection with any and all Third Party Claims arising from or occurring as a result of: (a) the Exploitation or Manufacture of any Supplied Product by Horizon, its Affiliates or any of their respective Sublicensees, (b) the gross negligence or willful misconduct of any Horizon Indemnitee, or (c) the breach by Horizon of any warranty, representation, covenant or agreement made by Horizon in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any AstraZeneca Indemnitee or the breach by AstraZeneca of any warranty, representation, covenant or agreement made by AstraZeneca in this Agreement, as to which Losses each Party shall indemnify the other Party and the AstraZeneca Indemnitees or the Horizon Indemnitees, as applicable, to the extent of its liability for such Losses.

12.3 **Indemnification Procedures.** All indemnification claims in respect of Horizon or any Horizon Indemnitees shall be made solely by Horizon and all indemnification claims in respect of AstraZeneca or any AstraZeneca Indemnitee shall be made solely by AstraZeneca and, in each case, shall be governed by Section 7.2 of the Asset Purchase Agreement. Notwithstanding anything herein to the contrary, the Parties’ respective indemnification obligations under this Article 12 shall not apply to any Losses for which such Party is entitled to indemnification under the Asset Purchase Agreement (excluding for this purpose, application of the limitations in Section 7.3 of the Asset Purchase Agreement).

12.4 **Insurance.** Each Party will have and maintain such types and amounts of liability insurance as is normal and customary in the industry generally for parties similarly situated, and will upon request provide the other Party with a copy of its policies of insurance in that regard, along with any amendments and revisions thereto.
13. LIMITATION OF LIABILITY

13.1 [...***...]

13.2 NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, WITH RESPECT TO ANY LOSSES OR DAMAGES UNDER THIS AGREEMENT THAT [...***...] OF ANY [...***...] WITH RESPECT TO SUCH [...***...] TO THE [...***...]; PROVIDED THAT [...***...] WITH RESPECT TO [...***...] WITH THE [...***...].

14. MISCELLANEOUS

14.1 AstraZeneca’s Third Party Manufacturers. The Parties acknowledge and agree that AstraZeneca plans to use the Pass-Through Supply Vendors in connection with the supply of Supplied Products under this Agreement and that AstraZeneca’s obligations, and Horizon’s rights, under this Agreement are subject to the terms and conditions of the applicable Pass-Through Supply Agreements. AstraZeneca shall not amend any Pass-Through Supply Agreement in a manner that materially and adversely affects Horizon’s rights under this Agreement and the Quality Agreement nor terminate any such Pass-Through Supply Agreement if such termination materially and adversely affects Horizon’s rights under this Agreement, in either case, without prior written consent of Horizon, such consent not to be unreasonably conditioned, withheld or delayed.

14.2 Governing Law, Jurisdiction, Venue and Service.

14.2.1 Governing Law. This Agreement shall be governed by and construed in *** Confidential Treatment Requested
14.2.2 Jurisdiction. Subject to Section 14.3 and 14.13, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial.

14.2.3 Venue. Subject to Section 14.3 and 14.13, the Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or in the United States District Court for the Southern District of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

14.2.4 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 14.4 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any court.

14.3 Dispute Resolution.

14.3.1 Except as provided in Section 14.13, if a Dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a “Dispute”), then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of 10 Business Days. Any final decision mutually agreed to by the Senior Officers in writing shall be conclusive and binding on the Parties.

14.3.2 If such Senior Officers are unable to resolve any such Dispute within such 10-Business Day period, either Party shall be free to institute binding arbitration in accordance with this Section 14.3.2 upon written notice to the other Party (an “Arbitration Notice”) and seek such remedies as may be available. Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three (3) experts with relevant industry experience (the “Arbitrators”). Each of Horizon and AstraZeneca shall promptly select one Arbitrator, which selections shall in no event be made later than thirty (30) days after the notice of initiation of arbitration. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Horizon and the Arbitrator chosen by AstraZeneca, but in no event later than thirty (30) days after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery; provided that the Arbitrators shall permit such discovery as they deem necessary
to permit an equitable resolution of the Dispute. The arbitration shall be administered by the American Arbitration Association ("AAA") (or its successor entity) in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Agreement. The arbitration shall be held in New York, New York, USA, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The Arbitrators shall, within fifteen (15) days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with applicable Law in the State of New York or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.

14.3.3 Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Section 14.3, and shall pay an equal share of the fees and costs of the Arbitrators and all other general fees related to any arbitration described in Section 14.3.3; provided, however, the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges, or travel expenses) and/or the fees and costs of the Arbitrators. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Section 14.3.3 is pending under this Agreement, the Parties shall continue to comply with all terms and provisions of this Agreement. All arbitration proceedings and decisions of the Arbitrator under this 14.3 shall be deemed Confidential Information of both Parties under Section 10. For clarity, nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding.

14.4 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement (each, a "Notice") shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in this Section 14.4 or to such other address as the Party to whom notice is to be given may have provided to the other Party at least five (5) days’ prior to such address taking effect in accordance with this Section 14.4. Such Notice shall be deemed to have been given as of the date delivered by hand or internationally recognized overnight delivery service or confirmed that it was received by facsimile (with receipt confirmed by telephone or email). Any Notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter.
If to AstraZeneca, to:
AstraZeneca LP
1800 Concord Pike
Wilmington, Delaware 19803
USA
Attention: General Counsel
Facsimile: (302) 886-1578

With a copy (which shall not constitute notice) to:
and to:
Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
Facsimile: (202) 662-6291
Attention: John Hurvitz
Michael J. Riella

If to Horizon, to:
Horizon Pharma USA, Inc.
520 Lake Cook Road, Suite 520
Deerfield, Illinois 60015
USA
Attention: Chief Executive Officer
Facsimile: 847-572-1372

With a copy (which shall not constitute notice) to:
Cooley LLP
4401 Eastgate Mall
San Diego, California 92121
USA
Attention: L. Kay Chandler, Esq.
Facsimile: 858-550-6420

14.5 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement if such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any

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Governmental Authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement) (each, a “Force Majeure Event”). The non-performing Party shall notify the other Party of such Force Majeure Event within thirty (30) days after such occurrence by giving written notice to the other Party stating the nature of the Force Majeure Event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

14.6 No Benefit to Third Parties. The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and, except for the rights of Horizon Indemnites and AstraZeneca Indemnites under Article 12, they shall not be construed as conferring any rights on any other Persons.

14.7 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

14.8 Assignment. Except as expressly set forth in this Agreement, neither Party shall have the right or the power to assign, in whole or in part, any of its rights, or delegate the performance of any of its obligations, under this Agreement without the prior written authorization of the other Party, which authorization shall not be unreasonably withheld, conditioned or delayed, and any assignment or delegation of this Agreement or any of such rights or obligations without such authorization shall be void and of no effect; provided, however, that either Party may assign the Agreement, in whole or in part, to an Affiliate without the prior written authorization of the other Party; and provided, further, that either Party shall have the right to assign this Agreement, in whole or in part, in connection with a merger or other acquisition of the capital stock or all or substantially all of its assets, without the prior written authorization of the other Party. Any permitted assignment or delegation hereunder by a Party shall not relieve such Party of any of its obligations under this Agreement (whether by operation of law or otherwise), unless, with respect an assignment to a Third Party, such assignee agrees in writing to assume such Party’s obligations under this Agreement, in which case such Party shall be relieved of its obligations hereunder from and after the effective date of such assignment and assumption. Subject to the foregoing, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns.

14.9 Use of Affiliates. Either Party shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates without authorization of the other Party. For clarity, AstraZeneca is permitted to perform its obligations hereunder using any Pass-Through Supply Vendor.

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14.10 Amendment. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by both Parties.

14.11 Independent Contractors. In the exercise of their respective rights, and the performance of their respective obligations, under this Agreement, the Parties are, and shall remain, independent contractors. Nothing in this Agreement shall be construed to constitute the Parties as partners, joint venturers, or participants in a joint enterprise or undertaking, or to constitute either of the Parties as the agent of the other Party for any purpose whatsoever. Neither Party shall bind, or attempt to bind, the other Party hereto to any contract or the performance of any other obligation, or represent to any Third Party that it is authorized to enter into any contract or binding obligation on behalf of the other Party hereto.

14.12 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

14.13 Equitable Relief. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in any court of the United States or any state having jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity. Each Party hereby waives (a) any requirement that the other Party post a bond or other security as a condition for obtaining any such relief, and (b) any defenses in any action for specific performance, including the defense that a remedy at law would be adequate.

14.14 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

14.15 Counterparts. This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

14.16 Entire Agreement. This Agreement, together with the Schedules and Exhibits
expressly contemplated hereby and attached hereto, the Ancillary Agreements, the Confidentiality Agreement and the other agreements, certificates and
documents delivered in connection herewith or therewith or otherwise in connection with the transactions contemplated hereby and thereby, contain the
entire agreement between the Parties with respect to the transactions contemplated hereby or thereby and supersede all prior agreements, understandings,
promises and representations, whether written or oral, between the Parties with respect to the subject matter hereof and thereof. In the event of any
inconsistency between any such Schedules and Exhibits and this Agreement, the terms of this Agreement shall govern.

14.17 Construction. Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any
gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of
reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this
Agreement. The term “including” as used herein does not limit the generality of any description preceding such term. The language of this Agreement shall
be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party. Unless otherwise
specified or where the context otherwise requires, (a) references in this Agreement to any Article, Section, Schedule or Exhibit are references to such Article,
Section, Schedule or Exhibit of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; (c) “hereof,”
“herein,” “hereby,” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any
particular provision of this Agreement; (d) references to a Person are also to its permitted successors and assigns; (e) references to a Law include any
amendment or modification to such Law and any rules or regulations issued thereunder, in each case, as in effect at the relevant time of reference thereto;
(f) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed
or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of
reference thereto; and (g) references to monetary amounts are denominated in United States Dollars.

23.
IN WITNESS WHEREOF, the Parties have executed this SUPPLY AGREEMENT by their respective authorized representatives as of the date first written above.

HORIZON PHARMA USA, INC.  

By: /s/ Timothy P. Walbert  
Name: Timothy P. Walbert  
Title: President and Chief Executive Officer

ASTRAZENECA LP  

By: /s/ Steve Mohr  
Name: Steve Mohr  
Title: Deputy General Counsel, North America and US General Counsel

SIGNATURE PAGE TO SUPPLY AGREEMENT
SCHEDULE 1.41

PACKAGING TECHNOLOGY

[...***...]

*** Confidential Treatment Requested
SCHEDULE 1.44

PASS-THROUGH SUPPLY AGREEMENTS

[...***...]

*** Confidential Treatment Requested
SCHEDULE 1.49

PRODUCT SPECIFICATIONS

(SEE ATTACHED)
### SCHEDULE 3.1.1

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*** Confidential Treatment Requested
**SCHEDULE 3.2.2**

**INITIAL PURCHASE ORDER**

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[...***...]

*** Confidential Treatment Requested
### Schedule 4.1

**Transfer Prices**

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*** Confidential Treatment Requested
SCHEDULE 9.2(A)

THIRD PARTY MANUFACTURERS

[...***...]

*** Confidential Treatment Requested
EXHIBIT A

PATHEON SIDE LETTER

(SEE ATTACHED)
AMENDED AND RESTATED
COLLABORATION AND LICENSE AGREEMENT FOR THE UNITED STATES

by and between

POZEN INC.

and

ASTRAZENECA AB

November 18, 2013
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SCHEDULES

Schedule 1.43 – Licensed Patents
Schedule 1.83 - Vimovo Trademarks
Schedule 8.1.3 – Market Reduction Example
AMENDED AND RESTATED COLLABORATION AND LICENSE AGREEMENT
FOR THE UNITED STATES

THIS AMENDED AND RESTATED COLLABORATION AND LICENSE AGREEMENT FOR THE UNITED STATES (the “Agreement”) is made and entered into as of November 18, 2013 (the “Amended and Restated Execution Date”), by and between POZEN INC., a Delaware corporation having offices at 1414 Raleigh Road, Suite 400, Chapel Hill, North Carolina ("POZEN"), and ASTRAZENECA AB, a Swedish corporation having an office at SE-431 83, Mölndal, Sweden ("Licensee"). POZEN and Licensee each may be referred to herein individually as a “Party,” or collectively as the “Parties.”

RECITALS

A. WHEREAS, POZEN and Licensee are parties to that certain Collaboration and License Agreement, dated as of August 1, 2006 and as amended as of September 6, 2007, October 1, 2008 and September 16, 2013 (as amended, the "Original Agreement");

B. WHEREAS, Licensee is in discussions with Horizon Pharma USA, Inc. ("Horizon") to divest Licensee’s (and its Affiliates’) rights to Products (as defined below) in the United States (such transaction, the "Divestiture"); and

C. WHEREAS, to facilitate the proposed Divestiture, Licensee and POZEN desire to amend and restate the terms of the Original Agreement in two separate agreements: (a) this Agreement, which contains the terms and conditions pursuant to which Licensee (or its assignee) will have a license to POZEN’s intellectual property to manufacture, develop and commercialize the Products (as defined below) in the United States, which will be assigned to Horizon in connection with the Divestiture, and (b) another agreement that contains the terms and conditions pursuant to which Licensee (or its designee) will have a license to POZEN’s intellectual property to manufacture, develop and commercialize the Products throughout the world outside of the United States and Japan (the "ROW Agreement").

In consideration of the foregoing premises, the mutual promises and covenants set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, POZEN and Licensee hereby agree as follows:

AGREEMENT

1. DEFINITIONS

When used in this Agreement, capitalized terms will have the meanings as defined below and throughout the Agreement. All financial and accounting terms not otherwise defined in this Agreement, whether capitalized or not, shall have the meanings assigned to them in accordance with generally accepted accounting principles based on International Accounting Standards/International Financial Reporting Standards as in effect from time to time (“IFRS”).
1.1 **“Adverse Event”** means any adverse medical occurrence in a patient or clinical investigation subject that is administered a pharmaceutical product, as designated under 21 CFR § 312.32 and any other Applicable Law in the Territory.

1.2 **“Affiliate”** means a legal entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with an entity. For purposes of this definition only, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” means (a) the possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) the ownership, directly or indirectly, of more than 50% of the voting securities or other ownership interest of a legal entity; provided, that if local law restricts foreign ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests.

1.3 **“Amended and Restated Effective Date”** has the meaning set forth in Section 12.1.

1.4 **“Amended and Restated Execution Date”** has the meaning set forth in the preamble.

1.5 **“Applicable Law”** means the laws, rules, and regulations, including any statutes, rules, regulations, guidelines, or other requirements that may be in effect from time to time and apply to the activities contemplated by this Agreement in the Territory.

1.6 **“Blocking Patent”** means a Patent owned or controlled by a Third Party, one or more Valid Claims of which, in the absence of a license thereunder, would be infringed by the making, use, sale, offering for sale, or importation of a POZEN Product in the Territory.

1.7 **“Business Combination”** means any merger, consolidation, sale of stock, sale or transfer of all or substantially all of the assets, or other similar transaction to which POZEN is a party, other than (i) any merger, consolidation, or similar transaction following which the individuals and entities who were the beneficial owners of the outstanding voting securities of POZEN immediately prior to such transaction still beneficially own, directly or indirectly, more than fifty percent (50%) of the voting power of the surviving entity immediately after such transaction; or (ii) any merger, consolidation, sale of stock, sale or transfer of all or substantially all of the assets, or other similar transaction permitted under Section 15.1 (Assignment).

1.8 **“Business Day”** means any day other than (i) Saturday or Sunday or (ii) any other day on which banks in New York, New York, United States, the United Kingdom or Sweden are permitted or required to be closed.

1.9 **“Calendar Quarter”** means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.10 **“cGCP”** means current good clinical practices as defined in U.S. Regulations 21 CFR §§ 50, 54, 56, 312 and 314, (or in the case of foreign jurisdictions, comparable regulatory standards), the International Conference of Harmonization (ICH) E6 “Good Clinical Practice:
1.11 “cGLP” means current good laboratory practice standards as defined by the FDA pursuant to 21 CFR Part 58 (or in the case of foreign jurisdictions, comparable regulatory standards), and in any successor regulation or any official guidance documents issued by a Regulatory Authority.

1.12 “cGMP” means current good manufacturing practices as contained in 21 CFR Parts 210 and 211 as amended from time to time and any equivalents contained in regulations in countries outside the U.S.

1.13 “Change of Corporate Control” means the occurrence of either of the following:

   (a) a Business Combination involving POZEN; or

   (b) the acquisition (whether in a single transaction or series of related transactions) after the Effective Date by a Third Party or Group of beneficial ownership of [...***...] ([…***…]) […***…] of POZEN’s voting securities.

1.14 “Combination Product” means a Product that includes one or more pharmaceutically active ingredients (in addition to a single Gastroprotective Agent and a single NSAID) and is sold in final form either in a single fixed combination oral solid dosage or as separate doses in a single package and priced as one item.

1.15 “Commercial Launch” means the nationwide commercial sale, promotion and distribution of POZEN Product in the Territory following receipt of Marketing Approval in the Territory.

1.16 “Commercialization” means all activities relating to the manufacture, marketing, promotion, advertising, selling and distribution of Product in the Territory, including pre-Commercial Launch market development activities conducted in anticipation of Marketing Approval of Product, including, without limitation, seeking pricing and reimbursement approvals for Product, preparing advertising and promotional materials, sales force training, and all interactions and activities (e.g., dossier preparations and filings) associated with Regulatory Authorities regarding the commercialization of Product and the maintenance of Marketing Approvals. The term “Commercialize” has a correlative meaning.

1.17 “Commercialized POZEN Product” has the meaning set forth in Section 12.8 (Formulation Technology).

1.18 “Competing Product” means, with respect to a particular Product being Commercialized by Licensee or any of its Affiliates or Sublicensees in the Territory, a product being marketed by or on behalf of a Third Party (other than a Sublicensee) in the Territory containing at least [...***...] that are [...***…] those in the [...***…] and are [...***…].
1.19 “Controlled” means, with respect to any Know-How, Patent, or other intellectual property right, the possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such Know-How, Patent or right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party.

1.20 “Develop” or “Development” means all activities relating to pre-clinical and clinical development of a Product and all development activities relating to the preparation and filing of NDAs and obtaining of Marketing Approvals, price and reimbursement approvals in the Territory, including, without limitation, preparing and conducting pre-clinical testing, toxicology testing, human clinical studies, regulatory affairs.

1.21 “Diligent Efforts” means, with respect to the Development, Manufacture or Commercialization by Licensee of a product, at any given time as the case may be, efforts and resources reasonably used by Licensee or its Affiliates (giving due consideration to relevant industry standards) for Licensee’s own products (including internally developed, acquired and in-licensed products) with similar commercial potential at a similar stage in their lifecycle (assuming continuing development of such product), taking into consideration their safety, tolerability and efficacy, the profitability (taking into account any payments payable under this Agreement or the Three-Party Agreement), the extent of market exclusivity, patent protection, cost to develop the product, promotable claims, and health economic claims.

1.22 “Divestiture” has the meaning set forth in the recitals.

1.23 “Duexis” means the pharmaceutical product containing ibuprofen and famotidine in a single fixed combination dosage form, which product is being commercialized as of the Amended and Restated Effective Date by Horizon or its Affiliates in the Territory as Duexis®.

1.24 “Effective Date” means the date on which the Original Agreement became effective pursuant to the terms thereof.

1.25 “Esomeprazole” means that certain pharmaceutical compound with the name (5-methoxy-2-\{(S)-\[(4-methoxy-3,5-dimethylpyridin-2-yl)methyl\]sulfinyl\}-1H-benzimidazole), including any [...***...].

1.26 “Execution Date” means August 1, 2006.

1.27 “FDA” means the United States Food and Drug Administration, or any successor agency thereto.

1.28 “Field of Use” means the treatment of human diseases and conditions by means of a pharmaceutical product.

1.29 “First Commercial Sale” means, with respect to a Product, the date on which Licensee or its Affiliate or Sublicensee first sells the Product intended for commercial distribution to any Third Party after receipt of NDA Approval of such Product in the Territory (including, without limitation, sale in an individual state or similar sub-national political subdivision in which Marketing Approval may be received); provided, that with respect to the

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“First Commercial Sale” means July 6, 2010. Sale of a Product for clinical studies, compassionate use, named patient programs, under a treatment IND, test marketing, any clinical studies, or any similar instance where the Product is supplied with or without charge will not constitute a First Commercial Sale.

1.30 “Formulation Technology” means any Know-How Controlled by Licensee in the Licensee Inventions that are used by Licensee in the manufacture, use, sale or import of the formulation of a Commercialized POZEN Product, and any Patents Controlled by Licensee claiming such Licensee Inventions; provided, that Formulation Technology will not include any Patents or Know-How to the extent directed to a Gastroprotective Agent, non-steroidal anti-inflammatory, or other drug or chemical agent, or any methods of manufacture or use thereof.

1.31 “Gastroprotective Agent” means proton pump inhibitors and H2 receptor antagonists for the treatment, prevention or amelioration of injury to the gastrointestinal tract.

1.32 “Group” means a group of related persons or entities deemed a “person” for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended.

1.33 “Horizon” has the meaning set forth in the recitals.

1.34 “IND” means an Investigational New Drug Application filed with the FDA pursuant to 21 CFR § 312.20.

1.35 “Indirect Tax” means value added taxes, sales taxes, consumption taxes and other similar taxes.

1.36 “Initial POZEN Product” means the POZEN Product containing non-enteric coated Esomeprazole and enteric-coated Naproxen that is the subject of NDA #22-511.

1.37 “Invention” means any invention, discovery or Know-How that is conceived during the Term in the performance of activities undertaken pursuant to this Agreement by employees, agents, or independent contractors of either Party, its Affiliates or Sublicensees and is Controlled by such Party, Affiliates or Sublicensees.

1.38 “Joint Invention” means any Invention that is conceived jointly by one or more employees, agents, or independent contractors of Licensee or its Affiliate(s) and one or more employees, agents, or independent contractors of POZEN or its Affiliate(s).


1.40 “JSC” has the meaning set forth in Section 2.1.2 (Joint Steering Committee).

1.41 “Know-How” means any non-public, documented or otherwise recorded or memorialized knowledge, experience, know-how, technology, information, and data, including formulas and formulations, processes, techniques, unpatented inventions, discoveries, ideas, and developments, test procedures, and results, together with all documents and files embodying the foregoing.
1.42 “Licensed Know-How” means any Know-How that is necessary or useful for the Development, Manufacture or Commercialization of Product in the Field of Use in the Territory and that is Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term.

1.43 “Licensed Patents” means: (a) the Patents set forth on Schedule 1.43, and any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, or extensions of such Patents, (b) any Patents in the Territory Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term that claim Inventions (including without limitation POZEN’s interest in Joint Inventions), and (c) all other Patents in the Territory Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term that are necessary or useful for the Development, Manufacture or Commercialization of a Product in the Territory. Notwithstanding anything in this Section 1.43 to the contrary, Licensed Patents shall not include any Patents Controlled by POZEN with Valid Claims that do not cover any Product (e.g., any Patents with Valid Claims solely directed to any product containing acetyl salicylic acid).

1.44 “Licensed Technology” means the Licensed Patents and the Licensed Know-How.

1.45 “Licensee House Marks” means any trademarks, trade names, domain names, or other names or marks used or registered by Licensee or its Affiliates at any time during the Term to identify itself.

1.46 “Licensee Invention” means any Invention that is conceived solely by one or more employees, agents, or independent contractors of Licensee or its Affiliate(s).

1.47 “Manufacture” means all activities related to the manufacturing of a Product, or any ingredient thereof, in the Territory, including but not limited to formulation development and process development for the manufacture of a Product, manufacturing supplies for Development, manufacturing for commercial sale, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, ongoing stability tests and regulatory activities related to any of the foregoing. “Manufacture” shall not include any of the above activities with respect to Esomeprazole as an active ingredient.

1.48 “Market Reduction” has the meaning set forth in Section 8.1.3 (Rate Step Down for Competing Product Entrants).

1.49 “Marketing Approval” means all approvals (including NDA Approvals and, where available under Applicable Law, pricing and reimbursement approvals in accordance with Applicable Law) of any Regulatory Authority in the Territory, that are necessary or useful to be obtained prior to the manufacture or Commercialization of a Product in the Territory. For purposes of clarification, “Marketing Approval” in the U.S. shall have the same meaning as NDA Approval in the U.S.
1.50 “Naproxen” means that certain pharmaceutical compound with the chemical name (S)-6-methoxy-(alpha)-methyl-2-naphthaleneacetic acid, including any [...***...].

1.51 “NDA” means a New Drug Application filed with the FDA as described in 21 CFR § 314.

1.52 “NDA Approval” means receipt of a letter from the FDA approving an NDA.

1.53 “Net Sales” means with respect to any Product, the gross amounts recognized by Licensee, its Sublicensees or its Affiliates from Third Party customers for sales of a Product in the Territory, less the following deductions made by Licensee (to the extent not already taken by Licensee in the Product invoice or in amounts recognized), its Sublicensees or its Affiliates in arriving at net sales as reported in the Licensee statutory accounts prepared in accordance with IFRS:

(a) actual credited allowances to such Third Party customers for spoiled, damaged, rejected, recalled, outdated and returned Product and for retroactive price reductions;

(b) the amounts of trade and cash discounts actually granted to Third Party customers, to the extent such trade and cash discounts are specifically allowed on account of the purchase of such Product;

(c) sales taxes, excise taxes and import/export duties actually due or incurred in connection with the sales of a Product to any Third Party customer;

(d) allowances, adjustments, reimbursements, discounts, chargebacks and rebates actually granted to Third Party customers (not in excess of the selling price per unit of such Product);

(e) other deductions from gross sales made in arriving at net sales as reported in the Licensee statutory accounts; and

(f) allowance for transportation costs, distribution expenses, special packaging and related insurance charges in the amount of [...***...]( [...***...]) of the Net Sales calculated after applying the deductions of items (a)-(e) above.

Net Sales shall be calculated using Licensee’s internal audited systems used to report such sales as adjusted for any of items (a)-(f) above not taken into account in such systems. Notwithstanding the foregoing, if Product is sold as a Combination Product, the Net Sales used for the calculation of the royalties under Section 8.1 (Royalties) shall be determined as follows:

\[
\frac{A}{A+B} \times \text{Net Sales of the Combination Product, where:}
\]

\[
A = \text{Standard Sales Price of the ready-for-sale form of the Product if sold separately from the Combination Product in question, in the Territory.}
\]

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B = Standard Sales Price of the ready-for-sale form of a product containing the same amount of the other therapeutically active ingredient(s) that is contained in the Combination Product in question, in the Territory.

If (a) the other therapeutically active ingredient(s) in such Combination Product are not sold separately in the Territory, Net Sales shall be adjusted by multiplying actual Net Sales of such Combination Product by the fraction A/C, where C is the Standard Sales Price in the Territory of such Combination Product, and (b) if a Product contained in the Combination Product is not sold separately, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction (C-B)/C, where B is the Standard Sales Price in the Territory of the other therapeutically active ingredient(s) in the Combination Product and C is the Standard Sales Price in the Territory of the Combination Product. If both a Product in a Combination Product and a product containing the other active ingredients in such Combination Product are not sold separately, a market price for such Product and such other active ingredients shall be negotiated by the Parties in good faith based upon the market price of products that are comparable to such Product or such other active ingredients, as applicable. If the Product in the Combination Product is marketed in the Territory, the Standard Sales Price of the Product in such Combination Product for purposes of calculating the royalty payable to POZEN will be no less than [...***...] ([… ***…]) of the Standard Sales Price of the Product sold outside of such Combination Product in the Territory.

In addition, and notwithstanding the foregoing, if a Product is sold together with other goods with or without a separate price for such Product (such group of products including the Product a “Product Set”), then the Net Sales applicable to the quantity of such Product included in any such transaction will be calculated as follows:

\[
\frac{A}{A+B} \times \text{Net Sales of the Product Set, where:}
\]

A = Standard Sales Price of the Product if sold separately from the Product set in question, in the Territory.

B = The total of the Standard Sales Prices of all products in the Product Set other than the Product, in the Territory.

1.54 “Nexium” means AstraZeneca AB’s and its Affiliates’ products containing Esomeprazole as the sole active ingredient in any presentation form.

1.55 “Nexium Business” means AstraZeneca AB’s and its Affiliates’ development and commercialization activities pertaining to Esomeprazole and Esomeprazole based products.

1.56 “NSAID” means any non-steroidal anti-inflammatory drug, the primary mechanism of action of which is inhibition of cyclooxygenase, but excluding acetyl salicylic acid (including salts and derivatives thereof).

1.57 “Original Agreement” has the meaning set forth in the recitals.

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1.58 “Patent Challenge” has the meaning set forth in Section 9.9.

1.59 “Patents” means (a) all patents and patent applications in any country or supranational jurisdiction, and (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patents or patent applications.

1.60 “Post-Approval Failure” means: (a) a mandatory withdrawal or recall of a Product by a Regulatory Authority, or (b) any voluntary withdrawal or recall of a Product that arises from risks associated with a serious adverse health consequence or death reported to a Regulatory Authority anywhere in the world. Notwithstanding the foregoing, any such recall that results primarily from Licensee’s or its Affiliate’s or Sublicensee’s gross negligence, willful misconduct, or failure to comply with Applicable Law in the Development, Manufacture or Commercialization of a Product in the Territory shall not be considered a Post-Approval Failure for purposes of this Agreement.

1.61 “POZEN House Marks” means any trademarks, trade names, domain names, or other names or marks used or registered by POZEN or its Affiliates at any time during the Term to identify itself.

1.62 “POZEN Invention” means any Invention that is conceived solely by one or more employees, agents, or independent contractors of POZEN or its Affiliate(s).

