UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
☐ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2013

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

For the transition period from ______ to ______

Commission File Number 001-35238

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

Delaware
(State or other jurisdiction of incorporation or organization)

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

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

60015
(Zip code)

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

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act:

☑ Large accelerated filer ☐ Accelerated filer
☐ Non-accelerated filer ☐ (do not check if a smaller reporting company)
☐ Smaller reporting company ☐

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

Number of shares of registrant’s common stock, par value $0.0001, outstanding as of November 5, 2013: 65,857,686.
<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Page No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Financial Statements:</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>- Condensed Consolidated Balance Sheets as of September 30, 2013 and as of</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>December 31, 2012 (Unaudited).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Condensed Consolidated Statements of Comprehensive Loss for the Three</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>and Nine Months Ended September 30, 2013 and 2012 (Unaudited).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Condensed Consolidated Statements of Cash Flows for the Nine Months</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Ended September 30, 2013 and 2012 (Unaudited).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Notes to Condensed Consolidated Financial Statements (Unaudited)</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>Management’s Discussion and Analysis of Financial Condition and Results of</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>Operations.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Quantitative and Qualitative Disclosures About Market Risk.</td>
<td>35</td>
</tr>
<tr>
<td>4</td>
<td>Controls and Procedures.</td>
<td>36</td>
</tr>
<tr>
<td>1</td>
<td>Legal Proceedings.</td>
<td></td>
</tr>
<tr>
<td>1A</td>
<td>Risk Factors.</td>
<td>37</td>
</tr>
<tr>
<td>2</td>
<td>Unregistered Sales of Equity Securities and Use of Proceeds.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Other Information.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Exhibits.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Signatures.</td>
<td></td>
</tr>
</tbody>
</table>
HORIZON PHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share data)

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2013</th>
<th>December 31, 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>$58,650</td>
<td>$104,087</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>800</td>
<td>800</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>16,677</td>
<td>3,463</td>
</tr>
<tr>
<td>Inventories, net</td>
<td>6,895</td>
<td>5,245</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>2,842</td>
<td>3,323</td>
</tr>
<tr>
<td>Total current assets</td>
<td>85,864</td>
<td>116,918</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>3,524</td>
<td>3,725</td>
</tr>
<tr>
<td>Developed technology, net</td>
<td>65,380</td>
<td>68,892</td>
</tr>
<tr>
<td>Other assets</td>
<td>3,447</td>
<td>4,449</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>$158,215</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>$5,044</td>
<td>$5,986</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>22,909</td>
<td>16,784</td>
</tr>
<tr>
<td>Deferred revenues—current portion</td>
<td>1,619</td>
<td>2,230</td>
</tr>
<tr>
<td>Notes payable—current portion</td>
<td>15,913</td>
<td>11,935</td>
</tr>
<tr>
<td>Total current liabilities</td>
<td>45,485</td>
<td>36,935</td>
</tr>
<tr>
<td><strong>LONG-TERM LIABILITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notes payable, net of current</td>
<td>29,672</td>
<td>36,866</td>
</tr>
<tr>
<td>Deferred revenues, net of current</td>
<td>9,508</td>
<td>9,554</td>
</tr>
<tr>
<td>Deferred tax liabilities, net</td>
<td>3,496</td>
<td>4,408</td>
</tr>
<tr>
<td>Other long term liabilities</td>
<td>165</td>
<td>243</td>
</tr>
<tr>
<td>Total long-term liabilities</td>
<td>42,841</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, $0.0001 par value; 200,000,000 shares authorized; 65,857,321 and 61,722,247 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively.</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>426,871</td>
<td>417,455</td>
</tr>
<tr>
<td>Accumulated other comprehensive loss</td>
<td>(2,774)</td>
<td>(3,372)</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(354,215)</td>
<td>(308,111)</td>
</tr>
<tr>
<td>Total stockholders' equity</td>
<td>69,889</td>
<td>105,978</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</strong></td>
<td>$158,215</td>
<td>$193,984</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Three Months Ended September 30,</th>
<th>Nine Months Ended September 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
</tr>
<tr>
<td><strong>REVENUES:</strong></td>
<td></td>
</tr>
<tr>
<td>Gross sales</td>
<td>$31,524</td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(5,306)</td>
</tr>
<tr>
<td>Net sales</td>
<td>26,218</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>5,313</td>
</tr>
<tr>
<td>Gross profit</td>
<td>20,905</td>
</tr>
<tr>
<td><strong>OPERATING EXPENSES:</strong></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>2,154</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>15,621</td>
</tr>
<tr>
<td>General and administrative</td>
<td>5,874</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>23,649</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(2,744)</td>
</tr>
<tr>
<td><strong>OTHER (EXPENSE) INCOME, NET:</strong></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(3,601)</td>
</tr>
<tr>
<td>Foreign exchange gain (loss)</td>
<td>1,118</td>
</tr>
<tr>
<td>Other, net</td>
<td>(2,483)</td>
</tr>
<tr>
<td>Total other expense, net</td>
<td>(2,483)</td>
</tr>
<tr>
<td>Loss before expense (benefit) for income taxes</td>
<td>(5,227)</td>
</tr>
<tr>
<td>EXPENSE (BENEFIT) FOR INCOME TAXES</td>
<td>265</td>
</tr>
<tr>
<td>NET LOSS</td>
<td>$ (5,492)</td>
</tr>
<tr>
<td>NET LOSS PER COMMON SHARE—Basic and diluted</td>
<td>$ (0.08)</td>
</tr>
<tr>
<td><strong>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING</strong></td>
<td></td>
</tr>
<tr>
<td>Basic and diluted</td>
<td>64,645,677</td>
</tr>
<tr>
<td><strong>OTHER COMPREHENSIVE INCOME (LOSS), NET OF TAX</strong></td>
<td></td>
</tr>
<tr>
<td>Foreign currency translation adjustments</td>
<td>993</td>
</tr>
<tr>
<td>Other comprehensive income (loss)</td>
<td>993</td>
</tr>
<tr>
<td>COMPREHENSIVE LOSS</td>
<td>$ (4,499)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Nine Months Ended September 30,</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CASH FLOWS FROM OPERATING ACTIVITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$(46,104)</td>
<td>$(63,461)</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash used in operating activities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization expense</td>
<td>5,838</td>
<td>3,648</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>3,206</td>
<td>3,662</td>
</tr>
<tr>
<td>Non-cash interest expense and amortization of deferred charges</td>
<td>3,043</td>
<td>1,827</td>
</tr>
<tr>
<td>Paid in kind interest expense</td>
<td>2,228</td>
<td>1,860</td>
</tr>
<tr>
<td>Foreign exchange (gain) loss</td>
<td>(667)</td>
<td>312</td>
</tr>
<tr>
<td>Loss on disposal of assets</td>
<td>—</td>
<td>76</td>
</tr>
<tr>
<td>Changes in operating assets and liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>(13,211)</td>
<td>(3,600)</td>
</tr>
<tr>
<td>Inventories</td>
<td>(1,626)</td>
<td>(2,475)</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>499</td>
<td>(1,577)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>(951)</td>
<td>(1,314)</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>6,161</td>
<td>2,937</td>
</tr>
<tr>
<td>Deferred revenues</td>
<td>(869)</td>
<td>3,498</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>(988)</td>
<td>(4,866)</td>
</tr>
<tr>
<td>Other non-current assets and liabilities</td>
<td>332</td>
<td>—</td>
</tr>
<tr>
<td>Net cash used in operating activities</td>
<td>(43,109)</td>
<td>(59,473)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM INVESTING ACTIVITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td>(643)</td>
<td>(1,012)</td>
</tr>
<tr>
<td>Increase in restricted cash</td>
<td>—</td>
<td>(50)</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>(643)</td>
<td>(1,062)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM FINANCING ACTIVITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeds from the sale of common stock under an ATM agreement, net of issuance costs</td>
<td>5,998</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from the issuance of common stock through ESPP program and stock option exercises</td>
<td>213</td>
<td>147</td>
</tr>
<tr>
<td>Proceeds from the issuance of notes payable, net of issuance costs</td>
<td>—</td>
<td>55,578</td>
</tr>
<tr>
<td>Proceeds from private equity offerings, net of issuance costs</td>
<td>—</td>
<td>128,092</td>
</tr>
<tr>
<td>Repayment of notes payable</td>
<td>(7,956)</td>
<td>(19,780)</td>
</tr>
<tr>
<td>Proceeds from the issuance of common stock through warrant exercises</td>
<td>—</td>
<td>149</td>
</tr>
<tr>
<td>Net cash (used in) provided by financing activities</td>
<td>(1,745)</td>
<td>164,186</td>
</tr>
<tr>
<td>Effect of foreign exchange rate changes on cash</td>
<td>60</td>
<td>(291)</td>
</tr>
<tr>
<td><strong>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</strong></td>
<td>(45,437)</td>
<td>103,360</td>
</tr>
<tr>
<td>CASH AND CASH EQUIVALENTS, beginning of the year</td>
<td>104,087</td>
<td>17,966</td>
</tr>
<tr>
<td>CASH AND CASH EQUIVALENTS, end of the year</td>
<td>$58,650</td>
<td>$121,326</td>
</tr>
<tr>
<td><strong>Supplemental cash flow information:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash paid for interest</td>
<td>$5,517</td>
<td>$5,762</td>
</tr>
<tr>
<td>Cash paid for income taxes</td>
<td>35</td>
<td>44</td>
</tr>
<tr>
<td>Commitment fee paid on notes payable</td>
<td>—</td>
<td>600</td>
</tr>
</tbody>
</table>

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

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

The unaudited condensed consolidated financial statements presented herein include the accounts of Horizon Pharma, Inc. (the “Company”) and its wholly-owned subsidiaries. All inter-company transactions and balances have been eliminated. Additionally, certain reclassifications have been made to prior period financial statements to conform to the current period presentation.

Business Overview

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

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

On April 23, 2011, the U.S. Food and Drug Administration (“FDA”) approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis (“RA”), osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. In the second-half of 2011, the Company hired its initial commercial organization, including approximately 80 sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In June 2012, the Company licensed DUEXIS rights in Latin America to Grünenthal S.A. (“Grünenthal”), 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 175 representatives. In March 2013, the Company announced that the United Kingdom (“UK”) Medicines and Healthcare products Regulatory Agency granted a National Marketing Authorization for DUEXIS in the UK. The Company will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded non-steroidal anti-inflammatory drugs, the Company does not expect a material level of sales from DUEXIS in European markets.
The Company’s second approved product in the U.S., RAYOS, known as LODOTRA outside the U.S., is a proprietary delayed-release formulation of low-dose prednisone for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, polymyalgia rheumatica (“PMR”), psoriatic arthritis, ankylosing spondylitis, asthma and chronic obstructive pulmonary disease and a number of other conditions. The Company is focusing its promotion of RAYOS in the U.S. on rheumatology indications, including RA and PMR. The Company began detailing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of U.S. rheumatologists and key primary care physicians. LODOTRA is currently marketed outside the U.S. by the Company’s distribution partner, Mundipharma International Corporation Limited (“Mundipharma”).

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

The accompanying unaudited condensed consolidated financial statements are prepared on a going concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business. As of September 30, 2013, the Company had cash and cash equivalents totaling $58,650. The Company believes that it has sufficient liquidity and capital resources to operate into the third quarter of 2014 and potentially beyond based on the Company’s current expectations of continued revenue growth. However, the Company is highly dependent in the near term on the commercial success of DUEXIS and RAYOS in the U.S. market. The Company has incurred net operating losses and negative cash flows from operations since its inception. In order to continue its operations, the Company must generate sufficient revenue to meet the trailing twelve month net revenue covenants of its $60,000 senior secured loan facility with a group of institutional lenders (the “Senior Secured Loan”) and achieve profitable operations or it may be required to obtain additional debt or equity financing. There can be no assurance, however, that such financing will be available or on terms acceptable to the Company. While the Company did meet the trailing twelve month net revenue covenants of its Senior Secured Loan as of the quarter ended September 30, 2013, should the Company not meet these quarterly minimum trailing twelve month net revenue covenants in the future, in addition to an increase in the interest rate payable under the loan facility, the lenders would have the right to demand repayment of the obligations under the loan. The Company also cannot predict whether the lenders would demand repayment of the outstanding balance of the loan if the Company was unable to meet the minimum quarterly trailing twelve month net revenue covenants. The inability to meet the covenants under the loan facility could have an adverse impact on the Company’s financial position and results of operations. These uncertainties and lack of commercial operating history raise substantial doubt about the Company’s ability to continue as a going concern.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Segment Information

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

Use of Estimates

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

Foreign Currency Translation and Transactions

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

Gains and losses resulting from foreign currency translations are reflected within the Company’s results of operations. During the three months ended September 30, 2013 and 2012, the Company recorded gains from foreign currency translations of $1,118 and $588, respectively. During the nine months ended September 30, 2013, the Company recorded a gain from foreign currency translations of $667 compared to a loss from foreign currency translations during the nine months ended September 30, 2012 of $312. 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 up-front license fees

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

Revenue from milestone receipts

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

Revenue from product deliveries

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

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

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
September 30, 2013 and December 31, 2012, deferred revenues related to the sale of LODOTRA were $984 and $1,939, respectively. Additionally, as of
September 30, 2013 and December 31, 2012, deferred revenues related to milestone and upfront payments received under existing agreements were $8,493
and $8,175, respectively.

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

During the fourth quarter of 2012, the Company changed from recognizing DUEXIS revenue upon product being dispensed through patient
prescriptions to recognizing revenue when product is sold into the wholesale pharmaceutical distributor and retail chain channel. This change was based on
approximately one year of minimal product return quantities and an enhanced ability and historical experience upon which to monitor DUEXIS inventory
levels in the distribution channel and to assess the relative risk of potential product returns. The Company believes it has the ability to reliably estimate
returns and recognizes revenue on the sale of DUEXIS and RAYOS at the point of sale to the wholesaler.

**DUEXIS/RAYOS Product Sales Discounts and Allowances**

Prior to the fourth quarter of 2012, the Company recorded DUEXIS sales to wholesale pharmaceutical distributors and retail chains as deferred
revenue. Allowances for product returns, rebates and discounts were also deferred at the time of sale to wholesale pharmaceutical distributors and national
and regional retail chains. These deferred expenses were recognized to arrive at net product sales at the time 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.

**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.

**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 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 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.

**Cost of Goods Sold**

The Company recognizes cost of goods sold in connection with its sale of DUEXIS and RAYOS. The Company accrues fees based on the contractually defined terms with each wholesaler for distribution and inventory management services and records the expense as cost of goods sold.

Cost of goods sold of DUEXIS includes all costs directly related to the acquisition of product from the Company’s third party manufacturers, including freight charges and costs of distribution. Also included in cost of goods sold are distribution service fees paid to wholesalers.

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

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.
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 September 30, 2013 and December 31, 2012, the Company had inventories of $6,895 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 September 30, 2013 and December 31, 2012, the Company had product sample inventory of $517 and $875, respectively.

Preclinical Studies and Clinical Trial Accruals

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

Net Loss Per Share

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

Fair Value of Financial Instruments

The carrying amounts of the Company’s financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities. The estimated fair value of the Senior Secured Loan was determined using Level 3 inputs and was based on the notional amounts of the outstanding debt instrument and borrowing rates of recent debt transactions. At September 30, 2013, the estimated fair value of the Senior Secured Loan was $60,073.

Cash and Cash Equivalents

Cash and cash equivalents primarily consist of cash balances and money market funds. Cash and cash equivalents were $58,650 and $104,087 as of September 30, 2013 and December 31, 2012, respectively. The Company’s policy is to invest excess cash in money market funds, which are generally of a short-term duration based upon operating requirements.