1.63 “POZEN Product” means any product that combines a Gastroprotective Agent and any NSAID in a single fixed combination dosage form, that would, if made, used, sold, offered for sale, had made, imported or exported in the Territory without a license from POZEN of the Licensed Patents, infringe one or more Valid Claims of the Licensed Patents.

1.64 “Product” means: (a) any POZEN Product, and (b) any other product that combines a Gastroprotective Agent and any NSAID in a single fixed combination oral solid dosage form (with or without one or more additional therapeutically active agents), which product is developed or commercialized by or for, invented or acquired by, or comes under the Control of Licensee or its Affiliates during the Term, but in each case excluding Duexis. For the avoidance of doubt, “Product” does not include any product containing acetyl salicylic acid (including salts and derivatives thereof).

1.65 “Product Labeling” means (a) the full prescribing information for a POZEN Product approved by the applicable Regulatory Authority in the Territory, and (b) all labels and other written, printed or graphic information included in or placed upon any container, wrapper or package insert used with or for the POZEN Product in the Territory.

1.66 “Product Trademarks” means (a) the VIMOVO Trademarks and (b) any other trademarks, trade dress (including packaging design), logos, slogans, domain names and designs, whether or not registered in a country or territory, selected by Licensee and used to identify or promote a POZEN Product, but excluding any POZEN House Marks and Licensee House Marks.
1.67 “Promotional Materials” means all sales representative training materials and all written, printed, graphic, electronic, audio or video presentations of information, including, without limitation, journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct-to-consumer advertising, internet postings, broadcast advertisements and sales reminder aides (for example, note pads, pens and other such items) intended for use or used by Licensee or its Affiliates in connection with any promotion of the Initial POZEN Product hereunder in the Territory, but excluding Product Labeling.

1.68 “PT” means Licensee’s product team operating pursuant to Licensee’s instructions for product teams for the Initial POZEN Product in the Territory with representatives of Licensee having expertise in the areas of research & development, marketing, regulatory, intellectual property, finance, toxicology, and other areas.

1.69 “PT Chair” will have the meaning set forth in Section 2.2.1 (PT).

1.70 “Regulatory Authority” means, in a particular country or jurisdiction, any applicable government regulatory authorities involved in granting approval to market or sell a Product, including any pricing and reimbursement approvals, in such country or jurisdiction, including, (a) in the United States, the FDA, and any successor government authority having substantially the same function, (b) any non-United States equivalent thereof, and (c) in the EU, the European Medicines Agency, or any successor agency thereto, and any national regulatory authority in any EU country.

1.71 “Regulatory Materials” means regulatory applications, submissions, notifications, registrations, Marketing Approvals or other submissions made to or with a Regulatory Authority that are necessary or reasonably desirable in order to develop, manufacture, market, sell or otherwise Commercialize the Initial POZEN Product in the Territory. Regulatory Materials include, without limitation, INDs and NDAs, and amendments and supplements for any of the foregoing, and applications for pricing and reimbursement approvals.

1.72 “ROW Agreement” has the meaning set forth in the recitals.

1.73 “ROW Party” has the meaning set forth in Section 7.4(b).

1.74 “Royalty Term” has the meaning set forth in Section 8.1.2 (Royalty Term).

1.75 “Standard Sales Price” means, as reported by IMS (or ACNielsen in the case of over-the-counter products) in the Territory, the average sales price for the preceding Calendar Quarter for the Product or, in the case of a Combination Product, the average sales price for the applicable presentation and dosage strength of all marketed brands of the other therapeutically active ingredient(s). As used herein, “presentation” means the method of administration of a pharmaceutical substance into the human body, including, but not limited to, solid oral (including tablets, capsules, gelcaps, sachets and caplets), other oral (including suspension and solution), parenteral (including intramuscular, subcutaneous and intravenous), transdermal, suppository and intranasal.
1.76  “Sublicense Agreement” means any agreement under which Licensee grants a Third Party a sublicense, option or other right under the Licensed Technology to make, use, have made, sell, offer for sale, import and export Products in the Field of Use in the Territory.

1.77  “Sublicensee” means any Third Party that has entered into a Sublicense Agreement.

1.78  “Term” has the meaning assigned to it in Section 12.2 (Term).

1.79  “Territory” means the United States.

1.80  “Third Party” means any entity other than POZEN, Licensee, or any of their respective Affiliates.

1.81  “Third Party Royalties” means upfront, commercialization milestone, royalty and any other similar payments paid by Licensee or any Licensee Affiliate or Sublicensee to any Third Party in consideration for a license to a Blocking Patent for the Development or Commercialization of POZEN Products in the Territory.

1.82  “Three-Party Agreement” means that certain letter agreement of even date herewith by and among AstraZeneca AB, POZEN and Horizon.

1.83  “Vimovo Trademarks” means the trademark VIMOVO and the other trademarks and logos listed on Schedule 1.83 and any variations thereof.

1.84  “U.S.” or “United States” means the United States of America and its possessions and territories.

1.85  “Valid Claim” means any claim of any issued and unexpired patent or a patent application that has not been disclaimed or held invalid or unenforceable by judgment or decree entered in any judicial proceeding that is not further reviewable through the exhaustion of all permissible applications for rehearing or review by a superior tribunal, or through the expiration of the time permitted for such applications; provided, that any claim in a pending Patent application that does not issue as a patent claim within [...***...] ([…***…]) years after the earliest priority date of such application will not be a “Valid Claim” until such claim issues as a patent claim.

2.  COLLABORATION GOVERNANCE.

2.1  Establishment.

2.1.1  Product Team. Within twenty (20) days after the Amended and Restated Effective Date, the Parties will appoint representatives to the PT in accordance with the terms of this Section 2.1 and convene the first PT meeting. The PT will coordinate and oversee the Commercialization of the Initial POZEN Product hereunder. The purposes of the PT will be, with respect to the Initial POZEN Product only, to develop Licensee’s marketing plans for the Initial POZEN Product in the Territory. The PT will have the membership and will operate by the procedures set forth in Section 2.2 (Membership and Procedures).
2.1.2 Joint Steering Committee

Promptly following the Amended and Restated Effective Date, the Parties will create a joint steering committee (the “JSC”) to provide strategic guidance to the PT in decisions pertaining to the Initial POZEN Product in the Territory. The purposes of the JSC will be to resolve disputes of the PT. The JSC will have the membership and will operate by the procedures set forth in Section 2.2 (Membership and Procedures).

2.2 Membership and Procedures.

2.2.1 PT.

(a) Membership. In addition to members designated by Licensee, the PT shall have up to three (3) representatives designated by POZEN, attending, observing and participating in meetings of the PT at POZEN’s expense, such representatives having the relevant experience and skill appropriate for service on such team. Attendance of POZEN representatives at PT meetings shall be agenda-driven, as determined in the sole discretion of Licensee. Licensee shall be entitled to have as many representatives serve as members of the PT as it desires. POZEN may replace its representatives on the PT at any time upon written notice to Licensee. Licensee shall provide POZEN with office space at its facilities for such representatives to facilitate such participation; provided, that such representatives shall comply with all policies and reasonable restrictions imposed by Licensee and provided to POZEN in writing. Upon prior written consent of Licensee, which consent will not be unreasonably withheld, a reasonable number of employees, consultants, representatives or advisors of POZEN who are not POZEN’s PT representatives may attend PT meetings as observers; provided, that such persons shall comply with all policies and reasonable restrictions imposed by Licensee and provided to POZEN in writing.

(b) Chairpersons. The product director designated by Licensee for the Initial POZEN Product will chair the PT (“PT Chair”).

(c) Meetings. The PT will hold meetings when called by the PT Chair. Meetings may be held in person or by means of telecommunication (telephone, video, or web conference). Face-to-face PT meetings that require POZEN attendance will be convened on an as-needed basis as mutually agreed by Licensee and POZEN, but in any event, at least twice per annum. The location of these meetings, will be based on business requirements and determined by mutual agreement between Licensee and POZEN. Following any PT meeting, the PT Chair will be responsible for preparing and issuing minutes of such meeting within fifteen (15) Business Days thereafter. When POZEN has participated in the meeting, such minutes will not be finalized until a representative of the PT designated by each Party has reviewed and confirmed the accuracy of such minutes in writing. If a disagreement regarding the accuracy of such minutes cannot be resolved, the minutes will reflect such disagreement.

2.2.2 JSC.

(a) Membership. Each Party will designate an equal number of representatives, but in no event less than three (3) each, with appropriate expertise to serve as
members of the JSC. Each Party may replace its representatives on the JSC at any time upon written notice to the other Party.

(b) Co-Chairpersons. One of each Party’s representatives to the JSC will be designated as a co-chairperson. The co-chairpersons will be responsible for calling meetings and preparing and circulating an agenda in advance of each meeting, and preparing minutes of each meeting.

(c) Meetings. The JSC will hold meetings at least once every Calendar Quarter, or more frequently as the Parties may agree with at least two meetings held in person annually. Subject to the preceding sentence, meetings may be held in person at locations to be determined by the mutual agreement of the Parties or by means of telecommunication (telephone, video, or web conferences). Following any JSC meeting, the co-chairpersons will be responsible for preparing and issuing minutes of each meeting within fifteen (15) Business Days thereafter. Such minutes will not be finalized until a representative of each Party has reviewed and confirmed the accuracy of such minutes in writing. If a disagreement regarding the accuracy of such minutes cannot be resolved, the minutes will reflect such disagreement.

2.2.3 Limitations of Powers. The PT and JSC will have only such powers as are specifically delegated to them hereunder and will not be a substitute for the rights of the Parties. Without limiting the generality of the foregoing, the PT and JSC will not have any power to amend this Agreement. Any amendment to the terms and conditions of this Agreement may only be implemented pursuant to Section 15.6 (Entire Agreement; Modifications) below.

2.2.4 Expenses. Each Party will be responsible for all of its own expenses of participating in the PT and JSC.

2.3 Decision-Making.

2.3.1 PT Decisions. Subject to the terms of this Section 2.3 (Decision-Making), the PT will act by decision of the PT Chair. If a POZEN representative objects to any decision, then such dispute will be referred to the JSC.

2.3.2 JSC Decisions. Subject to the terms of this Section 2.3 (Decision-Making), the JSC will take action by unanimous vote with each Party having a single vote, irrespective of the number of representatives actually in attendance at a meeting, or by a written resolution signed by the designated representatives of each of the Parties. If the JSC fails to reach unanimous consent on a particular matter within [...] ( [... ] ) Business Days of POZEN having requested a formal vote on such matter (or any earlier period mutually agreed to by the Parties if a delay may reasonably be anticipated to have an adverse effect on the Commercialization of the Initial POZEN Product in the Territory), then such dispute will be subject to the resolution procedures described in Section 2.3.3 (Dispute Resolution) below.

2.3.3 Dispute Resolution. In the event of any dispute in the JSC that is not resolved pursuant to the terms of Section 2.3.2 (JSC Decisions), either Party may provide written notice of such failure (a “Notice of Disagreement”) to the Chief Executive Officer of the other Party (or his or her designee). The Chief Executive Officers or designees of each of the Parties will meet at least once in person or by means of live telecommunication (telephone, video, or ***Confidential Treatment Requested***

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web conferences) to discuss the matter on which the JSC failed to reach unanimous consent and use their good faith efforts to resolve the matter within [...***...][…***…]) Business Days after receipt of the Notice of Disagreement by the applicable Chief Executive Officer of a Party. If any such disagreement is not resolved by the Chief Executive Officers or designees within such [...***…][…***…]) Business Day period, then the Chief Executive Officer or designee of Licensee will have the final decision-making authority with respect to disagreement relating to any and all matters.

2.3.4 Limitation. Notwithstanding this Section 2.3 (Decision-Making), any dispute regarding the interpretation of this Agreement, the performance or alleged nonperformance of a Party’s obligations under this Agreement, or any alleged breach of this Agreement will be resolved in accordance with the terms of Section 15.4 (Governing Law; Dispute Resolution).

2.4 Operating Principles. Promptly after the Amended and Restated Effective Date, the Parties will agree in writing on operating principles to guide the conduct of the PT and JSC. To the extent there is any conflict between such operating principles and the terms and conditions of the Agreement, then the Agreement will control.

3. [INTENTIONALLY OMITTED]

4. REGULATORY MATTERS.

4.1 Responsibilities. Licensee shall have the sole right at its own expense to (a) seek any Marketing Approval for Products in the Territory, including Marketing Approval for claims not obtained in the initial NDA Approval for the Initial POZEN Product, and (b) prepare or make any filings or submissions to, or otherwise communicate with, any Regulatory Authority in the Territory regarding Products. For clarity, Licensee shall own all Marketing Approvals and Regulatory Materials pertaining to Products in the Territory. Without limiting the foregoing, as owner of the NDA Approval for the Initial POZEN Product, Licensee will be the sole owner of all data exclusivity protection related to the Initial POZEN Product in the Territory as provided by Applicable Law.

4.2 Access to Filings. Licensee and its Affiliates will have the right of cross-reference to all NDAs or other filings made by or on behalf of POZEN for the purpose of prosecuting Marketing Approval applications for Products in the Territory, and POZEN and its Affiliates will, or will use reasonable efforts to cause their licensees to, take all such reasonable actions to allow such cross-reference.

4.3 Interactions with Regulatory Authorities.

4.3.1 Consultation. Each Party will consult with the other Party regarding (and provide copies of materials prior to any submission to a Regulatory Authority and materials after receipt from a Regulatory Authority), and keep such other Party reasonably and regularly informed of, the status of the preparation of all Regulatory Materials in the Territory, review of such materials by the relevant Regulatory Authority in the Territory, and Marketing Approvals received for the Initial POZEN Product in the Territory.

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4.3.2 **Communications.** Except as may be required by Applicable Law, only Licensee will communicate regarding POZEN Products, including the Initial POZEN Product, with any Regulatory Authority in the Territory. If POZEN is required to make such a communication by a Regulatory Authority, then POZEN will [...***...].

4.4 **Exchange of Know-How; Information Sharing.** As of the Amended and Restated Effective Date, each Party has provided to the other Party copies of all Know-How in its possession relating to the Initial POZEN Product, including, without limitation, procedures, formulations, manufacturing reports, pre-clinical and clinical protocols and data, regulatory filings, and toxicology reports with respect to the Initial POZEN Product, including any final versions of any study reports and any drafts outstanding of any study reports, all to the extent reasonably required for a Party to perform its obligations under this Agreement. Each Party will provide to the other Party copies of any Know-How that comes into its possession on or after the Amended and Restated Effective relating to the Initial POZEN Product, including, without limitation, procedures, formulations, manufacturing reports, pre-clinical and clinical protocols and data, regulatory filings, and toxicology reports with respect to the Initial POZEN Product, including any final versions of any study reports and any drafts then-outstanding of any study reports, all to the extent reasonably required for a Party to perform its obligations under this Agreement. In addition, each Party will provide the other Party, in a timely manner, with copies of, and all information received by it pertaining to, notices, questions, actions and requests from or by Regulatory Authorities with respect to the Initial POZEN Product in the Territory, or the testing, Manufacture, packaging, distribution or facilities in relation thereto, including any notices of non-compliance with laws in connection with the Initial POZEN Product (e.g., warning letters or other notices of alleged non-compliance), audit notices, notices of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the Initial POZEN Product (or its manufacture, distribution, or facilities connected thereto), notice of violation letters (i.e., an untitled letter), warning letters, service of process or other inquiries. Except as otherwise set forth in this Agreement or to comply with Applicable Law, [...***...].

4.5 **Regulatory Audits.** If a Regulatory Authority in the Territory desires to conduct an inspection or audit of a Party's facility, or a facility under contract with a Party, with regard to a POZEN Product, then such Party will promptly notify the other Party and permit and cooperate with such inspection or audit, and will cause the contract facility to permit and cooperate with such Regulatory Authority and such other Party during such inspection or audit. Licensee will have the right upon request (which request shall not be unreasonably withheld) to have a representative observe such inspection or audit with respect to a POZEN facility, or a facility under contract with POZEN. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which the audited Party will immediately provide to the other Party), the audited Party will prepare the response to any such observations, and will provide a copy of such response to the other Party. The audited Party agrees to conform its activities under this Agreement to any commitments made in such a response, except to the extent it believes in good faith that such commitments violate Applicable Laws.

4.6 **Adverse Event Reporting.**

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4.6.1 Licensee will maintain and will be the recognized holder of the safety database for AE and SAE reports related to POZEN Products in the Territory. Direct access to this database will not be granted to POZEN. Upon request, all reasonable assistance will be provided by either Party in responding to safety inquiries in the Territory.

4.6.2 Each Party shall keep the other Party informed of notification of any action by, or notification or other information which it receives (directly or indirectly) from any Regulatory Authority in the Territory which: (i) raises any material concerns regarding the safety or efficacy of the Initial POZEN Product; (ii) indicates or suggests a potential material liability for either Party to Third Parties in connection with the Initial POZEN Product; (iii) is reasonably likely to lead to a “Dear Doctor” letter, recall or market withdrawal of the Initial POZEN Product; (iv) relates to the Initial POZEN Product, Regulatory Materials, Promotional Materials, samples, package inserts, the indications, labeling, expedited and periodic Adverse Event Reports, medical inquiries, Initial POZEN Product complaints, this Agreement, or (v) is otherwise important to the Development and/or Commercialization of the Initial POZEN Product.

4.7 Records and Reports. Each Party will retain all records required by Applicable Law to be maintained in connection with such Party’s performance of Development activities under this Agreement.

5. DEVELOPMENT AND COMMERCIALIZATION.

5.1 Development and Commercialization. As between the Parties, Licensee will be solely responsible for the Development and Commercialization of POZEN Products in the Territory during the Term.

5.2 Regulatory Obligations. Licensee will own and maintain all regulatory filings and Marketing Approvals in the Territory for POZEN Products, including all INDs and NDAs for the Initial POZEN Product. As between the Parties, but subject to [...***...], Licensee will be solely responsible for all activities in connection with maintaining Marketing Approvals required for the Commercialization and manufacture of POZEN Products in the Territory, including communicating and preparing and filing all reports (including Adverse Event reports) with the applicable Regulatory Authorities in the Territory.

5.3 Performance; Diligence. Licensee will use Diligent Efforts to Commercialize a POZEN Product in the Territory. The foregoing Diligent Efforts requirement will apply only to one POZEN Product in the Territory, irrespective of the number of POZEN Products Licensee elects to Develop and Commercialize, and Licensee may elect to fulfill its Diligent Efforts obligation in the Territory in respect to any POZEN Product of its choice in the exercise of its reasonable and good faith judgment. Licensee will have the right to Develop and Commercialize Products during the Term in the Territory, for so long as Licensee is using Diligent Efforts to Commercialize at least one POZEN Product in accordance with this Section 5.3, it being understood that the Parties intend for Licensee to focus its initial efforts on the Commercialization of the Initial POZEN Product in the Territory.

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5.4 **Threatened Removal.** In the event that any governmental authority threatens or initiates any action to remove any POZEN Product from the market in the Territory, Licensee will promptly notify POZEN of such communication. Any voluntary recall or withdrawal of any POZEN Product in the Territory will be at Licensee’s sole discretion and expense. Before Licensee initiates a recall or withdrawal in the Territory, the Parties will promptly and in good faith discuss the reasons therefor; provided, that such discussions do not delay the recall or withdrawal. In the event of any recall or withdrawal of any POZEN Product in the Territory, Licensee will implement any necessary action, with assistance from POZEN as reasonably requested by Licensee.

5.5 **Compliance.** Each Party will comply with all Applicable Laws relating to activities performed or to be performed by such Party (or its Affiliates or contractors) under or in relation to the Commercialization of the Initial POZEN Product in the Territory pursuant to this Agreement. Each Party represents, warrants and covenants to the other Party that as of the Effective Date and during the Term, such Party and its Affiliates have adequate policies and procedures in place: (i) to ensure their compliance with such laws; (ii) to bring any non-compliance therewith by any of the foregoing entities to its attention; and (iii) to promptly remedy any such non-compliance.

5.6 **Branding; Trademarks; Domain Names; Trade Dress; Logos.**

5.6.1 **Responsibilities.** As between the Parties, Licensee will select all Product Trademarks for use on or in connection with POZEN Products in the Territory, will be the sole owner of the Product Trademarks in the Territory and, except with respect to the Vimovo Trademarks, which are addressed in the last sentence of this Section 5.6.1, will be responsible for the filing, prosecution, maintenance and defense of all registrations of the Product Trademarks in the Territory, and will be responsible for the payment of any costs relating to filing, prosecution, maintenance and defense of the Product Trademarks in the Territory. The Parties acknowledge and agree that AstraZeneca AB (or its Affiliate) is the sole owner of any Vimovo Trademark that may be used by Licensee in connection with POZEN Products in the Territory pursuant to a separate agreement between Licensee and AstraZeneca AB, and that the filing, prosecution, maintenance and defense of all registrations of the Vimovo Trademarks in the Territory shall be governed by the terms of such separate agreement.

5.6.2 **Use.** Licensee will use the Product Trademarks in connection with the Commercialization of POZEN Products hereunder. The packaging, Promotional Materials and Product Labeling for POZEN Products will carry the POZEN House Marks only if and to the extent required by Applicable Law.

5.6.3 **Licensee Marks.** Licensee reserves all rights in the Licensee House Marks. POZEN acknowledges Licensee’s exclusive right, title and interest in and to such trademarks and acknowledges that nothing herein will be construed to accord to POZEN any rights in such trademarks. POZEN agrees not to use or file any application to register any trademark or trade name that is confusingly similar to any Product Trademarks or Licensee House Mark.
5.6.4 **POZEN Marks.** POZEN reserves all rights in the POZEN House Marks not expressly granted to Licensee in this Agreement. Licensee acknowledges POZEN’s exclusive right, title and interest in and to the POZEN House Marks and acknowledges that nothing herein will be construed to accord to Licensee any rights in such trademarks except as expressly provided herein. Licensee further acknowledges that its use of the POZEN House Marks will not create in Licensee any right, title or interest in such trademarks, and that all use of such trademarks and the goodwill generated thereby will inure solely to the benefit of POZEN. Licensee agrees not to use or file any application to register any trademark or trade name that is confusingly similar to any POZEN House Mark.

5.6.5 **Promotional Materials.** As between the Parties, Licensee will own all right, title and interest in and to any Promotional Materials created by or on behalf of Licensee (or its Affiliates) relating to POZEN Product in the Territory, but excluding the POZEN House Marks. The PT will approve a standard template for use of the POZEN House Marks in Promotional Materials, and Licensee will use the POZEN House Marks in accordance with approved template.

5.7 **Commercial Supply.** Licensee will be solely responsible, at its own expense, for the Manufacture and supply of Licensee’s entire requirements of supplies of POZEN Product for Commercialization in the Territory.

6. [INTENTIONALLY OMITTED].

7. **LICENSES.**

7.1 **Licensed Technology.** Subject to the terms and conditions of this Agreement, POZEN hereby grants to Licensee an exclusive (including with regard to POZEN and its Affiliates), royalty-bearing license, with the right to grant sublicenses as described in Section 7.3 (Sublicenses), under the Licensed Technology to make, use, have made, sell, offer for sale, import and export Products in the Field of Use in the Territory. For the avoidance of doubt, Licensee shall have no license or other right under the Licensed Technology to make, use, have made, sell, offer for sale, import, and export any product containing acetyl salicylic acid (including salts and derivatives thereof).

7.2 **Trademarks.** Subject to the terms and conditions set forth in this Agreement, POZEN hereby grants to Licensee a license to use the POZEN House Marks in connection with the Commercialization of POZEN Products in the Field of Use in the Territory.

7.3 **Sublicenses.** Licensee may grant a sublicense, option to sublicense, or any other right relating to any Licensed Technology to any of its Affiliates without the right to grant further sublicense rights to any Third Party. Licensee may grant a sublicense, option to sublicense, or any other right relating to any Licensed Technology to any Third Party solely as provided in this Section 7.3 (Sublicenses). Licensee may enter into Sublicense Agreements only with POZEN’s prior consent. In order for rights under Licensed Technology to be validly granted to a Sublicensee, the Sublicense Agreement with such Sublicensee must be consistent with the following terms and conditions of this Agreement, and will include provisions for the benefit of POZEN corresponding to Section 11 (Confidentiality), 14 (Limitation of Liability), 8.2
7.4 Reservation of Rights; No Implied Licenses.

(a) POZEN retains rights under the Licensed Technology to the extent necessary to perform its obligations under this Agreement. Except for the rights specifically granted in this Agreement, POZEN reserves all rights to the Licensed Technology. No implied licenses are granted under this Agreement. In particular POZEN is not by this Agreement, by implication or otherwise, granted any license or other right relating to Esomeprazole, Nexium or the Nexium Business or any Esomeprazole based products or any products containing acetyl salicylic acid (including salts and derivatives thereof) or any right in relation to any patent, trademark or other intellectual property right belonging to Licensee or any of its Affiliates, and likewise Licensee is not by this Agreement, by implication or otherwise, granted any license or other right under the Licensed Technology relating to any products containing acetyl salicylic acid (including salts and derivatives thereof) or any right in relation to any patent, trademark or other intellectual property right belonging to POZEN or any of its Affiliates, in each case, except as expressly set forth in this Agreement.

(b) Licensee understands that POZEN has retained rights to the Products outside the Territory and has licensed such rights to a Person under the ROW Agreement (the “ROW Party”).

7.5 Restrictive Covenant. Licensee hereby covenants and agrees not to use any Licensed Technology, nor grant any Third Party any license or right under any Licensed Technology, other than as expressly permitted in this Agreement. The Parties agree that nothing in this Agreement restricts or prohibits Licensee from by itself or with Third Parties exploiting any products, including without limitation any products containing non-steroidal anti-inflammatory drugs (e.g., acetyl salicylic acid and esters and derivatives thereof); provided, that Licensee shall not use or practice Licensed Technology in connection with the development, manufacture or commercialization of any product that is not a Product, and nothing requires Licensee to compensate POZEN if Licensee so exploits such products.

8. FINANCIAL TERMS.

8.1 Royalties.
8.1.1 **Royalty Rate.** Subject to the terms and conditions of this Agreement, Licensee will pay to POZEN royalties based on the aggregate annual Net Sales of Products sold by Licensee, its Affiliates or Sublicensees, at the rate of 10% of aggregate Net Sales of Products sold in the Territory.

8.1.2 **Royalty Term.** Licensee acknowledges that it will continue to enjoy substantial benefit from its license under, and the transfer to Licensee of certain elements of, the Licensed Technology pursuant to this Agreement (including the Licensed Know-How and the regulatory data to be provided to Licensee pursuant to this Agreement) as well as from Licensee’s own development of technology derived from the practice of such license and Licensee’s use of such Licensed Technology, even after expiration of all Valid Claims of the Licensed Patents covering the composition of matter, manufacture, use or sale of POZEN Product in the Territory. Accordingly, subject to the terms of Section 8.1.3 (Rate Step Down for Competing Product Entrants), Licensee’s royalty payment obligations under this Section 8.1 (Royalties) will commence upon First Commercial Sale of a Product in the Territory and will expire upon the later of: (i) expiration of the last-to-expire Valid Claim of the Licensed Patents that, but for the licenses granted in this Agreement, would be infringed by the sale of such Product in the Territory, and (ii) ten (10) years after the First Commercial Sale of such Product in the Territory (such period ending at the later of the periods set forth in clause (i) and (ii) above, the “Royalty Term”).

8.1.3 **Rate Step Down For Competing Product Entrants.** With respect to any particular Product in the Territory, if in any Calendar Quarter there is a Market Reduction of such Product (based on prescription market data published by IMS Health, Scott-Levin, or such other industry standard source as the Parties may agree), then the royalty rates which would otherwise apply to Net Sales of such Product during such Calendar Quarter will be reduced to [***...***] percent ([***...***]%). Such reduced royalty rates will continue in effect, on a Product-by-Product basis, until expiration of the applicable Royalty Term. As used in this Section 8.1.3, the term “Market Reduction” of a Product in a Calendar Quarter occurs when (i) the cumulative share achieved by Competing Products for such Product commercialized by Third Parties in such [***...***] of the [***...***] in the Territory of the Product and Competing Products and (ii) the sales of the Product(s) in such [***...***] are reduced by [***...***] to the [***...***] in which the [***...***] of a Competing Product occurred. The example set forth in Schedule 8.1.3 illustrates the application of this Section 8.1.3.

8.1.4 **Third Party Payments.** If Licensee or a Sublicensee determines that a license to certain Third Party technology is reasonably necessary for the successful Development, Manufacture or Commercialization of a Product in the Territory, then Licensee will notify POZEN in writing of such determination. The Parties will consult in good faith regarding the need for such Third Party technology and, subject to POZEN’s consent (not to be unreasonably withheld, conditioned or delayed), Licensee (or Sublicensee, if applicable) will negotiate the terms on which such a Third Party license would be granted to Licensee and will serve as the primary point of contact with the applicable Third Party licensor following the execution of the license agreement. The royalties required to be paid by Licensee with respect to a Product pursuant to Section 8.1 (Royalties) shall be subject to a reduction by Licensee in an

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amount equal to [***] ([***]%) of the amount of [***] that are [***] under such [***] in the [***] for the [***] of such [***] during the [***]; provided, that (i) [***] of the [***] of such [***] pursuant to [***] for such [***], and (ii) if such [***] is a [***] (i.e., [***] for such [***]). For clarity, and notwithstanding anything to the contrary in this Agreement, AstraZeneca AB and its Affiliates shall be solely responsible for any Third Party payment obligations it may have to Merck & Co., Inc. or its affiliates, without any offset or deduction. Any amount of Third Party Royalties that may, pursuant to the preceding paragraph be used to reduce royalties due hereunder, in any Calendar Quarter, but are not so used as a result of the limitation described in clause (i) of this paragraph may be carried over and used for further reduction in any succeeding royalty payment due for such Product.

8.1.5 [***].

8.2 Payments and Sales Reporting

8.2.1 Sales Reporting. Licensee will provide POZEN, within [***] ([***]) of the end of each Calendar Quarter, with a report setting forth, on a Product-by-Product basis, the amount of gross sales of each Product in the Territory, a calculation of Net Sales and a calculation of the amount of royalty payment due on such Net Sales, provided that Licensee shall use reasonable efforts to provide such report as soon as practicable to accommodate POZEN's SEC filing requirements and to provide such reports in a shorter time period than the periods specified above if Licensee has such reports available for its own internal purposes. If any payment reduction is claimed by Licensee under this Agreement from the full royalty rates set forth in Section 8.1 (Royalties), then the report will set forth in detail the claimed reduction and the related facts.

8.2.2 Payment Timing. Licensee will make royalty payments to POZEN within [***] ([***]) days of the last day of each Calendar Quarter for which such payments are due under Section 8.1 (Royalties).

8.2.3 Payment Method. All amounts due hereunder will be paid in United States Dollars by wire transfer in immediately available funds to the following account, or such other account as may be designated in writing by POZEN:

Receiving bank name: [***]
Receiving bank address: [***]
ABA routing number (1): [***] (1) - required for domestic transfers
SWIFT BIC address (2): [***] (2) - required for international transfers
For credit to the account of: POZEN Inc.

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8.2.4 **Currency.** All payments required under this Article 8 shall be made in U.S. Dollars.

8.2.5 **Late Payments.** If a Party does not receive payment of any sum due to it on or before the due date, simple interest will thereafter accrue on the sum due to such Party until the date of payment at the per annum rate of [...] percent ([... ***...%]) over the then-current [...] quoted by Citibank in New York City, or the maximum rate allowable by Applicable Law, whichever is lower.

8.3 **Records; Audit.** Licensee will maintain complete and accurate records in sufficient detail to permit POZEN to confirm the accuracy of the calculation of payments under this Agreement. Upon reasonable prior notice, such records will be available during regular business hours of Licensee for a period of [...] ([... ***...]) calendar years following the year in which such records were created, for examination at POZEN’s expense, and not more often than once each calendar year, by an independent certified public accountant selected by POZEN and reasonably acceptable to Licensee, for the sole purpose of verifying the accuracy of the financial reports furnished by Licensee pursuant to this Agreement. Any such auditor will not disclose Licensee’s Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Licensee or the amount of payments due by Licensee under this Agreement. Any amounts shown to be owed but unpaid will be paid within [...] ([... ***...]) days from the accountant’s report, plus interest (as set forth in Section 8.2.5 (Late Payments)) from the original due date. Any amounts determined to be overpaid will be refunded within [...] ([... ***...]) days from the accountant’s report. POZEN will bear the full cost of such audit unless such audit discloses an underpayment of the amount actually owed during the applicable calendar year of more than [...] percent ([... ***...%]), in which case Licensee will bear the full cost of such audit.

8.4 **Taxes.**

8.4.1 **General.** The royalties, milestones and other amounts payable by one Party to the other Party pursuant to this Agreement or the Three-Party Agreement (“Payments”) shall not be reduced on account of any taxes unless required by Applicable Law. The Party receiving any Payment shall be responsible for paying any and all taxes (other than withholding taxes or deduction of tax at source required by Applicable Law to be paid by the paying Party) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The paying Party shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if the Party receiving payment is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to the paying Party or the appropriate governmental authority (with the assistance of the paying Party to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding tax or to relieve the paying Party of its obligation to withhold tax, and the paying Party shall apply the reduced rate of withholding tax, or dispense with withholding tax, as the case may be, provided that the paying Party has received evidence, in a form satisfactory to the paying Party, of the other Party’s delivery of all applicable forms (and, if necessary, its receipt of

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appropriate governmental authorization) at least [...] ([...]) days prior to the time that the Payments are due. If, in accordance with the foregoing, the paying Party withholds any amount, it shall pay to the other Party the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to the other Party proof of such payment within [...] ([...]) days following that payment.

8.4.2 Indirect Taxes. Notwithstanding anything contained in Section 8.4.1 (General), this Section 8.4.2 (Indirect Taxes) shall apply with respect to Indirect Taxes. All Payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any Payments, the paying Party shall pay the Indirect Taxes at the applicable rate in respect of any such Payments following the receipt of an Indirect Taxes invoice in the appropriate form issued by the Party receiving Payments in respect of those Payments, such Indirect Taxes to be payable on the due date of the payment of the Payments to which such Indirect Taxes relate.

9. INTELLECTUAL PROPERTY.

9.1 Prosecution and Maintenance of Licensed Patents. POZEN will be responsible for the preparation, filing, prosecution and maintenance of the Licensed Patents (other than Joint Patents), at its own expense. POZEN will provide a copy of all proposed filings at least [...] ([...]) days in advance of the filing date and will consider in good faith the requests and suggestions of Licensee with respect to filing and prosecuting the Licensed Patents and will keep Licensee promptly informed of progress with regard to the preparation, filing, prosecution and maintenance of Licensed Patents. In the event that POZEN desires to abandon any Licensed Patent, POZEN will provide reasonable prior written notice to Licensee of such intention to abandon (which notice will, in any event, be given no later than [...] ([...]) days prior to the next deadline for any action that may be taken with respect to such Licensed Patent with the U.S. Patent & Trademark Office), and Licensee will have the right to assume responsibility for such Licensed Patent. For clarity, any Patent with Valid Claims solely directed to any product containing acetyl salicylic acid (including salts and derivatives thereof) is not a Licensed Patent; therefore, Licensee will have no right to assume responsibility for such Patent as provided under this Section 9.1 should Pozen decide to abandon such Patent.

9.2 Prosecution and Maintenance of Joint Patents. Licensee will be responsible for the preparation, filing, prosecution and maintenance of Joint Patents, at its own expense. Licensee will provide to POZEN a copy of all proposed filings at least [...] ([...]) days in advance of the filing date and will consider in good faith the requests and suggestions of POZEN with respect to filing and prosecuting the Joint Patents and will keep POZEN promptly informed of progress with regard to the preparation, filing, prosecution and maintenance of Joint Patents. In the event that Licensee desires to abandon any Joint Patent, Licensee will provide reasonable prior written notice to POZEN of such intention to abandon (which notice will, in any event, be given no later than [...] ([...]) days prior to the next deadline for any action that may be taken with respect to such Joint Patent with the U.S. Patent & Trademark Office), and POZEN will have the right to assume responsibility for such Joint Patent.

9.3 Ownership of Inventions. Inventorship of Inventions will be determined in accordance with the rules of inventorship under United States patent laws. Subject to the licenses granted under this Agreement, as between the Parties, Licensee will own all Licensee

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Inventions, POZEN will own all POZEN Inventions, and Joint Inventions will be owned jointly by Licensee and POZEN; provided, however, that during the Term of this Agreement: (i) neither POZEN nor Licensee shall [...] other than as expressly provided in this Agreement, including Section 7.1 (Licensed Technology), without the consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, and (ii) neither Party shall assign, pledge, encumber, license or otherwise transfer any of its rights in any Joint Invention or Joint Patent without the other Party’s prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Upon any expiration or termination of this Agreement, each Party will have the right to exploit, license and grant rights to sublicense each such Joint Invention and Joint Patent, without any duty of accounting to the other Party, and each Party hereby consents, and agrees to consent, without payment of any further consideration or royalty, to the Joint Party’s exploitation and licensing of said Joint Party’s interest in such Joint Invention or Joint Patent to Third Parties; provided, that nothing in this Section 9.3 gives either Party any right or license under any intellectual property rights Controlled by the other Party other than Joint Inventions and Joint Patents, regardless of whether such rights are necessary in order to exploit the Joint Inventions and Joint Patents pursuant to this Section 9.3. The Parties acknowledge and agree that AstraZeneca AB owns all AstraZeneca Inventions (as defined in the Original Agreement) conceived under the Original Agreement in the performance of activities undertaken pursuant to the Original Agreement solely by employees, agents, or independent contractors of AstraZeneca AB, its Affiliates or sublicensees prior to the Amended and Restated Effective Date.

9.4 Disclosure. Each Party will promptly disclose to the other Party in writing, and will cause its Affiliates, agents, and independent contractors to so disclose to the other Party, the conception and reduction to practice of any Invention.

9.5 Cooperation. Each Party acknowledges the importance of securing and maintaining effective patent protection for the Licensed Technology and Joint Patents. Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of the Licensed Patents and Joint Patents and in the obtaining and maintenance of any patent extensions, supplementary protection certificates and the like with respect to the Licensed Patents and Joint Patents. Such cooperation includes, but is not limited to: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as to effectuate the ownership of Inventions set forth in Section 9.3 (Ownership of Inventions), and Patents in the Territory claiming or disclosing such Inventions, and to enable the other Party to apply for and to prosecute patent applications in the Territory; and (b) promptly informing the other Party of any matters coming to such Party’s attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

9.6 Enforcement of Licensed Patents.

9.6.1 Infringement by Third Parties. Licensee and POZEN will each, within [...] Business Days of learning of any alleged or threatened infringement of the Licensed Patents or Joint Patents, notify the other Party in writing. [...] will have the first right, but not the obligation, to prosecute any such infringement. If [...] does not commence an infringement action against the alleged or threatened infringement (i) within [...] days following the detection of the alleged infringement, or (ii) [...] days before the

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time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then […]***[…] will so notify […]***[…] promptly, and […]***[…] may commence litigation with respect to the alleged or threatened infringement at its own expense. For clarity, any Patent with Valid Claims solely directed to any product containing acetyl salicylic acid (including salts and derivatives thereof) is not a Licensed Patent; therefore, […]***[…] will have no right to prosecute any infringement of such Patent under this Section 9.6.1. Notwithstanding anything in this Section 9.6.1 to the contrary, […]***[…] shall not have the right to prosecute an infringement action under this Section 9.6.1 unless such action involves a Product.

9.6.2 Challenge by Third Parties. Licensee and POZEN will each notify the other Party in writing within […]***[…] ( […]***[…] ) Business Days of learning of any alleged or threatened opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability of the Licensed Patents or Joint Patents by a Third Party. […]***[…] will have the first right, but not the obligation, to defend any such challenge. If […]***[…] does not commence Diligent Efforts to defend against the alleged or threatened challenge (i) within […]***[…] ( […]***[…] ) days following the detection of the alleged challenge, or (ii) […]***[…] ( […]***[…] ) Business Days before the time limit, if any, set forth in appropriate laws and regulations for making a filing in defense of such a challenge, whichever comes first, then […]***[…] will so notify […]***[…] promptly, and […]***[…] may take action with respect to the alleged or threatened challenge at its own expense. For clarity, any Patent with Valid Claims solely directed to any product containing acetyl salicylic acid (including salts and derivatives thereof) is not a Licensed Patent; therefore, […]***[…] will have no right to defend any challenge of such Patent under this Section 9.6.2.

9.6.3 Cooperation. In the event a Party brings an infringement action pursuant to Section 9.6.1 (Infringement by Third Parties), the other Party will cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or to join such action as a necessary party, executing all papers and instruments, or requiring its employees or contractor, to execute such papers and instruments, so as to successfully prosecute any such actions. Neither Party will have the right to settle any patent infringement litigation under this Section 9.6.3 (Cooperation) in a manner that could be reasonably expected to diminish the rights or interest of the other Party, or adversely affect the validity or enforceability of such other Party’s Patents, without the express written consent of such other Party. The Party commencing the litigation will provide the other Party with copies of all pleadings and other documents filed with the court and will consider reasonable input from the other Party during the course of the proceedings.

9.6.4 Recovery. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such litigation described in Section 9.6.1 (Infringement by Third Parties) (whether by way of settlement or otherwise) will be first allocated to reimbursement of unreimbursed legal fees and all litigation expenses incurred by the Party initiating the proceeding, then toward reimbursement of any of unreimbursed legal fees and all litigation expenses of the other Party, and then the remainder will be divided between the Parties as follows: (a) settlements, damages or other monetary awards recovered pursuant to a suit, action or proceeding brought by […]***[…] will be […]***[…] and subject to […]***[…] set forth in […]***[…] ; and
9.7 Defense of Infringement Claims. If the manufacture, sale or use of a POZEN Product pursuant to this Agreement results in any claim, suit, or proceeding by a Third Party alleging that such activities infringe a Third Party patent, or if a Third Party threatens such a claim, suit or proceeding, each Party will promptly notify the other Party thereof. [...] will have the exclusive right to defend and control the defense of any such claim, suit or proceeding at its own expense, using counsel of its own choice; provided, that if any such proceedings involve matters relating to the validity or enforceability of the Licensed Patents or Joint Patents, then the provisions of Section 9.6.3 (Cooperation) above shall apply. In any claim, suit or proceeding under this Section 9.7, [...] will keep [...] reasonably informed of all material developments in connection with any such claim, suit, or proceeding; provided, that if [...] is named as a defendant in any such claim, suit or proceeding, that [...] shall have the right to participate in the defense using counsel of its choice at its own expense. In any claim, suit or proceeding under this Section 9.7, [...] agrees to provide [...] with copies of all pleadings filed in such action and to allow [...] reasonable opportunity to participate in the defense of the claims.

9.8 Patent Term Extension and Supplementary Protection Certificate. Upon receiving Marketing Approval for a POZEN Product, the Parties agree to coordinate the application for any patent term extension or supplementary protection certificates that may be available. The primary responsibility of applying for any extension or supplementary protection certificate will be the Party having the right to make the application under the Applicable Law. The Party responsible for filing the application will keep the other Party fully informed of its efforts to obtain such extension or supplementary protection certificate. Each Party will provide prompt and reasonable assistance, without additional compensation, to obtain such patent extension or supplementary protection certificate. The Party filing such request will pay all expenses in regard to obtaining the extension or supplementary protection certificate.

9.9 Consequence of Patent Challenge. If Licensee or its Affiliates challenge the validity or enforceability of any of the Licensed Patents by any opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof before any governmental agency, court or other similar adjudicative forum (any such proceeding, a “Patent Challenge”), such Patent Challenge shall give POZEN the right to terminate this Agreement as provided in Section 12.3 (Termination for Material Breach) or to terminate all licenses granted under any of the Licensed Patents subject to such Patent Challenge; provided, that the foregoing provisions of this Section 9.9 (Consequence of Patent Challenge) will not apply in the event that, prior to such Patent Challenge, POZEN or any of its licensees or assignees initiates or threatens litigation against, or makes claims or assertions against, Licensee or its Affiliates, Sublicensees or Third Party contractors, that allege that any of such parties infringe a Licensed Patent.

9.10 Patent Certifications.

9.10.1 Orange Book Listings. To the extent required or permitted by Applicable Law, Licensee will use Diligent Efforts to promptly list and maintain with the applicable

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9.10.2 Hatch-Waxman Act. Notwithstanding Section 9.6.1 (Infringement by Third Parties) above, each Party will immediately give notice to the other Party of any notice it receives of certification filed under the Hatch-Waxman Act claiming that any of the Licensed Patents is invalid, unenforceable or that any infringement will not arise from the manufacture, use or sale of the POZEN Product by a Third Party. If Licensee decides not to bring infringement proceedings against the entity making such a certification with respect to any such Licensed Patents, Licensee will give notice to POZEN of its decision not to bring suit within [...] of receipt of notice of such certification (or, if the time period permitted by law is less than [...] Business Days, within [...] Business Days after receipt of notice of such certification). POZEN may then, but is not required to, bring suit against the Third Party that filed the certification. Any suit by either Party may be in the name of either or both Parties, as may be required by law. For this purpose, the Party not bringing suit will execute such legal papers necessary for the prosecution of such suit as may be reasonably requested by the Party bringing suit. For clarity, any Patent with Valid Claims solely directed to any product containing acetyl salicylic acid (including salts and derivatives thereof) is not a Licensed Patent; therefore, Licensee will have no right to bring infringement proceedings of such Patent under this Section 9.10.2. Notwithstanding anything in this Section 9.10.2 to the contrary, Licensee shall not have the right to bring an infringement proceeding under this Section 9.10.2 unless such proceeding involves a POZEN Product.

9.11 Patent Marking. Any POZEN Product marketed and sold by Licensee under this Agreement will be marked with appropriate patent numbers or indicia as permitted or required by law. The Parties agree to cooperate to reach a decision on the marking requirements.

10. REPRESENTATIONS, WARRANTIES; COVENANTS.

10.1 POZEN Representations and Warranties. POZEN hereby warrants and represents to Licensee as of the Amended and Restated Execution Date and the Amended and Restated Effective Date that POZEN is the sole and exclusive owner of the Licensed Patents and has the right to perform its obligations hereunder and to grant to Licensee the rights and licenses set forth in this Agreement in and to the Licensed Technology.

10.2 Reciprocal Representations and Warranties. Each Party represents and warrants to the other Party that: (a) this Agreement is a legal and valid obligation binding upon its execution and enforceable against it in accordance with its terms and conditions; and (b) the...
execution, delivery and performance of this Agreement by such Party has been duly authorized by all necessary corporate action, and the person executing this Agreement on behalf of such Party has been duly authorized to do so by all requisite corporate actions.

10.3 DISCLAIMER OF WARRANTY. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES SET FORTH IN SECTIONS 10.1 (POZEN WARRANTIES) AND 10.2 (RECIPROCAL REPRESENTATIONS AND WARRANTIES), EACH PARTY MAKES NO REPRESENTATIONS AND GRANTS NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND POZEN AND LICENSEE EACH SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY OR MERCHANTABILITY, OR ANY WARRANTY AS TO THE VALIDITY OR ENFORCEABILITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

10.4 POZEN Non-Compete. POZEN covenants that it will not at any time prior to the expiration of the Royalty Term, and will ensure that its Affiliates do not, directly or indirectly, develop or commercialize or license any Third Party to develop or commercialize any product having a [...***...]. Without limiting Licensee’s rights under this Agreement or otherwise, in case of any breach of this 10.4 (POZEN Non-Compete), Licensee will notify POZEN and, if such breach is not cured by POZEN within [... ***…]([…***…]) days after receipt of such notice, […***…].

10.5 Other Covenants.

10.5.1 POZEN will not enter into any agreement, whether written or oral with respect to, or otherwise assign, transfer, license, convey or otherwise encumber its rights, title or interest in the Licensed Technology (including by granting any covenant not to sue with respect thereto) to any Person in a manner that is inconsistent with the rights and licenses granted to Licensee under this Agreement.

10.5.2 Each Party will obtain from each of its Affiliates, sublicensees, employees and agents and from the employees and agents of its Affiliates, sublicensees and agents who are or will be involved in the Development of the POZEN Products or of the Licensed Technology, rights to any and all inventions, information, and intellectual property rights conceived in the course of performance of this Agreement, necessary to enable such Party to grant the licenses and other rights granted to the other Party under this Agreement.

11. CONFIDENTIALITY.

11.1 Definition. “Confidential Information” means information, including scientific and manufacturing information and plans, marketing and business plans, and financial and personnel matters relating to a Party or its present or future products, sales, suppliers, customers, employees, investors or business, communicated by a Party (a “Disclosing Party”) to the other
11.2 Exclusions. Notwithstanding the foregoing, information of a Disclosing Party will not be deemed Confidential Information with respect to a Receiving Party for purposes of this Agreement to the extent the Receiving Party can demonstrate by competent evidence that such information:

11.2.1 was already known to the Receiving Party or its Affiliates, as evidenced by their written records, other than under an obligation of confidentiality or non-use, at the time of disclosure to the Receiving Party;

11.2.2 was generally available or was otherwise part of the public domain at the time of its disclosure to the Receiving Party;

11.2.3 became generally available or otherwise became part of the public domain after its disclosure to the Receiving Party, through no fault of or breach of its obligations under this Section 11 (Confidentiality) by the Receiving Party;

11.2.4 was disclosed to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the Party that controls such information and know-how not to disclose such information or know-how to others; or

11.2.5 was independently discovered or developed by the Receiving Party or its Affiliates, as evidenced by their written records, without the use of, and by personnel who had no access to, Confidential Information belonging to the Party that controls such information and know-how.

11.3 Disclosure and Use Restriction. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, the parties agree that, during the Term and for [...] years thereafter, the Receiving Party will keep confidential and will not publish or otherwise disclose and will not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the Disclosing Party. The Receiving Party may use such Confidential Information only to the extent required to accomplish the purposes of this Agreement or in connection with the exercise of its rights hereunder. The Receiving Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving

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Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information.

11.4 Authorized Disclosure. A Receiving Party may disclose Confidential Information of a Disclosing Party to the extent that such disclosure is:

11.4.1 made in response to a valid order of a court of competent jurisdiction or other governmental or regulatory body of competent jurisdiction; provided, however, that such Receiving Party will have given notice to the Disclosing Party within [...***...] ([…***…]) Business Days of receipt of such order and given the Disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or governmental or regulatory body or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order;

11.4.2 otherwise required by law; provided, that the Disclosing Party will provide the Receiving Party with notice of such disclosure at least [...***...] ([…***…]) days in advance thereof to the extent practicable and take reasonable steps as requested by the Disclosing Party to protect the Disclosing Party’s rights;

11.4.3 made by a Receiving Party, in connection with the performance of this Agreement, (a) to Affiliates, employees, consultants, representatives or agents, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Section 11 (Confidentiality) or (b) to Regulatory Authorities in the Territory (provided, that in the case of disclosures to Regulatory Authorities, the Receiving Party will, to the extent practicable, provide the Disclosing Party with notice of such disclosure at least [...***...] ([…***…]) days in advance thereof and will reasonably consider any comments received from the Disclosing Party);

11.4.4 made by a Receiving Party to existing or potential acquirers or merger candidates; potential sublicensees or collaborators (to the extent contemplated hereunder); investment bankers; existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing; or Affiliates, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Section 11 (Confidentiality); or

11.4.5 made by the Receiving Party with the prior written consent of the Disclosing Party.

11.5 Use of Name. Neither Party may make public use of the other Party’s name except (a) in connection with announcements and other disclosures relating to this Agreement and the activities contemplated hereby as permitted in Section 11.6 (Press Releases), (b) as required by Applicable Law, and (c) otherwise as agreed in writing by such other Party.

11.6 Press Releases.

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11.6.1 On or after the Amended and Restated Effective Date of this Agreement at a mutually agreed time, each Party (including, for clarity, Horizon as assignee of Licensee in connection with the Divestiture) will issue a mutually agreed press release announcing the existence of this Agreement each in the form and substance to be mutually agreed upon in advance. For subsequent press releases and other written public disclosures relating to this Agreement or the Parties’ relationship hereunder (each, a “Public Disclosure”), each Party will use reasonable efforts to submit to the other Party a draft of such Public Disclosures for review and comment by the other Party at least […***…] ([…***…]) Business Days prior to the date on which such Party plans to release such Public Disclosure, and in any event will submit such drafts at least […***…] prior to the release of such Public Disclosure, and will review and consider in good faith any comments provided in response.

11.6.2 If a Party is unable to comply with the foregoing […***…] notice requirement because of a legal obligation or stock exchange requirement to make more rapid disclosure, such Party will not be in breach of this Agreement but will in that case provide notice as promptly as practicable under the circumstances.

11.6.3 A Party may publicly disclose, without regard to the preceding requirements of this Section 11.6 (Press Releases), information that was previously disclosed in a Public Disclosure that was in compliance with such requirements.

11.7 Terms of Agreement to be Maintained in Confidence. The Parties agree that the terms of this Agreement are confidential and will not be disclosed by either Party to any Third Party (except to a Party’s professional advisors, including without limitation accountants, financial advisors, and attorneys) without prior written permission of the other Party; provided, however, that (a) either Party may make any filings of this Agreement required by law or regulation in any country so long as such Party uses its reasonable efforts to obtain confidential treatment for portions of this Agreement as available, consults with the other Party, and permits the other Party to participate, to the greatest extent practicable, in seeking a protective order or other confidential treatment; (b) either Party may disclose this Agreement on a confidential basis to existing or potential Third Party investors, lenders or acquirors or, in the case of Licensee, to existing or potential Sublicensees, in each case in connection with due diligence or similar investigations; and (c) a Party may publicly disclose, without regard to the preceding requirements of this Section 11.7, information that was previously disclosed in compliance with such requirements.

12. TERM AND TERMINATION.

12.1 Amended and Restated Effective Date. This Agreement (other than this Section 12.1, which is binding and effective as of the Amended and Restated Execution Date), shall not become effective unless and until the closing of a Divestiture occurs (the date of such closing, the “Amended and Restated Effective Date”), and upon the Amended and Restated Effective Date this Agreement and all of its terms and provisions shall be automatically effective and binding on both Parties. The Original Agreement shall not be amended and restated or otherwise superseded by this Agreement until the Amended and Restated Effective Date. If the Amended and Restated Effective Date has not occurred by December 31, 2013, then this Agreement, including this Section 12.1, shall terminate and be of no further force and effect. For

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12.2 Term. The term of this Agreement will commence as of the Effective Date and, unless earlier terminated in accordance with this Section 12 (Term and Termination), will expire upon the expiration of the Royalty Term for all POZEN Products in the Territory (the “Term”).

12.3 Termination for Material Breach. In the event that either Party (the “Breaching Party”) shall be in material default of any of its material obligations under this Agreement, in addition to any other right and remedy the other Party (the “Non-Breaching Party”) may have, the Non-Breaching Party may terminate this Agreement in its entirety by [...***...]( [...***...]) days prior written notice (the “Notice Period”) to the Breaching Party, specifying the breach and its claim of right to terminate; provided, that the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach complained about during the Notice Period (or, if such default cannot be cured within such Notice Period, if the Breaching Party commences actions to cure such default within the Notice Period and thereafter diligently continues such actions). It is understood that termination pursuant to this Section 12.3 (Termination for Material Breach) shall be a remedy of last resort and may be invoked only in the case where the breach cannot be reasonably remedied by the payment of money damages or other remedy under applicable law. If either Party initiates a dispute resolution procedure as permitted under this Agreement prior to the end of the Notice Period to resolve the dispute for which termination is being sought and is diligently pursuing such procedure, including any litigation following therefrom, the termination shall become effective only if and when such dispute is finally resolved through such dispute resolution procedure. This Section 12.3 (Termination for Material Breach) defines exclusively the Parties’ right to terminate in case of any material breach of this Agreement.

12.4 Termination for Cause. If a Post-Approval Failure occurs in the Territory, Licensee may, at its option, terminate the Agreement in its entirety; provided, that written notice of termination must be delivered to POZEN within [...***...]( [...***...]) days following such Post-Approval Failure.

12.5 Consequences of Expiration and Termination.

12.5.1 Effect of Expiration. Upon expiration (but not earlier termination) of the Term pursuant to Section 12.2 (Term), Licensee will have a non exclusive, irrevocable, perpetual, fully-paid license, with the right to sublicense, under the Licensed Technology to research, develop, make, use, sell, offer for sale, and import the POZEN Product in the Field of Use in the Territory.

12.5.2 Effect of Termination. The use by either party hereto of a termination right provided for under this Agreement and in accordance with this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other party with respect thereto. Subject to the preceding sentence, termination of this Agreement shall not preclude either party from claiming any other damages, compensation or relief that it may be entitled to upon such termination or for any breach of this Agreement. If either Party terminates ***Confidential Treatment Requested

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12.6 Termination for Insolvency. This Agreement may be terminated by written notice by either Party at any time during the Term upon the declaration by a court of competent jurisdiction that the other Party is bankrupt and, pursuant to the U.S. Bankruptcy Code such other Party’s assets are to be liquidated; upon the filing or institution of bankruptcy, liquidation or receivership proceedings (other than reorganization proceedings under Chapter 11 of the U.S. Bankruptcy Code); or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; or in the event a receiver or custodian is appointed for such Party’s business; provided, however, that in the case of any involuntary proceeding, such right to terminate shall only become effective if the proceeding is not dismissed within 60 days after the filing thereof (each of the foregoing, a “Bankruptcy Event”).

12.7 Effect of Bankruptcy. All rights and licenses with respect to Patents and Know-How granted under or pursuant to this Agreement by one Party to the other Party are, for all purposes of Section 365(n) of Title 11 of the United States Code (“Title 11”), licenses of rights to “intellectual property” as defined in Title 11. Each Party agrees that the other Party, as licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under Title 11. POZEN [***…] Licensee [***…]: (i) [***…], (ii) [***…], (iii) [***…], (iv) [***…], (v) [***…], (vi) [***…], and (vii) [***…], and (viii) [***…]. POZEN agrees not to interfere with Licensee and its Affiliates’ exercise of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement and agrees to use commercially reasonable efforts to assist Licensee and its Affiliates to obtain such intellectual property and embodiments thereof in the possession or control of Third Parties as reasonably necessary or desirable for Licensee or its Affiliates to exercise such rights and licenses in accordance with this Agreement. Each party agrees and acknowledges that all payments by Licensee to POZEN payable under this Agreement other than royalty payments pursuant to Section 8.1 (Royalties) and commercialization milestone payments under the Three-Party Agreement do not constitute “royalties” within the meaning of Section 365(n) of Title 11 or relate to licenses of intellectual property hereunder.