Restricted Cash

Restricted cash consists of balances included in interest-bearing money market accounts required by a vendor for the Company’s sponsored employee credit card program and by the lessor for the Company’s corporate office. As of September 30, 2013 and December 31, 2012, the Company had restricted cash in the amount of $800.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation. Depreciation is recognized using the straight-line method over the estimated useful lives of the related assets for financial reporting purposes and an accelerated method for income tax reporting purposes. Upon retirement or sale of an asset, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operations. Repair and maintenance costs are charged to expenses as incurred and improvements are capitalized.
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 to 7 years</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>3 to 7 years</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>3 years</td>
</tr>
<tr>
<td>Software</td>
<td>5 years</td>
</tr>
<tr>
<td>Trade show equipment</td>
<td>3 years</td>
</tr>
</tbody>
</table>

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

Intangible Assets

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

Research and Development Expenses

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

Sales and Marketing Expenses

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

Concentration of Credit Risk and Other Risks and Uncertainties

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

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

To achieve profitable operations, the Company must successfully develop, obtain regulatory approval for, manufacture and market its products and product candidates, and/or acquire 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 or in-licensed by the Company. These factors could have a material adverse effect on the Company’s operations.
The Company relies on third parties to manufacture its commercial supplies of DUEXIS and RAYOS/LODOTRA. The commercialization of any of its products or product candidates could be stopped, delayed or made less profitable if those third parties fail to provide the Company with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

The Company is required to maintain compliance with applicable Swiss laws with respect to its Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. The Company reviews on a regular basis whether its Swiss subsidiary is overindebted. As of September 30, 2013, 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 September 30, 2013, Horizon Pharma AG had $1,290 in cash and cash equivalents. Based upon the cash and cash equivalents held by Horizon Pharma AG as of September 30, 2013 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. The Company’s top three customers, Mundipharma, McKesson Corporation and Cardinal Health, Inc., accounted for approximately 83% of total consolidated gross sales during the year ended December 31, 2012. During the nine months ended September 30, 2013, the Company’s top three customers, McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen, accounted for approximately 76% of total consolidated gross sales. In addition, three customers, Cardinal Health, Inc., Walgreen Company and McKesson Corporation, accounted for approximately 77% of the Company’s total outstanding accounts receivable balances at December 31, 2012. At September 30, 2013, three customers, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen, accounted for approximately 91% 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 basis FASB Accounting Standards Update 2013-02, Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (“ASU 2013-02”). ASU 2013-02 requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under GAAP to be reclassified in its entirety to net income. For other amounts that are not required under GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under GAAP that provide additional detail about those amounts. As of September 30, 2013 and December 31, 2012, accumulated other comprehensive loss was $2,774 and $3,372, respectively.
NOTE 3 – EARNINGS PER SHARE

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

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended September 30</th>
<th>Nine Months Ended September 30</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
<td>2012</td>
</tr>
<tr>
<td>Basic and diluted earnings per share calculation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$(5,492)</td>
<td>$(16,953)</td>
</tr>
<tr>
<td>Weighted average of common shares outstanding</td>
<td>64,645,677</td>
<td>35,972,657</td>
</tr>
<tr>
<td>Basic and diluted net loss per share</td>
<td>$(0.08)</td>
<td>$(0.47)</td>
</tr>
</tbody>
</table>

The following securities were excluded from the computation of diluted earnings per share for the three and nine months ended September 30, 2013 and 2012 due to the anti-dilutive effects resulting from the Company’s net loss for the periods presented:

- Outstanding stock options to purchase an aggregate of 4,236,675 and 2,463,777 shares of common stock at September 30, 2013 and 2012, respectively, and outstanding and unsettled restricted stock units covering an aggregate of 903,710 and 816,208 shares of common stock at September 30, 2013 and 2012, respectively.
- Outstanding warrants to purchase an aggregate of 16,114,746 and 18,026,441 shares of common stock at September 30, 2013 and 2012, respectively.

NOTE 4 – INVENTORIES

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

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

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2013</th>
<th>December 31, 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw materials</td>
<td>$ 130</td>
<td>$ 40</td>
</tr>
<tr>
<td>Work-in-process</td>
<td>977</td>
<td>824</td>
</tr>
<tr>
<td>Finished goods</td>
<td>5,788</td>
<td>4,381</td>
</tr>
<tr>
<td>Net inventories</td>
<td>$ 6,895</td>
<td>$ 5,245</td>
</tr>
</tbody>
</table>

NOTE 5 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2013</th>
<th>December 31, 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product samples inventory</td>
<td>$ 517</td>
<td>$ 875</td>
</tr>
<tr>
<td>Prepaid software license fees</td>
<td>571</td>
<td>518</td>
</tr>
<tr>
<td>Prepaid clinical trial studies</td>
<td>676</td>
<td>661</td>
</tr>
<tr>
<td>Prepaid marketing expenses</td>
<td>526</td>
<td>607</td>
</tr>
<tr>
<td>Prepaid insurance</td>
<td>301</td>
<td>265</td>
</tr>
<tr>
<td>Prepaid FDA product and manufacturing fees</td>
<td>—</td>
<td>139</td>
</tr>
<tr>
<td>Other prepaid expenses</td>
<td>251</td>
<td>227</td>
</tr>
<tr>
<td>Other current assets</td>
<td>—</td>
<td>31</td>
</tr>
<tr>
<td>Total prepaid and other current assets</td>
<td>$ 2,842</td>
<td>$ 3,323</td>
</tr>
</tbody>
</table>
NOTE 6 – PROPERTY AND EQUIPMENT

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

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2013</th>
<th>December 31, 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery and equipment</td>
<td>$2,352</td>
<td>$2,248</td>
</tr>
<tr>
<td>Furnace and fixtures</td>
<td>112</td>
<td>116</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>1,618</td>
<td>1,211</td>
</tr>
<tr>
<td>Software</td>
<td>758</td>
<td>646</td>
</tr>
<tr>
<td>Trade show equipment</td>
<td>228</td>
<td>228</td>
</tr>
<tr>
<td>Leasehold improvement</td>
<td>783</td>
<td>783</td>
</tr>
<tr>
<td>Less-accumulated depreciation</td>
<td>(2,327)</td>
<td>(1,507)</td>
</tr>
<tr>
<td>Total property and equipment</td>
<td>$3,524</td>
<td>$3,725</td>
</tr>
</tbody>
</table>

Depreciation expense was $303 and $167 for the three months ended September 30, 2013 and 2012, respectively, and was $861 and $559 for the nine months ended September 30, 2013 and 2012, respectively.

NOTE 7 – INTANGIBLE ASSETS

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

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 third quarter of 2013, the Company did not identify any events or circumstances that would require a review of its intangible assets.

As of September 30, 2013 and December 31, 2012, intangible assets consisted of the following:

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2013</th>
<th>December 31, 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost Basis</td>
<td>$84,779</td>
<td>$84,779</td>
</tr>
<tr>
<td>Accumulated Amortization</td>
<td>(16,095)</td>
<td>(11,118)</td>
</tr>
<tr>
<td>Currency Translation</td>
<td>(3,304)</td>
<td>(4,769)</td>
</tr>
<tr>
<td>Net Book Value</td>
<td>$65,380</td>
<td>$68,892</td>
</tr>
</tbody>
</table>

Amortization expense was $1,680 and $1,341 for the three months ended September 30, 2013 and 2012, respectively, and was $4,977 and $3,089 for the nine months ended September 30, 2013 and 2012, respectively.

As of September 30, 2013, estimated future amortization expense was as follows:

<table>
<thead>
<tr>
<th></th>
<th>2013 (remainder of the year)</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017 and thereafter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>$1,659</td>
<td>6,637</td>
<td>6,637</td>
<td>6,637</td>
<td>43,810</td>
</tr>
</tbody>
</table>

Total $65,380
NOTE 8 – ACCRUED LIABILITIES

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

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2013</th>
<th>December 31, 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payroll related expenses</td>
<td>$8,093</td>
<td>$6,290</td>
</tr>
<tr>
<td>Accrued rebates and royalties</td>
<td>8,999</td>
<td>2,704</td>
</tr>
<tr>
<td>Interest expense</td>
<td>2,388</td>
<td>2,538</td>
</tr>
<tr>
<td>Sales and marketing expenses</td>
<td>1,079</td>
<td>1,265</td>
</tr>
<tr>
<td>Deferred rent</td>
<td>760</td>
<td>876</td>
</tr>
<tr>
<td>Consulting and professional services</td>
<td>735</td>
<td>627</td>
</tr>
<tr>
<td>Clinical and regulatory expenses</td>
<td>304</td>
<td>652</td>
</tr>
<tr>
<td>Co-promotion agreement</td>
<td></td>
<td>226</td>
</tr>
<tr>
<td>Contract manufacturing expenses</td>
<td>136</td>
<td>1,094</td>
</tr>
<tr>
<td>Accrued other</td>
<td>415</td>
<td>512</td>
</tr>
<tr>
<td><strong>Total accrued liabilities</strong></td>
<td><strong>$22,909</strong></td>
<td><strong>$16,784</strong></td>
</tr>
</tbody>
</table>

NOTE 9 – FAIR VALUE MEASUREMENTS

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

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

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

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

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

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

### As of September 30, 2013

<table>
<thead>
<tr>
<th>Assets:</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Money market funds</td>
<td>$49,186</td>
<td>—</td>
<td>—</td>
<td>$49,186</td>
</tr>
<tr>
<td><strong>Total assets at fair value</strong></td>
<td>$49,186</td>
<td>—</td>
<td>—</td>
<td>$49,186</td>
</tr>
</tbody>
</table>

### As of December 31, 2012

<table>
<thead>
<tr>
<th>Assets:</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Money market funds</td>
<td>$97,670</td>
<td>—</td>
<td>—</td>
<td>$97,670</td>
</tr>
<tr>
<td><strong>Total assets at fair value</strong></td>
<td>$97,670</td>
<td>—</td>
<td>—</td>
<td>$97,670</td>
</tr>
</tbody>
</table>
NOTE 10 – COMMITMENTS AND CONTINGENCIES

Lease Obligations

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

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

Purchase Commitments

In August 2007, the Company entered into a manufacturing and supply agreement with Jagotec AG (“Jagotec”). Under the agreement, Jagotec or its affiliates are required to manufacture and supply RAYOS/LODOTRA exclusively to the Company in bulk. The Company committed to a minimum purchase of RAYOS/LODOTRA tablets from Jagotec for five years from the date of first launch of RAYOS/LODOTRA in a major country, as defined in the agreement, which was in April 2009. At September 30, 2013, the minimum remaining purchase commitment based on tablet pricing in effect under the agreement was $3,291. The agreement automatically renews on a yearly basis until either party provides two years advance written notice of termination. In April 2013, the agreement automatically renewed and the earliest the current agreement can expire according to this advance notice procedure is April 15, 2016.

In May 2011, the Company entered into a manufacturing and supply agreement with sanofi-aventis U.S., 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 September 30, 2013, the Company had a binding purchase commitment to sanofi-aventis U.S. for DUEXIS of $10,286, with $3,672 of such amount to be delivered in the fourth quarter of 2013 and $6,614 of such amount to be delivered in 2014.

Royalty Agreement

In connection with the August 2004 development and license agreement with SkyePharma AG (“SkyePharma”) and Jagotec, a wholly-owned subsidiary of SkyePharma, regarding certain proprietary technology and know-how owned by SkyePharma, Jagotec is entitled to receive a single digit percentage royalty on net sales of RAYOS/LODOTRA and on any sub-licensing income, which includes any payments not calculated based on the net sales of RAYOS/LODOTRA, such as license fees, lump sum and milestone payments. Royalty expense recognized in cost of goods sold for the three months ended September 30, 2013 and 2012 was $221 and $136, respectively, and for the nine months ended September 30, 2013 and 2012 was $551 and $395, respectively.

Contingencies

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

Indemnification

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

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

**NOTE 11 – LEGAL PROCEEDINGS**

On February 15, 2012, the Company received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. 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 preventing Par from selling a generic version of DUEXIS. In January 2013, the Company filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par’s ANDA and/or preventing Par from selling a generic version of DUEXIS.

On August 21, 2013, the Company entered into a Settlement Agreement (the “Settlement Agreement”) and License Agreement (the “License Agreement”) with Par relating to the Company’s patent infringement litigation. The 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 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 U.S. 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 (collectively, the “License”). The License covers all patents owned or controlled by the Company during the term of the 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 U.S. Unless terminated sooner pursuant to the terms of the License Agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity. Under the terms of the 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 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 License Agreement based on the manufacture, use, sale, offer for sale, or importation of Par’s generic version of DUEXIS in the U.S.

The License Agreement may be terminated by the Company 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 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 License Agreement will terminate automatically upon termination of the 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”). 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. Par Pharmaceutical, Inc. has not advised the Company as to the timing or status of the FDA’s review of its filing. 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. 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. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Par’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

NOTE 12 – DEBT AGREEMENTS

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

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2013</th>
<th>December 31, 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior Secured Loan</td>
<td>$ 56,184</td>
<td>$ 61,843</td>
</tr>
<tr>
<td>Current debt maturities</td>
<td>(15,913)</td>
<td>(11,935)</td>
</tr>
<tr>
<td>Debt discount</td>
<td>(10,599)</td>
<td>(13,042)</td>
</tr>
<tr>
<td>Long-term debt, net of current maturities</td>
<td>$ 29,672</td>
<td>$ 36,866</td>
</tr>
</tbody>
</table>

In February 2012, the Company entered into the $60,000 Senior Secured Loan with a group of institutional lenders. Under the terms of the Senior Secured Loan, the outstanding principal accrues interest until maturity in January 2017 at a rate of 17% per annum, payable quarterly unless repaid earlier. The Senior Secured Loan allows the Company to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt (i.e., payment in kind borrowings). Beginning in April 2013, and each quarter thereafter, the lenders have the option to require the Company to repay $3,978 of the loan principal. The Company may also prepay the loan at any time, subject to certain prepayment premiums. In March 2013, 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 ongoing 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. The warrants became exercisable 180 days after issuance and will remain exercisable until the maturity date of the Loan on January 22, 2017, subject to limited exceptions. The Senior Secured Loan is secured by a lien on substantially all of the Company’s assets including intellectual property, and the Company pledged all of its equity interests in Horizon Pharma USA, Inc. and 65% of its equity interests in Horizon Pharma AG.
The Senior Secured Loan restricts the Company’s ability to incur additional indebtedness, incur liens, pay dividends and engage in significant business transactions, such as a change of control, so long as the Company owes any amounts to the lenders under the related loan agreements. If the Company defaults under its Senior Secured Loan, its lenders may accelerate all of its repayment obligations and take control of the pledged assets. The Company’s lenders could declare the Company in default under its debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect upon it as defined under the loan agreements, thereby requiring the Company to repay the loan immediately or to attempt to reverse the lenders’ declaration through negotiation or litigation. Among other loan covenant requirements, the Senior Secured Loan also requires the Company to maintain a minimum level of liquidity of at least $10,000 at all times during the term of the loan unless its quarterly consolidated EBITDA is at least $6,000 and to meet specified minimum net revenues during a trailing twelve-month period, which commenced on June 30, 2012. The negative covenants include, among other things, restrictions on transferring or licensing the Company’s assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on the Company’s assets, in each case subject to customary exceptions. During 2012, the Company elected to pay the 12% interest in cash, and the remaining 5% interest due of $1,842 was added to the principal loan balance as a payment in kind borrowing. During 2013, the Company has elected to pay the 12% interest in cash, and the remaining 5% interest due of $2,298 as of September 30, 2013 was added to the principal loan balance as a payment in kind borrowing.

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

In lieu of paying a cash fee in consideration for entering into the Senior Secured Loan Amendment, the Company agreed to issue an aggregate of 1,250,000 shares of the Company’s common stock to the lenders. The fair value of the common stock issued in connection with the Senior Secured Loan Amendment was $5,075 and was classified as debt discount in the Company’s consolidated balance sheets and is being amortized to interest expense over the remaining life of the Senior Secured Loan. At September 30, 2013, the outstanding balance on the Senior Secured Loan was $56,184 and the Company was in compliance with all applicable financial loan covenants.

NOTE 13 – STOCKHOLDERS’ EQUITY

In August 2012, the Company entered into a sales agreement with Cowen and Company, LLC (“Cowen”) pursuant to which the Company may sell its common stock through Cowen in at-the-market (“ATM”) offerings. Subject to the terms and conditions of the sales agreement, Cowen may sell the shares by methods deemed to be an ATM offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including sales made through The NASDAQ Global Market, on any other existing trading market for the Company’s common stock or to or through a market maker. On March 25, 2013, the Company requested Cowen to begin making sales under the sales agreement and provided Cowen both daily volume and minimum price restrictions under which Cowen could sell the Company’s common stock. During July 2013, Cowen sold 1,182,414 shares of the Company’s common stock for gross proceeds of $3,061 and net proceeds of $2,959, after deducting $102 in commissions and other issuance costs. Cowen has not sold shares under the ATM since July 2013 and as of September 30, 2013, $21,152 worth of the Company’s common stock was available for future issuance under the ATM sales agreement.