12.8 Formulation Technology. If Licensee terminates this Agreement for any reason other than for material breach by POZEN under Section 12.3 or as a result of POZEN’s insolvency under Section 12.7, then, subject to the terms and conditions of this Agreement, Licensee agrees to grant to POZEN, and does hereby grant effective automatically upon such termination, (a) a perpetual, irrevocable, non-exclusive license or sublicense under the Formulation Technology, with the right to grant sublicenses and authorize the grant of sublicenses to the extent provided in this Section 12.8, to make, have made, use, sell, offer for ***Confidential Treatment Requested

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sale, and import POZEN Products in the Territory and (b) a perpetual, irrevocable, non-exclusive license or sublicense, as applicable, under the Formulation Technology, with the right to grant sublicenses and authorize the grant of sublicenses to the extent provided in this Section 12.8, to Develop and Manufacture (but not sell or otherwise Commercialize) POZEN Products outside the Territory solely in support of the Development or Commercialization of the POZEN Products in the Territory; provided, that nothing herein gives POZEN any right or license under any other intellectual property rights Controlled by Licensee, regardless of whether such rights are necessary in order to exploit the Formulation Technology pursuant to this Section 12.8. POZEN may grant sublicenses and the right to grant further sublicenses under the foregoing license only as follows: (i) for any sublicense relating to the development or commercialization of a POZEN Product Commercialized by Licensee in the Territory at the time of such termination (a “Commercialized POZEN Product”) in the Territory, POZEN may grant such sublicense upon notice to Licensee, but without obtaining Licensee’s consent, and (ii) for any sublicense relating to POZEN Products other than Commercialized POZEN Products in the Territory, POZEN may grant such sublicense with Licensee’s prior written consent (such consent not to be unreasonably withheld, conditioned or delayed).

12.9 Survival. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. The provisions of Sections 8.1 (Royalties), 8.2 (Payments and Sales Reporting), 8.3 (Records; Audits), 9.2 (Prosecution and Maintenance of Joint Patents), 9.3 (Ownership of Inventions), 10.3 (Disclaimer of Warranty), 11 (Confidentiality), 12.5 (Consequences of Expiration and Termination), 12.7 (Effect of Bankruptcy), 12.8 (Formulation Technology), 12.9 (Survival), 13 (Indemnification and Insurance), 14 (Limitation of Liability), and 15 (Miscellaneous) will survive any termination or expiration of this Agreement (other than a termination pursuant to Section 12.1).

13. INDEMNIFICATION AND INSURANCE.

13.1 Indemnification by POZEN. POZEN hereby agrees to save, defend and hold Licensee and its Affiliates and their respective directors, officers, employees and agents (each, a “Licensee Indemnitee”) harmless from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys’ fees (collectively, “Losses”), to which any Licensee Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (i) the gross negligence or willful misconduct of any POZEN Indemnitee or (ii) the breach by POZEN of any warranty, representation, covenant or agreement made by POZEN in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Licensee Indemnitee or the breach by Licensee of any warranty, representation, covenant or agreement made by Licensee in this Agreement.

13.2 Indemnification by Licensee. Licensee hereby agrees to save, defend and hold POZEN and its Affiliates and their respective directors, officers, employees and agents (each, an “POZEN Indemnitee”) harmless from and against any and all Losses to which any POZEN Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (i) the development, manufacture, use, handling, storage, sale or other disposition of any Product by Licensee, its Affiliates or any of their respective Sublicensees, (ii) the gross negligence or willful misconduct
of any Licensee Indemnitee, or (iii) the breach by Licensee of any warranty, representation, covenant or agreement made by Licensee in this Agreement, in each case (i), (ii) and (iii), after the Amended and Restated Effective Date; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any POZEN Indemnitee or the breach by POZEN of any warranty, representation, covenant or agreement made by POZEN in this Agreement.

13.3 Indemnification Procedure.

13.3.1 Notice of Claim. The indemnified Party will give the indemnifying Party (the “Indemnifying Party”) prompt written notice (an “Indemnification Claim Notice”) of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under Section 13.1 (Indemnification by POZEN) or Section 13.2 (Indemnification by Licensee); provided, however, that the failure to give such prompt written notice will not relieve Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. In no event will the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). The indemnified Party will furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents (collectively, the “Indemnitees” and each an “Indemnitee”) will be made solely by such Party to this Agreement (the “Indemnified Party”).

13.3.2 Control of Defense. At its option, the Indemnifying Party may assume the defense of any claim for which indemnification is sought (a “Third Party Claim”) by giving written notice to the Indemnified Party within [...] days after the Indemnifying Party’s receipt of an Indemnification Claim Notice. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party will immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnitee in connection with the Third Party Claim. Should the Indemnifying Party assume the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party or any other Indemnitee for any legal expenses subsequently incurred by such Indemnified Party or other Indemnitee in connection with the analysis, defense or settlement of the Third Party Claim.

13.3.3 Right to Participate in Defense. Without limiting Section 13.3.2 (Control of Defense) above, any Indemnitee will be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnitee’s own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing, or (ii) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 13.3.2 (Control of Defense) (in which case the Indemnified Party will control the defense).
13.3.4 Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnitee’s becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnitee in any manner, and as to which the Indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnitee hereunder, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, will deem appropriate, and will transfer to the Indemnified Party all amounts which said Indemnified Party will be liable to pay prior to the time prior to the entry of judgment. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 13.3.2 (Control of Defense), the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent will be at the Indemnified Party’s sole and absolute discretion). The Indemnifying Party will not be liable for any settlement or other disposition of a Loss by an Indemnitee that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnitee will admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the Indemnifying Party.

13.3.5 Cooperation. The Indemnified Party will, and will cause each other Indemnitee to, cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection with the defense or prosecution of any Third Party Claim. Such cooperation will include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemniteses and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

13.4 Expenses. Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim will be reimbursed on a Calendar Quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party’s right to contest the Indemnified Party’s right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

13.5 Insurance. Each Party will have and maintain such types and amounts of liability insurance as is normal and customary in the industry generally for parties similarly situated, and will upon request provide the other Party with a copy of its policies of insurance in that regard, along with any amendments and revisions thereto.

14. LIMITATION OF LIABILITY
IN NO EVENT WILL EITHER PARTY BE LIABLE FOR LOST PROFITS, LOSS OF DATA, OR FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, ARISING UNDER ANY CAUSE OF ACTION AND ARISING IN ANY WAY OUT OF THIS AGREEMENT. THE FOREGOING LIMITATIONS WILL NOT APPLY TO AN AWARD OF ENHANCED DAMAGES AVAILABLE UNDER THE PATENT LAWS FOR WILLFUL PATENT INFRINGEMENT AND WILL NOT LIMIT EITHER PARTY’S LIABILITY TO THE OTHER PARTY UNDER SECTIONS 7.5 (RESTRICTIVE COVENANT), 10.4 (POZEN NON-COMPETE), 11 (CONFIDENTIALITY), AND 13 (INDEMNIFICATION AND INSURANCE) OF THIS AGREEMENT.

15. MISCELLANEOUS.

15.1 Assignment.

15.1.1 Without the prior written consent of the other Party hereto (which may be granted at the other Party’s discretion), neither Party will sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that either Party hereto may assign or transfer this Agreement or any of its rights or obligations hereunder without the consent of the other Party (a) to any Affiliate of such Party; or (b) in connection with the transfer or sale of all or substantially all of the business of such party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale of assets or otherwise. Except as set forth in that certain side letter agreement between POZEN and AstraZeneca AB dated September 16, 2013, the assigning Party (except if it is not the surviving entity) will remain jointly and severally liable with the relevant Affiliate or Third Party assignee under this Agreement, and the relevant Affiliate assignee, Third Party assignee or surviving entity will assume in writing all of the assigning Party’s obligations under this Agreement. Any purported assignment or transfer in violation of this Section 15.1 (Assignment) will be void ab initio and of no force or effect.

15.1.2 In the event that POZEN desires to sell all or a part of its rights to receive payments under this Agreement, then upon POZEN’s written request, Licensee shall enter into a consent in substantially the form of the Consent Agreement attached hereto as Schedule 15.1.2 with respect to such transaction.

15.2 Termination of Certain Rights Upon POZEN Change of Corporate Control. POZEN shall promptly notify Licensee in writing following consummation of a Change of Corporate Control of POZEN. Notwithstanding anything else in this Agreement to the contrary, in the event of a Change of Corporate Control of POZEN, then Licensee will have the right, exercisable by written notice to POZEN or its successor in interest given within […] ([…] days after Licensee receives written notice from POZEN of the completion of such Change of Corporate Control; (a) to terminate […] established pursuant to this Agreement; and (b) to terminate its obligation to make […] to POZEN pursuant to this Agreement other than […] and as reasonably required to […]

***Confidential Treatment Requested

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15.3 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision prohibited or unenforceable in any respect.

15.4 Governing Law; Dispute Resolution.

15.4.1 This Agreement, and any disputes between the Parties related to or arising out of this Agreement, including the Parties’ relationship created hereby, the negotiations for and entry into this Agreement, its conclusion, binding effect, amendment, coverage, termination, or the performance or alleged non-performance of a Party of its obligations under this Agreement (each a “Dispute”), will be governed by the laws of the State of New York without reference to any choice of law principles thereof that would cause the application of the laws of a different jurisdiction.

15.4.2 In the event of any Dispute, a Party may notify the other Party in writing of such Dispute, and the Parties will try to settle such Dispute amicably between themselves. If the Parties are unable to resolve the Dispute within [...] Business Days of receipt of the written notice by the other Party, such Dispute will be referred to the Chief Executive Officers of each of the Parties (or their respective designees) who will use their good faith efforts to resolve the Dispute within [...] Business Days after it was referred to the Chief Executive Officers.

15.4.3 Any Dispute that is not resolved as provided in Section 15.4.2, whether before or after termination of this Agreement, will be resolved by litigation in the courts of competent jurisdiction located in New York, New York. Each Party hereby agrees to the exclusive jurisdiction of such courts and waives any objections as to the personal jurisdiction or venue of such courts.

15.4.4 Notwithstanding the foregoing, nothing in this Section 15.4 (Governing Law; Dispute Resolution) will limit either Party’s right to seek immediate temporary injunctive

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or other temporary equitable relief whenever the facts or circumstances would permit a Party to seek such relief in a court of competent jurisdiction.

15.5 Notices. All notices or other communications that are required or permitted hereunder will be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier as provided herein), or sent by internationally-recognized overnight courier addressed as follows:

If to POZEN, to:

POZEN Inc.
1414 Raleigh Road, Suite 400
Chapel Hill, NC 27517
USA
Attention: President and CEO
Facsimile: (919) 913-1039

With a copy to:

DLA Piper LLP (US)
51 John F. Kennedy Parkway, Suite 120
Short Hills, New Jersey 07078
USA
Attention: Andrew P. Gilbert
Facsimile: (973) 520-2575

If to Licensee, to:

AstraZeneca AB
SE-431 83
Mölndal
Sweden
Attention: Manager Legal Department Mölndal
Facsimile: +46 31 776 38 71

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication will be deemed to have been given (i) when delivered, if personally delivered or sent by facsimile on a Business Day, and (ii) on the second Business Day after dispatch, if sent by nationally-recognized overnight courier. It is understood and agreed that this Section 15.5 (Governing Law; Dispute Resolution) is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

15.6 Entire Agreement; Modifications. This Agreement including the Exhibits attached hereto, each of which is hereby incorporated and made part of in this Agreement by reference, together with that certain side letter between POZEN and AstraZeneca AB, dated
September 16, 2013, and the Three-Party Agreement, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersedes all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment or modification of this Agreement will be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

15.7 Relationship of the Parties. It is expressly agreed that the Parties’ relationship under this Agreement is strictly one of licensor-licensee, and that this Agreement does not create or constitute a partnership, joint venture, or agency. Neither Party will have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding (or purport to be binding) on the other.

15.8 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of claims based on the failure to perform or a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

15.9 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

15.10 No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns (including Horizon), and they will not be construed as conferring any rights on any Third Party.

15.11 Further Assurance. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

15.12 No Drafting Party. This Agreement has been submitted to the scrutiny of, and has been negotiated by, both Parties and their counsel, and will be given a fair and reasonable interpretation in accordance with its terms, without consideration or weight being given to any such terms having been drafted by any Party or its counsel. No rule of strict construction will be applied against either Party.

15.13 Construction. Except where the context otherwise requires, wherever used, the use of any gender will be applicable to all genders and the word “or” is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no
way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including” as used herein means including, without limiting the generality of any description preceding such term. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document refer to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any laws refer to such laws as from time to time enacted, repealed or amended, (c) the words “herein”, “hereof” and “hereunder”, and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, and (d) all references herein to Sections and Exhibits, unless otherwise specifically provided, refer to the Sections and Exhibits of this Agreement.

15.14 Assignment to Horizon. POZEN acknowledges that, in connection with the Divestiture, AstraZeneca AB will assign this Agreement to Horizon, effective as of the Amended and Restated Effective Date, and that, notwithstanding Section 15.1, AstraZeneca AB may assign this Agreement to Horizon in connection with the Divestiture without the prior written consent of POZEN. Without limiting any provision of the Three-Party Agreement, from and after the Amended and Restated Effective Date, all references to “Licensee” in this Agreement, other than references to Licensee in connection with anticipated actions to be taken by AstraZeneca AB as Licensee in connection with the Divestiture, shall automatically be deemed references to Horizon.

15.15 Amendment and Restatement. This Agreement, together with the ROW Agreement, constitutes an amendment and restatement of the Original Agreement effective from and after the Amended and Restated Effective Date. All rights or obligations owing under the Original Agreement, or based on facts or events occurring or existing prior to the Amended and Restated Effective Date, shall be governed by the Original Agreement. As of the Amended and Restated Effective Date, the Original Agreement is hereby amended, supplemented, modified and restated in its entirety as described herein and in the ROW Agreement. For clarity, in no event shall this Section 15.15 or any other provision in this Agreement be deemed to limit or otherwise affect the agreements made by AstraZeneca AB, Horizon and POZEN in the Three-Party Agreement or that certain side letter agreement between POZEN and AstraZeneca AB dated September 16, 2013 with respect to each party’s respective liability in connection with the Original Agreement, this Agreement or the ROW Agreement.

[Remainder of page intentionally left blank. Signature page follows.]
IN WITNESS WHEREOF, the Parties have executed this Amended and Restated Collaboration and License Agreement for the United States by their respective authorized representatives as of the date first written above.

POZEN INC.
By: /s/ John R. Plachetka
Name: John R. Plachetka
Title: Chairman, President and CEO

ASTRAZENECA AB (publ)
By: /s/ Jan-Olof Jacke
Name: Jan-Olof Jacke
Title: President

[Signature Page to Pozen US Agreement]
## Schedule 1.43

### Licensed Patents

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## Vimovo Trademarks

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<td>App 77670350 Reg 3941225</td>
<td>(Class 5) pharmaceutical preparations and substances for the treatment of pain and inflammation</td>
<td>REGISTERED</td>
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Schedule 8.1.3

Market Reduction Example

For Products sold in the Territory:

[...***...]

***Confidential Treatment Requested
Schedule 15.1.2
Form of Consent Agreement

[...***...]

____________________

***Confidential Treatment Requested
AMENDMENT NO. 1 TO AMENDED AND RESTATED COLLABORATION AND LICENSE AGREEMENT FOR THE UNITED STATES

This AMENDMENT NO. 1 TO AMENDED AND RESTATED COLLABORATION AND LICENSE AGREEMENT FOR THE UNITED STATES (the “Amendment”) is made by and between POZEN Inc., a Delaware corporation (“POZEN”), and Horizon Pharma USA, Inc., a Delaware corporation (“Horizon,” and together with POZEN, the “Parties”). Reference is made to that certain Amended and Restated Collaboration and License Agreement for the United States, dated as of November 18, 2013, by and between POZEN and Horizon, as successor in interest to AstraZeneca AB (“AZ”) (the “Agreement”). All capitalized terms not herein defined shall have the meaning ascribed to them in the Agreement. This Amendment shall be effective automatically as of the Amended and Restated Effective Date.

WHEREAS, subject to that certain (i) Letter Agreement, dated as of the date hereof, by and among POZEN, Horizon and AZ, and (ii) Supply Agreement, dated as of the date hereof by and between Horizon and AZ, Horizon is acquiring all of AZ’s rights, title and interest in and to the Agreement, including, except as otherwise explicitly provided in the Agreement or the Amended and Restated Collaboration and License Agreement (the “ROW License Agreement”), by and between AstraZeneca and POZEN, all of AZ’s rights and obligations under the Agreement (the “Divestiture”);

WHEREAS, it is a condition precedent that POZEN consent to the Divestiture;

WHEREAS, POZEN has conditioned its consent to the Divestiture upon the simultaneous execution of this Amendment; and

WHEREAS, in consideration for POZEN’s consent, the Parties agree that simultaneously with the consummation of the Divestiture, the Agreement shall be amended pursuant to the terms and conditions of this Amendment.

NOW THEREFORE, in consideration of the mutual promises and covenants hereinafter set forth, the parties hereto agree to amend the Agreement as follows:

1. Amendment to Section 8.1.1. Section 8.1.1 is hereby amended and restated to read in its entirety as follows:

   “8.1.1 Royalty Rate. Subject to the terms and conditions of this Agreement, Licensee will pay to POZEN royalties based on the aggregate annual Net Sales of Products sold by Licensee, its Affiliates or Sublicensees, at the rate of 10% of aggregate Net Sales of Products sold in the Territory. In addition, effective only upon completion of the Divestiture, and only for each calendar year during which (i) the manufacture, use, sale, offer for sale, import or export of Products in the Territory would, without a license from POZEN to the Licensed Patents, infringe one or more Valid Claims of the Licensed Patents; and (ii) there are no Competing Products in the Territory, Licensee shall be required to pay POZEN the following minimum annual royalties (each a “Minimum Annual Royalty Amount”):
(a) for calendar year 2014 (January 1, 2014 – December 31, 2014), Licensee shall pay POZEN a minimum royalty payment of Five Million Dollars ($5,000,000); and

(b) for each calendar year beginning after January 1, 2015, Licensee shall pay POZEN a minimum royalty payment of Seven Million Five Hundred Thousand Dollars ($7,500,000).

2. **Amendment to Section 8.2.1.** Section 8.2.1 is hereby amended and restated to read in its entirety as follows:

   **“8.2.1 Sales Reporting.**

   (a) Licensee will provide POZEN, within (i) […] (…[…]) of the end of each of the first, second and third Calendar Quarters in each calendar year, and (ii) […] (…[…]) of the end of the fourth Calendar Quarter in each calendar year, with a preliminary report setting forth for such Calendar Quarter and, with respect to the fourth Calendar Quarter, the calendar year, on a Product-by-Product basis, the amount of gross sales of each Product in the Territory, a calculation of Net Sales and a calculation of the amount of royalty payment due on such Net Sales, subject to the Minimum Annual Royalty Amounts set forth in Section 8.1.1 (Royalties), provided such report shall be based on preliminary financials of Licensee and Licensee shall be permitted to revise such reports as reasonably necessary in light of its review process at any time up to (i) […] (…[…]) following the end of the relevant Calendar Quarter (with respect to the first, second and third Calendar Quarters); and (ii) […] (…[…]) following the end of the fourth Calendar Quarter. If any payment reduction is claimed by Licensee under this Agreement from the full royalty rates set forth in Section 8.1.1 (Royalties), then the report will set forth in detail the claimed reduction and the related facts.

   (b) Licensee will provide POZEN, within (i) […] (…[…]) of the end of each of the first, second and third Calendar Quarters in each calendar year, and (ii) […] (…[…]) of the end of the fourth Calendar Quarter in each calendar year, with a final report setting forth for such Calendar Quarter and, with respect to the fourth Calendar Quarter, the calendar year, on a Product-by-Product basis, the amount of gross sales of each Product in the Territory, a calculation of Net Sales and a calculation of the amount of royalty payment due on such Net Sales, subject to the Minimum Annual Royalty Amounts set forth in Section 8.1.1 (Royalties), provided that Licensee shall use reasonable efforts to provide such report as soon as practicable to accommodate POZEN’s SEC filing requirements and to provide such reports in a shorter time period than the periods specified above if Licensee has such reports available for its own internal purposes. If any payment reduction is claimed by Licensee under this Agreement from the full royalty rates set forth in Section 8.1.1 (Royalties), then the report will set forth in detail the claimed reduction and the related facts.

   (c) At the request of POZEN, Licensee will, within (i) […] (…[…]) of the end of each of the first, second and third Calendar Quarters in each calendar year
year, and (ii) [...***... ([...***...]) of the end of the fourth Calendar quarter in each calendar year, conduct a teleconference with POZEN (the “Quarterly Update Call”) in order to report, on a Product-by-Product basis, the commercial results for the Calendar Quarter. These results will include gross sales and Net Sales and [...***...] for Products. These results will also include other information available to Licensee that would be relevant to explaining the results, for example, [...***...]. During that call, Licensee will also provide POZEN with an update concerning [...***...], as well as any [...***...]. Licensee will provide POZEN with a reasonable opportunity to comment on such plans and agrees to reasonably consider all POZEN comments and suggestions with respect to such matters.

(d) POZEN acknowledges and agrees that all information disclosed by Licensee pursuant to [...***...] shall be subject to the restrictions set forth in Section 11 (Confidentiality) and [...***...] of the [...***...] on a [...***...] or [...***...] to be [...***...] and [...***...]. Notwithstanding the foregoing, Licensee and POZEN [...***...] to [...***...] of all [...***...] in [...***...], to the [...***...] or [...***...].”

3. **Amendment to Section 8.2.2.** Section 8.2.2 is hereby amended and restated to read in its entirety as follows:

“**8.2.2 Payment Timing.** Licensee will make royalty payments to POZEN within [...***... ([...***...]) [...***...] of the last day of each Calendar Quarter for which such payments are due under Section 8.1 (Royalties). Such quarterly payments shall be equal to the greater of (i) the applicable portion of the Minimum Annual Royalty Amount (i.e., Q1 = 25%; Q2 = 50%; Q3 = 75%; Q4 = 100%), minus the aggregate royalty amount paid by Licensee to POZEN during the then-current calendar year through the immediately preceding Calendar Quarter, or (ii) the actual royalty amount payable under the Section 8.1 (Royalties), calculated year-to-date, minus the aggregate royalty amount paid by Licensee to POZEN during the then-current calendar year through the immediately preceding Calendar Quarter. For purposes of clarity, the Parties agree with the following examples which assume the 2014 Minimum Annual Royalty Amount is applicable:

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(a) If Net Sales in the first Calendar Quarter of 2014 equal $10 million, then the royalty payment to be made by Licensee to POZEN under this Section 8.2.2 shall equal $1,250,000 (i.e., the applicable Minimum Annual Royalty Amount ($1,250,000) exceeded the actual royalty payment ($1,000,000 (10% of $10,000,000 of Net Sales) for the Calendar Quarter).

(b) If year-to-date Net Sales in the second Calendar Quarter of 2014 equal $40 million ($10 million in Q1 and $30 million in Q2), then the royalty payment to be made by Licensee to POZEN under this Section 8.2.2 for Q2 shall equal $2,750,000 (i.e., the actual royalty payment, calculated year-to-date, for the second Calendar Quarter ($4,000,000 (10% of $40,000,000 of Net Sales)), minus the aggregate royalty amount paid by Licensee to POZEN during the then-current calendar year ($1,250,000))."

4. Amendment to Section 9.10.2. Section 9.10.2 is hereby amended and restated to read in its entirety as follows:

"9.10.2 Hatch-Waxman Act. Notwithstanding Section 9.6.1 (Infringement by Third Parties) above, each Party will immediately give notice to the other Party of any notice it receives of certification filed under the Hatch-Waxman Act claiming that any of the Licensed Patents is invalid, unenforceable or that any infringement will not arise from the manufacture, use or sale of the POZEN Product by a Third Party. With regard to litigation arising out of or related to the submission of Abbreviated New Drug Applications to FDA referencing NDA #22-511 (the “Vimovo Litigation”), Licensee, at its cost and expense and with counsel selected by Licensee, controls and directs the Vimovo Litigation with respect to the Licensed Patents (including Joint Patents). POZEN shall cooperate with regard to the Vimovo Litigation in accordance with this Section 9.10.2, and POZEN’s litigation counsel may participate in the Vimovo Litigation with respect to the Licensed Patents (including Joint Patents) (without in any way limiting Licensee’s control thereof), at POZEN’s cost and expense; provided that Licensee will reimburse POZEN for the reasonable legal fees of POZEN’s litigation counsel incurred for the Vimovo Litigation from and after the Amended and Restated Effective Date, up to a maximum of […] for calendar year 2014 and […] for any other calendar year during the Term of this Agreement (pro-rated for any period less than a full calendar year), such reimbursement to be made within […] days after receipt of invoices with reasonably detailed supporting information for such fees. The Parties agree that settlement of any action hereunder will be controlled as set forth in Section 9.6.3 (Cooperation). Any recovery realized as a result of an action hereunder will be allocated in accordance with Section 9.6.4 (Recovery). For purposes of clarity any other litigation matters with respect to the Licensed Patents (including Joint Patents) that in any way relate to the Hatch-Waxman Act shall be subject to the terms of this Section 9.10.2 and all other litigation matters related to infringement of the Licensed Patents and the Joint Patents shall be covered by Section 9.6. Any suit hereunder may be in the name of either or both Parties, as may be required by law and each Party agrees to cooperate fully in the prosecution of such action, including, if required to bring or maintain such action, the furnishing of a power-

***Confidential Treatment Requested
of-attorney or the joining of such action as a necessary party, executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments so as to successfully prosecute any such action. For clarity, any Patent with Valid Claims solely directed to any product containing acetyl salicylic acid (including salts and derivatives thereof) is not a Licensed Patent; therefore, Licensee will have no right to bring infringement proceedings of such Patent under this Section 9.10.2. Notwithstanding anything in this Section 9.10.2 to the contrary, Licensee shall not have the right to bring an infringement proceeding under this Section 9.10.2 unless such proceeding involves a POZEN Product.”

5. **Amendment to Section 10.1.** Section 10.1 is hereby amended by inserting this section 10.1A in its entirety as follows:

   “10.1A Additional POZEN Representations and Warranties. POZEN hereby warrants and represents to Licensee as of the Amended and Restated Execution Date and the Amended and Restated Effective Date that, except with respect to the Vimovo Litigation, none of the Licensed Patents, including the Joint Patents, is involved in any litigation, claim, proceeding, inventorship challenge, reissue, interference, reexamination or opposition in the Territory.”

6. **Amendment to Section 15.5.** Section 15.5 is hereby amended and restated to read in its entirety as follows:

   “15.5 Notices. All notices or other communications that are required or permitted hereunder will be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier as provided herein), or sent by internationally-recognized overnight courier addressed as follows:

   If to POZEN, to:

   POZEN Inc.
   1414 Raleigh Road, Suite 400
   Chapel Hill, NC 27517
   USA
   Attention: President and CEO
   Facsimile: (919) 913-1039

   With a copy to:

   DLA Piper LLP (US)
   51 John F. Kennedy Parkway, Suite 120
   Short Hills, New Jersey 07078
   USA
   Attention: Andrew P. Gilbert
   Facsimile: (973) 520-2575
If to Licensee, to:

Horizon Pharma USA, Inc.
520 Lake Cook Rd.
Suite 520
Deerfield, IL 60015
Attention: President and CEO

With a copy to:

Horizon Pharma USA, Inc.
520 Lake Cook Rd.
Suite 520
Deerfield, IL 60015
Attention: Brian K. Beeler

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication will be deemed to have been given (i) when delivered, if personally delivered or sent by facsimile on a Business Day, and (ii) on the second Business Day after dispatch, if sent by nationally-recognized overnight courier. It is understood and agreed that this Section 15.5 (Governing Law; Dispute Resolution) is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.”

7. **Reference to Agreement.** Upon and after the effectiveness of this Amendment, each reference in the Agreement to “this Agreement,” “hereunder,” “hereof” or words of like import referring to the Agreement shall mean and be a reference to the Agreement as modified and amended by this Amendment; provided nothing herein shall affect the Three-Party Agreement, which shall remain in full force and effect in accordance with its terms.

8. **Effectiveness of Agreement.** The Amendment set forth above shall not be effective until execution and delivery of this Amendment by both Parties. Except as specifically amended above, the Agreement is and shall continue to be in full force and effect and is hereby in all respects ratified and confirmed and shall constitute the legal, valid, binding and enforceable obligations of the Parties; provided nothing herein shall affect the Three-Party Agreement, which shall remain in full force and effect in accordance with its terms.

9. **No Waiver.** The execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of either Party under the Agreement, nor constitute a waiver of any provision of the Agreement.

10. **Governing Law; Dispute Resolution.** Section 15.4 of the Agreement governs any dispute arising out of or related to this Amendment.
11. **Notices.** All notices or other communications that are required or permitted hereunder will be made according to Section 15.5 of the Agreement.

12. **Headings.** The headings for each Article and Section in this Amendment have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

13. **Counterparts.** This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

14. **No Strict Construction.** This Amendment has been submitted to the scrutiny of, and has been negotiated by, both Parties and their counsel, and will be given a fair and reasonable interpretation in accordance with its terms, without consideration or weight being given to any such terms having been drafted by any Party or its counsel. No rule of strict construction will be applied against either Party.

7
IN WITNESS WHEREOF, the Parties have executed this Amendment in duplicate originals by their duly authorized representatives as of November 18, 2013.

POZEN INC.

/s/ John R. Plachetka  
Name:  John R. Plachetka  
Title:  Chairman, President & CEO

HORIZON PHARMA USA, INC.

/s/ Timothy P. Walbert  
Name:  Timothy P. Walbert  
Title:  Chairman, President & Chief Executive Officer
November 18, 2013

AstraZeneca AB
SE-431 83
Mölndal
Sweden
Attn: President

POZEN Inc.
1414 Raleigh Road, Suite 400
Chapel Hill, North Carolina 27517
U.S.A
Attn: President and Chief Executive Officer

Re: Acknowledgements and agreements regarding rights and responsibilities of the parties in relation to the License Agreements

Ladies and Gentlemen:

As you are aware, AstraZeneca AB, a corporation organized under the laws of Sweden ("AstraZeneca") and Horizon Pharma U.S.A. Inc., a corporation organized under the laws of Delaware ("Horizon") have, on the date of this letter agreement, executed that certain Asset Purchase Agreement by and between AstraZeneca and Horizon (the "APA") pursuant to which AstraZeneca has agreed, subject to the terms and conditions of the APA, to transfer, assign and license to Horizon all rights of AstraZeneca and its affiliates to Vimovo® and other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with non-steroidal anti-inflammatory drugs in the United States and its territories and possessions (the "U.S."), including, without limitation, all licenses and other rights granted to AstraZeneca by POZEN, Inc. ("POZEN") with respect to such products in the U.S. (the "Divestiture").

The parties acknowledge that, as of the date of this letter agreement, AstraZeneca and POZEN are parties to that certain Collaboration and License Agreement, dated August 1, 2006, by and between AstraZeneca and POZEN, as amended prior to the date of this letter agreement (the "Original License Agreement"). In order to facilitate the transactions contemplated by the APA, AstraZeneca and POZEN have, on the date of this letter agreement, amended and restated the Original License Agreement in two separate agreements, each of which shall become effective on the closing of the APA: (i) that certain Amended and Restated Collaboration and License Agreement for the United States, by and between AstraZeneca and POZEN (as may be amended in accordance with its terms, the "U.S. License Agreement"), which sets forth all rights and obligations as between AstraZeneca and POZEN with respect to Products (as defined below) in the U.S., and (ii) that certain Amended and Restated Collaboration and License Agreement, by and between AstraZeneca and POZEN (as
may be amended in accordance with its terms, the “ROW License Agreement”), which sets forth all rights and obligations as between AstraZeneca and POZEN with respect to Products (as defined below) outside the U.S. Pursuant to the APA, AstraZeneca has agreed, among other things, to assign to Horizon, and Horizon has agreed to assume, the U.S. License Agreement effective on the closing of the transactions contemplated under the APA. The date on which such closing occurs is referred to as the “Transfer Date.”

The parties are executing this letter agreement to (i) facilitate the transactions contemplated by the APA with respect to the assignment by AstraZeneca, and assumption by Horizon, of the U.S. License Agreement, and (ii) acknowledge and agree to certain matters relating to the rights, obligations and liabilities of the parties in relation to the Original License Agreement, the U.S. License Agreement and the ROW License Agreement.

In consideration of the foregoing, the parties acknowledge and agree to the following:

1. **Definitions.** For purposes of this letter agreement, the following terms are defined as indicated:

   “Affiliate” means a legal entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with an entity. For purposes of this definition only, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” means (a) the possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) the ownership, directly or indirectly, of more than 50% of the voting securities or other ownership interest of a legal entity; provided, that if local law restricts foreign ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests.

   “AstraZeneca Territory” means worldwide, excluding the Horizon Territory and Japan.

   “AstraZeneca Net Sales” means Net Sales as defined in the ROW License Agreement.

   “Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

   “Esomeprazole” means that certain pharmaceutical compound with the name (5-methoxy-2-{{(S)-[4-methoxy-3,5-dimethylpyridin-2-yl]methyl}sulfinyl}-1H-benzimidazole), including any [...] ***...

   “Field of Use” means the treatment of human diseases and conditions by means of a pharmaceutical product.

   “Horizon Territory” means the United States and its territories and possessions.

   “Horizon Net Sales” means Net Sales as defined in the U.S. License Agreement.

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“Licensed Technology” has the meaning set forth in (a) for purposes of paragraph 7(a) below, the U.S. License Agreement and (b) for purposes of paragraph 7(d) below, the ROW License Agreement.

“Milestone Event” means an event set forth in the table in paragraph 5 below.

“Milestone Payment” means a payment set forth in the table in paragraph 5 below.

“Milestone Share” means (a) with respect to AstraZeneca, (i) the applicable Milestone Payment multiplied by (ii) a fraction, the numerator of which is the AstraZeneca Net Sales for the applicable calendar year, and the denominator of which is the sum of (A) the AstraZeneca Net Sales for such calendar year and (B) the Horizon Net Sales for such calendar year; and (b) with respect to Horizon, (i) the applicable Milestone Payment multiplied by (ii) a fraction, the numerator of which is the Horizon Net Sales for the applicable calendar year, and the denominator of which is the sum of (A) the Horizon Net Sales for such calendar year and (B) the AstraZeneca Net Sales for such calendar year.

“Nexium” means AstraZeneca AB’s and its Affiliates’ products containing Esomeprazole as the sole active ingredient in any presentation form.

“Nexium Business” means AstraZeneca AB’s and its Affiliates’ development and commercialization activities pertaining to Esomeprazole and Esomeprazole based products.

“ROW Licensed Patents” means Licensed Patents as defined in the ROW License Agreement.

“Products” has the meaning set forth in (a) with respect to references in this letter agreement to development, manufacture, commercialization or other exploitation of Products in the AstraZeneca Territory, the ROW License Agreement and (b) with respect to references in this letter agreement to development, manufacture, commercialization or other exploitation of Products in the Horizon Territory, the U.S. License Agreement.

“Sublicensees” has the meaning set forth in (a) for purposes of paragraph 7(a) below, except as otherwise expressly provided in paragraph 7(a) below, the ROW License Agreement and (b) for purposes of paragraph 7(d) below, except as otherwise expressly provided in paragraph 7(d) below, the U.S. License Agreement.

“Supply Agreement” means that certain supply agreement to be entered into by Horizon and AstraZeneca LP in connection with the Divestiture pursuant to which AstraZeneca LP will supply Horizon with Vimovo® until December 31, 2014.

“US Licensed Patents” means Licensed Patents as defined in the U.S. License Agreement.

2. Consent to Assignment of U.S. License Agreement, Joint Inventions and Joint Patents, POZEN hereby consents to the assignment by AstraZeneca, and assumption by
Horizon, of the U.S. License Agreement and all of AstraZeneca’s and its Affiliates’ right, title and interest in and to the Joint Inventions (as defined in the Original License Agreement) and Joint Patents (as defined in the Original License Agreement) in the Horizon Territory conceived under the Original Agreement, in each case, effective as of the Transfer Date. Each of POZEN and AstraZeneca hereby represents and warrants to Horizon as of the date hereof that the Original License Agreement is in full force and effect.

3. Assumption of Transferred Rights and Obligations. Pursuant to the APA, effective as of the Transfer Date, Horizon will assume and accept all rights, liabilities and obligations of AstraZeneca under the U.S. License Agreement arising on or after the Transfer Date. All rights, liabilities and obligations of AstraZeneca with respect to POZEN other than those transferred to Horizon in connection with the Divestiture, will remain rights, liabilities and obligations of AstraZeneca. The foregoing does not modify the agreements as between AstraZeneca and POZEN set forth in the side letter agreement between AstraZeneca and POZEN dated September 16, 2013.

4. Release of Liabilities. The parties hereby agree that Horizon will not be responsible for, and POZEN, on behalf of itself and its Affiliates and its and their respective successors and assigns, officers, employees and directors and any third parties claiming through POZEN (collectively, the “Releasors”), hereby releases and forever discharges Horizon, its Affiliates and its and their respective successors and assigns, and the shareholders, officers, directors, employees, agents, trustees and beneficiaries of each of the foregoing (each individually, a “Horizon Party”) of and from, any and all claims, suits, acts, damages, demands, liabilities, rights of action and causes of action, both in law and equity, whether known or unknown, foreseen or unforeseen, matured or contingent, that the Releasors ever had, now have, or in the future may have against any Horizon Party arising out of or directly related to the Original License Agreement, including matters arising after the Transfer Date that arise out of or directly relate to the Original License Agreement (the “Claims”). Furthermore, POZEN, on behalf of itself and its respective Releasors, agrees not to sue, or otherwise institute or cause to be instituted, or in any way voluntarily participate in, assist in (financially or otherwise) or authorize the prosecution of any Claim against any Horizon Party in any federal, state, local or other court, or in any other forum.

5. Sales Milestones.

a. If any Milestone Event is achieved during the term of either the U.S. License Agreement or ROW License Agreement, each of AstraZeneca and Horizon shall pay to POZEN directly its Milestone Share (if any) with respect to the applicable Milestone Event within […] following the achievement of such Milestone Event. AstraZeneca shall not be liable for Horizon’s failure to pay Horizon’s Milestone Share to POZEN, and Horizon shall not be liable for AstraZeneca’s failure to pay AstraZeneca’s Milestone Share to POZEN.

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<table>
<thead>
<tr>
<th>Milestone Event</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. End of first calendar year during which aggregate annual Horizon Net Sales and AstraZeneca Net Sales were at least $550,000,000</td>
<td>$[...***...]</td>
</tr>
<tr>
<td>2. End of first calendar year during which aggregate annual Horizon Net Sales and AstraZeneca Net Sales were at least $[...***...]</td>
<td>$[...***...]</td>
</tr>
<tr>
<td>3. End of first calendar year during which aggregate annual Horizon Net Sales and AstraZeneca Net Sales were at least $[...***...]</td>
<td>$[...***...]</td>
</tr>
<tr>
<td>4. End of first calendar year during which aggregate annual Horizon Net Sales and AstraZeneca Net Sales were at least $1,250,000,000</td>
<td>$[...***...]</td>
</tr>
</tbody>
</table>

Each Milestone Payment shall be payable only once, and not for each time that the applicable Milestone Event is achieved.

b. Until each Milestone Event has been achieved, AstraZeneca shall provide Horizon a copy of each report AstraZeneca provides to POZEN under Section 8.3.1 of the ROW License Agreement. AstraZeneca shall provide such copies to Horizon within [...***...] ( [...***...]) [...***...] after the end of the applicable Calendar Quarter with respect to the first (1st) three (3) Calendar Quarters of a calendar year and within [...***...] ( [...***...]) [...***...] after the end of the fourth Calendar Quarter of the applicable calendar year.

c. Until each Milestone Event has been achieved, Horizon shall provide AstraZeneca a copy of each report Horizon provides to POZEN under Section 8.2.1 of the U.S. License Agreement. Horizon shall provide such copies to AstraZeneca within [...***...] ( [...***...]) [...***...] after the end of the applicable Calendar Quarter with respect to the first (1st) three (3) Calendar Quarters of a calendar year and within [...***...] ( [...***...]) [...***...] after the end of the fourth Calendar Quarter of the applicable calendar year.

d. Until each Milestone Event has been achieved, promptly after receipt by each of Horizon and AstraZeneca of the reports described in the immediately preceding two paragraphs, and in any event no later than [...***...] ( [...***...]) [...***...] after the end of the fourth Calendar Quarter of the applicable calendar year, AstraZeneca and Horizon shall confer regarding whether a Milestone Event has been achieved during the preceding calendar year and, if so, the Milestone Share payable by each of Horizon and AstraZeneca for the achievement of any such Milestone Event. [...***...] and [...***...] of [...***...] and [...***...] to [...***...] in an [...***...] and [...***...] of [...***...] and in the [...***...]

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e. AstraZeneca shall not be responsible for failure to pay its Milestone Share for achievement of a Milestone Event when due, and such failure shall not be deemed a breach of this letter agreement by AstraZeneca, to the extent such failure is the result of Horizon failing to timely report Horizon Net Sales to AstraZeneca in accordance with this letter agreement. Horizon shall not be responsible for failure to pay its Milestone Share for achievement of a Milestone Event when due, and such failure shall not be deemed a breach of this letter agreement by Horizon, to the extent such failure is the result of AstraZeneca failing to timely report AstraZeneca Net Sales to Horizon in accordance with this letter agreement.

f. The terms and conditions of Section 8.3.3, Section 8.3.4, Section 8.3.5 and Section 8.5 of the ROW License Agreement shall apply with respect to any Milestone Share of AstraZeneca and the terms and conditions of Section 8.2.3, Section 8.2.4, Section 8.2.5 and Section 8.4 of the U.S. License Agreement shall apply with respect to any Milestone Share of Horizon.

g. For clarity, in the event the ROW Agreement or U.S. Agreement is terminated, AstraZeneca or Horizon, respectively, will (i) continue to provide reports to the other party as described above with respect to AstraZeneca Net Sales and Horizon Net Sales, respectively, to the extent any AstraZeneca Net Sales and Horizon Net Sales, respectively, are achieved after such termination, and (ii) be obligated to pay its Milestone Share with respect to any Milestone Event achieved during an applicable calendar year following such termination based on AstraZeneca Net Sales and Horizon Net Sales achieved during such calendar year.

6. Transition Payments; […***…]. Beginning on the Transfer Date, and continuing for a period ending on the later of (i) […***…] ([…***…]) ([…***…]) thereafter, and (ii) the date on which […***…]. AstraZeneca acknowledges and agrees to the following:

a. As part of its reporting obligations under Section 8.3.1 of the ROW Agreement, AstraZeneca will include in its report provided to POZEN within […***…] ([…***…]) of the end of the fourth (4th) Calendar Quarter of each year a summary profit and loss statement relating to VIMOVO […***…], which will include […***…].

b. AstraZeneca will pay to POZEN, or credit against royalties otherwise payable by AstraZeneca to POZEN under the ROW License Agreement, […***…]% of any […***…]; provided, that if for any reason there are no longer royalties payable by AstraZeneca under the ROW License Agreement, then POZEN will pay to AstraZeneca any amount that would otherwise be credited against such royalties.

c. AstraZeneca will make any royalty payments to POZEN or take any credit due under this paragraph 6 in accordance with Article 8 of the ROW License Agreement.

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7. **Ex-Territory Sublicenses Under U.S. and ROW License Agreements; Supply Agreement Sublicense**

   a. Horizon hereby grants to AstraZeneca, effective as of the Transfer Date, a non-exclusive, royalty-free sublicense, with the right to grant sublicenses through multiple tiers solely to Sublicensees, under the Licensed Technology to develop, make and have made (but not market, sell or otherwise commercialize) Products in the Field of Use in the Horizon Territory solely in support of the development, commercialization or other exploitation of the Products in the Field of Use in the AstraZeneca Territory. If the U.S. License Agreement is terminated or otherwise ceases to be in effect for any reason other than expiration thereof pursuant to its terms, then POZEN shall and does hereby automatically and without any additional consideration grant to AstraZeneca, with effect from the effective date of the termination of the U.S. License Agreement, a direct non-exclusive, royalty-free license, with the right to grant sublicenses pursuant to Section 7.3 of the ROW License Agreement, under the Licensed Technology to develop, make and have made (but not market, sell or otherwise commercialize) Products in the Field of Use in the Horizon Territory solely in support of the development, commercialization or other exploitation of the Products in the Field of Use in the AstraZeneca Territory, and such direct license shall continue in effect for the duration of the ROW License Agreement.

   b. Each of AstraZeneca and Horizon represents and warrants to POZEN as of the date hereof that under the Supply Agreement Horizon grants AstraZeneca LP a non-exclusive, royalty-free, non-transferable (except in connection with a permitted assignment of the Supply Agreement pursuant to its terms) license under the Licensed Technology, with the right to grant further sublicenses, to the extent necessary for AstraZeneca and its Affiliates to perform their obligations under the Supply Agreement.

   c. POZEN hereby consents to the sublicense granted by Horizon to AstraZeneca under paragraph 7(a) and the sublicense granted by Horizon to AstraZeneca LP under the Supply Agreement as described in paragraph 7(b) and acknowledges and agrees that the provisions of Section 7.3 of the U.S. License Agreement shall not apply with respect to either sublicense (including any obligation to guarantee performance of AstraZeneca or AstraZeneca LP as a sublicensee), neither AstraZeneca nor AstraZeneca LP shall be deemed to be a Sublicensee (as defined in the U.S. License Agreement) under the U.S. License Agreement and Horizon shall not be responsible to POZEN for compliance by AstraZeneca or AstraZeneca LP with the terms of the U.S. License Agreement with respect to AstraZeneca’s exercise of the sublicense granted herein or AstraZeneca LP’s exercise of the sublicense granted under the Supply Agreement, as applicable.

   d. AstraZeneca hereby grants to Horizon, effective as of the Transfer Date, a non-exclusive, royalty-free sublicense, with the right to grant sublicenses through multiple tiers solely to Sublicensees, under the Licensed Technology to develop, make and have made (but not market, sell or otherwise commercialize) Products in the Field of Use in the AstraZeneca Territory solely in support of the development, commercialization or other exploitation of the Products in the Field of Use in the Horizon Territory. POZEN hereby consents to such sublicense and acknowledges and agrees that the provisions of Section 7.3 of the ROW License
Agreement shall not apply with respect to such sublicense (including any obligation to guarantee performance of Horizon as a sublicensee), Horizon shall not be deemed to be a Sublicensee (as defined in the ROW License Agreement) under the ROW License Agreement and AstraZeneca shall not be responsible to POZEN for compliance by Horizon with the terms of the ROW License Agreement with respect to Horizon’s exercise of the sublicense granted herein. If the ROW License Agreement is terminated or otherwise ceases to be in effect for any reason other than expiration thereof pursuant to its terms, then POZEN shall and does hereby automatically and without any additional consideration grant to Horizon, with effect from the effective date of the termination of the ROW License Agreement, a direct non-exclusive, royalty-free license, with the right to grant sublicenses pursuant to Section 7.3 of the U.S. License Agreement, under the Licensed Technology to develop, make and have made (but not market, sell or otherwise commercialize) Products in the Field of Use in the AstraZeneca Territory solely in support of the development, commercialization or other exploitation of the Products in the Field of Use in the Horizon Territory, and such direct license shall continue in effect for the duration of the U.S. License Agreement.

8. Patent Prosecution Information

a. The parties acknowledge and agree that (i) in connection with the prosecution and maintenance of the US Licensed Patents pursuant to the U.S. License Agreement it may be necessary or useful for the prosecuting and maintaining party to access the prosecution histories of the ROW Licensed Patents and any other information with respect to the prosecution of the ROW Licensed Patents that is necessary or useful for the prosecution or maintenance of the US Licensed Patents pursuant to the U.S. License Agreement, (ii) notwithstanding any provision in the ROW License Agreement to the contrary, such prosecuting and maintaining party shall have the right, at its sole expense, to obtain copies of such prosecution histories and other information solely for use in connection with the prosecution and maintenance of the US Licensed Patents under the U.S. License Agreement and (iii) any information disclosed under this paragraph 8(a) shall be deemed Confidential Information (as defined in the U.S. License Agreement) of POZEN and subject to the provisions of Article 11 of the U.S. License Agreement, provided that such prosecuting and maintaining party may disclose such Confidential Information to any patent authorities in the Horizon Territory to the extent such disclosure is made in connection with the performance of the U.S. License Agreement.

b. The parties acknowledge and agree that (i) in connection with the prosecution and maintenance of the ROW Licensed Patents pursuant to the ROW License Agreement it may be necessary or useful for the prosecuting and maintaining party to access the prosecution histories of the US Licensed Patents and any other information with respect to the prosecution of the US Licensed Patents that is necessary or useful for the prosecution or maintenance of the ROW Licensed Patents pursuant to the ROW License Agreement, (ii) notwithstanding any provision in the U.S. License Agreement to the contrary, such prosecuting and maintaining party shall have the right, at its sole expense, to obtain copies of such prosecution histories and other information solely for use in connection with the prosecution and maintenance of the ROW Licensed Patents under the ROW License Agreement and (iii) any information disclosed under this paragraph 8(b) shall be deemed Confidential Information (as defined in the ROW License Agreement) of POZEN and subject to the provisions of Article 11.
9. […***…].

a. Capitalized terms used in this paragraph 9 but not defined in this letter agreement shall have the meaning set forth in the U.S. License Agreement.

b. If POZEN is required by Applicable Law to provide to a Regulatory Authority in the […] any communication that relates to […] and […] as it […] that […] to […] the […]

c. Except as otherwise set forth in the U.S. License Agreement or ROW License Agreement or to comply with Applicable Law, […] or […] the […]

d. If POZEN is required by Applicable Law to make any statements in an AE or SAE report in the […] pertaining to […] of […] and […] the […] to […]

e. POZEN is not by the U.S. License Agreement, by implication or otherwise, granted any license or other right relating to […] to […] or […] to […] or […]

f. Notwithstanding anything to the contrary in the U.S. License Agreement, […] of […] or […] of its […] or […] of the […]

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g. Except as provided in paragraphs 9(b) or 9(d) above, without [***] prior written consent, [***] will not make, and will prohibit its Affiliates, third party contractors, and agents from [***] or [***].

h. [***] in the [***] that is [***] and [***] the [***] the [***] that [***] in the [***] to be [***].

i. [***] to the [***].

10. Payment of U.S. Royalties During Transition Period. POZEN acknowledges and agrees that notwithstanding the assignment of the U.S. License Agreement by AstraZeneca to Horizon as of the Transfer Date, AstraZeneca shall continue to be responsible for paying POZEN any royalties that are payable under the U.S. License Agreement with respect to any Net Sales (as defined in the U.S. License Agreement) of any Product in the Horizon Territory during the period that begins on the Transfer Date and ends on December 31, 2013 and providing POZEN the corresponding sales reports required under the U.S. License Agreement with respect to such period, and POZEN shall accept such amounts from AstraZeneca in satisfaction of Horizon’s obligations with respect thereto under the U.S. License Agreement.

11. Assignment

a. AstraZeneca shall not sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this letter agreement or any of its rights or duties hereunder other than in connection with a permitted assignment of the ROW License Agreement or any of its rights or duties thereunder pursuant to the terms thereof (an "AstraZeneca Permitted Assignment"). In the event of an AstraZeneca Permitted Assignment, this letter agreement, and AstraZeneca’s rights and obligations hereunder, shall be automatically assigned to the assignee of AstraZeneca’s rights and duties under the ROW License Agreement.

b. Horizon shall not sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this letter agreement or any of its rights or duties hereunder other than in connection with a permitted assignment of the U.S. License Agreement or any of its rights or duties thereunder pursuant to the terms thereof (a "Horizon Permitted Assignment"). In the event of a Horizon Permitted Assignment, this letter agreement, and Horizon’s rights and obligations hereunder, shall be

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automatically assigned to the assignee of Horizon’s rights and duties under the U.S. License Agreement.

c. POZEN shall not sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this letter agreement or (i) its rights or duties hereunder with respect to AstraZeneca’s Milestone Share (paragraph 5) or Horizon’s sublicense to AstraZeneca (paragraph 7(a)), (ii) its duties hereunder with respect to patent prosecution information for the ROW Licensed Patent (paragraph 8(a)) and (iii) its rights hereunder with respect to patent prosecution information for the US Licensed Patents (paragraph 8(b)) (collectively, the “POZEN ROW Provisions”) other than in connection with a permitted assignment of the ROW License Agreement or any of its rights or duties thereunder pursuant to Section 15.1 thereof (a “POZEN Permitted ROW Assignment”). In the event of a POZEN Permitted ROW Assignment, this letter agreement and POZEN’s rights and obligations under the POZEN ROW Provisions shall be automatically assigned to the assignee of POZEN’s rights and duties under the ROW License Agreement.

d. POZEN shall not sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this letter agreement or (i) its rights or duties under paragraph 2 or paragraph 4, (ii) its rights or duties hereunder with respect to Horizon’s Milestone Share (paragraph 5), AstraZeneca’s sublicense to Horizon (paragraph 7(d)), or the Nexium-related restrictions (paragraph 9), (iii) its rights hereunder with respect to patent prosecution information for the ROW Licensed Patent (paragraph 8(a)) and (iv) its duties hereunder with respect to patent prosecution information for the US Licensed Patents (paragraph 8(b)) (collectively, the “POZEN US Provisions”) other than in connection with a permitted assignment of the U.S. License Agreement or any of its rights or duties thereunder pursuant to Section 15.1 thereof (a “POZEN Permitted US Assignment”). In the event of a POZEN Permitted US Assignment, this letter agreement and POZEN’s rights and obligations under the POZEN US Provisions shall be automatically assigned to the assignee of POZEN’s rights and duties under the U.S. License Agreement. For clarity, in no event will any sale, transfer, assignment, delegation, pledge or other disposal of the POZEN US Provisions relieve POZEN of its agreements and duties under paragraph 4.

12. **Representation of AstraZeneca.** AstraZeneca represents and warrants to POZEN as of the date hereof that pursuant to the APA AstraZeneca provides Horizon the representation and warranty set forth on Attachment A, and such representation and warranty is true and accurate in all material respects as of the date hereof.

13. **Miscellaneous.**

  a. With respect to the rights and obligations of AstraZeneca and POZEN with respect to the POZEN ROW Provisions, this letter agreement is subject to Articles 11 through 14 of the ROW License Agreement. With respect to the rights and obligations of Horizon and POZEN with respect to the POZEN US Provisions, this letter agreement is subject to Articles 11 through 14 of the U.S. License Agreement. Any breach of this letter agreement by AstraZeneca or POZEN with respect to the POZEN ROW Provisions shall be deemed a breach of the ROW License Agreement by such party and subject to such parties’ respective rights and
remedies (and any applicable limitations) thereunder. Any breach of this letter agreement by Horizon or POZEN with respect to the POZEN US Provisions shall be deemed a breach of the U.S. License Agreement by such party and subject to such parties' respective rights and remedies (and any applicable limitations) thereunder. This letter agreement automatically shall terminate with respect to AstraZeneca and POZEN with respect to the POZEN ROW Provisions upon the termination of the ROW License Agreement (subject to Sections 12.10 thereof). This letter agreement automatically shall terminate with respect to Horizon and POZEN with respect to the POZEN US Provisions upon the termination of the U.S. License Agreement (subject to Sections 12.9 thereof). For clarity, the consent under paragraph 2, and the release and other agreements of POZEN under paragraph 4, will survive any expiration or termination of this letter agreement.

b. Each of AstraZeneca, POZEN and Horizon acknowledges and agrees that the terms of this letter agreement shall not become effective until the Transfer Date.

c. The agreements set forth in this letter agreement are being relied upon by each of AstraZeneca and Horizon in connection with its determination to execute the APA. The parties hereto agree that irreparable damage would occur in the event that any of the provisions of this letter agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the parties hereto shall be entitled to an injunction or injunctions to prevent breaches of this letter agreement and to enforce specifically the terms and provisions of this letter agreement in any court of the U.S. or any state having jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity. Each party hereto hereby waives (i) any requirement that the other party post a bond or other security as a condition for obtaining any such relief, and (ii) any defenses in any action for specific performance, including the defense that a remedy at law would be adequate.

d. This letter agreement shall be governed by and construed in accordance with the laws of the State of New York applicable to contracts executed and performed in such state, without giving effect to the conflicts of laws principles thereof to the extent such principles would require or permit the application of the laws of another state. This letter agreement may be executed in multiple counterparts, all of which taken together shall constitute a single instrument. Delivery of an executed counterpart of a signature page of this letter agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this letter agreement. No amendment or modification of this letter agreement will be binding upon the parties unless in writing and duly executed by authorized representatives of AstraZeneca, Horizon and POZEN.

Please confirm the agreement of AstraZeneca and POZEN with the terms of this letter agreement by countersigning in the space provided below. This letter agreement, once fully executed by AstraZeneca and POZEN, shall be deemed to have been executed as of the date first above written.

-Signature page to follow-
Sincerely,

Horizon Pharma U.S.A, Inc.

By:  /s/ Timothy P. Walbert
Name:  Timothy P. Walbert
Title:  President and Chief Executive Officer

Acknowledged and Agreed:

AstraZeneca AB

By:  /s/ Jan-Olof Jacke
Name:  Jan-Olof Jacke
Title:  President

POZEN, Inc.

By:  /s/ John R. Plachetka
Name:  John R. Plachetka
Title:  Chairman, President and CEO
Attachment A

The Purchased Assets, together with the Merck Covenant and rights granted to Horizon under the License Agreement, the Licensed Regulatory Documentation, the APA Manufacturing Technology and any software or other ordinary course and immaterial Third Party licenses that are commercially available (excluding, for clarity, any license of any Patent Rights), constitute all of the intellectual property, Regulatory Approvals and Regulatory Documentation necessary to (i) operate the Product Business, (ii) Manufacture or have Manufactured the Product in the Horizon Territory, and (iii) Manufacture, have Manufactured, research and develop the Product in the AstraZeneca Territory solely for exportation and use of the Product in connection with the Exploitation of Product in the Horizon Territory, in each case ((i)—(iii)) in the same manner that AstraZeneca and its Affiliates are operating the Product Business, Manufacturing or having Manufactured the Product in the Horizon Territory, and Manufacturing, having Manufactured, researching and developing the Product in the AstraZeneca Territory for exportation and use of the Product in connection with the Exploitation of Product in the Horizon Territory, as applicable, as of the Execution Date and as of the Closing. In the event this Section 3.1.6(b) is breached because AstraZeneca has failed to convey any Purchased Assets or to identify and either transfer to Horizon, or grant Horizon a license to or right of reference and use with respect to, as applicable, any intellectual property, Regulatory Approvals or Regulatory Documentation necessary for the representation and warranty in this Section 3.1.6(b) to be true and correct in all respects, such breach shall be deemed cured as of the date AstraZeneca or any of its Affiliates specifically performs its obligation under this Agreement or any Ancillary Agreement to convey title to all Purchased Assets to Horizon or to transfer to Horizon, or grant Horizon a license to or right of reference and use with respect to, as applicable, such intellectual property, Regulatory Approvals or Regulatory Documentation at no additional cost or expense to Horizon; provided that such breach shall not be deemed cured with respect to any Losses incurred by any Horizon Indemnitee prior to such transfer or grant.
Master Manufacturing Services Agreement

October 31, 2013
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MASTER MANUFACTURING SERVICES AGREEMENT

THIS MASTER MANUFACTURING SERVICES AGREEMENT (the “Agreement”) is made as of October 31, 2013 (the “Effective Date”) between:

PATHEON PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware

(“Patheon”),

- and -

Horizon Pharma Inc.,
a corporation existing under the laws of the State of Delaware

(“Client”).