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 14 – CO-PROMOTION AGREEMENT

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

Each party could terminate the agreement early upon certain failures to achieve minimum levels of prescriptions for a specified period of time. On June 1, 2013, the Company provided written notice to Mallinckrodt of termination of the Mallinckrodt Agreement, effective 30 days after the date of such notice. The Mallinckrodt Agreement was terminated as a result of Mallinckrodt not achieving minimum levels of prescriptions from targeted physicians for two consecutive quarters during the period prior to September 30, 2013.

NOTE 15 – RELATED PARTY TRANSACTIONS

The Company has entered into a consulting agreement with a former director of Horizon Pharma USA, Inc. and Horizon Pharma AG has entered into a consulting agreement with a former owner and majority shareholder of Nitec. Consulting fees paid to related parties during the three months ended September 30, 2013 and 2012 were $197 and $176, respectively, and were $590 and $543 for the nine months ended September 30, 2013 and 2012, respectively.

NOTE 16 – INCOME TAXES

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

The following table presents the benefit for income taxes for the three and nine months ended September 30, 2013 and 2012, as follows:

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended September 30</th>
<th></th>
<th>Nine Months Ended September 30</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
<td>2012</td>
<td>2013</td>
</tr>
<tr>
<td>Net loss before benefit for income taxes</td>
<td>$ (5,227)</td>
<td>$ (21,465)</td>
<td>$ (47,071)</td>
</tr>
<tr>
<td>Expense (benefit) for income taxes</td>
<td>265</td>
<td>(4,512)</td>
<td>(967)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (5,492)</td>
<td>$ (16,953)</td>
<td>$ (46,104)</td>
</tr>
</tbody>
</table>

At September 30, 2013, the Company had a net deferred tax liability of $3,496 primarily related to temporary differences associated with its intangible assets. During the three months ended September 30, 2013, the Company recorded an income tax expense of $265 compared to an income tax benefit of $4,512 during the three months ended September 30, 2012. The decrease in income tax benefit during the three months ended September 30, 2013 was primarily due to a reduction in the Company’s deferred tax assets associated with lower projected pre-tax operating losses and the absence of a one-time tax benefit recorded in the prior year period. During the third quarter of 2012, the Company recorded a $4,258 income tax benefit adjustment related to a reduction in the Company’s deferred tax asset positions resulting from the reclassification of its indefinite-lived in-process research and development (“IPR&D”) asset to a finite-lived intangible asset. The reclassification of the Company’s IPR&D indefinite-lived intangible asset to a finite-lived intangible asset required the Company to begin amortizing this asset, which resulted in additional income tax benefits due to the Company’s deferred tax liability position.

During the nine months ended September 30, 2013, the Company recorded an income tax benefit of $967 compared to an income tax benefit of $4,835 during the nine months ended September 30, 2012. The decrease in income tax benefit during the nine months ended September 30, 2013 was primarily associated with the $4,258 income tax benefit adjustment recorded during the third quarter of 2012 as described above, partially offset by a higher income tax benefit recorded during the nine months ended September 30, 2013 associated with an increase in intangible amortization expense. The increase in intangible amortization expense was incurred in connection with the FDA approval of RAYOS on July 26, 2012, which required the Company to reclassify its IPR&D indefinite-lived intangible asset to a finite-lived intangible asset.
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 Purchase Plan”) and in June 2011, the Company’s stockholders approved the 2011 Purchase Plan and it became effective upon the signing of the underwriting agreement related to the Company’s initial public offering in July 2011. The Company reserved a total of 463,352 shares of common stock for issuance under the 2011 Purchase Plan. The 2011 Purchase Plan provides that an additional number of shares will automatically be added to the shares authorized for issuance under the 2011 Purchase Plan each year on January 1, until 2021. The number of shares added each year will be equal to the least of: (a) 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (b) 1,053,074 shares of common stock; or (c) a number of shares of common stock that may be determined each year by the Company’s Board of Directors that is less than (a) and (b). Subject to certain limitations, the Company’s employees may elect to have 1% to 15% of their compensation withheld through payroll deductions to purchase shares of common stock under the 2011 Purchase Plan. Employees purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of the six-month offering period.

On December 14, 2012, pursuant to the terms of the 2011 Purchase Plan, the Company’s Board of Directors approved an increase in the number of shares available for issuance under the 2011 Purchase Plan of 200,000 shares, effective January 1, 2013. As of September 30, 2013, 201,381 shares have been issued and an aggregate of 544,199 shares of common stock were authorized and available for issuance under the 2011 Purchase Plan.

Stock-Based Compensation Plans

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

In July 2010, the Company’s Board of Directors adopted the 2011 Plan and in June 2011, the Company’s stockholders approved the 2011 Plan, and it became effective upon the signing of the underwriting agreement related to the Company’s initial public offering on July 28, 2011. The 2011 Plan had an initial reserve of 3,366,228 shares of common stock, including 460,842 shares of common stock previously reserved for future issuance under the 2005 Plan, 1,304,713 shares of common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan as of the 2011 Plan’s effective date and 1,600,673 new shares of common stock reserved. The 2011 Plan provides that an additional number of shares will automatically be added to the shares authorized for issuance each year on January 1, until 2021. The number of shares added each year will be equal to the least of: (a) 5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; (b) 1,474,304 shares of common stock; or (c) a number of shares of common stock that may be determined each year by the Company’s Board of Directors that is less than (a) and (b). On December 14, 2012, pursuant to the terms of the 2011 Plan, the Company’s Board of Directors approved an increase in the number of shares available for issuance under the 2011 Plan of 1,474,304 shares, effective January 1, 2013. As of September 30, 2013, there were 61,578 shares available for future grants under the 2011 Plan.

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

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

<table>
<thead>
<tr>
<th>Options</th>
<th>Weighted Average Exercise Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2012</td>
<td>2,746,918 $8.85</td>
</tr>
<tr>
<td>Granted</td>
<td>1,833,350 $2.39</td>
</tr>
<tr>
<td>Exercised</td>
<td>(3,827) $2.40</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(339,766) $3.93</td>
</tr>
<tr>
<td>Outstanding as of September 30, 2013</td>
<td>4,236,675 $6.46</td>
</tr>
<tr>
<td>Exercisable as of September 30, 2013</td>
<td>1,894,215 $10.07</td>
</tr>
</tbody>
</table>

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The determination of the fair value of each stock option is affected by the Company’s stock price on the date of grant, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company’s expected stock price volatility over the expected life of the awards and actual and projected stock option exercise behavior.

The weighted average fair value per share of stock option awards granted during the nine months ended September 30, 2013 and 2012, and assumptions used to value stock options, are as follows:

| Nine Months Ended September 30, |
|----------------|----------------|
| 2013           | 2012           |
| Dividend yield | —              |
| Risk-free interest rate | 1.1% | 1.0% |
| Weighted average volatility | 87.7% | 89.6% |
| Expected life (in years) | 5.98 | 5.94 |
| Weighted average grant date fair value per share of options granted | $2.39 | $2.92 |

**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 does not have sufficient trading history for its common stock.

**Expected Term**

Given the Company’s limited historical exercise behavior, the expected term of options granted was determined using the “simplified” method since the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. Under this approach, the expected term is presumed to be the average of the vesting term and the contractual life of the option.
During the nine months ended September 30, 2013 and 2012, the Company utilized a forfeiture rate of 5% for estimating the forfeitures of stock options granted.

**Restricted Stock Units**

The following table summarizes restricted stock unit activity during the nine months ended September 30, 2013 as follows:

<table>
<thead>
<tr>
<th></th>
<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>
<td>$4.92</td>
</tr>
<tr>
<td>Granted</td>
<td>730,000</td>
<td>$2.41</td>
</tr>
<tr>
<td>Vested</td>
<td>(2,500)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(55,948)</td>
<td>$2.86</td>
</tr>
<tr>
<td>Outstanding as of September 30, 2013</td>
<td>903,710</td>
<td>$3.02</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Stock-based compensation expense:</th>
<th>Nine Months Ended September 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
</tr>
<tr>
<td>Research and development</td>
<td>$700</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>1,000</td>
</tr>
<tr>
<td>General and administrative</td>
<td>1,506</td>
</tr>
<tr>
<td>Net effect of stock-based compensation expense on net loss</td>
<td>$3,206</td>
</tr>
</tbody>
</table>

The Company estimates that, as of September 30, 2013, pre-tax compensation expense was $7,370 for all unvested share-based awards, including both stock options and restricted stock units that will be recognized through the third quarter of 2016. The Company expects to satisfy the exercise of stock options and future distribution of shares of restricted stock by issuing new shares of its common stock which have been reserved under the 2011 Plan.

**NOTE 18 – SUBSEQUENT EVENTS**

On November 7, 2013, the Company’s Board of Directors approved an amendment to the 2011 Plan to reserve an additional 200,000 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)”). The 2011 Plan was amended by the Company’s Board of Directors without stockholder approval pursuant to Rule 5635(c)(4).
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

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

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

OUR BUSINESS

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

On April 23, 2011, the U.S. Food and Drug Administration, or FDA, approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis, or RA, and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. Between July and November 2011, we hired our initial commercial organization, including approximately 80 sales representatives, completed sales force training and began detailing DUEXIS to physicians in December 2011. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products. In the third quarter of 2012, we expanded our sales force to approximately 150 representatives and have subsequently further expanded our sales force to approximately 175 representatives. In March 2013, we announced that the United Kingdom, or UK, Medicines and Healthcare products Regulatory Agency granted a National Marketing Authorization for DUEXIS in the UK. We will seek to license rights to DUEXIS in Europe to a commercial partner or partners. Given the current state of the market in Europe for pain products and the revenue being generated there by existing branded non-steroidal anti-inflammatory drugs, we do not expect a material level of sales from DUEXIS in European markets.

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

Comparison of Three Months Ended September 30, 2013 and 2012

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

<table>
<thead>
<tr>
<th>Three Months Ended September 30,</th>
<th>2013</th>
<th>2012</th>
<th>Increase / (Decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross sales</td>
<td>$31,524</td>
<td>$7,311</td>
<td>$24,213</td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(5,306)</td>
<td>(790)</td>
<td>(4,516)</td>
</tr>
<tr>
<td>Net sales</td>
<td>26,218</td>
<td>6,521</td>
<td>19,697</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>5,313</td>
<td>3,810</td>
<td>1,503</td>
</tr>
<tr>
<td>Gross profit</td>
<td>20,905</td>
<td>2,711</td>
<td>18,194</td>
</tr>
</tbody>
</table>

Operating expenses

| Research and development         | 2,154  | 3,796  | (1,642)               |
| Sales and marketing              | 15,621 | 12,951 | 2,670                 |
| General and administrative       | 5,874  | 4,678  | 1,196                 |
| Total operating expenses         | 23,649 | 21,425 | 2,224                 |

Operating loss

| Interest expense, net            | (3,601) | (3,339) | 262                  |
| Foreign exchange gain            | 1,118   | 588     | (530)                |
| Total other expense, net         | (2,483) | (2,751) | (268)                |

Loss before expense (benefit) for income taxes

| Expense (benefit) for income taxes | (5,227) | (21,465) | (16,238) |
| Net loss                          | (5,492) | (16,953) | (11,461) |

Sales. During the three months ended September 30, 2013, gross and net sales were $31,524 and $26,218, respectively, compared to $7,311 and $6,521 in gross and net sales, respectively, during the three months ended September 30, 2012. DUEXIS gross and net sales during the three months ended September 30, 2013 were $28,480 and $23,462, respectively, after deducting sales discounts and allowances of $1,106 and co-pay assistance costs of $3,912, and represented 90% of gross sales and 89% of net sales during the quarter, compared to gross and net sales of $2,966 and $2,572, respectively, during the three months ended September 30, 2012. The increase in DUEXIS sales during the three months ended September 30, 2013 compared to the same period in the prior year was primarily the result of our expanded sales force in addition to product price increases implemented during the course of 2013.

RAYOS gross and net sales were $2,290 and $2,030, respectively, during the three months ended September 30, 2013 after deducting sales discounts and allowances of $145 and co-pay costs of $115, compared to no RAYOS sales during the three months ended September 30, 2012 as the product was launched in late 2012.

LODOTRA gross and net sales during the three months ended September 30, 2013 were $754 and $726, respectively, after deducting trade allowances of $28, compared to gross and net sales of $4,345 and $3,949, respectively, during the three months ended September 30, 2012. The decrease in LODOTRA sales during the three months ended September 30, 2013 compared to the same period in the prior year was the result of lower product shipments to our European distribution partner, Mundipharma, and a decline 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, our LODOTRA sales are not linear or tied to Mundipharma sales to the market and can therefore fluctuate from quarter to quarter.
Sales discounts and allowances. During the three months ended September 30, 2013, sales discounts and allowances were $5,306, compared to $790 during the three months ended September 30, 2012. As a percentage of gross product sales, sales discounts and allowances increased to 17% during the three months ended September 30, 2013 compared to 11% during the three months ended September 30, 2012. The increase in sales discounts and allowances was attributable to a significant increase in product sales during the three months ended September 30, 2013, which resulted in a corresponding increase in customer discounts and prompt pay allowances. Additionally, our distribution channel mix during the third quarter of 2013 resulted in higher government rebates and chargebacks. Co-pay assistance costs increased $3,701 during the three months ended September 30, 2013 compared to the same period in 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. The increase in product sales discounts and allowances during the three months ended September 30, 2013 was partially offset by a $2,378 benefit resulting from the renegotiation of a managed care contract and from sales channel mix. We expect our sales discounts and allowances as a percent of gross product sales to be in the 35-40% range in subsequent periods as we will not benefit from the managed care contract adjustment made in the third quarter of 2013.

The following table presents our sales discounts and allowances for the three months ended September 30, 2013 and 2012:

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended September 30, 2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross product sales</td>
<td>$31,524</td>
<td>$7,311</td>
</tr>
<tr>
<td>Customer discounts and rebates</td>
<td>$(1,423)</td>
<td>306</td>
</tr>
<tr>
<td>Co-pay assistance</td>
<td>4,027</td>
<td>326</td>
</tr>
<tr>
<td>Government rebates and chargebacks</td>
<td>1,802</td>
<td>40</td>
</tr>
<tr>
<td>Product returns and prompt pay allowances</td>
<td>900</td>
<td>118</td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>5,306</td>
<td>790</td>
</tr>
<tr>
<td>Product sales, net</td>
<td>$26,218</td>
<td>$6,521</td>
</tr>
<tr>
<td>Sales discounts and allowances, as a percent of gross product sales</td>
<td>17%</td>
<td>11%</td>
</tr>
</tbody>
</table>

Cost of Goods Sold. Cost of goods sold during the three months ended September 30, 2013 was $5,313, an increase of $1,503 compared to cost of goods sold of $3,810 during the three months ended September 30, 2012. The increase in cost of goods sold during the three months ended September 30, 2013 was primarily due to increased DUEXIS product sales and RAYOS product sales during the three months ended September 30, 2013 with no corresponding RAYOS sales during the third quarter of 2012, partially offset by lower LODOTRA cost of sales in the third quarter of 2013 due to lower product shipments to Mundipharma.

Research and Development Expenses. Research and development expenses during the three months ended September 30, 2013 were $2,154, a decrease of $1,642 compared to research and development expenses of $3,796 during the three months ended September 30, 2012. The decrease in research and development expenses during the third quarter of 2013 was primarily associated with the classification of $1,161 in medical affairs expenses to sales and marketing expenses and a $319 reduction in quality control expenses associated with our Swiss subsidiary, Horizon Pharma AG. 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 three months ended September 30, 2013 were $15,621, an increase of $2,670 compared to sales and marketing expenses of $12,951 during the three months ended September 30, 2012. The increase in sales and marketing expenses during the three months ended September 30, 2013 was primarily attributable to an increase of $2,887 in salaries and benefits expenses due to the increase in staffing of our field sales force and the inclusion of $1,196 of medical affairs expenses in sales and marketing expenses, partially offset by a $1,294 reduction in marketing and commercialization costs compared to the same period in the prior year which included substantial launch and prelaunch spending.

General and Administrative Expenses. General and administrative expenses during the three months ended September 30, 2013 were $5,874, an increase of $1,196 compared to general and administrative expenses of $4,678 during the three months ended September 30, 2012. The increase in general and administrative expenses during the third quarter of 2013 was primarily associated
with an increase of $527 related to intellectual property related matters, a $298 increase in salaries and benefits expenses associated with higher administrative headcount compared to the prior year period and a $274 increase in legal and consulting expenses.