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

STRUCTURE OF AGREEMENT AND INTERPRETATION

1.1 Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Affiliate of Patheon may perform Manufacturing Services for Client or any Affiliate of Client, at the manufacturing site where the Affiliate of Patheon resides. This “master” form of agreement is intended to allow the parties, or any of their Affiliates, to contract for the manufacture of multiple Products through Patheon’s global network of manufacturing sites through the issuance of site specific Product Agreements without having to re-negotiate the basic terms and conditions contained herein.

1.2 Product Agreements.

This Agreement is structured so that a Product Agreement may be entered into by the parties for the manufacture of a particular Product or multiple Products at a Patheon manufacturing site. Each Product Agreement will be governed by the terms and conditions of this Agreement unless the parties to the Product Agreement expressly modify the terms and conditions of this Agreement in the Product Agreement. Unless otherwise agreed by the parties, each Product Agreement will be in the general form and contain the information set forth in Appendix 1 hereto.
1.3 Definitions

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

“Active Materials”, “Active Pharmaceutical Ingredients” or “API” means the materials listed in a Product Agreement on Schedule D;

“Active Materials Credit Value” means the value of the Active Materials for certain purposes of this Agreement, as set forth in a Product Agreement on Schedule D;

“Actual Annual Yield” or “AAY” has the meaning specified in Section 2.2(a);

“Affiliate” means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement;

For this definition, “control” means the ownership of shares carrying at least a majority of the votes for the election of the directors of a corporation;

“Annual Product Review Report” means the annual product review report prepared by Patheon as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

“Annual Report” means the annual report to the FDA prepared by Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

“Annual Volume” means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B;

“Applicable Laws” means (i) for Patheon, the Laws of the State of Ohio [or local jurisdiction for Patheon Affiliate], being the jurisdiction where the Manufacturing Site is located; and (ii) for Client and the Products, the Laws of all jurisdictions where the Products are manufactured, distributed, and marketed as these are agreed and understood by the parties in this Agreement;

“Authority” means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

“Bill Back Items” means the expenses for all third party supplier fees for the purchase or use of columns, standards, tooling, non-standard pallets, PAPR or PPE suits (where applicable), RFID tags and supporting equipment, and other project-specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Components;

“Breach Notice” will have the meaning specified in Section 8.2(a);
“Business Day” means a day other than a Saturday, Sunday or a day that is a statutory holiday in the United States;
“cGMPs” means, as applicable, current good manufacturing practices as described in:
(a) Division 2 of Part C of the Food and Drug Regulations (Canada);
(b) Parts 210 and 211 of Title 21 of the United States’ Code of Federal Regulations; and
(c) EC Directive 2003/94/EC,
together with the latest Health Canada, FDA and EMEA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;
“Client Intellectual Property” means Intellectual Property generated or derived by Client before entering into this Agreement or during any Term of this Agreement, or by Patheon while performing any Manufacturing Services or otherwise generated or derived by Patheon in its business which Intellectual Property is specific to, integral or dependent upon, Client’s Active Material or Product;
“Client Property” will have the meaning specified in Section 8.4(e);
“Client-Supplied Components” means those Components to be supplied by Client or that have been supplied by Client;
“CMC” has the meaning specified in Section 7.8(c);
“Components” means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture the Products in accordance with the Specifications, other than the Active Materials;
“Confidentiality Agreement” means the agreement about the non-disclosure of confidential information between Patheon and Client dated September 27, 2013;
“Deficiencies” has the meaning specified in Section 7.8(d);
“Deficiency Notice” has the meaning specified in Section 6.1(a);
“Delivery Date” means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(d);
“EMA” means the European Medicines Agency;
[“Equipment” will have the meaning ascribed to it in {the Capital Equipment Agreement related to this MSA if any}]
“FDA” means the United States Food and Drug Administration;
“Firm Orders” has the meaning specified in Section 5.1(b);
“Force Majeure” will have the meaning specified in Section 13.7;

“Health Canada” means the section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

“Initial Product Term” has the meaning specified in Section 8.1;

“Initial Set Exchange Rate” means as of the Effective Date of a Product Agreement, the initial exchange rate set forth in the Product Agreement to convert one unit of the billing currency into the Patheon Manufacturing Site local currency, calculated as the daily average interbank exchange rate for conversion of one unit of the billing currency into the Patheon Manufacturing Site local currency during the 90 day period immediately preceding the Effective Date as published by OANDA.com “The Currency Site” under the heading “FxHistory: historical currency exchange rates” at www.OANDA.com/convert/fxhistory;

“Initial Term” has the meaning specified in Section 8.1;

“Intellectual Property” includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

“Invention” means information about any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

“Inventory” means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the Active Materials;

“Late Delivery” has the meaning specified in Section 5.5;

“Laws” means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

“Manufacturing Services” means the manufacturing, quality control, quality assurance, stability testing, bulk packaging and finished product packaging (if agreed between the parties in the relevant Product Agreement), and related services, as set forth in this Agreement, required to manufacture Product or Products using the Active Materials, Components, and Bill Back Items;

“Manufacturing Site” means the facility owned and operated by Patheon where the Manufacturing Services will be performed as identified in a Product Agreement;

“Materials” means all Components and Bill Back Items required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

“Maximum Credit Value” means the maximum value of Active Materials that may be credited by Patheon under this Agreement, as set forth in a Product Agreement on Schedule D;
“Minimum Order Quantity” means the minimum number of batches of a Product to be produced during the same cycle of manufacturing as set forth in a Product Agreement on Schedule B;

“Patheon Competitor” means an entity that generates greater than [...]\% of its gross revenues from performing contract pharmaceutical commercial manufacturing services pursuant to arrangements with unrelated third party companies;

“Patheon Intellectual Property” means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, or generated or derived by Patheon in its business which Intellectual Property is not specific to, integral to, or dependent upon, Client’s Active Material or Product including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products, drug product dosage forms or drug delivery systems unrelated to the specific requirements of the Product(s);

“Price” means the price measured in US Dollars to be charged by Patheon for performing the Manufacturing Services, and includes the cost of Components (other than Client-Supplied Components), certain cost items as set forth in a Product Agreement on Schedule B, and annual stability testing costs as set forth in Schedule C;

“Product(s)” means the product(s) listed in a Product Agreement on Schedule A;

“Product Agreement” means the agreement between Patheon and Client issued under this Agreement in the form set forth in Appendix 1 (including Schedules A to D) under which Patheon will perform Manufacturing Services at a particular Manufacturing Site;

“Quality Agreement” means the agreement (the general form of which is set forth in Exhibit B) between the parties entering a Product Agreement that sets out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client;

“Recall” has the meaning specified in Section 6.2(a);

“Regulatory Authority” means the FDA, EMA, and Health Canada and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products including the Products in the Territory;

“RFID” means Radio Frequency Identification Devices which (at present or in the future) may be affixed to Products or Materials to assist in inventory control, tracking, and identification;

“Remediation Period” has the meaning specified in Section 8.2(a);

“Set Exchange Rate” means the exchange rate to convert one unit of the billing currency into the Patheon Manufacturing Site local currency for each Year, calculated as the average daily interbank exchange rate for conversion of one unit of the billing currency into the Patheon Manufacturing Site local currency during the full year period (October 1st [preceding year] to September 30th) as published by OANDA.com “The Currency Site” under the heading “FxHistory: historical currency exchange rates” at www.OANDA.com/convert/fxhistory;

“Shortfall” has the meaning specified in Section 2.2(b);
“Specifications” means the file, for each Product, which is given by Client to Patheon in accordance with the procedures listed in a Product Agreement on Schedule A and which contains documents relating to each Product, including, without limitation:

(a) specifications for Active Materials and Components;
(b) manufacturing and testing specifications, directions, and processes;
(c) storage requirements;
(d) all environmental, health and safety information for each Product including material safety data sheets; and
(e) the finished Product specifications, packaging specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

“Target Yield” has the meaning specified in Section 2.2(a);

“Target Yield Determination Batches” has the meaning specified in Section 2.2(a);

“Technical Dispute” has the meaning specified in Section 12.2;

“Territory” means the geographic area described in a Product Agreement where Products manufactured by Patheon will be distributed by Client;

“Third Party Rights” means the Intellectual Property of any third party; and

“Year” means in the first year of this Agreement or in the first year of a Product Agreement, the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year.

1.4 Currency

Unless otherwise agreed in a Product Agreement, all monetary amounts expressed in this Agreement are in United States Dollars (USD).

1.5 Sections and Headings

The division of this Agreement into Articles, Sections, Subsections, an Appendix, and Exhibits and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix or Exhibit refers to the specified Section, Appendix, or Exhibit to this Agreement. In this Agreement, the terms “this Agreement”, “hereof”, “herein”, “hereunder” and similar expressions refer to this Agreement and not to any particular part, Section, Appendix or Exhibit of this Agreement.
1.6 **Singular Terms**

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

1.7 **Appendix 1 and Exhibits**

Appendix 1 and the following Exhibits are attached to, incorporated in, and form part of this Agreement:

- **Appendix 1** - Form of Product Agreement (Including Schedules A to D)
- **Exhibit A** - Technical Dispute Resolution
- **Exhibit B** - Commercial Quality Agreement
- **Exhibit C** - Quarterly Active Materials Inventory Report
- **Exhibit D** - Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
- **Exhibit E** - Example of Price Adjustment Due to Currency Fluctuation
ARTICLE 2

PATHEON’S MANUFACTURING SERVICES

2.1 Manufacturing Services

Patheon will perform the Manufacturing Services for the Territory for the fees specified in a Product Agreement in Schedules B and C to manufacture Products for Client. Schedule B to a Product Agreement sets forth a list of cost items that are included in the Price for Products; all cost items that are not included in this list are excluded from the Price and are subject to additional fees to be paid by the Client. Patheon may amend the fees set out in Schedules B and C to a Product Agreement as set forth in Article 4. Patheon may change the Manufacturing Site for the Products only with the prior written consent of Client, this consent not to be unreasonably withheld. Unless otherwise agreed in a Product Agreement, Patheon will manufacture at least [...***...]% of the Products offered for sale by Client in the Territory if Patheon remains in material compliance with its obligations under this Agreement and the Product Agreement. In performing the Manufacturing Services, Patheon and Client agree that:

(a) Conversion of Active Materials and Components. Patheon will convert Active Materials and Components into Products.

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon’s quality assurance group. Patheon will perform its batch review and release responsibilities in accordance with Patheon’s standard operating procedures. Each time Patheon ships Products to Client, it will give Client a certificate of analysis and certificate of compliance, including deviations as specified by the Quality Agreement, including a statement that the batch has been manufactured and tested in accordance with Specifications and cGMPs. Client will have sole responsibility for the release of Products to the market. The form and style of batch documents, including, but not limited to, batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of Patheon. Specific Product related information contained in those batch documents is Client property.

(c) Components. Patheon will purchase and test all Components (with the exception of Client-Supplied Components) at Patheon’s expense and as required by the Specifications.

(d) Stability Testing. Patheon will conduct stability testing on the Products in accordance with the protocols set out in the Specifications for the separate fees and during the time periods set out in Schedule C to a Product Agreement. Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs, Patheon will notify Client within [...***...], after which Patheon and Client will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure, including which party will bear the cost of the investigation. Patheon will not be liable for these costs unless it has failed to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws. Patheon will give Client all stability test data and results at Client’s request.

(e) Packaging. Patheon will package the Products as set out in the Specifications. Client will be responsible for the cost of artwork development. Patheon will determine and imprint the batch numbers and expiration dates for each Product shipped. The batch numbers...

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and expiration dates will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Those changes will be submitted by Client to all applicable governmental agencies and other third parties responsible for the approval of the Products. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon’s name will not appear on the label or anywhere else on the Products unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name.

(f) **Active Materials and Client-Supplied Components.** At least [...] days before the scheduled production date, Client will deliver the Active Materials and any Client-Supplied Components to the Manufacturing Site [...] (Incoterms 2010), at no cost to Patheon, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If the Active Materials and/or Client-Supplied Components are not received [...] days before the scheduled production date, Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials and/or Client-Supplied Components. But if Patheon is unable to manufacture Product to meet this new shipment date due to prior third party production commitments, Patheon may delay the shipment until a later date as agreed to by the parties. All shipments of Active Material will be accompanied by certificate(s) of analysis from the Active Material manufacturer and the Client, confirming the identity and purity of the Active Materials and its compliance with the Active Material specifications. At a minimum, Patheon will perform identity testing on each incoming lot of API and a full testing will be performed at least for one batch per year. Additional incoming tests to be performed on the API will be defined in the respective Product Agreement.

(g) **Bill Back Items.** Bill Back Items will be charged to Client at Patheon’s cost plus a [...]% handling fee for an item costing $[…] or less or, for an item costing in excess of $[…] , a handling fee of [...]%. 

(h) **Validation Activities.** Patheon may assist in the development and approval of the validation protocols for analytical methods and manufacturing procedures (including packaging procedures) for the Products. The fees associated with Patheon’s assistance in providing validation development assistance are set out in Schedule C to a Product Agreement.

(i) **Product Rejection for Finished Product Specification Failure.** Internal process specifications will be defined and agreed upon. If it is determined by a quality investigation that Patheon manufactured Product in accordance with the agreed upon process specifications, the batch production record, and Patheon’s standard operating procedures for manufacturing, but a batch or portion of batch of Product does not meet a Finished Product Specification, Client will pay Patheon the applicable fee per unit for the non-conforming Product. The API in the non-conforming Product will be included in the “Quantity Converted” for purposes of calculating the “Actual Annual Yield” under Section 2.2(a).

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2.2 **Active Material Yield.**

(a) **Reporting.** Patheon will give Client a quarterly inventory report of the Active Materials held by Patheon using the inventory report form set out in Exhibit C, which will contain the following information for the quarter:

**Quantity Received:** The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

**Quantity Dispensed:** The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by [...] The Quantity Dispensed will only include Active Materials received and dispensed in commercial manufacturing of Products and, for certainty, will not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or dispensed in technical transfer activities or development activities during the applicable period, including without limitation, any regulatory, stability, validation or test batches manufactured during the applicable period.

**Quantity Converted:** The total amount of Active Materials contained in the Products manufactured with the Quantity Dispensed (including any additional Products produced in accordance with Section 6.3(a) or 6.3(b)), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 because of Patheon’s failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Within [...] days after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials on the reconciliation report form set forth in Exhibit D including the calculation of the “Actual Annual Yield” or “AAY” for the Product at the Manufacturing Site during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Products and is calculated as follows:

\[
\text{Quantity Converted during the Year} \times \frac{100}{\text{Quantity Dispensed during the Year}}
\]

Unless otherwise agreed in a Product Agreement, after Patheon has produced a minimum of [...] successful commercial production batches of Product and has produced commercial production batches for at least [...] months at the Manufacturing Site (collectively, the “Target Yield Determination Batches”), the parties will agree on the target yield for the Product at the Manufacturing Site (each, a “Target Yield”), The Target Yield will be revised annually to reflect the actual manufacturing experience as agreed to by the parties.

(b) **Shortfall Calculation.** If the Actual Annual Yield falls more than [...] below the respective Target Yield in a Year, then the shortfall for the Year (the “Shortfall”) will be calculated as follows:

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(c) **Credit for Shortfall.** If there is a Shortfall for a Product in a Year, then Patheon will credit Client’s account for the amount of the Shortfall not later than [...***…] days after the end of the Year.

Each credit under this Section 2.2(c) will be summarized on the reconciliation report form set forth in Exhibit D. Upon expiration or termination of a Product Agreement, any remaining credit owing under this Section 2.2 will be paid to Client. The Annual Shortfall, if any, will be disclosed by Patheon on the reconciliation report form.

(d) **Maximum Credit.** Patheon’s liability for Active Materials calculated in accordance with this Section 2.2 [for any Product] in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D to a Product Agreement.

(e) **No Material Breach.** It will not be a material breach of this Agreement by Patheon under Section 8.2(a) if the Actual Annual Yield is less than the Target Yield.

ARTICLE 3

**CLIENT’S OBLIGATIONS**

3.1 **Payment.**

Client will pay Patheon for performing the Manufacturing Services according to the Prices specified in Schedules B and C in a Product Agreement. These Prices may be subject to adjustment under other parts of this Agreement. Client will also pay Patheon for any Bill Back Items.

3.2 **Active Materials and Qualification of Additional Sources of Supply.**

Client will, at its sole cost and expense, deliver the Active Materials to Patheon (in accordance with Section 2.1(f)) sufficient for Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If applicable, Patheon and the Client will reasonably cooperate to permit the import of the Active Materials to the Manufacturing Site. Client’s obligation will include obtaining the proper release of the Active Materials from the applicable Customs Agency and Regulatory Authority. Client or Client’s designated broker will be the “Importer of Record” for Active Materials imported to the Manufacturing Site. The Active Materials will be held by Patheon on behalf of Client as set forth in this Agreement. Title to the Active Materials will at all times remain the property of Client. Any Active Materials received by Patheon will only be used by Patheon to perform the Manufacturing Services. If the Parties mutually determine a need to change the supplier of any Active Material or Component (other than a supplier that is specifically described in an applicable Product Agreement), they will work together to develop a plan to qualify such additional supplier.
ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing

The tiered Price and annual stability Price for the Products for the first Year are listed in Schedules B and C in a Product Agreement and are subject to the adjustments set forth in Sections 4.2 and 4.3. Upon Client’s request, Patheon will provide a breakdown of the manufacturing conversion costs, packaging conversion costs, and the Component costs for a Product.

4.2 Price Adjustments – Subsequent Years’ Pricing

After the first Year of the Product Agreement, but in no case before [...***...], Patheon may adjust the Price effective January 1st of each Year as follows:

(a) Manufacturing and Stability Testing Costs. For Products manufactured in the United States or Puerto Rico, Patheon may adjust the Price for inflation, based upon the preliminary number for any increase in the Producer Price Index pceu325412325412 for Pharmaceutical Preparation Manufacturing ("PPI") published by the United States Department of Labor, Bureau of Labor Statistics in August of the preceding Year compared to the final number for the same month of the Year prior to that, unless the parties otherwise agree in writing. On or about November 1st of each Year, Patheon will give Client a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year. For Products manufactured outside the United States or Puerto Rico, Patheon may similarly adjust the Price for inflation using an inflation index to be agreed by the parties in a Product Agreement.

(b) Component Costs. If Patheon incurs an increase in Component costs during the Year, it may increase the Price for the next Year to pass through the additional Component costs. On or about November 1st of each Year, Patheon will give Client information about the increase in Component costs which will be applied to the calculation of the Price for the next Year to reasonably demonstrate that the Price increase is justified.

(c) Pricing Basis. Client acknowledges that the Price in any Year is quoted based upon the Minimum Order Quantity and the Annual Volume specified in Schedule B to a Product Agreement. The Price is subject to change if [...***...].

(d) Adjustments Due to Currency Fluctuations. If the parties agree in a Product Agreement to invoice in a currency other than the local currency for the Manufacturing Site, Patheon will adjust the Price to reflect currency fluctuations. The adjustment will be calculated after all

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other annual Price adjustments under this Section 4.2 have been made. The adjustment will proportionately reflect the increase or decrease, if any, in the Set Exchange Rate compared to the Set Exchange Rate established for the prior Year or the Initial Set Exchange Rate, as the case may be. An example of the calculation of the price adjustment (for a Canadian Manufacturing Site invoiced in USD) is set forth in Exhibit E.

(e) **Tier Pricing (if applicable).** The pricing in Schedule B of a Product Agreement is set forth in Annual Volume tiers based upon the Client’s volume forecasts under Section 5.1. The Client will be invoiced during the Year for the unit price set forth in the Annual Volume tier based on the […] forecast provided in September of the previous Year. Within […] days of each Year or of the termination of the Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by the Client during the Year with the pricing tiers. If Client has overpaid during the Year, Patheon will issue a credit to the Client for the amount of the overpayment within […] days of the end of the Year or will issue payment to the Client for the overpayment within […] days of the termination of the Agreement. If Client has underpaid during the Year, Patheon will issue an invoice to the Client under Section 5.6 for the amount of the underpayment within […] days of the end of the Year or termination of the Agreement. If Client disagrees with the reconciliation, the parties will work in good faith to resolve the disagreement amicably. If the parties are unable to resolve the disagreement within […] days, the matter will be handled under Section 12.1.

(f) **Process Improvement Efforts.** Patheon continually works to improve its processes to eliminate waste, improve cost efficiencies, deliver product as promised and adhere to strict quality standards. Patheon believes in the continuous improvement of its performance, which led Patheon to create the Patheon Advantage program. Patheon Advantage incorporates Lean6Sigma to identify opportunities and implement changes to maximize the efficiency of Patheon’s processes. If these improvement efforts result in quantifiable reductions in costs in providing the Services contemplated under this Agreement Patheon will promptly notify Client of the reductions, and the Price hereunder will be reduced by […]% of the cost reduction from and after the date of the notice.

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or about November 1st of each Year a revised Schedule B to the Product Agreement to be effective for Product delivered on or after the first day of the next Year.

4.2.1 **Price Adjustment due to Volume Changes from Yearly Forecast Volumes for Sterile Products.**

On the execution of a Product Agreement, Client will give to Patheon a forecast of the volume of Product required for the first […] Years of the Product Agreement (the “Yearly Forecast Volume” or “YFV”) that will become part of the Product Agreement. If at the end of the first Year the aggregate actual volume of Product ordered by Client and invoiced by Patheon under Section 5.6 (“Actual Yearly Volume” or “AYV”) during the Year is less than the YFV as set out in the Product Agreement, then Client will pay Patheon for its non-absorbed fixed manufacturing costs incurred during the Year in an amount to be determined as follows:

\[
\text{Amount due to Patheon} = […]\]

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On or before June 10 of each Year, the parties will agree on the YFV for the next [...] Years of the Product Agreement on a rolling forward basis. The forecast of the volume of Product for the second Year may not vary by more than [...]% from the original YFV for the second Year. Once agreed, the YFV for the next Year will become binding on the parties and any amount due to Patheon will be determined as set forth above.

4.3 Price Adjustments – Current Year Pricing

During any Year, the Prices set out in Schedule B of a Product Agreement will be adjusted as follows:

Extraordinary Increases in Component Costs. If, at any time, market conditions result in Patheon’s cost of Components being materially greater than normal forecasted increases, then Patheon will be entitled to an adjustment to the Price for any affected Product to compensate it for the increased Component costs. Changes materially greater than normal forecasted increases will have occurred if: (i) the cost of a Component increases by [...]% of the cost for that Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases by [...]% of the total Component costs for the Product upon which the most recent fee quote was based. If Component costs have been previously adjusted to reflect an increase in the cost of one or more Components, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Components.

For a Price adjustment under this Section 4.3, Patheon will deliver to Client a revised Schedule B to the Product Agreement and budgetary pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. The revised Price will be effective for any Product delivered on or after the first day of the month following Client’s receipt of the revised Schedule B to the Product Agreement.

4.4 Adjustments Due to Technical Changes

Amendments to the Specifications or the Quality Agreement requested by Client will only be implemented following a technical and cost review that Patheon will perform at Client’s cost, and are subject to Client and Patheon reaching agreement on Price changes required because of the amendment. Amendments to the Specifications, the Quality Agreement, or the Manufacturing Site requested by Patheon will only be implemented following the written approval of Client, the approval not to be unreasonably withheld. If Client accepts a proposed Price change, the proposed change in the Specifications will be implemented at Client’s cost, and the Price change will become effective, only for those orders of Products that are manufactured under the revised Specifications. In addition, Client agrees to purchase, at Patheon’s cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), all Inventory used under the “old” Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 5.2, if the Inventory can no longer be used under the revised Specifications. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 will be cancelled where possible, and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Client. If an amendment to the Specifications or the Quality Agreement becomes necessary as the result of changes to a compendia, the Parties will discuss the necessary changes and Client will be solely responsible for the costs associated with these changes.

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4.5 Multi-Country Packaging Requirements.

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional costs for Components (other than Client-Supplied Components) and the change over fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

ARTICLE 5
ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Rolling [...] Month Forecast. When each Product Agreement is executed, Client will give Patheon a non-binding [...] month forecast of the volume of Product that Client expects to order in the first [...] months of commercial manufacture of the Product. This forecast will then be updated by Client on or before the [...] day of each month on a rolling forward basis. Client will update the forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than [...]. The most recent [...] month forecast will prevail.

(b) Firm Orders. On a rolling basis during the term of the Product Agreement, Client will issue an updated [...] month forecast on or before the [...] day of each month. This forecast will start on the first day of the next month. The first [...] months of this updated forecast will be considered binding firm orders. Concurrent with the [...] month forecast, Client will issue a new firm written order in the form of a purchase order or otherwise ("Firm Order") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Products. The Delivery Date will not be less than [...] days following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client’s purchase order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. The quantities of Products ordered in those written orders will be firm and binding on Client and may not be reduced by Client.

(c) [...] Year Forecast. On or before the [...] day of each Year, Client will give Patheon a written non-binding [...] year forecast, broken down by quarters for the [...] and [...] years of the forecast, of the volume of each Product Client then anticipates will be required to be manufactured and delivered to Client during the [...] year period.

(d) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within [...] Business Days of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from the Client, the Delivery Date for the Product ordered. The Delivery Date may be amended by agreement of the parties or as set forth in Section 2.1(f).

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5.2 **Reliance by Patheon.**

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Sections 5.1(a), and (b) in ordering the Components (other than Client-Supplied Components) required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in sufficient volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components to satisfy the Manufacturing Services requirements for Products for the first [***] months contemplated in the most recent forecast given by Client under Section 5.1(a). Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties. The Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon. If Components ordered by Patheon under Firm Orders or this Section 5.2 are not included in finished Products manufactured for Client within [***] months after the forecasted month for which the purchases have been made (or for a longer period as the parties may agree) or if the Components have expired during the period, then Client will pay to Patheon its costs therefor (including all costs incurred by Patheon for the purchase and handling of the Components). But if these Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

(b) If Client fails to take possession or arrange for the destruction of Components within [***] months of purchase or, in the case of finished Product, within [***] months of manufacture, Client will pay Patheon [***] per pallet, per month thereafter for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at [***] per pallet per month. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship finished Product held by it longer than [***] to the Client at Client’s expense on [***] days written notice to the Client.

5.3 **Minimum Orders.**

Client may only order Manufacturing Services for batches of Products in multiples of the Minimum Order Quantities as set out in Schedule B to a Product Agreement.

5.4 **Shipments.**

Shipments of Products will be made [(Incoterms 2010) Patheon’s shipping point unless otherwise agreed in a Product Agreement. Risk of loss or of damage to Products will remain with Patheon until Patheon loads the Products onto the carrier’s vehicle for shipment at which time risk of loss or damage will transfer to Client. Patheon will, in accordance with Client’s instructions and as agent for Client, (i) arrange for shipping to be paid by Client and (ii) obtain any export license or other official authorization necessary to export the Products. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon’s shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications.

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5.5 Late Delivery
If Patheon is unable to deliver the quantity of Product ordered under a Firm Order within [...***... of the Delivery Date due to an act or omission by Patheon (a “Late Delivery”), Client will receive a credit from Patheon for the Late Delivery that will be applied against the purchase price under the next Firm Order. The credit will be [...***...% of the Price of the quantities of Product not delivered by Patheon under the Firm Order within [...***... of the Delivery Date [...***...]. An additional credit of [...***...% of the Price of the quantities of Product not delivered by Patheon under a Firm Order will accrue for each additional [...***... of the Late Delivery up to a maximum aggregate credit of [...***...%]. A Late Delivery will not be a material breach of this Agreement by Patheon for the purposes of Section 8.2(a). For clarity, a Late Delivery will not include any delay in shipment of Product caused by events outside of Patheon’s reasonable control, such as a Force Majeure Event, a delay in delivery of API or Materials, a delay in Product release approval from Client, inaccurate Client forecasts, receipt of non-conforming API or Client-Supplied Components, or any market driven delays in deliveries from approved vendors.

5.6 Invoices and Payment
Invoices will be sent by fax or email to the fax number or email address given by Client to Patheon in writing. Invoices will be sent when the Product is manufactured and released by Patheon to the Client. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement. Each invoice will, to the extent applicable, identify Client’s Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within [...***...] days of the date thereof. If any portion of an invoice is disputed, the Client will pay Patheon for the undisputed amount and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Beginning [...***...] days after the date of the invoice, interest on undisputed past due accounts will accrue at [...***...]% per month which is equal to an annual rate of [...***...]. The Late Delivery credits set forth in Section 5.5 are only available to Client if all outstanding undisputed invoices have been paid in full or are within [...***...] days outstanding from the invoice date when the Late Delivery arose.

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims
(a) Product Claims. Client has the right to reject any portion of any shipment of Products that deviates from the Specifications, cGMPs, or Applicable Laws without invalidating any remainder of the shipment. Client will inspect the Products manufactured by Patheon upon receipt and will give Patheon written notice (a “Deficiency Notice”) of all claims for Products that deviate from the Specifications, cGMPs, or Applicable Laws within [...***...] days after Client’s receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within [...***...] days after discovery by Client, but not after the expiration date of the Product). Should Client fail to give Patheon the Deficiency Notice within the applicable [...***...] day period, then the delivery will be deemed to have been accepted by Client on the [...***...] day after delivery or discovery, as applicable. Except as set out in Section 6.3, Patheon will have no liability for any deviations for which it has not received notice within the applicable [...***...] day period.

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(b) **Determination of Deficiency.** Upon receipt of a Deficiency Notice, Patheon will have [...***...] days to advise Client by notice in writing that it disagrees with the contents of the Deficiency Notice. If Client and Patheon fail to agree within [...***...] days after Patheon’s notice to Client as to whether any Products identified in the Deficiency Notice deviate from the Specifications, cGMPs, or Applicable Laws, then the parties will mutually select an independent laboratory to evaluate if the Products deviate from the Specifications, cGMPs, or Applicable Laws. This evaluation will be binding on the parties. If the evaluation certifies that any Products deviate from the Specifications, cGMPs, or Applicable Laws, Client may reject those Products in the manner contemplated in this Section 6.1 and Patheon will be responsible for the cost of the evaluation. If the evaluation does not so certify for any of the Products, then Client will be deemed to have accepted delivery of the Products on the [...***...] day after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the [...***...] day after discovery thereof by Client, but not after the expiration date of the Product) and Client will be responsible for the cost of the evaluation.

(c) **Shortages.** Claims for shortages in the amount of Products shipped by Patheon will be dealt with by reasonable agreement of the parties.

### 6.2 Product Recalls and Returns

(a) **Records and Notice.** Patheon and Client will each maintain records necessary to permit a Recall of any Products delivered to Client or customers of Client. Each party will promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Products or which might result in the Recall or seizure of the Products. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Products in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. "Recall" will mean any action (i) by Client to recover title to or possession of quantities of the Products sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any regulatory authorities to detain or destroy any of the Products. Recall will also include any action by either party to refrain from selling or shipping quantities of the Products to third parties which would have been subject to a Recall if sold or shipped.

(b) **Recalls.** If (i) any governmental or regulatory authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a “Dear Doctor” letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by Client, having regard to all applicable laws and regulations.

(c) **Product Returns.** Client will have the responsibility for handling customer returns of the Products. Patheon will give Client any assistance that Client may reasonably require to handle the returns.

### 6.3 Patheon’s Responsibility for Defective and Recalled Products

(a) **Defective Product.** If Client rejects Products under Section 6.1 and the deviation is determined to have arisen from Patheon’s failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will credit Client’s account for Patheon’s invoice price for the defective Products. If Client previously paid for the defective Products, Patheon will promptly, at Client’s election, either: (i) refund the invoice price for the defective Products; (ii) offset the...
amount paid against other amounts due to Patheon hereunder; or (iii) replace the Products with conforming Products without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products. For greater certainty, Patheon’s responsibility for any loss of Active Materials in defective Product will be captured and calculated in the Active Materials Yield under Section 2.2.

(b) **Recalled Product.** If a Recall or return results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will be responsible for the documented out-of-pocket expenses of the Recall or return and will use its commercially reasonable efforts to replace the Recalled or returned Products with new Products, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products. For greater certainty, Patheon’s responsibility for any loss of Active Materials in Recalled Product will be captured and calculated in the Active Materials Yield under Section 2.2. If Patheon is unable to replace the Recalled or returned Products (except where this inability results from a failure to receive the required Active Materials and Client-Supplied Components), then Client may request Patheon to reimburse Client for the price that Client paid to Patheon for Manufacturing Services for the affected Products. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client’s cost and expense.

(c) Except as set forth in Sections 6.3(a) and (b) above, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it, (collectively, "**Product Claims**"). For greater certainty, Patheon will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Products or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iii) results from a defect in the Active Materials or Client-Supplied Components that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iv) is caused by actions of third parties occurring after the Product is shipped by Patheon under Section 5.4, (v) is due to packaging design or labelling defects or omissions for which Patheon has no responsibility, (vi) is due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Specifications, cGMP’s, and Applicable Laws, or (vii) is due to any other breach by Client of its obligations under this Agreement.

### 6.4 Disposition of Defective or Recalled Products

Client will not dispose of any damaged, defective, returned, or Recalled Products for which it intends to assert a claim against Patheon without Patheon’s prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.3. In all other circumstances, Client will bear the cost of disposition, including all applicable fees for Manufacturing Services, for any damaged, defective, returned, or Recalled Products.

### 6.5 Healthcare Provider or Patient Questions and Complaints

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client’s customers, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will give Client all agreed upon information that will enable Client to respond properly to questions or complaints about the Products as
set forth in the Quality Agreement. Unless it is determined that the cause of the complaint resulted from a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, all costs incurred under this Section 6.5 will be borne by Client.

6.6 Sole Remedy.

Except for the indemnity set forth in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 will be Client’s sole remedy for any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws.

ARTICLE 7

CO-OPERATION

7.1 Quarterly Review.

Each party will forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet not less than quarterly to review the current status of the business relationship and manage any issues that have arisen.

7.2 Governmental Agencies.

Subject to Section 7.8, each party may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Products, regarding the Products if, in the opinion of that party’s counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any law, governmental order or regulation. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a party will permit the other party to accompany and take part in any communications with the agency, and to receive copies of all communications from the agency.

7.3 Records and Accounting by Patheon.

Patheon will keep records of the manufacture, testing, and shipping of the Products, and retain samples of the Products as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for [...***...] following the date of Product expiry, or longer if required by law, at which time Client will be contacted concerning the delivery and destruction of the documents and/or samples of Products. Client is responsible for retaining samples of the Products necessary to comply with the legal/regulatory requirements applicable to Client.

7.4 Inspection.

Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, but a Patheon representative must be present during the inspection.

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7.5 **Access.**

Patheon will give Client reasonable access at agreed times to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws. But, with the exception of “for-cause” audits, Client will be limited each Year to one cGMP-type audit, lasting no more than [...***...] days, and involving no more than [...***...] auditors. Client may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of a fee of $[…***...] per audit day and $[…***...] per audit day for each additional auditor. The right of access set forth in this Section 7.5 will not include a right to access or inspect Patheon’s financial records. In addition to any other rights to audit, otherwise described in this Agreement, Client will have the right to have up to [...***...] representatives present for [...***...] days during the manufacturing campaigns of any Product during normal business hours and upon reasonable advance notice to Patheon. If Client’s representatives are present for more than [...***...] days during the manufacturing campaigns of any Products, Client will pay Patheon a fee of $[…***...] per day for each additional day.

7.6 **Notification of Regulatory Inspections.**

Patheon will notify Client within [...***...] of any inspections by any governmental agency specifically involving the Products. Patheon will also notify Client of receipt of any form 483’s or warning letters or any other significant regulatory action which Patheon’s quality assurance group determines could impact the regulatory status of the Products.

7.7 **Reports.**

Patheon will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA. Any additional report requested by Client beyond the scope of cGMPs and customary FDA requirements will be subject to an additional fee to be agreed upon between Patheon and the Client.

7.8 **Regulatory Filings.**

(a) **Regulatory Authority.** Client will have the sole responsibility for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture of the Products. Patheon will assist Client, to the extent consistent with Patheon’s obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible.

(b) **Verification of Data.** Prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, Client will give Patheon a copy of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and regulatory validity of those documents as they relate to Patheon generated data. Patheon requires [...***...] days to perform this review but the parties may agree to a shorter time for the review as needed.

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(c) **Verification of CMC.** Prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA’s Chemistry and Manufacturing Controls (all such documentation herein referred to as “CMC”) related to any Marketing Authorization, such as a New Drug Application or Abbreviated New Drug Application, Client will give Patheon a copy of the CMC as well as all supporting documents which have been relied upon to prepare the CMC. This disclosure will permit Patheon to verify that the CMC accurately describes the work that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Patheon requires […***…] days to perform this review but the parties may agree to a shorter time for the review as needed. Client will give Patheon copies of all FDA filings which contain CMC information regarding the Product within […***…] days of the approval submission.

(d) **Deficiencies.** If, in Patheon’s sole discretion, acting reasonably, Patheon determines that any of the information given by Client under clauses (b) and (c) above is inaccurate or deficient in any manner whatsoever (the “Deficiencies”), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to any pre-approval inspection.

(e) **Client Responsibility.** For clarity, the parties agree that in reviewing the documents referred to in clause (b) above, Patheon’s role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Patheon. Subject to the foregoing, Patheon will not assume any responsibility for the accuracy of any application for receipt of an approval by a Regulatory Authority. The Client is solely responsible for the preparation and filing of the application for approval by the Regulatory Authority and any relevant costs will be borne by the Client.

(f) **Inspection by Regulatory Authorities.** If Client does not give Patheon the documents requested under clause (b) above within the time specified and if Patheon reasonably believes that Patheon’s standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents.

### ARTICLE 8

**TERM AND TERMINATION**

8.1 **Initial Term.**

This Agreement will become effective as of the Effective Date and will continue until December 31, 2019 (the “**Initial Term**”), unless terminated earlier by one of the parties in accordance herewith. This Agreement will automatically renew after the Initial Term for successive terms of […***…] Years each if there is a Product Agreement in effect, unless either party gives written notice to the other party of its intention to terminate this Agreement at least […***…] months prior to the end of the then current term. In any event, the legal terms and conditions of this Agreement will continue to govern any Product Agreement in effect as provided in Section 1.2. Each Product Agreement will have an initial term of […***…] Years from the start of commercial manufacture at the Manufacturing Site for the Product unless the parties agree to a different number of Years in the applicable Product Agreement (each, an “**Initial Product Term**”). Product Agreements will automatically renew after the Initial Product Term for successive terms of […***…] Years each unless either party gives written notice to the other party of its intention to terminate the Product Agreement at least […***…] months prior to the end of the then current term.

8.2 **Termination for Cause.**

(a) Either party at its sole option may terminate this Agreement or a Product Agreement upon written notice where the other party has failed to remedy a material breach of any of its representations,

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warranties, or other obligations under this Agreement or the Product Agreement within [...***...] days following receipt of a written notice (the “Remediation Period”) of the breach that expressly states that it is a notice under this Section 8.2(a) (a “Breach Notice”). The aggrieved party’s right to terminate this Agreement or a Product Agreement under this Section 8.2(a) may only be exercised for a period of [...***...] days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be deemed to have waived the breach of the representation, warranty, or obligation described in the Breach Notice.

(b) Either party at its sole option may immediately terminate this Agreement or a Product Agreement upon written notice, but without prior advance notice, to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement or a Product Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate a Product Agreement upon [...***...] days’ prior written notice if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product. But if this occurs, Client must still fulfill all of its obligations under Section 8.4 below and under any Capital Equipment Agreement regarding the Product.

(d) Patheon may terminate this Agreement or a Product Agreement upon [...***...] months’ prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement or a Product Agreement to an assignee that, in the reasonable opinion of Patheon, is: (i) not a credit worthy substitute for Client or (ii) a Patheon Competitor.

8.3 Product Discontinuation.
Client will give at least [...***...] months’ advance notice if it intends to no longer order Manufacturing Services for a Product due to this Product’s discontinuance in the market.

8.4 Obligations on Termination.
If a Product Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

(a) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged under a Firm Order, at the price in effect at the time the Firm Order was placed, subject to Client’s right to reject any such Product as described in Article 6 of this Agreement;

(b) Client will purchase, at Patheon’s cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), the Inventory applicable to the Products which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2, but not including Components which Patheon can use in its other Manufacturing operations and not including any Inventory that has been stored or otherwise maintained in an environment that a Regulatory Authority has determined, or would reasonably determine, is not cGMP compliant;

(c) Client will satisfy the purchase price payable under Patheon’s orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2;
(d) Client acknowledges that no Patheon Competitor will be permitted access to the Manufacturing Site; and

(e) Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within [...***...] days, all unused Active Material and Client-Supplied Components, all applicable Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, [E]quipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon’s care and control (“Client Property”). If Client fails to remove the Client Property within [...***...] days following the completion, termination, or expiration of the Product Agreement, Client will pay Patheon [...***...] per pallet, per month, one pallet minimum (except that Client will pay [...***...] per pallet, per month, one pallet minimum, for any of the Client Property that contains controlled substances, requires refrigeration or other special storage requirements) thereafter for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.6 of this Agreement.

(f) The parties will reasonably cooperate to support the transfer of the manufacture of the Products to a third party manufacturer.

Any termination or expiration of this Agreement or a Product Agreement will not affect any outstanding obligations or payments due prior to the termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement or a Product Agreement or any related Capital Equipment Agreement. For greater certainty, termination of this Agreement or of a Product Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 6, 10 and 11 and Sections 5.4, 5.6, 8.4, 13.1, 13.2, 13.3, and 13.16, all of which survive any termination.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

9.2 Client Warranties

Client covenants, represents, and warrants that:

(a) Non-Infringement

(i) the Specifications for each of the Products are its or its Affiliate’s property and that Client may lawfully disclose the Specifications to Patheon;

(ii) any Client Intellectual Property, used by Patheon in performing the Manufacturing Services according to the Specifications (A) is Client’s or its Affiliate’s unencumbered property, (B) may be lawfully used as directed by Client, and (C) does not infringe and will not infringe any Third Party Rights;

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(iii) the performance of the Manufacturing Services by Patheon for any Product under this Agreement or any Product Agreement or the use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement or under any Product Agreement does not and will not infringe any Third Party Rights;

(iv) there are no actions or other legal proceedings, concerning the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Components, or the sale, use, or other disposition of any Product made in accordance with the Specifications;

(b) Quality and Compliance.

(i) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws;

(ii) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets the Products, (ii) will be fit for the purpose intended, and (iii) will be safe for human consumption;

(iii) on the date of shipment, the API will conform to the specifications for the API that Client has given to Patheon and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

9.3 Patheon Warranties

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws; and

(b) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon’s or its Affiliate’s unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights.

9.4 Debarred Persons

Patheon covenants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the Federal Food, Drug, and Cosmetic Act (United States).
9.5 **Permits.**

Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

Patheon will maintain at all relevant times all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

9.6 **No Warranty.**

**PATHEON MAKES NO WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OF MERCHANTABILITY FOR THE PRODUCTS.**

**ARTICLE 10**

**REMEDIES AND INDEMNITIES**

10.1 **Consequential Damages.**

Under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

10.2 **Limitation of Liability.**

(a) **Active Materials.** Except as expressly set forth in Section 2.2, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials. Patheon’s maximum responsibility for loss or damage to the Active Materials will not exceed the Maximum Credit Value set forth in Schedule D of a Product Agreement.

(b) **Maximum Liability.** Patheon’s maximum liability to Client under this Agreement or any Product Agreement for any reason whatsoever, including, without limitation, any liability arising under Article 6 hereof or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement or any Product Agreement, but excluding [...]***..., will not exceed on a per Product basis [...]***...% of revenues per Year to Patheon under the applicable Product Agreement, up to a maximum of [...]***... in the aggregate per Year for all Products.

10.3 **Patheon.**

Patheon agrees to defend and indemnify Client, its officers, employees, and agents against all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any claim of personal injury or property damage to the extent that the injury or damage is the result of a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws except to the extent that the

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losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Client, its officers, employees, agents, or Affiliates.

If a claim occurs, Client will: (a) promptly notify Patheon of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Patheon in the defense of the claim; and (d) permit Patheon to control the defense and settlement of the claim, all at Patheon’s cost and expense.

10.4 Client

Client agrees to defend and indemnify Patheon, its officers, employees, and agents against all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any claim of infringement or alleged infringement of any Third Party Rights in the Products, or any portion thereof, or any claim of personal injury or property damage to the extent that the injury or damage is the result of a breach of this Agreement by Client, including, without limitation, any representation or warranty contained herein, except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Patheon, its officers, employees, or agents.

If a claim occurs, Patheon will: (a) promptly notify Client of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Client in the defense of the claim; and (d) permit Client to control the defense and settlement of the claim, all at Client’s cost and expense.

10.5 Reasonable Allocation of Risk

This Agreement (including, without limitation, this Article 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Products. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Products because Client has developed and holds the marketing approval for the Products, Client requires Patheon to manufacture and label the Products strictly in accordance with the Specifications, and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Products.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidentiality

The Confidentiality Agreement will apply to all confidential information disclosed by the parties under this Agreement or any Product Agreement. If the Confidentiality Agreement expires or is terminated prior to the expiration or termination of this Agreement or any Product Agreement, the terms of the Confidentiality Agreement will continue to govern the parties’ obligations of confidentiality for any confidential or proprietary information disclosed by the parties hereunder, for the term of this Agreement or any Product Agreement, as though the Confidentiality Agreement remained in full force and effect.
ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Disputes

If any dispute arises out of this Agreement or any Product Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined herein), the parties will first try to resolve it amicably. In that regard, any party may send a notice of dispute to the other, and each party will appoint, within [...***...] Business Days from receipt of the notice of dispute, a single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within [...***...] from their appointment, or if a party fails to appoint a representative within the [...***...] Business Day period set forth above, the dispute will immediately be referred to the Chief Operating Officer (or another officer as he/she may designate) of each party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.16.

12.2 Technical Dispute Resolution

If a dispute arises (other than disputes under Sections 6.1(b) or 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement (a “Technical Dispute”), the parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, senior representatives of each party will, as soon as possible and in any event no later than [...***...] Business Days after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within [...***...] Business Days of the written request, the Technical Dispute will, at the request of either party, be referred for determination to an expert in accordance with Exhibit A. If the parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

ARTICLE 13

MISCELLANEOUS

13.1 Corporate Responsibility. Patheon, while performing the Manufacturing Services under this Agreement, will comply, in all material respects, with all applicable laws, rules, regulations, and standards that relate to the Agreement including, but not limited to, those relating to environmental matters, public health, wages, hours and conditions of employment, subcontractor selection, discrimination and occupational health/safety. Without limiting the foregoing, Patheon covenants that neither Patheon nor any of its subcontractors will utilize child or any form of forced or involuntary labor while performing the Manufacturing Services under this Agreement. Upon Client’s reasonable written request, Patheon will certify in writing its compliance with this Section 13.1 and will provide copies of all applicable permits, certificates and licenses that may be required for its performance under this Agreement. Upon Client’s reasonable written request, Patheon will allow Client or its authorized representatives to audit the Manufacturing Site to verify Patheon’s performance against the requirements

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in this Section 13.1. This audit right does not include the right to interview any Patheon employee or subcontractor or to review any personnel or medical files of Patheon’s employees, any Environmental, Health or Safety files of Patheon, any internal audit files of Patheon, or any financial records, including payroll records, of Patheon. Client will have the right to terminate this Agreement in whole or in part, as set forth in Section 8.2(a), if Patheon fails to materially comply with the requirements of this Section 13.1.

13.2 Inventions.

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client’s Intellectual Property which Patheon must use in order to perform the Manufacturing Services.

(b) All Intellectual Property generated or derived by Patheon while performing the Manufacturing Services, to the extent it is specific to the development, manufacture, use, and sale of Client’s Product that is the subject of the Manufacturing Services, will be the exclusive property of Client.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable license to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services to enable Client to manufacture the Product(s).

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

(e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Products or processes or technology owned or otherwise controlled by the party.

13.3 Intellectual Property.

Subject to Section 13.1, all Client Intellectual Property will be owned by Client and all Patheon Intellectual Property will be owned by Patheon. Neither party has, nor will it acquire, any interest in any of the other party’s Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13.4 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of three years thereafter. This insurance will have policy limits of not less than (i) $[...***...] for each occurrence for personal injury or property damage liability; and (ii) $[...***...] in the aggregate per annum for product and completed operations liability. If requested each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of [...***...] days’ written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will forthwith notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

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13.5 **Independent Contractors.**

The parties are independent contractors and this Agreement and any Product Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.6 **No Waiver.**

Either party’s failure to require the other party to comply with any provision of this Agreement or any Product Agreement will not be deemed a waiver of the provision or any other provision of this Agreement or any Product Agreement, with the exception of Sections 6.1 and 8.2 of this Agreement.

13.7 **Assignment.**

(a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld. But Patheon may arrange for subcontractors to perform specific testing services arising under any Product Agreement without the consent of Client. Further it is specifically agreed that Patheon may subcontract any part of the Manufacturing Services under a Product Agreement to any of its Affiliates with Client’s written consent, this consent not to be unreasonably withheld.

(b) Subject to Section 8.2(d), Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement or the Product Agreement, and Client will remain liable hereunder. Any partial assignment will be subject to Patheon’s cost review of the assigned Products and Patheon may terminate this Agreement or any Product Agreement or any assigned part thereof, on [...***...] months’ prior written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time.

(c) Despite the foregoing provisions of this Section 13.6, either party may assign this Agreement or any Product Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound hereunder.

13.8 **Force Majeure.**

Neither party will be liable for the failure to perform its obligations under this Agreement or any Product Agreement if the failure is caused by an event beyond that party’s reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within colour of right (a “**Force Majeure Event**”). A party claiming a right to excused performance under this Section 13.7 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for

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delayed payment) which would otherwise be due and payable under this Agreement or any Product Agreement.

13.9 Additional Product

Additional Products may be added to, or existing Products deleted from, any Product Agreement by amendments to the Product Agreement including Schedules A, B, C, and D as applicable.

13.10 Notices

Unless otherwise agreed in a Product Agreement, any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery, by telecopy, facsimile communication, or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses, telecopy or facsimile numbers or electronic mail addresses set forth below:

If to Client:
Horizon Pharm Inc.
520 Lake Cook Road Suite 520
Deerfield, IL 60015
Attention: Jeff Sherman
Telecopier No.: (224) 383-3001
Email address: JSherman@horizonpharma.com

With a copy to:
Horizon Pharm Inc.
520 Lake Cook Road Suite 520
Deerfield, IL 60015
Attention: Brian Beeler
Telecopier No.: (224) 383-3001
Email address: BBeeler@horizonpharma.com

If to Patheon:
Patheon Pharmaceuticals Inc
2110 East Galbraith Road
Cincinnati, OH 45237-1625
Attention: [...***...]
Telecopier No.: [...***...]
Email address: [...***...]

With a copy to:
Patheon Inc.
4721 Emperor Boulevard
Research Triangle Park,
NC 27703

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given by personal delivery, telecopy, facsimile, or electronic mail will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner.

13.11 **Severability.**

If any provision of this Agreement or any Product Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.12 **Entire Agreement.**

This Agreement, together with the applicable Product Agreement, Quality Agreement and the Confidentiality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement or any Product Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Product Agreement, the Quality Agreement, and the Confidentiality Agreement.

13.13 **Other Terms.**

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement or any Product Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement or the applicable Product Agreement and is signed by both parties.

13.14 **No Third Party Benefit or Right.**

For greater certainty, nothing in this Agreement or any Product Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement or any Product Agreement.

13.15 **Execution in Counterparts.**

This Agreement and any Product Agreement may be executed in two or more counterparts, by original or facsimile signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.16 **Use of Client Name.**

Patheon will not make any use of Client’s name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client, which consent will not be unreasonably withheld. Despite this, Client agrees that Patheon may include Client’s name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon’s Manufacturing Services.
13.17 **Governing Law.**

This Agreement and, unless otherwise agreed by the parties, any Product Agreement, will be construed and enforced in accordance with the laws of the State of New York and the laws of the United States of America applicable therein and subject to the exclusive jurisdiction of the courts thereof. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

[Signature page to follow]

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IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the Effective Date.

PATHEON PHARMACEUTICALS INC.

By:   /s/ Dean Wilson
Name: Dean Wilson
Title: Corporate Controller

HORIZON PHARMA INC.

By:   /s/ Jeffrey W. Sherman
Name: Jeffrey W. Sherman, M.D., FACP
Title: Chief Medical Officer, EVP

HORIZON PHARMA INC.

By:   /s/ Todd N. Smith
Name: Todd N. Smith
Title: CCO, EVP
APPENDIX I

FORM OF PRODUCT AGREEMENT

(Includes Schedules A to D)

PRODUCT AGREEMENT

This Product Agreement (this “Product Agreement”) is issued under the Master Manufacturing Services Agreement dated October 31, 2013 between Patheon Pharmaceuticals Inc., and Horizon Pharma Inc., (the “Master Agreement”), and is entered into [insert effective date] (the “Effective Date”), between Patheon Pharmaceuticals Inc., [or applicable Patheon Affiliate], a corporation existing under the laws of the State of Delaware [or applicable founding jurisdiction for Patheon Affiliate], having a principal place of business at 2110 East Galbraith Road, Cincinnati, OH 45237-1625 [or Patheon Affiliate address] (“Patheon”) and [insert Client name, legal entity, founding jurisdiction and address] (“Client”).

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. **Product List and Specifications** (See Schedule A attached hereto)
2. **Minimum Order Quantity, Annual Volume, and Price** (See Schedule B attached hereto)
3. **Annual Stability Testing and Validation Activities (if applicable)** (See Schedule C attached hereto)
4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)
5. **Yearly Forecasted Volume**: (insert for sterile products in Italy if applicable under section 4.2.1)
6. **Territory**: (insert the description of the Territory here)
7. **Manufacturing Site**: (insert address of Patheon Manufacturing Site where the Manufacturing Services will be performed)
8. **Governing Law**: (if applicable under Section 13.16 of the Master Agreement)
9. **Inflation Index**: (if applicable under Section 4.2(a) of the Master Agreement for Products manufactured outside of the United States or Puerto Rico)
10. **Currency**: (if applicable under Section 1.4 of the Master Agreement)
11. **Initial Set Exchange Rate**: (if applicable under Section 4.2(d) of the Master Agreement)

12. **Initial Product Term**: (if applicable under Section 8.1 of the Master Agreement)

13. **Notices**: (if applicable under Section 13.9 of the Master Agreement)

14. **Other Modifications to the Master Agreement**: (if applicable under Section 1.2 of the Master Agreement)

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

**PATHEON PHARMA INC. [or applicable Patheon Affiliate]**

By: 
Name: 
Title: 

**HORIZON PHARMA INC. [or applicable Horizon Affiliate]**

By: 
Name: 
Title: 

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SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

[...***...]

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SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME, AND PRICE

[...***...]
SCHEDULE C

ANNUAL STABILITY TESTING [and VALIDATION ACTIVITIES (if applicable)]

[...***...]

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## SCHEDULE D

### ACTIVE MATERIALS

<table>
<thead>
<tr>
<th>Active Materials</th>
<th>Supplier</th>
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<td>✗</td>
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</tr>
</tbody>
</table>

### ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>ACTIVE MATERIALS</th>
<th>ACTIVE MATERIALS CREDIT VALUE</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>[...***...]</td>
</tr>
</tbody>
</table>

### MAXIMUM CREDIT VALUE

Patheon’s liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement [for any Product] in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>MAXIMUM CREDIT VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[% of revenues per Year to Patheon under this Product Agreement, up to a maximum of $[ ] in the aggregate per Year.</td>
</tr>
</tbody>
</table>

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EXHIBIT A

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 will be resolved in the following manner:

1. Appointment of Expert. Within [...] Business Days after a party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the parties are unable to so agree within the [...] Business Day period, or in the event of disclosure of a conflict by an expert under Paragraph 2 hereof which results in the parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.

2. Conflicts of Interest. Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the parties will, after the disclosure, have confirmed his appointment.

3. Not Arbitrator. No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert’s determination or the procedure by which the expert reaches his determination under this Exhibit A.

4. Procedure. Where an expert is appointed:

   (a) Timing. The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and that he issues the authorizations to the parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within [...] Business Days (or another other date as the parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.

   (b) Disclosure of Evidence. The parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within [...] Business Days of a written request from the relevant expert to do so.

   (c) Advisors. Each party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the parties will co-operate and seek to narrow and limit the issues to be determined.

   (d) Appointment of New Expert. If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment, a new expert may (at the request of either party) be appointed and the appointment of the

*** Confidential Treatment Requested

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existing expert will thereupon cease for the purposes of determining the matter at issue between the parties save this if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.

(e) **Final and Binding.** The determination of the expert will, except for fraud or manifest error, be final and binding upon the parties.

(f) **Costs.** Each party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

For greater certainty, the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.
EXHIBIT C

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

TO: HORIZON PHARMA INC

FROM: PATHEON PHARMACEUTICALS INC. [or applicable Patheon entity]

RE: Active Materials quarterly inventory report under Section 2.2(a) of the Master Manufacturing Services Agreement dated October 31, 2013 (the “Agreement”)

[***]

*** Confidential Treatment Requested

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EXHIBIT D

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL ANNUAL YIELD

TO:                  HORIZON PHARMA INC.
FROM:                PATHEON PHARMACEUTICALS INC. [or applicable Patheon entity]
RE:                  Active Materials annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.2(a) of the Master Manufacturing Services Agreement dated October 31, 2013 (the "Agreement")

[***]

*** Confidential Treatment Requested

- 2 -
Based on the foregoing reimbursement calculation Patheon will reimburse Client the amount of $___.

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

DATE: ____________

PATHEON PHARMACEUTICALS INC.
[or applicable Patheon entity]

Per: ___________________________
Name: _________________________
Title: _________________________

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- 2 -
EXAMPLE OF PRICE ADJUSTMENT DUE TO CURRENCY FLUCTUATION

Section 4.2(d)

SAMPLE EXCHANGE CALCULATION

<table>
<thead>
<tr>
<th></th>
<th>CAD/USD</th>
<th>USD/CAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Rate</td>
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<td></td>
</tr>
<tr>
<td>Set Rate</td>
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</tr>
<tr>
<td>Initial Price</td>
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<td></td>
</tr>
<tr>
<td>Revised Price</td>
<td>3.70</td>
<td></td>
</tr>
</tbody>
</table>

(Material price and PPI adjustments)

Calculation:

\[
\frac{\text{(Revised Price (After FX))}}{\text{(Revised Price (Before FX))}} = \frac{\text{(Initial Exchange Rate)}}{\text{(Set Exchange Rate)}}
\]

\[
= \frac{3.70 \times 1.000}{0.998}
\]

\[
= 3.71
\]
EXECUTIVE EMPLOYMENT
AGREEMENT BY AND BETWEEN
HORIZON PHARMA, INC., HORIZON PHARMA USA, INC. AND
ROBERT F. CAREY

This Executive Employment Agreement (hereinafter referred to as the “Agreement”), is entered into 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 Robert F. Carey (hereinafter referred to as the “Executive”). The terms of this Agreement shall remain confidential until the Executive’s first day of employment with the Company (the “Date of Hire”), which will be on March 5, 2014 and which is also the effective date of this Agreement (the “Effective Date”).