**Interest Expense, Net.** Interest expense, net was $3,601 during the three months ended September 30, 2013, an increase of $262 compared to interest expense, net of $3,339 during the three months ended September 30, 2012. The increase in interest expense was primarily due to higher debt discount expenses associated with a September 2012 amendment under our $60,000 senior secured loan facility with a group of institutional investors, or Senior Secured Loan, entered into in February 2012, partially offset by lower borrowing balances under the Senior Secured Loan as a result of principal debt repayments made during 2013.

**Foreign Exchange Gain/(Loss).** During the three months ended September 30, 2013 and 2012, we reported a foreign exchange gain of $1,118 and $588, respectively. The increase in foreign exchange gain during the three months ended September 30, 2013 was primarily the result of the impact of a strengthening of the Euro against the U.S. dollar at Horizon Pharma AG during the three months ended September 30, 2013.

**Income Tax Benefit.** During the three months ended September 30, 2013, we reported income tax expense of $265 compared to an income tax benefit of $4,512 during the three months ended September 30, 2012. The decrease in income tax benefit was primarily due to a reduction in our deferred tax assets associated with lower projected pre-tax operating losses and a one-time tax benefit recorded in the prior year period. During the third quarter of 2012, we recorded a one-time tax income benefit of $4,258 related to a reduction in our deferred tax asset positions resulting from the reclassification of our indefinite-lived in-process research and development, or IPR&D, asset to a finite-lived intangible asset.

**Net Loss.** Net loss during the three months ended September 30, 2013 was $5,492, a decrease of $11,461 from a net loss of $16,953 during the three months ended September 30, 2012 primarily as a result of the increase in sales and related gross profits, partially offset by an increase in expenses as described above.
Comparison of Nine Months Ended September 30, 2013 and 2012

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

<table>
<thead>
<tr>
<th>Segment</th>
<th>Nine Months Ended September 30,</th>
<th>Increase / (Decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
<td>2012</td>
</tr>
<tr>
<td>Gross sales</td>
<td>$59,859</td>
<td>$14,827</td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>(12,216)</td>
<td>(1,942)</td>
</tr>
<tr>
<td>Net sales</td>
<td>47,643</td>
<td>12,885</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>13,077</td>
<td>8,732</td>
</tr>
<tr>
<td>Gross profit</td>
<td>34,566</td>
<td>4,153</td>
</tr>
<tr>
<td>Operating expenses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>7,185</td>
<td>12,098</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>48,475</td>
<td>34,466</td>
</tr>
<tr>
<td>General and administrative</td>
<td>15,998</td>
<td>14,436</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>71,658</td>
<td>61,000</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(37,092)</td>
<td>(56,847)</td>
</tr>
<tr>
<td>Other (expense) income</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(10,646)</td>
<td>(11,081)</td>
</tr>
<tr>
<td>Foreign exchange gain (loss)</td>
<td>667</td>
<td>(312)</td>
</tr>
<tr>
<td>Other expense</td>
<td>(9,979)</td>
<td>(11,449)</td>
</tr>
<tr>
<td>Total other expense, net</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss before benefit for income taxes</td>
<td>(47,071)</td>
<td>(68,296)</td>
</tr>
<tr>
<td>Benefit for income taxes</td>
<td>(967)</td>
<td>(4,835)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (46,104)</td>
<td>$ (63,461)</td>
</tr>
</tbody>
</table>

Sales. During the nine months ended September 30, 2013, gross and net sales were $59,859 and $47,643, respectively, compared to $14,827 and $12,885 in gross and net sales, respectively, during the nine months ended September 30, 2012. DUEXIS gross and net sales during the nine months ended September 30, 2013 were $50,973 and $39,353, respectively, after deducting sales discounts and allowances of $5,291 and co-pay assistance costs of $6,329, and represented 85% of gross sales and 83% of net sales during the first nine months of 2013, compared to gross and net sales of $6,177 and $5,074, respectively, during the nine months ended September 30, 2012. The increase in DUEXIS sales during the nine months ended September 30, 2013 compared to the same period in the prior year was primarily the result of our expanded sales force in addition to product price increases implemented during the course of 2013.

RAYOS gross and net sales were $3,403 and $2,956, respectively, during the nine months ended September 30, 2013 after deducting sales discounts and allowances of $248 and co-pay costs of $199 compared to no RAYOS sales during the nine months ended September 30, 2012 as the product was launched in late 2012.

LODOTRA gross and net sales during the nine months ended September 30, 2013 were $5,483 and $5,334, respectively, after deducting trade allowances of $149, compared to gross and net sales of $8,650 and $7,811, respectively, during the nine months ended September 30, 2012. The decrease in LODOTRA sales during the nine months ended September 30, 2013 compared to the same period in the prior year was the result of lower product shipments to our European distribution partner, Mundipharma, and a decline 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.
Sales discounts and allowances. During the nine months ended September 30, 2013, sales discounts and allowances were $12,216 compared to $1,942 during the nine months ended September 30, 2012. As a percentage of gross product sales, sales discounts and allowances increased to 20% during the nine months ended September 30, 2013 compared to 13% during the nine months ended September 30, 2012. The increase in sales discounts and allowances was attributable to a significant increase in product sales during the nine months ended September 30, 2013, which resulted in a corresponding increase in customer discounts, prompt pay allowances and customer rebates. Additionally, co-pay assistance costs increased $5,800 during the nine months ended September 30, 2013 compared to the same period in 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. Partially offsetting the increase in product sales discounts and allowances during the nine months ended September 30, 2013 was a $2,378 benefit recorded during the third quarter of 2013 associated with the renegotiation of a managed care contract and from sales channel mix. The following table presents our sales discounts and allowances for the nine months ended September 30, 2013 and 2012:

<table>
<thead>
<tr>
<th>Nine Months Ended September 30,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
</tr>
<tr>
<td>Gross product sales</td>
<td>$59,859</td>
</tr>
<tr>
<td>Customer discounts and rebates</td>
<td>912</td>
</tr>
<tr>
<td>Co-pay assistance</td>
<td>6,528</td>
</tr>
<tr>
<td>Government rebates and chargebacks</td>
<td>3,329</td>
</tr>
<tr>
<td>Product returns and prompt pay allowances</td>
<td>1,447</td>
</tr>
<tr>
<td>Sales discounts and allowances</td>
<td>12,216</td>
</tr>
<tr>
<td>Product sales, net</td>
<td>$47,643</td>
</tr>
<tr>
<td>Sales discounts and allowances, as a percent of gross product sales</td>
<td>20%</td>
</tr>
</tbody>
</table>

Cost of Goods Sold. Cost of goods sold during the nine months ended September 30, 2013 was $13,077, an increase of $4,345 compared to cost of goods sold of $8,732 during the nine months ended September 30, 2012. The increase in cost of goods sold during the nine months ended September 30, 2013 was primarily due to increased DUEXIS product sales during the nine months ended September 30, 2013 and RAYOS product sales during the nine months ended September 30, 2013 with no corresponding RAYOS sales during the nine months ended September 30, 2012, partially offset by lower LODOTRA cost of sales during the nine months ended September 30, 2013 due to lower product shipments to Mundipharma.

Research and Development Expenses. Research and development expenses during the nine months ended September 30, 2013 were $7,185, a decrease of $4,913 compared to research and development expenses of $12,098 during the nine months ended September 30, 2012. The decrease in research and development expenses during the nine months ended September 30, 2013 was primarily associated with the classification of $3,758 in medical affairs expenses to sales and marketing expenses, a $604 decrease in consulting fees and a $572 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 nine months ended September 30, 2013 were $48,475, an increase of $14,009 compared to sales and marketing expenses of $34,466 during the nine months ended September 30, 2012. The increase in sales and marketing expenses during the nine months ended September 30, 2013 was primarily attributable to an increase of $11,663 in salaries and benefits expenses due to the expansion of our field sales force during 2013 and the inclusion of $3,758 of medical affairs expenses to sales and marketing expenses, partially offset by a $1,290 decrease in marketing and commercialization expenses.

General and Administrative Expenses. General and administrative expenses during the nine months ended September 30, 2013 were $15,998, an increase of $1,562 compared to general and administrative expenses of $14,436 during the nine months ended September 30, 2012. The increase in general and administrative expenses during the nine months ended September 30, 2013 was primarily associated with an increase of $735 related to intellectual property related matters, a $834 increase in salaries and benefits.
expenses associated with higher administrative headcount compared to the prior year period, and a $486 increase in facilities expenses, partially offset by a $517 reduction in consulting related expenses.

Interest Expense, Net. Interest expense, net was $10,646 during the nine months ended September 30, 2013, a decrease of $435 compared to interest expense, net of $11,081 during the nine months ended September 30, 2012. The decrease in interest expense was primarily associated with lower average borrowing balances under our Senior Secured Loan during 2013 as a result of principal debt repayments made during the nine months ended September 30, 2013, partially offset by higher debt discount expenses as a result of incremental costs associated with the amendment to our Senior Secured Loan in the third quarter of 2012. Additionally, during the nine months ended September 30, 2012, we incurred approximately $2,500 in prepayment and end of loan payments associated with the extinguishment of prior debt facilities.

Foreign Exchange Gain/(Loss). During the nine months ended September 30, 2013, we reported a foreign exchange gain of $667 compared to a foreign exchange loss of $312 during the nine months ended September 30, 2012. The foreign exchange gain was the result of a reduction in U.S. dollar denominated transactions for our Horizon Pharma AG subsidiary in addition to a strengthening of the Euro against the U.S. dollar during the nine months ended September 30, 2013.

Income Tax Benefit. During the nine months ended September 30, 2013, income tax benefit was $967, a decrease of $3,868, compared to an income tax benefit of $4,835 during the nine months ended September 30, 2012. The decrease in income tax benefit during the nine months ended September 30, 2013 was primarily associated with the $4,258 income tax benefit adjustment recorded during the third quarter of 2012, partially offset by a higher income tax benefit recorded during the nine months ended September 30, 2013 associated with an increase in intangible amortization expense. The increase in intangible amortization was incurred in connection with the FDA approval of RAYOS on July 26, 2012, which required us to reclassify our IPR&D indefinite-lived intangible asset to a finite-lived intangible asset. The reclassification of our IPR&D indefinite-lived intangible asset to a finite-lived intangible asset required us to begin amortizing this asset, which resulted in additional income tax benefits due to our deferred tax liability position.

Net Loss. Net loss during the nine months ended September 30, 2013 was $46,104, a decrease of $17,357 from a net loss of $63,461 during the nine months ended September 30, 2012 primarily as a result of the increase in DUEXIS product sales and gross profits, and the launch of RAYOS in 2013, partially offset by an increase in expenses as described above.

SUMMARY OF CRITICAL ACCOUNTING POLICIES

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

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

Revenue Recognition

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

Revenue from product deliveries

We recognize revenue from the delivery of our products when delivery has occurred, title has transferred, the selling price is fixed or determinable, the right of return no longer exists (which is the earlier of product being dispensed through patient prescriptions or the expiration of the right of return) or product returns can be reasonably estimated, collectability is reasonably assured and we have no further performance obligations. Prior to October 2012, revenue for products sold in the U.S. to our wholesale pharmaceutical
Revenue from up-front license fees

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

Revenue from milestone receipts

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

Customer-Related Accruals and Allowances

DUEXIS/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.

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.

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 September 30, 2013:

<table>
<thead>
<tr>
<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, 2012</td>
<td>$1,455</td>
<td>$422</td>
<td>$321</td>
<td>$77</td>
</tr>
<tr>
<td>Current provisions relating to sales in current year</td>
<td>908</td>
<td>6,020</td>
<td>3,331</td>
<td>1,274</td>
</tr>
<tr>
<td>Adjustments relating to prior years</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Payments/returns relating to sales in current year</td>
<td>(344)</td>
<td>(3,174)</td>
<td>(1,424)</td>
<td>(754)</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>
</tr>
<tr>
<td>Balance at September 30, 2013</td>
<td>$1,256</td>
<td>$3,136</td>
<td>$2,190</td>
<td>$404</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. Also included in cost of goods sold are distribution service fees paid to wholesalers for distribution and inventory management services.

Cost of goods sold for RAYOS includes all costs directly related to the 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. Also included in cost of goods sold are distribution service fees paid to wholesalers for distribution and inventory management services.

Cost of goods sold for 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.

**Inventories**

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

**Provision for Income Taxes**

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

**Stock-Based Compensation**

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

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

**LIQUIDITY, FINANCIAL POSITION AND CAPITAL RESOURCES**

We have incurred losses since our inception in June 2005 and, as of September 30, 2013, we had an accumulated deficit of $354,215. We anticipate that we will continue to incur net losses until such time as the revenues we generate from DUEXIS 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 moderately as a result of our commercialization of DUEXIS and RAYOS/LODOTRA. As a result, we will need to generate significant net product sales, and royalty and other revenues to achieve profitability.

We have financed our operations to date through equity financings, debt financings and the issuance of convertible notes. As of September 30, 2013, we had $58,650 in cash and cash equivalents. In February 2012, we entered into the $60,000 Senior Secured Loan. Under the terms of the Senior Secured Loan, the outstanding principal accrues interest until maturity in January 2017 at a rate of 17% per annum, payable quarterly unless repaid earlier. The Senior Secured Loan allows us to pay the full 17% interest when due or pay 12% interest in cash and the remaining 5% interest in the form of incremental debt. We may prepay the loan at any time, subject to certain prepayment premiums. In connection with the Senior Secured Loan, we also issued warrants to the lenders to purchase up to an aggregate of approximately 3,277,191 shares of our common stock at an exercise price of $0.01 per share. The warrants became exercisable 180 days after issuance and will remain exercisable until the maturity date of the Senior Secured Loan on January 22, 2017, subject to limited exceptions. The Senior Secured Loan is secured by a lien covering substantially all of our assets including...
intellectual property in addition to a pledge of all of our equity interests in Horizon Pharma USA, Inc. and 65% of our equity interests in Horizon Pharma AG.

The Senior Secured Loan restricts our ability to incur additional indebtedness, incur liens, pay dividends and engage in significant business transactions, such as a change of control, so long as we owe any amounts to the lenders under the related loan agreements. If we default under our Senior Secured Loan, our lenders may accelerate all of our repayment obligations and take control of our pledged assets. Our lenders could declare us in default under our debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect upon us as defined under the loan agreements, thereby requiring us to repay the loans immediately or to attempt to reverse the lenders’ declaration through negotiation or litigation. Among other loan covenant requirements, the Senior Secured Loan requires us to maintain a minimum level of liquidity of at least $10,000 at all times during the term of the loan unless our quarterly consolidated EBITDA is at least $6,000 and to meet specified minimum net revenues during a trailing 12 month period commencing on June 30, 2012. The negative covenants include, among other things, restrictions on transferring or licensing our assets, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions and creating other liens on our assets, in each case subject to customary exceptions. During 2012, we paid 12% interest in cash and elected to add the remaining 5% interest due of $1,842 to the principal loan balance as payment in kind borrowings. During 2013, we paid 12% interest in cash and elected to add the remaining 5% interest due of $2,298 as of September 30, 2013 to the principal loan balance as payment in kind borrowings.

In September 2012, we and the lenders entered into an amendment of the Senior Secured Loan, or the Senior Secured Loan Amendment, whereby affirmative covenants under the Senior Secured Loan with respect to minimum levels of liquidity and net revenue were modified. Under the Senior Secured Loan Amendment, we were required to have a minimum liquidity of $30,000 as of December 31, 2012, rather than the $10,000 required at all other times, and we were no longer required to achieve minimum net revenue levels for the trailing 12 month periods at the end of the third and fourth quarters of 2012, and the minimum trailing 12 month net revenues as of the end of each quarter of 2013 and the first quarter of 2014 were reduced. In lieu of paying a cash fee in consideration for entering into the Senior Secured Loan Amendment, we agreed to issue an aggregate of 1,250,000 shares of our common stock to the lenders.