RECITALS

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

WHEREAS, Executive desires to be in the employ of the Company, and is willing to accept such 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. 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, Chief Business Officer (hereinafter referred to as “CBO”) of the Company and shall serve in such other capacity or capacities commensurate with his position as CBO as the President and Chief Executive Officer 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 CBO including being responsible for the Company’s business development, alliance management, corporate strategy and investor relations. The Executive shall report to the President and Chief Executive Officer.

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 headquarters office for the Company in the Deerfield, Illinois area. The Company may from time to time require the Executive to travel temporarily to other locations outside of the Northbrook, Illinois area 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 Executive’s duties under this Agreement. Subject to the prior written consent of the President and Chief Executive Officer, the Executive is permitted to serve on the board of directors of up to two public companies, so long as the other companies do not compete with the Company.

2.2 **Exclusive Employment.** Except with the prior written consent of the Board, 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 Executive is a passive investor. 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 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. Notwithstanding the foregoing, Executive may invest and/or maintain investments in public or private life sciences companies up to an amount of 2% of an entity’s fully diluted shares and on a passive basis.
3. **Compensation to Executive.**

3.1 **Base Salary.** The Company shall pay the Executive a base salary at the initial annualized rate of four hundred thousand dollars ($400,000.00) 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. Executive’s Base Salary will be reviewed annually each December and 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 material reduction in the Base Salary of the Executive, without his written consent, may 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 fifty percent (50%) of the Executive’s Base Salary, subject to standard deductions and withholdings. The bonus shall be based upon (a) the Chief Executive Officers recommendation and the Board’s determination, in good faith, of whether the Executive achieved certain performance milestones established for the Executive by the Board in good faith (herein referred to as the "Performance Milestones") and (b) company performance objectives as set by the Board. 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 materially reduced upon 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 performance calendar year.

3.3 **Equity Awards.** As an inducement to the Executive’s commencement of employment with the Company, at the next scheduled Compensation Committee meeting that follows the Date of Hire the Executive will be granted the following equity awards as "Inducement Awards" pursuant to and subject to the terms of the Company’s 2011 Equity Incentive Plan and its form of stock option and restricted stock unit award agreements, in the forms provided to Executive concurrently with this Agreement (collectively the “Equity Plan Documents”) and compliance with applicable securities laws:

3.3.1 **Inducement Option.** A non-qualified stock option to purchase up to 100,000 shares of the Company’s common stock (the “Inducement Option”). The
Inducement Option will have an exercise price equal to the fair market value of the Company’s common stock on the applicable date of grant. Subject to Executive’s continuous service with the Company through the first anniversary of the Date of Hire, the Inducement Option will vest 1/12th monthly and be vested in full on the first anniversary of the Date of Hire.

3.3.2 New Hire Option. An additional non-qualified stock option to purchase up to 140,000 shares of the Company’s common stock (the “New Hire Option”). The New-Hire Option will have an exercise price equal to the fair market value of the Company’s common stock on the applicable date of grant. Subject to Executive’s continued provision of services to the Company through the applicable vesting dates, the New Hire Option shall vest as follows: 25% of the total number of shares subject to the New Hire Option shall vest on the first anniversary of the Date of Hire and 1/36 of the remaining number of shares subject to the New-Hire Option shall vest on each monthly anniversary thereafter so that the New Hire Option would fully vest on the four (4) year anniversary of the Date of Hire subject to Executive’s continued services with the Company through such date.

3.3.3 New Hire Restricted Stock Unit Award. A restricted stock unit award in respect of 124,000 shares of the Company’s common stock granted at a price of $0 in consideration of the Executive’s continued services hereunder (the “RSU Award”). Subject to Executive’s continued provision of services to the Company through the applicable vesting dates, the RSU Award shall vest as follows: 25% of the total number of units subject to the RSU Award shall vest on each anniversary of the Date of Hire so that the RSU Award would fully vest on the four (4) year anniversary of the Date of Hire subject to Executive’s continued services with the Company through such date.

3.4 Retention Bonus. Within thirty (30) days of Executive’s Date of Hire, Executive will be advanced a one-time bonus of one hundred thousand dollars ($100,000.00) (the “Retention Bonus”). Additionally, the Company shall also pay the Executive additional amounts (the “Gross-Up Payments”) such that after payment by Executive of all applicable federal, state and local taxes, imposed upon the Retention Bonus and such Gross-Up Payments, Executive will retain a net amount equal to the amount of the Retention Bonus ($100,000.00). For purposes of this provision, Executive’s applicable federal, state and local taxes shall be computed at the maximum marginal rates, taking into account the effect of any loss of personal exemptions resulting from receipt of the Gross-Up Payments. The Retention Bonus and the Gross-Up Payments are intended to compensate Executive for the costs of relocating Executive’s residence to Deerfield Illinois. To earn the Retention Bonus and the Gross-Up Payments, the Executive must remain employed with the Company through the first anniversary of the Date of Hire. If, prior to the first anniversary of the Date of Hire, Executive resigns for any reason other than for Good Reason, or the Company terminates his employment for Cause, Employee must repay to the Company, on or within thirty (30) days after the
employment termination date, an amount equal to the sum of the Retention Bonus and the Gross-Up Payments.

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 up to $10,000.00 of such legal fees subject to receipt of appropriate proof and verification of such legal fees no later than sixty (60) days of receipt of an invoice for legal services from the Executive and/or his attorneys. To be eligible for reimbursement, the invoice must be submitted no later than ninety (90) days after the legal fees are incurred.

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 CEO 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 Executive, and/or 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.

(i) Not in Connection With a Change in Control. If the Company terminates the Executive’s employment without Cause or the Executive terminates his employment for Good Reason, and Section 4.4.3(ii) below does not apply, 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 Executive entering into no later than the Release Effective Date a non-competition agreement to be effective during the Severance Period (as defined below), substantially similar to Section 2.3, and continuing to abide by its terms during the Severance Period, the Executive shall be entitled to:

(a) the equivalent of the Executive’s Base Salary in effect at the time of termination will continue to be paid 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; and

(b) in the event the Executive timely elects continued coverage under COBRA, the Company will continue to pay the same portion of 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 Company paid for benefits to the qualifying family members of the Executive, following the date of termination 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 (such period, the “COBRA Payment Period”). Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive a taxable cash amount, which
payment shall be made regardless of whether the Executive or his qualifying family members elect COBRA continuation coverage (the “Health Care Benefit Payment”). The Health Care Benefit Payment shall be paid in monthly or bi-weekly installments on the same schedule that the COBRA premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the COBRA Payment Period.

(ii) In Connection With a Change in Control. If the Company (or its successor) terminates the Executive’s employment without Cause or the Executive terminates his employment for Good Reason within the period commencing ninety (90) days immediately prior to a Change in Control of the Company and ending eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the Executive shall receive 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 (or its successor) an executed 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, and subject to 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, then in lieu of (and not additional to) the benefits provided pursuant to Section 4.4.3(i) above, the Executive shall be entitled to:

(a) the equivalent of the Executive’s Base Salary in effect at the time of termination will continue to be paid during 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;

(b) Executive’s target Bonus in effect at the time of termination, or if none, the last target Bonus in effect for Executive, less standard deductions and withholdings, to be paid in a lump sum within ten (10) days following the later of (i) the Release Effective Date, or (ii) the effective date of the Change in Control; and

(c) in the event the Executive timely elects continued coverage under COBRA, the Company will continue to pay the same portion of 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 Company paid for benefits to the qualifying family members of the Executive, following the date of termination until the expiration of the COBRA Payment Period.
Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive the Health Care Benefit Payment, which payment shall be made regardless of whether the Executive or his qualifying family members elect COBRA continuation coverage. The Health Care Benefit Payment shall be paid in monthly or bi-weekly installments on the same schedule that the COBRA premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the COBRA Payment Period.

(iii) No Duplication of Benefits. For the avoidance of doubt, in no event will Executive be entitled to benefits under Section 4.4.3(i) and Section 4.4.3(ii). If Executive commences to receive benefits under Section 4.4.3(i) due to a qualifying termination prior to a Change in Control and thereafter becomes entitled to benefits under Section 4.4.3(ii), any benefits previously provided to Executive under Section 4.4.3(i) shall offset the benefits to be provided to Executive under Section 4.4.3(ii) and shall be deemed to have been provided to Executive pursuant to Section 4.4.3(ii).

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 the Inducement Option, the New Hire Option, the RSU Award and any other Company equity awards granted to Executive shall be fully accelerated such that on the effective date of such termination one hundred percent (100%) of the equity award shares granted to Executive prior to such termination shall be fully vested and immediately exercisable, if applicable, by the Executive.

(ii) Without Cause or for Good Reason. In the event that the Executive’s employment is terminated without Cause or for Good Reason, the vesting of the Inducement Option shall be fully accelerated such that on the effective date of such termination one hundred percent (100%) of the Inducement Option equity award shares granted to Executive prior to such termination shall be fully vested and immediately exercisable, if applicable, by the Executive.

(iii) 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 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 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 Executive’s termination of employment unless and until 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 Executive without causing 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 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 Executive’s Separation From Service, or (ii) the date of 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 Executive a lump sum amount equal to the sum of the Severance Benefit payments that 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, Executive shall receive the Severance Benefits described above, if and only if 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 Executive the Severance Benefits 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.

The severance benefits are intended to qualify for an exemption from application of Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences under Section 409A, and any ambiguities herein shall be interpreted accordingly.

4.7 Application of Internal Revenue Code Section 280G. If any payment or benefit 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 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 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, 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, Executive will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

Unless 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 Executive and the Company within fifteen (15) calendar days after the date on which Executive’s right to a Payment is triggered (if requested at that time by Executive or the Company) or such other time as requested by Executive or the Company.

4.8 Indemnification Agreement. Concurrently with the execution of this Agreement, the Company and the Executive shall enter into an indemnification agreement, a copy of which is attached hereto as Exhibit B.

4.9 Confidential Information and Invention Assignment Agreement. Concurrently with the execution of this Agreement, the Executive shall execute the Company’s Confidential Information and Invention Assignment Agreement, 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, assignee, administrator, 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 & Chief Executive Officer
Fax: 847-572-1372

If to the Executive:

Robert F. Carey
2534 Lake Shore Drive
Long Beach, IN 46360

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 Equity Plan Documents, 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 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:

Title: Chairman, President and Chief Executive Officer

Print Name: Timothy P. Walbert

/s/ Timothy P. Walbert

Signature:

As authorized agent of the Company

Date: March 5, 2014

EXECUTIVE:

Robert F. Carey

/s/ Robert F. Carey

Robert F. Carey, individually

Date: March 5, 2014
Subsidiaries of Horizon Pharma, Inc.:

<table>
<thead>
<tr>
<th>NAME</th>
<th>JURISDICTION OF INCORPORATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horizon Pharma USA, Inc.</td>
<td>Delaware</td>
</tr>
<tr>
<td>Horizon Pharma (UK) Limited</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Horizon Pharma AG</td>
<td>Switzerland</td>
</tr>
<tr>
<td>Horizon Pharma GmbH</td>
<td>Germany</td>
</tr>
</tbody>
</table>
CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-175876) and on Form S-3 (No. 333-0182975) of Horizon Pharma, Inc. of our report dated March 13, 2014 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Chicago, Illinois
March 13, 2014

1.
I, Timothy P. Walbert, certify that:

1. I have reviewed this annual report on Form 10-K of Horizon Pharma, Inc. (the “registrant”);

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c. 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
   d. 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: March 13, 2014

/s/ Timothy P. Walbert
Timothy P. Walbert
President, Chief Executive Officer and
Chairman of the Board
(Principal Executive Officer)
I, Robert J. De Vaere, certify that:

1. I have reviewed this annual report on Form 10-K of Horizon Pharma, Inc. (the “registrant”);

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c. 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
   d. 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: March 13, 2014

/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 Annual Report on Form 10-K for the fiscal year ended December 31, 2013 (the “Report”), to which this Certification is attached as Exhibit 32.1, 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: March 13, 2014

/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-K 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-K), 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2013 (the “Report”), to which this Certification is attached as Exhibit 32.2, 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: March 13, 2014

/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-K 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-K), irrespective of any general incorporation language contained in such filing.
UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENTS OF INCOME/(LOSS)

Introductory Note

Description of the Transactions

On November 18, 2013 we entered into an asset purchase agreement with AstraZeneca AB (“AstraZeneca”), pursuant to which we agreed to acquire from AstraZeneca and its affiliates certain intellectual property and other assets, and assume from AstraZeneca and its affiliates certain contingent liabilities, each with respect to VIMOVO®, and obtain rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with non-steroidal anti-inflammatory drugs in the United States (collectively, the “VIMOVO Acquisition”). In connection with the closing of the VIMOVO Acquisition, on November 22, 2013 our letter agreement with AstraZeneca and Pozen Inc. (“Pozen”) became effective, AstraZeneca assigned to us its amended and restated collaboration and license agreement for the United States with Pozen, as amended (the “Pozen License Agreement”), and we entered into a license agreement with AstraZeneca (the “AstraZeneca License Agreement”), a transition agreement with AstraZeneca and a supply agreement with AstraZeneca’s affiliate, AstraZeneca LP.

In addition, on November 22, 2013, we closed our offering of $150 million aggregate principal amount of 5.00% Convertible Senior Notes due 2018 (the “Notes”) pursuant to note purchase agreements (the “Note Purchase Agreements”) entered into by and between us and the purchasers of the Notes (the “Purchasers”). In connection with the closing, on November 22, 2013, we issued and sold to the Purchasers the Notes pursuant to the Note Purchase Agreements. The Notes are governed by an Indenture, dated as of November 22, 2013 (the “Indenture”), between us and U.S. Bank National Association, as trustee (the “Trustee”).

$70.4 million of the net proceeds we received from the sale and issuance of the Notes was used to repay all obligations under our previous senior secured loan as of November 22, 2013.

On November 22, 2013, we, at a cost of $18.7 million, also entered into capped call transactions to cover, subject to anti-dilution adjustments substantially similar to those applicable to the Notes, the number of shares of our common stock underlying the Notes. The capped call transactions were entered into to reduce potential dilution to our common stock upon any conversion of the Notes in excess of the principal amount of converted Notes if the market price per share of our common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the Notes. We expect the options that are part of the capped call transactions to be exercised shortly prior to the maturity date of the Notes and will settle on or about the maturity date of the Notes. We will not be required to make any cash payments to the option counterparties or their respective affiliates upon the exercise of such options, but will be entitled to receive from the option counterparties a number of shares of our common stock generally based on the amount by which the market price of our common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions during the relevant settlement averaging period under the capped call transactions.

Basis of Presentation

The determination of the accounting for the VIMOVO Acquisition as a business acquisition was based on a review of all pertinent facts and circumstances and was based on a number of factors outlined in ASC 805 “Business Combinations” which provides guidance in identifying transactions as an asset acquisition or a business acquisition. After consideration of the factors outlined in the prescribed ASC guidance, it was determined that the VIMOVO Acquisition should be accounted for as a business acquisition and accounted for using the “acquisition method” of accounting.

Further, pursuant to a number of factors outlined in ASC 815 “Derivatives and Hedging”, the conversion option in the Notes was deemed to be an embedded derivative that required bifurcation and separate accounting. As such, we recorded the fair value of the conversion option as if separate from the Note issuance and appropriately recorded that value as a derivative liability.

The following unaudited pro forma condensed combined financial information is presented to illustrate: (i) the VIMOVO Acquisition, (ii) the issuance of the Notes in connection with the VIMOVO Acquisition, (iii) the concurrent repayment of the Company’s previous senior secured loan, and (iv) the issuance of the capped call transactions, collectively the “Transactions.”

The unaudited pro forma condensed combined statements of income/(loss) were prepared using, and should be read in conjunction with, (1) the audited consolidated financial statements of Horizon for the year ended December 31, 2013 as included in Horizon’s Annual Report on Form 10-K for the year ended December 31, 2013 and (2) the unaudited statement of net revenue and direct expenses of VIMOVO for the nine months ended September 30, 2013 as included in Exhibit 99.1 and 99.2, respectively, to Horizon’s Current Report on Form 8-K/A filed on February 6, 2014. The unaudited pro forma condensed combined statements of income/(loss) for the year ended December 31, 2013 assume that the Transactions occurred on January 1, 2013. The unaudited pro forma condensed combined statements of income/(loss)
are provided for illustrative purposes only and are not necessarily indicative of the results that would have been achieved had the Transactions been completed as of the dates indicated or that may be achieved in future periods. The unaudited pro forma condensed combined statements of income/(loss) do not include the effects of any non-recurring costs or one-time transaction-related costs. The historical financial information has been adjusted in the accompanying unaudited pro forma condensed combined statements of income/(loss) to give effect to pro forma events that are (1) directly attributable to the Transactions, (2) factually supportable and (3) expected to have a continuing impact on the combined results.
HORIZON PHARMA, INC.
UNADITED PRO FORMA CONDENSED COMBINED STATEMENTS OF INCOME/(LOSS)
(in thousands, except share and per share data)

<table>
<thead>
<tr>
<th></th>
<th>Historical</th>
<th>Year Ended December 31, 2013</th>
<th>Adjustments</th>
<th>Pro forma</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVENUES:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gross sales</td>
<td>$102,995</td>
<td>$20,379a</td>
<td></td>
<td>$123,374</td>
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<tr>
<td>Sales discounts and allowances</td>
<td>$(28,979)</td>
<td></td>
<td>$(28,979)</td>
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<tr>
<td>Cost of goods</td>
<td>14,625</td>
<td>6,484</td>
<td>10,408b</td>
<td>31,517</td>
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<tr>
<td>Gross profit</td>
<td>59,391</td>
<td>13,895</td>
<td>(10,408)</td>
<td>62,878</td>
</tr>
<tr>
<td><strong>OPERATING EXPENSES:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>10,084</td>
<td></td>
<td></td>
<td>10,084</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>68,595</td>
<td>11,368</td>
<td></td>
<td>79,963</td>
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<tr>
<td>General and administrative</td>
<td>23,566</td>
<td></td>
<td></td>
<td>23,566</td>
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<tr>
<td>Total operating expenses</td>
<td>102,245</td>
<td>11,368</td>
<td></td>
<td>113,613</td>
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<tr>
<td>Operating income/(loss)</td>
<td>(42,854)</td>
<td>2,527</td>
<td>(10,408)</td>
<td>(50,735)</td>
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<tr>
<td><strong>OTHER (EXPENSE) INCOME, NET:</strong></td>
<td></td>
<td></td>
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<tr>
<td>Interest expense, net</td>
<td>(39,178)</td>
<td></td>
<td>22,345c</td>
<td>(16,833)</td>
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<tr>
<td>Foreign exchange gain/(loss)</td>
<td>1,206</td>
<td></td>
<td></td>
<td>1,206</td>
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<tr>
<td>Other, net</td>
<td>(69,300)</td>
<td></td>
<td></td>
<td>(69,300)</td>
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<tr>
<td>Total other expense, net</td>
<td>(107,272)</td>
<td></td>
<td>22,345</td>
<td>(84,927)</td>
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<tr>
<td>Income/(loss) before benefit for income taxes</td>
<td>(150,126)</td>
<td>2,527</td>
<td>11,937</td>
<td>(135,662)</td>
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<tr>
<td><strong>BENEFIT FOR INCOME TAXES</strong></td>
<td>(1,121)</td>
<td></td>
<td></td>
<td>(1,121)</td>
</tr>
<tr>
<td><strong>NET INCOME/(LOSS)</strong></td>
<td>$(149,005)</td>
<td>$2,527</td>
<td>$11,937</td>
<td>$(134,541)</td>
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<tr>
<td><strong>NET LOSS PER COMMON SHARE—Basic and diluted</strong></td>
<td>$(2.34)</td>
<td>$2.527</td>
<td>$11.937</td>
<td>$(2.11)</td>
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<tr>
<td><strong>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING—Basic and diluted</strong></td>
<td>63,657,924</td>
<td>63,657,924</td>
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<tr>
<td><strong>OTHER COMPREHENSIVE INCOME/(LOSS), NET OF TAX</strong></td>
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</tr>
<tr>
<td>Foreign currency translation adjustments</td>
<td>969</td>
<td></td>
<td></td>
<td>969</td>
</tr>
<tr>
<td>Other comprehensive income/(loss)</td>
<td>969</td>
<td></td>
<td></td>
<td>969</td>
</tr>
<tr>
<td><strong>COMPREHENSIVE LOSS</strong></td>
<td>$(148,036)</td>
<td></td>
<td></td>
<td>$(133,572)</td>
</tr>
</tbody>
</table>

See notes to unaudited pro forma condensed combined financial statements which are an integral part of these financial statements.

Notes: Unaudited Pro Forma Adjustments:

a. The presentation of product revenues net of sales discounts as one sales figure is consistent with AstraZeneca LP’s historical external reporting. Horizon will perform a review of VIMOVO accounting policies to determine if differences in policies require adjustment or reclassification of VIMOVO’s results of operations or assets/liabilities to conform to Horizon’s policies/classifications. As a result of that review, Horizon may identify differences between the accounting policies of the two companies that when conformed could have a material impact on these pro forma financial statements.

b. Represents amortization of acquired VIMOVO intellectual property of $11.8 million calculated at $67.7 million of acquired intellectual property amortized straight line over the 61.5 month estimated useful life of the intellectual property life for approximately ten and one half months from January 1, 2013 through November 21, 2013, offset by $1.4 million of actual intellectual property amortization recorded by AstraZeneca. The amortization of VIMOVO intellectual property for the period November 22, 2013 through December 31, 2013 is already included in Horizon’s 2013 results presented.

c. Represents ten and one half months of net interest expense totaling $15.0 million associated with the convertible debt issued November 22, 2013 and related amortization of debt discount and deferred financing expenses, offset by $11.0 million of interest, debt discount and deferred financing charges and a $26.4 million one-time, non-recurring expense related to the extinguishment loss associated with the senior secured loan extinguished on November 22, 2013.
NOTE 1 – ACQUISITION OF ASTRAZENECA VIMOVO

The unaudited pro forma condensed consolidated statements of income/(loss) reflect a total purchase price of approximately $35.0 million consisting entirely of cash.

Under the acquisition method of accounting, we have recognized net tangible and intangible assets acquired and contingent royalty liabilities, based upon their respective estimated fair values as of the acquisition date. The table below shows the preliminary fair values assigned to the assets acquired and liabilities assumed. Based on this analysis, the transaction resulted in neither a bargain purchase gain nor goodwill. We may make additional adjustments to the fair values, and these valuations could change significantly from those used to determine certain adjustments in the pro forma condensed combined financial statements.

<table>
<thead>
<tr>
<th>Category</th>
<th>Allocation (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples</td>
<td>$ 0.3</td>
</tr>
<tr>
<td>VIMOVO Intellectual Property</td>
<td>67.7</td>
</tr>
<tr>
<td>Contingent Royalty Liabilities</td>
<td>(33.0)</td>
</tr>
<tr>
<td>Total Cash Paid</td>
<td>$ 35.0</td>
</tr>
</tbody>
</table>

VIMOVO Intellectual Property and Contingent Royalty Liabilities

The valuation of the intellectual property acquired, an identifiable intangible asset, was based on management’s estimates, information and reasonable and supportable assumptions. The allocation was generally based on our estimated fair value of the rights to payments with respect to U.S. revenue associated with VIMOVO which were acquired in the transaction. This estimated fair value was determined using the income approach under the discounted cash flow method. Significant assumptions used in valuing the intellectual property intangible included revenue projections through 2030 based on assumptions relating to pricing and reimbursement rates and market size and market penetration rates, cost of goods sold based on current manufacturing experience, general and administrative expenses, sales and marketing expense, and research and development expenses for clinical and regulatory support. The calculated value of the VIMOVO intellectual property intangible asset is amortized using the straight-line method over an estimated useful life of 61.5 months. With respect to the acquired intellectual property acquired from AstraZeneca, we have assigned fair value to liabilities for contingent royalties to be paid applying the same fair value method described above with anticipated revenue streams. $33.0 million of fair value royalty payments to Pozen ($24.5 million guaranteed and $8.5 million contingent on certain revenue targets) for the years 2014 through 2018 were recorded at the time of the business acquisition.

NOTE 2 – FINANCING TRANSACTIONS

On November 22, 2013, we closed our offering of $150 million aggregate principal amount of 5.00% Convertible Senior Notes due 2018 (the “Notes”) pursuant to note purchase agreements (the “Note Purchase Agreements”) entered into by and between us and the purchasers of the Notes (the “Purchasers”). In connection with the closing, on November 22, 2013, we issued and sold to the Purchasers the Notes pursuant to the Note Purchase Agreements. The Notes are governed by an Indenture, dated as of November 22, 2013 (the “Indenture”), between us and U.S. Bank National Association, as trustee (the “Trustee”).

The Notes bear interest at a rate of 5.00% per year, payable in arrears on May 15 and November 15 of each year, beginning on May 15, 2014. The Notes will mature on November 15, 2018, unless earlier repurchased or converted.

The conversion rate for the Notes will initially be 186.4280 shares of common stock per $1,000 principal amount of Notes (equivalent to an initial conversion price of approximately $5.36 per share of common stock); provided that unless and until we obtain stockholder approval to issue more than 13,164,951 shares of our common stock, which is 19.99% of our common stock outstanding on November 18, 2013, upon conversion of the Notes in accordance with the listing standards of The NASDAQ Global Market, the number of shares of common stock deliverable upon conversion will be subject to a “conversion share cap.” Prior to receiving shareholder approval to issue enough authorized and unissued shares to cover the Conversion Option and satisfy the NASDAQ share cap rule, the Notes are required to be settled in cash up to their principal amount and any conversion spread is settled in cash or shares up to the NASDAQ share cap limit at the Company’s election.
$70.4 million of the net proceeds we received from the sale and issuance of the Notes was used to repay all obligations under our previous senior secured loan as of November 22, 2013 including $44.0 million carrying value of the senior secured loan extinguished, $25.0 million of penalties and accrued interest of $1.4 million.

On November 22, 2013, we, at a cost of $18.7 million, also entered into capped call transactions to cover, subject to anti-dilution adjustments substantially similar to those applicable to the Notes, the number of shares of our common stock underlying the Notes. The capped call transactions were entered into to reduce potential dilution to our common stock upon any conversion of the Notes in excess of the principal amount of converted Notes if the market price per share of our common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the Notes. If, however, the market price per share of our common stock exceeds the cap price of the capped call transactions, as measured under the terms of the capped call transactions, the number of shares of our common stock received upon exercise of the capped call transactions will be capped. In that case, there would nevertheless be dilution in respect of our common stock because the number of shares of common stock that we would owe upon conversion of the notes in excess of the principal amount of such converted Notes would exceed the number of shares of our common stock received upon exercise of the capped call transactions.

Pursuant to a number of factors outlined in ASC 815 “Derivatives and Hedging”, and based on our analysis of the factors surrounding the above noted transactions, we have concluded the conversion option is an embedded derivative that required bifurcation and separate accounting. As such, we recorded the fair value of the conversion option as if separate from the Note issuance as a derivative liability. The conversion option, initially valued at $40.1 million, will be fair valued at each reporting period with the changes in market value recorded in the income statement prior to receiving shareholder approval to issue enough authorized and unissued shares to cover the conversion option and satisfy the NASDAQ share cap rule. In addition, a corresponding debt discount of $40.1 million was recorded when the Notes were issued and will be charged to interest expense straight line over the life of the Notes.

At December 31, 2013, we conducted a fair value assessment to properly reflect the market value adjustments for the embedded derivative due to changes in our common stock value. To properly reflect the fair value of the embedded derivative of $109,410 as of December 31, 2013, we recorded a $69,300 expense in its results of operations for the three and twelve months ended December 31, 2013.

Additionally, under ASC 815, we have recorded the $18.7 million capped call as a freestanding instrument and classified in stockholder’s equity.

NOTE 3 – 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.

The deferred tax basis of the fair value of the intangible asset acquired in the acquisition of the VIMOVO intellectual property resulted in a deferred tax liability of approximately $3.2 million. This deferred tax liability was offset by a deferred tax asset equal to the future tax deductions associated with future contingent royalty payments. The effect of these outcomes resulted in no tax expense or tax benefit at the time of the acquisition.

NOTE 4 – EARNINGS PER SHARE

The following dilutive securities were excluded from the computation of diluted earnings per share for the year ended December 31, 2013 due to the anti-dilutive effects resulting from our net loss for the period presented:

- Outstanding stock options to purchase an aggregate of 4,411,080 shares of common stock at December 31, 2013, outstanding and unvested restricted stock units covering an aggregate of 833,001 shares of common stock at December 31, 2013.
- Outstanding warrants to purchase an aggregate of 16,114,746 shares of common stock at December 31, 2013.

Further, it was determined that the Notes have no impact on the denominator for the basic EPS calculation prior to conversion. Prior to receiving shareholder approval to issue enough authorized and unissued shares to cover the conversion option and satisfy the NASDAQ share cap rule, the Notes are required to be settled in cash up to their principal amount and any conversion spread is settled in cash or shares up to the NASDAQ share cap limit at our election.