At September 30, 2013, the outstanding balance on the Senior Secured Loan was $56,184 and we were in compliance with all applicable financial covenants under the Senior Secured Loan as amended. The inability to meet the covenants under the loan facility could have an adverse impact on our financial position and results of operations. These uncertainties and lack of commercial operating history raise substantial doubt about our ability to continue as a going concern. Additionally, our ability to comply with the operating and financial covenants under the Senior Secured Loan in future periods will be dependent on several factors including: the continued growth of the arthritis, pain and inflammation markets; acceptance of our products by patients, primary care specialists and other key specialists, including rheumatologists, orthopedic surgeons and pain specialists; the level of sales discounts and allowances we maintain for our products; and potential or perceived advantages or disadvantages of our products over alternative treatments, including cost of treatment and relative convenience and ease of administration. Changes in key markets or our inability to execute our operating plan could result in non-compliance with our operating and financial covenants which may adversely affect our cost of financing or cause an acceleration of our debt obligations.

Beginning in April 2013, and for each quarter thereafter, the lenders have the option to require us to repay $3,978 of the loan principal. In March 2013, 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 is 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 $5,836, which consisted of $3,978 in principal and $1,858 in interest. Additionally, on July 1, 2013, we made a payment of $5,761, which consisted of $3,978 in principal and $1,783 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. To the extent that we are required to make on-going quarterly prepayments of principal under the Senior Secured Loan, we may be required to seek additional funding earlier than we otherwise would in order to sustain our operations as well as maintain compliance with our minimum liquidity requirements under the Senior Secured Loan.

In August 2012, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may sell common stock in at-the-market, or ATM, offerings under our registration statement on Form S-3, which became effective on August 9, 2012. Subject to the terms and conditions of the sales agreement, Cowen will use its commercially reasonable efforts to sell
on our behalf any shares of common stock requested to be sold by us. Cowen and we each have the right, by giving written notice as specified in the sales agreement, to terminate the sales agreement in each party’s sole discretion at any time. The aggregate compensation payable to Cowen as sales agent will not exceed 3.0% of the gross sales price of the shares sold through it pursuant to the sales agreement. On March 25, 2013, we requested that Cowen begin to make sales under the sales agreement and provided them both daily volume and minimum price restrictions under which they could sell our common stock. During July 2013, Cowen sold 1,182,414 shares of our common stock for gross proceeds of $3,061 and net proceeds of $2,969, after deducting $92 in commissions and other issuance costs. Cowen has not sold shares under the ATM since July 2013 and as of September 30, 2013, Cowen had sold a cumulative total of 2,448,575 shares of our common stock with gross proceeds to us of $6,238 and we had $21,152 of common stock available for future issuance under the ATM sales agreement, after giving effect to the limited amount of securities registered under our shelf registration statement associated with the ATM sales agreement.

We are required to maintain compliance with applicable Swiss laws with respect to our Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. We review on a regular basis whether our Swiss subsidiary is overindebted. As of September 30, 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 September 30, 2013, Horizon Pharma AG had $1,290 in cash and cash equivalents. Based upon the cash and cash equivalents held by our Swiss subsidiary as of September 30, 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 flows for the nine months ended September 30, 2013 and 2012, as follows:

<table>
<thead>
<tr>
<th>Nine Months Ended September 30,</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>58,650</td>
<td>$63,460</td>
</tr>
<tr>
<td>Cash (used in) provided by :</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating activities</td>
<td>(43,109)</td>
<td>(59,473)</td>
</tr>
<tr>
<td>Investing activities</td>
<td>(643)</td>
<td>(1,062)</td>
</tr>
<tr>
<td>Financing activities</td>
<td>(1,745)</td>
<td>164,186</td>
</tr>
</tbody>
</table>

Sources and Uses of Cash

Operating Cash flows

During the nine months ended September 30, 2013 and 2012, net cash used in operating activities was $43,109 and $59,473, respectively. The decrease in net cash used in operating activities compared to the prior year period was primarily attributable to an increase in cash flows associated with higher product sales during the nine months ended September 30, 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.

Investing Cash Flows

During the nine months ended September 30, 2013 and 2012, net cash flows used in investing activities was $643 and $1,062, respectively. The decrease in net cash flows used in investing activities compared to the prior year period was due to capital expenditures related to computer and equipment expenses associated with the initial expansion of our field sales force during the third quarter of 2012.

Financing Cash Flows

During the nine months ended September 30, 2013, net cash used in financing activities was $1,745, compared to net cash provided by financing activities of $164,186 during the nine months ended September 30, 2012. During the nine months ended September 30, 2013, we repaid $7,956 in principal under our Senior Secured Loan. Additionally, we sold 2,448,575 shares of our

34
common stock through ATM offerings for gross proceeds of $6,238 and net proceeds of $5,998, after deducting $240 in commissions and other issuance costs. During the nine months ended September 30, 2012, net cash provided by financing activities was $164,186 and was primarily associated with debt refinancing and equity offerings completed. In February 2012, we entered into our $60,000 Senior Secured Loan. As part of the closing of the Senior Secured Loan, we repaid outstanding principal under prior existing debt facilities totaling $19,730. In March 2012, we received gross proceeds of $50,820 and net proceeds of $47,475, after deducting $3,345 in issuance costs, from the sale of 14,033,829 shares of our common stock and warrants to purchase an aggregate of 3,508,448 shares of our common stock to certain institutional and accredited investors in a private equity placement. In September 2012, we received gross proceeds of $86,236 and net proceeds of $80,961 after deducting $5,275 in issuance costs from the sale of 24,638,750 shares of common stock and warrants to purchase an aggregate of 12,319,375 shares of common stock to certain institutional and accredited investors in a public offering.

Contractual Obligations

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

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities, other than the indemnification agreements discussed in Note 10, “Commitments and Contingencies” in the notes to our condensed consolidated financial statements included in this report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

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

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

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

Credit Risk. Historically, our accounts receivable balances have been highly concentrated with a select number of customers, consisting primarily of large wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. Our top three customers, Mundipharma, McKesson Corporation and Cardinal Health, Inc., accounted for approximately 83% of total consolidated gross sales during the year ended December 31, 2012. During the nine months ended September 30, 2013, our top three customers, McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen, accounted for approximately 76% of total consolidated gross sales. In addition, three customers, Cardinal Health, Inc., Walgreen Company and McKesson Corporation, accounted for approximately 77% of our total outstanding accounts receivable balances at December 31, 2012. At September 30, 2013, three customers, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen, accounted for approximately 91% of
our total outstanding accounts receivable balances. Historically, we have not experienced any losses related to our accounts receivable balances.

Item 4. Controls and Procedures

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

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. 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 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 Settlement Agreement, and License Agreement, or License Agreement, with Par relating to our patent infringement litigation. The 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 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 U.S. 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 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 U.S. Unless terminated sooner pursuant to the terms of the License Agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the 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 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 License Agreement based on the manufacture, use, sale, offer for sale, or importation of Par’s generic version of DUEXIS in the U.S.
The 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 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 License Agreement will terminate automatically upon termination of the 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., Andrx 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 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. Our commencement of the patent infringement lawsuit stays, or bars, FDA approval of Par’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

**Item 1A: Risk Factors**

You should consider carefully the risks described below, together with all of the other information included in this report, and in our other filings with the Securities and Exchange Commission, or SEC, before deciding whether to invest in or continue to hold our common stock. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

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

**Risks Related to Our Business and Industry**

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

DUEXIS® and RAYOS®/LODOTRA®, and other product candidates that we may develop, acquire, 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 and announced in October 2012 that we had completed the expansion of our sales force. We began
commercial sales of RAYOS, which was approved by the U.S. Food and Drug Administration, or FDA, in July 2012, to a subset of rheumatologists in the fourth quarter of 2012 with the full launch to the majority of U.S. rheumatologists and key primary care physicians in late January 2013. Outside the U.S., LODOTRA has been sold in a limited number of countries. Sales of DUEXIS and LODOTRA have been limited to date outside the U.S. and sales may not grow to expected levels, in part because, with respect to LODOTRA, we depend on our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for commercialization outside the U.S. With respect to DUEXIS, we have only received marketing approval in the United Kingdom, or UK, thus far, and even if it is approved in other European countries, we do not expect the opportunity in Europe to be material to our business given the current state of the market in Europe for pain products and the revenue being generated by existing branded non-steroidal anti-inflammatory drugs, or NSAIDs, in Europe. We believe that the degree of market acceptance and our ability to generate revenues from our products will depend on a number of factors, including:

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

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

Our strategy is to build a fully-integrated U.S.-focused biopharmaceutical company to successfully execute the commercial launches of DUEXIS and RAYOS in the U.S. market. We may not be able to successfully commercialize either DUEXIS or RAYOS in the U.S. Prior to our commercial launch of DUEXIS in the U.S. in December 2011, we did not have any experience commercializing pharmaceutical products on our own. LODOTRA was commercially launched in Europe by our exclusive distribution partners Merck Serono and Mundipharma. In order to commercialize any approved products, we must continue to build
our sales, marketing, distribution, managerial and other non-technical capabilities. Although we have expanded our sales force to approximately 175 sales representatives, we currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market these products and any additional products we may acquire or in-license will be expensive and time-consuming and could delay any product launch. Nor can we be certain that we will be able to continue to successfully develop this capability. As a result of the evolving role of various constituents in the prescription decision making process, we adjusted the profile of the sales representatives we hire from those with traditional pharmaceutical sales experience to those with successful business to business experience. For example, we have faced challenges due to pharmacists increasingly switching a patient’s intended prescription from DUEXIS to a generic or over the counter brand. We have faced similar challenges for RAYOS with respect to generic brands. While we believe the new profile of our representatives is better suited for this evolving environment, we cannot be certain that our representatives will be able to successfully protect DUEXIS and RAYOS prescriptions or that we will be able to continue attracting and retaining sales representatives with our desired profile and skills. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain commercial personnel. To the extent we rely on additional third parties to commercialize any approved products, we may receive less revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of any third parties involved in our commercialization efforts. In the event we are unable to successfully develop and maintain our own commercial organization or collaborate with a third-party sales and marketing organization, we would not be able to commercialize our product candidates and execute on our business plan. If we are unable to successfully implement our commercial plans and drive adoption by patients and physicians of any approved products through our sales, marketing and commercialization efforts, or if our partners fail to successfully commercialize our products, then we will not be able to generate sustainable revenues from product sales which will have a material adverse effect on our business and prospects.

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

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

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

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

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

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

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

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

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

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

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

While we anticipate that LODOTRA will be marketed in additional countries as Mundipharma formulates its reimbursement strategy, the ability to market LODOTRA in additional countries will depend on Mundipharma’s ability to obtain regulatory and reimbursement approvals in these countries. Similarly, our ability to market DUEXIS outside of the U.S. will depend on obtaining regulatory and reimbursement approval in 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.*

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

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

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

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

In addition, we do not have the capability to package DUEXIS, RAYOS/LODOTRA or any other product candidates for distribution. Consequently, we have entered into an agreement with Temmler Werke GmbH, or Temmler, for packaging of RAYOS/LODOTRA in certain European countries, Israel and in the U.S., as well as any additional countries as may be agreed to by the parties. We intend to sell drug product finished and packaged by either Temmler or an alternate packager. At the end of 2012, Temmler was acquired by the Aenova Group. Valeant manufactures and supplies DUEXIS to us in final, packaged form for the U.S. as well as any additional countries as may be agreed to by the parties.

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

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.
We have experienced recent growth and expect to continue to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2010, we employed 41 full-time employees as a consolidated entity. In anticipation of the commercial launch of DUEXIS, we hired 80 sales representatives during the period from September 2011 through October 2011. As of December 31, 2012 and September 30, 2013, we employed 247 and 287 full-time employees, respectively, as a consolidated entity. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired in connection with the commercialization of DUEXIS and RAYOS, requiring us to hire and train new sales representatives. Our management, personnel, systems and facilities currently in place may not be adequate to support this recent growth, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses.

As our commercialization plans and strategies develop, we will need to continue recruiting and training sales and marketing personnel and expect to need to expand the size of our employee base for managerial, operational, financial and other resources. We may also need to expand these capabilities, along with our field sales force size and capabilities if we develop, acquire 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 DUEXIS and RAYOS;
- enhance our operational, financial and management controls, reporting systems and procedures;
- expand our international resources;
- manage the MAA review process for DUEXIS to ensure additional approvals in Europe beyond the UK;
- successfully identify, recruit, hire, train, maintain, motivate and integrate additional employees;
- establish and increase our access to commercial supplies of our products and product candidates;
- expand our facilities and equipment; and
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators, distributors and other third parties.

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

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

As DUEXIS and RAYOS were not fully commercially launched until January 2012 and January 2013, respectively, the members of our sales force have limited experience promoting DUEXIS and RAYOS. As a result, we are required to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense DUEXIS and RAYOS. In addition, we must train our sales force to ensure that a consistent and appropriate message about DUEXIS and RAYOS is being delivered to our potential customers. Our sales representatives may also experience challenges promoting two products when they call on physicians and their office staff, and our representatives may also be distracted from selling DUEXIS with the recent launch of RAYOS as all of our representatives were previously focused solely on selling DUEXIS. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired in connection with the commercial launch of DUEXIS and RAYOS, requiring us to train new sales representatives. As a result of the managed care environment and pharmacies switching patient’s prescriptions to a generic or over the counter brand, we have had to adjust the profile of the sales representatives we hire from the traditional pharmaceutical representative to a representative with business to business experience that is focused on the total office call in order to protect the prescription the physician has written and ensure the patient receives what their doctor ordered. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of DUEXIS and RAYOS and their proper administration and label indication, our efforts to successfully commercialize DUEXIS and RAYOS could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.
We face significant competition from other biotechnology and pharmaceutical companies, including those marketing generic products, and our operating results will suffer if we fail to compete effectively.*

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

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

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. 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., collectively 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 Settlement Agreement, and License Agreement, or License Agreement, with Par relating to our patent infringement litigation. Under the 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 U.S. 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 Settlement Agreement and 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.

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 active pharmaceutical ingredient 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 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. 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. Our commencement of the patent infringement lawsuit stays, or bars, FDA approval of Par’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.

If we are unsuccessful in either of the patent litigations with WLF or Par, we will likely face generic competition with respect to RAYOS and our sales of RAYOS will be substantially harmed.

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

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

- compliance with differing or unexpected regulatory requirements for our products;
- compliance with Swiss laws with respect to our Horizon Pharma AG subsidiary, including laws requiring maintenance of cash in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities;
- difficulties in staffing and managing foreign operations;
- in certain circumstances, including with respect to the commercialization of LODOTRA in Europe and certain Asian and Latin American countries, and commercialization of DUEXIS in Latin America, increased dependence on the commercialization efforts and regulatory compliance of our distributors or strategic partners;
- compliance with German laws with respect to our Horizon Pharma GmbH subsidiary through which Horizon Pharma AG conducts most of its European operations;
- foreign government taxes, regulations and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- 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 U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.
If we fail to develop, acquire 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. Since we do not have proprietary drug discovery technology, the success of this strategy depends in large part upon the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license clinically enabled product candidates for the treatment of pain-related diseases, or 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 DUEXIS and RAYOS/LODOTRA, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates to follow our existing products, and our business and prospects would therefore be harmed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We expect to experience pricing pressures in connection with the sale of DUEXIS, RAYOS/LODOTRA and any other products that we may develop, acquire or in-license, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. There may be additional pressure by payers and healthcare providers to use generic drugs that contain the active ingredients found in DUEXIS and RAYOS/LODOTRA or any other product candidates that we may develop, acquire 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, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.*

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

The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines up to $25,000 per violation and imprisonment for not more than five years, or both, and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.
Federal physician self-referral laws, such as the Stark laws and state equivalents, prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician’s family member has a financial interest and prohibit submission of a claim for reimbursement pursuant to a prohibited referral. Penalties for violations of the Stark laws include denial of payment, refund of payment, imposition of up to $15,000 in civil monetary penalties for each claim submitted in violation of the laws, up to $100,000 in civil monetary penalties for each “arrangement or scheme” that violates the laws, a civil monetary penalty of three times the amount claimed, and exclusion from participation in the Medicare program and/or other government health programs.

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

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

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

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.

Undesirable side effects caused by any product candidate that we develop may cause undesirable side effects or have other properties that could delay or prevent regulatory approval or commercialization or have a significant impact on customer demand.*

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

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

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

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

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

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

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

In addition, pursuant to a March 2011 letter agreement and in connection with our waiver of certain milestone payments, Mundipharma has initiated a separate Phase 3 clinical trial for LODOTRA for the potential treatment of PMR. We have limited control over the timing and implementation of the planned clinical trial and Mundipharma may carry the clinical trial out in a manner that does not maximize the trial’s chances of success or could lead to trial results that harm our and Mundipharma’s ability to market LODOTRA as a treatment for RA. If Mundipharma does not complete the trial on the timelines that we anticipate, or at all, our ability to obtain marketing approval in Europe for LODOTRA for the treatment of PMR will be delayed, and our business prospects would be harmed. While we have the right to use any data resulting from the planned clinical trial, we may not own the results from the trial, which could make it more difficult to pursue the development of LODOTRA as a treatment for PMR on our own.
We also, as part of the April 23, 2011 FDA approval of DUEXIS, have a commitment under the Pediatric Research Equity Act to conduct an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients. Although we are committed to carrying out these commitments, there are challenges in conducting studies in pediatric patients including availability of study sites, patients, and obtaining parental informed consent.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Financial Position and Capital Requirements

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

We have a limited operating history. We have financed our operations primarily through equity and debt financings and have incurred significant operating losses since our inception. We had a net loss of $46.1 million during the nine months ended September 30, 2013 and net losses of $87.8 million, $113.3 million and $27.1 million for the years ended December 31, 2012, 2011 and 2010, respectively. As of September 30, 2013, we had an accumulated deficit of $354.2 million. We do not know whether or when we will become profitable. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders’ deficit and working capital. Our losses have resulted principally from costs incurred in our development activities for our products and product candidates. We anticipate that we will continue to incur operating losses until such time as the revenues we generate from DUEXIS and RAYOS/LODTORA or any products we may acquire or in-license are sufficient to cover our operating expenses.
The terms of our senior debt facility require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.*

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

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

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

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

- commercializing DUEXIS, RAYOS/LODOTRA and any other product candidates for which we obtain approval;
- securing additional foreign regulatory approvals for LODOTRA and DUEXIS; and
- developing, acquiring or in-licensing and commercializing a portfolio of other product candidates in addition to DUEXIS and RAYOS/LODOTRA.
Even if we do generate additional product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

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

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

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

We believe that our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations into the third quarter of 2014 and potentially beyond based on our current expectations of continued revenue growth. We may need to raise additional funds sooner if we choose to expand our commercialization or development efforts more rapidly than we presently anticipate, if we develop, acquire or in-license additional products, or if our revenues do not meet expectations.

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

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

Even if we obtain additional financing, our Horizon Pharma AG subsidiary is subject to Swiss laws regarding overindebtedness that require Horizon Pharma AG to maintain assets in excess of its liabilities. As of September 30, 2013 and December 31, 2012, our Swiss subsidiary was overindebted, primarily as a result of operating losses at the subsidiary. We will continue to monitor and review steps to address any overindebtedness, until such time as our Swiss subsidiary may generate positive income at a statutory level, which could require us to have cash at our Swiss subsidiary in excess of its near term operating needs and could affect our ability to have sufficient cash at our U.S. subsidiary to meet its near term operating needs.

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

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

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

In August 2012, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may sell our common stock through Cowen in at-the-market, or ATM, offerings. As of September 30, 2013, $21.2 million worth of our common stock was available under the ATM sales agreement for future issuance. Subject to the terms and conditions of the sales agreement, Cowen may sell the shares by methods deemed to be an ATM offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including sales made through The NASDAQ Global Market, on any other existing trading market for our common stock or to or through a market maker. The sale of additional shares of our common stock pursuant to the sales agreement will have a dilutive impact on our existing stockholders and could cause the market price of our common stock to be lower than it would otherwise be absent sales activities by Cowen. Sales of our common stock under the sales agreement, or the perception that such sales will occur, could also encourage short sales by third parties, which could contribute to a decline of our stock price.

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

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

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

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

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

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. While there has been some recent improvement in some of these financial metrics, there can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate again, or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon commercialization or development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.
At September 30, 2013, we had $58.7 million of cash and cash equivalents consisting of cash and money market funds. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since September 30, 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.

Risks Related to Our Intellectual Property

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

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

Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. On 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 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. Our commencement of the patent infringement lawsuit stays, or bars, FDA approval of Par’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or invalid.
We intend to vigorously defend our intellectual property rights relating to DUEXIS and RAYOS, but we cannot predict the outcome of the Par, Alvogen or WLF matters related to RAYOS. Any adverse outcome in these matters or any new generic challenges that may arise could result in one or more generic versions of DUEXIS and/or RAYOS/LODOTRA being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of DUEXIS and/or RAYOS and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

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

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

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

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

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

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

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

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 SkyPharma 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 SkyPharma or our other license agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license, including RAYOS/LODOTRA.

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

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

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

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

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

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

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

Risks Related to Ownership of our Common Stock

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

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

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

- our failure to successfully execute our commercialization strategy with respect to our approved products, particularly our commercial launches of DUEXIS and RAYOS in the U.S.;
- disputes or other developments relating to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products and product candidates;
- unanticipated serious safety concerns related to the use of DUEXIS, RAYOS/LODOTRA or any of our other product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our products or product candidates, including but not limited to clinical trial requirements for approvals;
- inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;
- developments concerning our commercial partners, including but not limited to those with our sources of manufacturing supply;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse results or delays in clinical trials;
- our failure to successfully develop, acquire, 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;
- additions or departures of key management, commercial or regulatory personnel;
- issuances of debt or equity securities;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- effects of natural or man-made catastrophic events or other business interruptions; and
- other events or factors, many of which are beyond our control.
In addition, the stock market in general, and The NASDAQ Global Market and the stocks of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance.

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

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

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

Our officers, directors and funds affiliated with our directors held in the aggregate approximately 22% and 17% of our outstanding voting stock as of December 31, 2012 and September 30, 2013, respectively. Therefore, these stockholders have the ability to influence us through this ownership position, including through matters requiring stockholder approval. For example, these stockholders may be able to influence the elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

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

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

The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. If we fail to comply with the continued listing requirements of NASDAQ, our common stock could be delisted from The NASDAQ Global Market, which would adversely affect the liquidity of our common stock and our ability to obtain future financing.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform annual system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our independent registered public accounting firm is also required to deliver a report on the effectiveness of our internal control over financial reporting. Our testing, or the testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management efforts, particularly because of our holding company structure and international operations. We currently do not have an internal audit group, and we 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

65
of our common stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

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

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

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

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

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

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

In August 2012, we entered into a sales agreement with Cowen pursuant to which we may sell common stock in ATM offerings under our registration statement on Form S-3, which became effective on August 9, 2012. As of September 30, 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, and we had $21.2 million of common stock available for future issuance under the ATM sales agreement, after giving effect to the limited amount of securities registered under our shelf registration statement associated with the ATM sales agreement.

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

On December 14, 2012, pursuant to the terms of our 2011 EIP and 2011 ESPP, our board of directors approved increases in the number of shares available for issuance under the 2011 EIP and the 2011 ESPP of 1,474,304 shares and 200,000 shares, respectively, effective January 1, 2013.
Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

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

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

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

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

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

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

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

We completed the following issuances of unregistered securities during the three months ended September 30, 2013:

- In September 2013, we issued 29,904 shares of common stock to Royal Mail Pension Plan upon the cashless exercise of a warrant to purchase an aggregate of 30,000 shares of common stock.
In September 2013, we issued 405,657 shares of common stock to BIS (Postal Services Act 2011) Co Ltd. upon the cashless exercise of a warrant to purchase an aggregate of 406,959 shares of common stock.

In September 2013, we issued 108,845 shares of common stock to Beach Point Select Master Fund, L.P. upon the cashless exercise of a warrant to purchase an aggregate of 109,240 shares of common stock.

In September 2013, we issued 272,113 shares of common stock to Beach Point Total Return Master Fund, L.P. upon the cashless exercise of a warrant to purchase an aggregate of 273,099 shares of common stock.

In September 2013, we issued 544,227 shares of common stock to BPC Opportunities Fund LP upon the cashless exercise of a warrant to purchase an aggregate of 546,199 shares of common stock.

The offers, sales and issuances of the securities described above were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance on Rule 506 of Regulation D in that each issuance of securities was to an accredited investor under Rule 501 of Regulation D and did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

Item 5. Other Information

On November 7, 2013, our board of directors approved an amendment to our 2011 equity incentive plan, or 2011 EIP, to reserve an additional 200,000 shares 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). The 2011 EIP was amended by our board of directors without stockholder approval pursuant to Rule 5635(c)(4).

Item 6. Exhibits

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

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

HORIZON PHARMA, INC.

Date: November 8, 2013

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

Date: November 8, 2013

By: /s/ Robert J. De Vaere
Robert J. De Vaere
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)
<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(3)</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(4)</td>
<td>Form of Warrant issued in Public Offering of Units.</td>
</tr>
<tr>
<td>10.3*</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>10.4+</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>Exhibit Number</td>
<td>Description of Document</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------</td>
</tr>
<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(3)</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(4)</td>
<td>Form of Warrant issued in Public Offering of Units.</td>
</tr>
<tr>
<td>10.3*</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>10.4+</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>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>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 requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.  
(1) Incorporated by reference to Horizon Pharma, Inc.’s Registration Statement on Form S-1 (No. 333-168504), as amended.  
(2) Incorporated by reference to Horizon Pharma, Inc.’s Current Report on Form 8-K, filed on August 2, 2011.  
(3) Incorporated by reference to Horizon Pharma, Inc.’s Current Report on Form 8-K, filed on March 1, 2012.  
This SETTLEMENT AGREEMENT (this “Agreement”) dated August 21, 2013, (the “Execution Date”), is hereby entered into by and among HORIZON PHARMA, INC., a corporation organized and existing under the laws of Delaware having offices located at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015 (“Horizon Inc.”), and HORIZON PHARMA USA, INC., a corporation organized and existing under the laws of Delaware having offices located at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015 (“Horizon USA” and, together with Horizon Inc., the “Plaintiffs”), on the one hand, and PAR PHARMACEUTICAL COMPANIES, INC., a corporation organized and existing under the laws of Delaware, having offices located at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677 (“Par Co.”), and PAR PHARMACEUTICAL, INC., a corporation organized and existing under the laws of Delaware, having offices located at One Ram Ridge Road, Spring Valley, New York 10977 (“Par” and, together with Par Co., the “Defendants”), on the other hand. Each of Plaintiffs and Defendants is a “Party” and, collectively, the “Parties”.

WHEREAS, pursuant to 21 U.S.C. § 355(j), Par filed in the U.S., Abbreviated New Drug Application No. 203658, including any amendments or supplements thereto (the “ANDA”), to seek approval from the U.S. Food and Drug Administration, including any successor agency thereto (the “FDA”), to market and/or offer for sale the generic ibuprofen (800mg)/famotidine (26.6 mg) tablets as described in the ANDA (“Par’s Generic Tablets”);

WHEREAS, the Parties are currently involved in U.S. Civil Action Nos. 12-393-LPS and 13-102-LPS, consolidated under 12-393-LPS (the “U.S. District Court Case”) with respect to Par’s Generic Tablet in the United States District Court for the District of Delaware (the “Court”) involving United States Patent Nos. 8,067,033 (the “‘033 Patent”), 8,309,127 (the “‘127 Patent”) and 8,318,202 (the “‘202 Patent” and, together with the ’033 Patent and the ’127 Patent, the “Asserted Patents”);

WHEREAS, the Parties recognize the risks, unpredictability and expense of litigation and wish to resolve their disputes relating to the Asserted Patents with respect to Par’s Generic Tablets in the U.S. District Court Case through a negotiated and consensual agreement;

WHEREAS, Plaintiffs [...***...];

WHEREAS, the Parties wish to stipulate to the dismissal of the U.S. District Court Case without prejudice, and this Agreement sets forth the terms and conditions regarding same;

WHEREAS, contemporaneously with the execution of this Agreement, Plaintiffs and Defendants are entering into the License Agreement attached as Exhibit 1 (the “License Agreement” and, together with this Agreement, the “Settlement Documents”) and the Settlement Documents are the only agreements being entered into between the Plaintiffs and Defendant in connection with the settlement of the U.S. District Court Case;

***Confidential Treatment Requested
WHEREAS, as a result of the Settlement Documents, there will be an opportunity for U.S. generic entry which entry otherwise may not have occurred until the expiration of the Asserted Patents and the ’451 Patent; and

WHEREAS, this Agreement, the Stipulation of Dismissal (as defined below) and the License Agreement, are the only consideration exchanged by or on behalf of the Parties in reaching an agreement to dismiss the U.S. District Court Case and no Party has received any consideration from any other Party for their entry into this Agreement other than that which is described in this Agreement, the License Agreement, and the Stipulation of Dismissal.

NOW, THEREFORE, in consideration of the mutual agreements contained herein and through the License Agreement, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto, intending to be legally bound hereby, agree as follows:

I. Dismissal of Litigation

1. All of the terms and conditions set forth in this Agreement shall be binding on the Parties.

2. The Parties have entered into this Agreement, the Stipulation of Dismissal, and the License Agreement in an effort to avoid further litigation and contain associated fees, costs and expenses. The Parties acknowledge the sufficiency of the consideration recited herein and therein forming the basis of their agreement. Contemporaneously with the execution of this Agreement, the License Agreement shall be executed by the applicable Parties, and shall become effective in accordance with its own terms.

3. Within three (3) business days after the Execution Date, the Parties shall approach the Court and request that all associated deadlines be stayed pending the Regulatory Review Period described in Paragraph 13 below and the outcome thereof pursuant to Paragraphs 4 and 13 (a “Litigation Stay”). The proposed form of order for the Litigation Stay is attached as Exhibit 2. If the Court refuses to grant a Litigation Stay, the Parties will use reasonable efforts for a period of three (3) business days following such refusal to accommodate the requirements of the Court in order to obtain such a Litigation Stay or reach another mutually acceptable resolution.

4. Provided that the Agencies, as defined in Paragraph 13, have not filed for an injunction enjoining the Parties from entering into this Agreement or the License Agreement before the end of the Regulatory Review Period, the Parties will file with the Court, within three (3) business days following expiration of the Regulatory Review Period, all necessary papers, including the Stipulation of Dismissal attached as Exhibit 3, required to dismiss without prejudice all claims and counterclaims, motions, and petitions asserted in the U.S. District Court Case (the “Stipulation of Dismissal”). The date upon which the U.S. District Court Case is dismissed against all Parties pursuant to the Stipulation of Dismissal shall be referred to herein as the “Dismissal Effective Date.” This Agreement and the License Agreement shall terminate automatically, and all releases and admissions herein shall be null and void, if the Dismissal Effective Date has not occurred within seventy-five (75) days after the Execution Date (or by such later date as may be mutually agreed upon by the Parties).
II. Release of Claims

5. Subject expressly to the occurrence of the Dismissal Effective Date pursuant to Paragraph 4 above, Defendants, their Affiliates (as defined below), and each of their respective predecessors, successors, assigns, officers, directors, managers, employees and trustees (collectively, the “Defendants’ Releasees”), fully, finally and forever release, relinquish, acquit and discharge Plaintiffs, their Affiliates, and each of their respective predecessors, successors, assigns, officers, directors, managers, employees, and trustees (collectively, the “Plaintiffs’ Releasees”), of and from, and covenants not to sue, not to assign to any other entity a right to sue and not to authorize any other entity to sue any Plaintiffs’ Releasee for, any and all claims, counterclaims, actions, causes of action, suits, defenses, judgments, debts, offsets, accounts, torts, damages, demands and liabilities whatsoever, including costs, expenses, and attorneys’ fees (collectively, “Losses”) of every name and nature, both at law and in equity, known or unknown, suspected or unsuspected, accrued or unaccrued, that could have been, are or were asserted in the U.S. District Court Case, and that arise out of the specific patent issues that were the subject matter of the U.S. District Court Case, including any challenge to the infringement, validity or enforceability of the Asserted Patents and the ‘451 Patent. Notwithstanding this release, nothing herein shall preclude Defendants’ Releasees from asserting the invalidity, unenforceability and/or the non-infringement of the Asserted Patents and the ‘451 Patent in any future litigation concerning any product that is not the subject of the U.S. District Court Case and is not licensed under the License Agreement, and such defenses and/or counterclaims are reserved. Defendants’ Releasees acknowledge that the Asserted Patents are valid and enforceable solely with respect to Par's Generic Tablets and solely for purposes of enforcement of the Settlement Documents.

6. Subject expressly to the occurrence of the Dismissal Effective Date pursuant to Paragraph 4 above, Plaintiffs and each of the other Plaintiffs’ Releasees, as defined above, fully, finally and forever release, relinquish, acquit and discharge Defendants and each of the other Defendants’ Releasees of and from, and covenants not to sue, not to assign to any other entity a right to sue and not to authorize any other entity to sue any Defendants’ Releasee for, any and all Losses of every name and nature, both at law and in equity, known or unknown, suspected or unsuspected, accrued or unaccrued, that could have been, are or were asserted in the U.S. District Court Case and that arise out of the specific patent issues that were the subject matter of the U.S. District Court Case based upon activities of any of the Defendants’ Releasees before the Execution Date. Notwithstanding this release, nothing herein shall preclude Plaintiffs’ Releasees from asserting the validity, enforceability, and/or infringement of the Asserted Patents and the ‘451 Patent in any future litigation concerning any product that was not the subject of the U.S. District Court Case or any activities after the Execution Date, and all such claims are reserved.

7. For the purposes of this Agreement, “Affiliate” shall mean with respect to Plaintiffs, any person or entity that directly or indirectly controls, is controlled by, or is under common control with any of Plaintiffs; and with respect to Par, (a) for so long as Par is controlled directly or indirectly by investment funds affiliated with TPG Capital, L.P., Sky Growth Holdings Corporation, a Delaware corporation, to the extent it remains an indirect parent company of Par and including any successor entity to Sky Growth Holdings Corporation to the extent such successor is an indirect parent company of Par (“SGHC”), and any person or entity...
directly or indirectly controlled by SGHC or Par and (b) at any time that Par is not directly or indirectly controlled by investment funds affiliated with TPG Capital, L.P., any person or entity that directly or indirectly controls, is controlled by, or is under common control with Par. For purposes of this definition, “control” (including, with correlative meaning, the terms “controlled by”, and “under common control with”) means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such person or entity, whether through ownership of interests representing equity securities, or partnership interests or by contract, or otherwise, and ownership of more than fifty percent (50%) of such equity securities or partnership interests in a person or entity shall, without limitation, be deemed to be control for purposes of this definition.

8. Nothing in this Agreement shall preclude by release, contract, claim or issue preclusion or otherwise, Plaintiffs from raising any infringement assertion or Defendants from raising a non-infringement, invalidity or unenforceability defense of the Asserted Patents and the ‘451 Patent in connection with any product that is not the subject of the U.S. District Court Case and is not licensed under the License Agreement. This Agreement and the admissions herein shall not be admissible or otherwise relied upon or disclosed (unless such disclosure is required by law) in connection with any proceeding concerning the Asserted Patents and the ‘451 Patent and any product that is not the subject of the U.S. District Court Case, and is not licensed under the License Agreement.

9. Nothing in this Agreement releases or shall be deemed to release any Party from any violation of any provision of this Agreement or the License Agreement, and each Party is entitled to enforce the obligations hereunder and thereunder.

10. If this Agreement is terminated, the Parties agree, notwithstanding the existence of the Stipulation of Dismissal and/or Litigation Stay, that either Party may reinstate the U.S. District Court Case as if this Agreement had not been signed, and the Stipulation of Dismissal or the Litigation Stay had not been signed and entered, and any admissions as to liability, patent validity or patent enforceability in the Settlement Documents are null and void and each Party expressly reserves the right to litigate any and all claims, defenses and counterclaims that may have otherwise been barred, and each Party reserves the right to object to any previously unasserted claim, defense or counterclaim as untimely to the extent that the Party may have been able to do so at the time of the Litigation Stay or the Stipulation of Dismissal pursuant to this Agreement. Further, if the U.S. District Court Case is reinstated, Defendants agree (i) not to challenge the applicability or reinstatement of the full balance of any stay of FDA approval as to which the ANDA would have been subject but for the execution of the Settlement Documents and entry of the Litigation Stay, (ii) in the event the stay cannot be reinstated, Defendants consent to the entry of a preliminary injunction prohibiting Defendants from manufacture or sale of Par’s Generic Tablet for the full balance of any time the stay would have been in effect, but for the settlement; and not to market Par’s Generic Tablet prior to the date on which any such stay would have expired but for the execution of the Settlement Documents and entry of the Litigation Stay.
III. No Voluntary Assistance to Another’s Litigation

11. So long as this Agreement is in force, neither Defendants nor any other Defendants’ Releasees will voluntarily and knowingly assist or encourage any entity in, or provide (or assist or encourage any expert witnesses who are under Defendants’ or Defendants’ Releasees’ control to provide) any information to any entity for use in, attacking the validity or enforceability or defending against the alleged infringement of any of the Asserted Patents or the ‘451 Patent in connection with a product that is a generic equivalent of a product covered by the New Drug Application 022519 (as amended or supplemented), except as compelled by law. Nor shall Defendant nor any other Defendants’ Releasees release or provide any waiver to permit their outside counsel to provide such information concerning the Asserted Patents or the ‘451 Patent in a third-party litigation concerning a product that is a generic equivalent of a product covered by the New Drug Application 022519 (as amended or supplemented).

12. Nothing in this Agreement shall be deemed to impose any control by Plaintiffs over any exclusivity that any Defendant may hold, or otherwise restrict or limit such Defendant’s rights associated with such exclusivity.

IV. Regulatory Review

13. Within three (3) business days following the execution of this Agreement, the Parties shall submit this Agreement and the License Agreement to the Federal Trade Commission of the United States (“FTC”) and the Department of Justice of the United States (“DOJ” and, together with FTC, the “Agencies”) for review pursuant to Section 1112 of the Medicare Prescription Drug Improvement and Modernization Act of 2003. The Parties shall not file the Stipulation of Dismissal and any other documents referenced in Paragraph 4, for a period of forty-five (45) days following receipt of this Agreement by the Agencies (the “Regulatory Review Period”). The Parties, upon mutual agreement in writing, may extend this Regulatory Review Period. If such Agencies have not filed for an injunction enjoining the Parties from entering into this Agreement or the License Agreement before the end of the Regulatory Review Period, then the Parties shall then take all actions described in Paragraph 4 of this Agreement.

V. Confidentiality

14. The Parties hereby agree that, except as permitted herein or unless otherwise agreed to by the Parties in writing or required by law, the Parties, their Affiliates and their respective employees, officers, directors and other representatives shall not publish or otherwise disclose the contents of this Agreement, including any exhibits attached hereto, or of the negotiations of the Parties in respect of the U.S. District Court Case and/or the Settlement Documents. The Parties may state publicly that the U.S. District Court Case has been settled on terms that are confidential, but no public announcement concerning the terms or subject matter of this Agreement shall be made, either directly or indirectly, by any Party without first obtaining the approval of the other Party and agreement upon the nature and text of such public announcement or disclosure, such approval and agreement not to be unreasonably withheld, delayed or conditioned; provided, however, that a Party may make such public announcements that in the opinion of legal counsel for such Party are required by any applicable law, including the US Securities Act of 1933, as amended, the US Securities Exchange Act of 1934, as
amended, any governmental law or regulation, or the rules of any recognized stock exchange. Without limiting the foregoing, Defendants acknowledge that
Plaintiffs intend to (a) issue a press release (which shall be in substantially the form exchanged and agreed by the Parties prior to execution of this Agreement) and file a disclosure with the U.S. Securities and Exchange Commission (the “SEC”) upon execution of this Agreement and the License Agreement announcing settlement of the U.S. District Court Case and entry into this Agreement and the License Agreement, and outlining certain material terms thereof, and (b) publicly file copies of the Settlement Agreement and License Agreement with the SEC, which copies may be redacted by Plaintiffs after consultation with Par and consistent with the terms of this Paragraph 14. In addition, and notwithstanding the foregoing, the Parties agree that a Party may disclose the contents of this Agreement (i) to its Affiliates, (ii) to the extent necessary to enforce this Agreement, (iii) to third parties in connection with due diligence or similar investigations by such third parties, and disclosure to potential third party investors in confidential financing documents, provided that, in each case under this subclause (iii), any such third party agrees to be bound by obligations of confidentiality consistent with those set forth in this Paragraph 14 and (iv) to the extent necessary to comply with applicable law or regulation; provided, however, that if a Party believes that the disclosure of all or portions of this Agreement is required by applicable law, then that Party shall inform the other Party in sufficient time, if practicable, prior to any such disclosure to allow the other Party to seek a protective order or confidential treatment prior to any such disclosure; and provided further that such notice shall not be required for disclosure required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Each Party agrees that it shall cooperate fully with the other Party with respect to all disclosures regarding this Agreement to any governmental or regulatory agencies or any court, including requests for confidential treatment of proprietary information of any Party included in such disclosure. If the Parties are unable to agree on the form or content of any required disclosure, such disclosure shall be limited to the minimum required, as determined by the disclosing Party in consultation with its legal counsel. Without limiting the foregoing, each Party shall consult with the other Party on the provisions of this Agreement, together with any schedules or other attachments attached hereto, to be redacted in any filings made by Defendants and/or Plaintiffs with the SEC or as otherwise required by law, regulation or the rules of any recognized stock exchange.

VI. Representations and Warranties

15. Each Party represents and warrants to each of the other Parties, as of the Execution Date, that:

   (a) Such Party is validly existing and in good standing under the laws of the jurisdiction of its incorporation and has the corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

   (b) Such Party has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;
(c) This Agreement has been duly executed by such Party and constitutes a valid and legally binding obligation of such Party, enforceable in accordance with its terms;

(d) The execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it;

(e) Such Party has been advised by its counsel of its rights and obligations under this Agreement and enters into this Agreement freely, voluntarily, and without duress;

(f) Such Party is not relying on any promises, inducements, or representations other than those provided herein; and

(g) Such Party has not transferred, assigned, subrogated or pledged to any third party or to an Affiliate, the right to bring, pursue, or settle any of the claims, counterclaims, or demands made in the U.S. District Court Case.

16. Plaintiffs represent and warrant to Defendants, as of the Execution Date, that:

(a) Plaintiffs are the sole and exclusive owners of the Licensed Patents;

(b) Plaintiffs have the authority to grant the rights under the Licensed Patents upon the terms set forth in the License Agreement; and

(c) no entity other than the Plaintiffs has the right to enforce the Licensed Patents.

For purposes hereof, “Licensed Patents” means the Asserted Patents and the ’451 Patent and any other patents owned or Controlled (as defined in the License Agreement) by Horizon Inc. or Horizon USA as of the Execution Date or thereafter during the term of the License Agreement that would, absent the license granted under the License Agreement, be infringed by the manufacture, use, sale, offer for sale or import of Par’s Generic Tablets in the United States of America (including its territories, possessions and commonwealths), including all continuations, continuations-in-part, divisional, reissues and reexaminations and all extensions in the United States of America (including its territories, possessions and commonwealths), associated therewith.

17. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A
VII. Waiver

18. A waiver by any Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of any Party.

VIII. No Admission of Liability

19. Nothing in this Agreement shall be construed as or deemed to be an admission by the Parties hereto, or any of them, of any unlawful, improper, or actionable conduct or omission by any of them, and each Party hereto expressly denies liability of any kind whatsoever.

IX. Choice of Law and Remedies

20. This Agreement shall be governed and interpreted in accordance with the laws of the State of Delaware, and all claims relating to or arising out of this Agreement, or the breach thereof, whether sounding in contract, tort or otherwise, shall likewise be governed by the laws of Delaware, excluding such State’s choice-of-law principles. The Court shall have exclusive jurisdiction (to the extent that it has subject matter jurisdiction) in all matters arising under this Agreement, and the Parties hereto expressly consent and submit to the personal and subject matter jurisdiction of the Court. This Agreement does not limit or restrict the remedies available to any Party for the breach of another Party, and the Parties expressly reserve any and all remedies available to them, at law or in equity, for breach of this Agreement.

X. Assignments

21. This Agreement and the rights herein shall not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, that the prior written consent of the other Party shall not be required for a Party to assign or transfer this Agreement in its entirety in connection with a sale of substantially all of such Party’s assets or business or of the portion of such Party’s assets or business to which this Agreement relates, or pursuant to a merger, consolidation, reorganization or similar transaction related to such Party.

XI. Costs

22. Each Party shall each bear its own costs and legal fees associated with the U.S. District Court Case and the negotiation and preparation of this Agreement.
XII. Severability

23. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement.

XIII. Integration

24. This Agreement, including its Exhibits, which includes the License Agreement, shall constitute the entire agreement among the Parties with respect to the subject matter hereof and supersede all prior agreements and understandings, both oral and written, among the Parties with respect to such subject matter, including, without limitation, the [... ***...].

XIV. Amendments

25. No amendment, modification or supplement of any provisions of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

XV. Descriptive Headings

26. The captions and descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

XVI. No Presumption Against Drafting Party

27. This Agreement and its wording are the result of mutual arm’s length negotiation, and in the event of a dispute concerning the meaning of any term contained herein, no adverse inference or presumption shall be drawn against the Party who drafted such term.

XVII. Third Party Benefit

28. None of the provisions of this Agreement shall be for the benefit of or enforceable by any third party.

XVIII. Notice

29. Any notice or other communication to be given under this Agreement by a Party to the other Party shall be in writing and shall be (a) personally delivered, (b) mailed by registered or certified mail, postage prepaid with return receipt requested, (c) delivered by overnight express delivery service or same-day local courier service, or (d) delivered by facsimile transmission (followed by a copy by the preceding (a), (b) or (c)), to the address of the ***Confidential Treatment Requested

-9-
other Party as set forth below, or to such other address as may be designated by the Parties from time to time in accordance with this Section 29. Notices delivered personally, by overnight express delivery service or by local courier service shall be deemed given as of actual receipt. Mailed notices shall be deemed given five (5) business days after mailing. Notices delivered by facsimile transmission shall be deemed given upon receipt by the sender of the transmission confirmation if transmitted before 5:00 p.m. (recipient’s local time) on a business day, and otherwise on the following business day.

If to Horizon Inc.: Horizon Pharma, Inc.
520 Lake Cook Road, Suite 520
Deerfield, Illinois 60015
Attn: Timothy P. Walbert
Fax: (847) 572-1372

If to Horizon USA: Horizon Pharma USA, Inc.
520 Lake Cook Road, Suite 520
Deerfield, Illinois 60015
Attn: Timothy P. Walbert
Fax: (847) 572-1372

If to Par Co.: Par Pharmaceutical Companies, Inc.
300 Tice Boulevard
Woodcliff Lake, New Jersey 07677
Attn: General Counsel
Fax: (201) 802-4600

If to Par: Par Pharmaceutical, Inc.
One Ram Ridge Road
Spring Valley, New York 10977
Attn: General Counsel
Fax: (201) 802-4600

XIX. Waiver of Rule of Construction.

30. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

XX. Counterparts

31. This Agreement may be executed in any number of signature page counterparts transmitted via facsimile, any one of which need not contain the signature of more than one Party but all such counterparts taken together shall constitute one and the same Agreement.

SIGNATURES FOLLOW ON NEXT PAGE
IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed by its duly authorized representative as of the day and year first above written.

HORIZON PHARMA, INC.

By: /s/ Robert De Vaere

Name: Robert De Vaere
Title: Executive VP, CFO

HORIZON PHARM USA, INC.

By: /s/ Robert De Vaere

Name: Robert De Vaere
Title: Executive VP, CFO

PAR PHARMACEUTICAL COMPANIES, INC.

By: /s/ Thomas J. Haughey

Name: Thomas J. Haughey
Title: President

PAR PHARMACEUTICAL, INC.

By: /s/ Thomas J. Haughey

Name: Thomas J. Haughey
Title: President
EXHIBIT 1: LICENSE AGREEMENT

(See attached.)
EXHIBIT 2: LITIGATION STAY

(See attached.)

-2-
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORIZON PHARMA, INC. and HORIZON PHARMA USA, INC.,

Plaintiffs,

v.

PAR PHARMACEUTICAL COMPANIES, INC. AND PAR PHARMACEUTICAL, INC.

Defendants.

C.A. No. 12-393-LPS

STIPULATION AND ORDER

Whereas, plaintiffs, Horizon Pharma, Inc. and Horizon Pharma USA, Inc., and defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. have reached an agreement to settle their action, it is hereby stipulated and agreed that:

(1) The action among the above-named parties is stayed for sixty (60) days to permit review of the settlement agreement by certain government authorities; and

(2) If a stipulation of dismissal has not been filed within sixty (60) days, the parties shall contact the Court to report on the status of the settlement.

SO STIPULATED:
SO ORDERED this day of , 2013.

Hon. [ ], U.S.D.J.
EXHIBIT 3: STIPULATION OF DISMISSAL

(See attached.)
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORIZON PHARMA, INC. and HORIZON PHARMA USA, INC.,

Plaintiffs,

v.

PAR PHARMACEUTICAL COMPANIES, INC. AND PAR PHARMACEUTICAL, INC.

Defendants.

C.A. No. 12-393-LPS

STIPULATION OF DISMISSAL

Pursuant to Rules 41(a)(1) and 41(c) of the Federal Rules of Civil Procedure, the Plaintiffs and Defendants hereby stipulate and agree that the above actions, including all claims, counterclaims and affirmative defenses, are dismissed without prejudice, and without costs, disbursements or attorneys’ fees to any party.

-2-
SO ORDERED this day of , 2013.

Hon. [ ], U.S.D.J.

-3-
This LICENSE AGREEMENT (this “Agreement” or this “License Agreement”), dated August 21, 2013 (the “Execution Date”), is hereby entered into by and among HORIZON PHARMA, INC., a corporation organized and existing under the laws of Delaware having offices located at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015 (“Horizon Inc.”), and HORIZON PHARMA USA, INC., a corporation organized and existing under the laws of Delaware having offices located at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015 (“Horizon USA” and, together with Horizon Inc., the “Licensors”), on the one hand, and PAR PHARMACEUTICAL COMPANIES, INC., a corporation organized and existing under the laws of Delaware, having offices located at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677 (“Par Co.”), and PAR PHARMACEUTICAL, INC., a corporation organized and existing under the laws of Delaware, having offices located at One Ram Ridge Road, Spring Valley, New York 10977 (“Par” and, together with Par Co., the “Licensees”), on the other hand. Each of Licensors and Licensees is a “Party” and, collectively, the “Parties”).

WHEREAS, pursuant to 21 U.S.C. § 355(j), Par filed in the U.S., Abbreviated New Drug Application No. 203658, including any amendments or supplements thereto (the “ANDA”), to seek approval from the U.S. Food and Drug Administration, including any successor agency thereto (the “FDA”), to market and/or offer for sale the generic ibuprofen (800mg)/famotidine (26.6 mg) tablets as described in the ANDA (“Par’s Generic Tablets”);

WHEREAS, the Parties are currently involved in U.S. Civil Action Nos. 12-393-LPS and 13-102-LPS, consolidated under 12-393-LPS (the “U.S. District Court Case”) with respect to Par’s Generic Tablet in the United States District Court for the District of Delaware (the “Court”) involving United States Patent Nos. 8,067,033 (the “‘033 Patent”), 8,309,127 (the “‘127 Patent”) and 8,318,202 (the “‘202 Patent” and, together with the ‘033 Patent and the ‘127 Patent, the “Asserted Patents”);

WHEREAS, the Parties recognize the risks, unpredictability and expense of litigation and wish to resolve their disputes relating to the Asserted Patents with respect to Par’s Generic Tablets in the U.S. District Court Case through a negotiated and consensual agreement;

WHEREAS, Licensors [...***...];

WHEREAS, the Parties have entered into a Settlement Agreement related to the U.S. District Court Case (the “Settlement Agreement”);

WHEREAS, the Settlement Agreement provides for dismissing the U.S. District Court Case on the date that is deemed to be the “Dismissal Effective Date” (as defined in the Settlement Agreement, hereinafter the “Dismissal Effective Date”);

WHEREAS, as a result of the Settlement Agreement and this License Agreement, there will be an opportunity for U.S. generic entry which entry otherwise may not have occurred until the expiration of the Asserted Patents and the ‘451 Patent; and

***Confidential Treatment Requested
NOW, THEREFORE, in consideration of the mutual agreements contained herein and in the Settlement Agreement, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto, intending to be legally bound hereby, agree as follows:

I. Rights and Obligations

1. License. Subject to the terms and conditions of this License Agreement, the Licensor hereby grant Licensees, and Licensees hereby accept, a fully paid up, royalty-free (but subject to payment of the Profit Share pursuant to Paragraphs 3(a)(v) and 3(b)), non-exclusive license, with the right to sublicense solely to its Affiliates for only so long as such an entity remains an Affiliate of Par, under the Licensed Patents in each of the Licensees’ or its sublicensees’ names only and in the Territory to:

(a) effective as of the Dismissal Effective Date and prior to the applicable Generic Entry Date, make, have made, import, have imported, use and store Par’s Generic Tablets, and any components thereof, in the Territory, and otherwise take such steps in each case solely as reasonably necessary to develop inventory of, and obtain regulatory approval for, Par’s Generic Tablets in the Territory, and

(b) effective as of the applicable Generic Entry Date (as defined below), make, have made, import, have imported, store, use, distribute, have distributed, sell and offer for sale Par’s Generic Tablets in the Territory (all of the foregoing, the “License”).

Notwithstanding anything to the contrary in this Agreement or the Settlement Agreement, to the extent that Licensor is legally or otherwise required to in-license rights under patent(s) and/or patent application(s) in respect of the DUEXIS Product from a third party, and such license is subject to royalty, milestone or other payment obligations to such third party (each, a “Third-Party License”). In the event that any of the Licensor becomes aware of the need to obtain, or takes or otherwise acquires, a Third-Party License, Licensor shall provide prompt written notice thereof to Par. Licensor shall not aid or abet another Person in the assertion of the intellectual property that is the subject matter of such Third-Party License; and, to the extent any of the Licensor have standing to assert such intellectual property, shall covenant not to sue or assert such intellectual property against Par so long as Par is in compliance with this License Agreement.

2. Pre-Marketing Activities. Neither Licensees nor any of their Affiliates shall be allowed to engage in taking orders or any other marketing or pre-marketing activities before the Generic Entry Date; provided, however, that notwithstanding anything to the contrary in this License Agreement, reasonably associated pre-marketing activities, other than taking orders, including but not limited to offers to the trade that communicate information regarding the products to be offered for sale following the Generic Entry Date, may be conducted within [...***...]

---

***Confidential Treatment Requested***
3. Entry Date; Profit Share.

(a) For purposes of this License Agreement, the “Generic Entry Date” means the earliest to occur of the following:

(i) January 1, 2023;

(ii) The date of a final decision from which no appeal (other than a petition to the U.S. Supreme Court for a writ of certiorari) has been or can be taken, holding all claims of the Licensed Patents asserted and adjudicated against a third party to be invalid, unenforceable or not infringed by a third party’s filing of an Abbreviated New Drug Application for marketing approval of a generic version of the DUEXIS Product or sale of a product that is a generic equivalent of a DUEXIS Product;

(iii) The date (x) that is [...***...] days prior to a first commercial sale of a Generic Equivalent Product in the Territory by a third party pursuant to a license or other written authorization granted to such third party by any of the Licensors pursuant to the DUEXIS NDA (such prior date, “Par’s Prior-to-AG Date”) or (y) on which a commercial sale of a Generic Equivalent Product that is a Therapeutic Equivalent of the DUEXIS Product by a third party would be permitted in the Territory pursuant to a license or other written authorization granted to such third party by any of the Licensors; provided, however, that Licensors shall have provided written notice to Par within [...***...] business days after entering into any agreement with a third party that licenses or authorizes such third party to sell a Generic Equivalent Product, such date not to be later than [...***...] days prior to Par’s Prior-to-AG Date;

(iv) The date of a first commercial sale in the Territory by a third party, without license or authorization by the Licensors, of a Generic Equivalent Product; provided, however, that in the event such third party ceases the sale and distribution of such Generic Equivalent Product, or the Licensors subsequently obtain an injunction enjoining such third party’s sale and distribution of such Generic Equivalent Product, Par shall cease sale and distribution of any Par’s Generic Tablets in the Territory, and the Generic Entry Date shall be deemed not to have occurred (unless otherwise provided hereunder) unless and until sale and distribution of such Generic Equivalent Product in the Territory by such third party is resumed and, if Licensors obtained an injunction, following the lifting of such injunction, it being acknowledged and agreed, for the avoidance of doubt, that Par shall not be deemed to be in breach of this clause (iv), for which it might otherwise be subject to any damages, penalties or any other monetary award for

[***Confidential Treatment Requested]
sales made by Par of Par's Generic Tablets in the Territory after such third party ceases the sale and distribution of such Generic Equivalent Product or the Licensors subsequently obtain an injunction against such third party, if Par's sales and distribution prior to cessation thereof or obtainment of injunction was limited to its then.remaining inventory of Par's Generic Tablets; and

(v) Subject to Par’s payment of the Profit Share, the first day of the first [...***...] after a Market Decline that occurs based on [...***...].

(b) If the Generic Entry Date is determined based on the occurrence of the event set forth in Paragraph 3(a)(v), Par shall pay to Horizon USA, no later than [...***...] days after the end of each [...***...] and subject to the last sentence of this Paragraph 3(b), an amount equal to the Profit Share for [...***...] based on [...***...] of Par’s Generic Tablets during such [...***...].

(i) Each payment shall be accompanied by a report of Net Sales of Par’s Generic Tablets during such [...***...], which report shall include a calculation of such [...***...] and corresponding [...***...].

(ii) Licensees shall keep, and shall cause their Affiliates to keep, complete and accurate records pertaining to the sale or other disposition of Par’s Generic Tablets in sufficient detail to permit Horizon USA to confirm the accuracy of payments due hereunder, and Horizon USA shall have the right to cause an independent, certified public accountant reasonably acceptable to Par to review and/or audit such records on reasonable prior notice to Par and during normal business hours, solely to confirm Net Sales and accuracy of payments made hereunder. Par’s obligation to pay the Profit Share to Horizon USA shall commence after Par begins selling Par’s Generic Tablets pursuant to Paragraph 3(a)(v) and continue until the earliest occurrence of the events described in clause (i), (ii), (iii) or (iv) of Paragraph 3(a) (the “Profit Share Term”), it being acknowledged and agreed that Par shall be obligated to pay the Profit Share only for such portion of the [...***...] that has transpired prior to the occurrence of such event, and shall not be obligated to pay any Profit Share in respect of Par’s Generic Tablets sold after such occurrence.

(iii) The Parties acknowledge that any expenses or costs deducted from Net Sales of Par’s Generic Tablets under this Agreement may be based upon accruals, which accruals will be compliant with GAAP; provided, however, that when the actual results become known relative to any accrued amount, any difference between the actual results and the accrual shall be accounted for in the subsequent payments due hereunder (subject to customary processing delays). To the extent that the difference between such accruals and the actual results has led to an underpayment, Par shall pay Horizon USA the amount of such underpayment on the earlier of (a) [...***...] days after the underpayment is discovered and (b) the next date payment is due to Horizon USA hereunder. To the extent that the
difference between such accruals and the actual results has led to an overpayment to Horizon USA, Par may, at its option, set-off such overpayments against subsequent payments to be made to Horizon USA or issue an invoice for the overpayment, which shall be paid by Horizon USA within [...***...] days after Horizon USA's receipt thereof. By the date that is [...***...] days after the end of the [...***...] month following the expiration of Profit Share Term (or, with respect to returned goods only, [...***...] months following expiry of the last lot of Par's Generic Tablets sold during the Profit Share Term), Par shall reconcile (and give to Horizon USA a report of such reconciliation) all accrued calculations and deductions used in the calculations of Net Sales of Par's Generic Tablets with actual processed credits. If the report shows an underpayment to Horizon USA, Par shall pay Horizon USA the amount of the underpayment at the time it gives the report to Horizon USA. If the report shows an overpayment to Horizon USA, Horizon USA shall pay Par the amount of the overpayment within [...***...] days of the receipt of such reconciliation.

4. Releases.

(a) Licensees shall not, in the Territory before the applicable Generic Entry Date, directly or indirectly through its Affiliates, licensees, sublicensees, or others, market, offer for sale, sell or take orders for, Par's Generic Tablets, and Licensees shall not license, sublicense, enable, permit, or cause (or continue to license, sublicense, knowingly enable, permit or cause) any Person to do so. The Parties further agree that any violation of the foregoing would cause irreparable harm to Horizon Inc. and Horizon USA, and understanding this, Licensees hereby irrevocably and unconditionally consent to immediate entry of a temporary restraining order, preliminary injunction and permanent injunction in the event such relief is needed to prevent such harm in the event of a violation or imminent threat of a violation of the foregoing. Subject to Paragraph 4(b) and the remainder of this Paragraph 4(a), each of the Licensees, on behalf of itself, its Affiliates, and their respective predecessors, successors, assigns, officers, directors, managers, employees and trustees of the foregoing ("Releasees") agree that it will not challenge the validity, enforceability or infringement of the Licensed Patents or their foreign equivalents as they relate to any of Par's Generic Tablets. Notwithstanding this release, nothing herein shall preclude Releasees from asserting Losses (as defined in the Settlement Agreement) arising from any activities after the Execution Date to the extent Releasees are permitted to assert such Losses under Paragraph 5 of the Settlement Agreement, and all such claims are reserved. Subject to Paragraph 4(b), Licensees acknowledge that the Licensed Patents are valid and enforceable with respect to all of Par's Generic Tablets and for the purposes of enforcement of the Settlement Documents (as defined in the Settlement Agreement). Any action undertaken by Licensees or any of their respective Affiliates that, if undertaken by Par Co. or Par would be a breach of this License Agreement, shall be deemed a breach of this License Agreement by Licensees for which Licensees shall bear full responsibility.

(b) Notwithstanding anything else in this License Agreement to the contrary, the release and acknowledgement in Paragraph 4(a) shall become effective only upon the Dismissal Effective Date. Notwithstanding such release, nothing herein shall preclude Par's Releasees from ***Confidential Treatment Requested
asserting the invalidity, unenforceability and/or the non-infringement of the Asserted Patents and ‘451 Patent in any future litigation concerning any product that is not the subject of the U.S. District Court Case and is not licensed under the License Agreement, and such defenses and/or counterclaims are reserved.

5. **Limited Rights; No Implied Rights.** The License granted in Paragraph 1 above does not apply to any patent, patent application, or other intellectual property right owned by or licensed to Horizon Inc. or Horizon USA, other than the Licensed Patents. The License does not apply to any products other than Par’s Generic Tablets that are the subject of the ANDA. Nothing in this License Agreement shall preclude Horizon Inc. or Horizon USA from granting any sublicense/license or any other rights under any or all of the Licensed Patents, whether to an Affiliate of Horizon Inc. or Horizon USA or to any other Person. Except for the rights expressly granted under Paragraph 1 of this License Agreement, no other rights under any of the Licensed Patents or any other patents or intellectual property rights of Horizon Inc., Horizon USA or any of their Affiliates are granted under this License Agreement, by implication, estoppel or otherwise, and all other such rights are reserved. Licensee shall not practice the Licensed Patents except pursuant to the License granted in Paragraph 1.

6. **Covenant Not to Sue.** In addition to the license grants contained herein, subject to Licensees’ compliance with this Agreement, Horizon Inc. and Horizon USA, on behalf of themselves and each of their respective Affiliates, agree that neither of them nor their Affiliates will sue, assert any claim or counterclaim against, or otherwise participate in any action or proceeding against Par Co. or Par or any of their permitted sublicensees of the License or any of their respective customers, suppliers, importers, manufacturers or distributors, or any of their respective predecessors, successors, assigns, agents, officers, employees or representatives, or cause, support or authorize any third party to do any of the foregoing, in each case for infringement of any patent or patent application owned or Controlled at any time during the term of this Agreement by Horizon Inc. or Horizon USA based on or arising from the manufacture, use, sale, offer for sale or importation, within the scope of the License, of any of Par's Generic Tablets (and any components thereof, including the active ingredient for use in each instance in making any of such Par's Generic Tablets) in the Territory. Horizon Inc. and Horizon USA, and their Affiliates will impose the foregoing covenant not-to-sue on any Person that acquires from Horizon Inc. or Horizon USA or their Affiliates the right to enforce any such patent or patent application described in the immediately preceding sentence. For all patents described in the first sentence of this Paragraph 6 that may be listed in the Orange Book that may pertain to Par’s Generic Tablets, the foregoing covenant not to sue will be treated as a non-exclusive license solely for the purposes of permitting Par and its sublicensed Affiliates to file and maintain with the FDA a “Paragraph IV Certification” under 21 U.S.C. § 355(j)(2)(A)(vii) (IV) (as amended or replaced) with respect thereto.

7. **FDA Cooperation.** As Licensees may reasonably request, Horizon USA will submit, and will cause their respective Affiliates to submit, appropriate and reasonable documentation to the FDA evidencing the licenses set forth in this License Agreement to assist Par and its Affiliates in obtaining and maintaining FDA approval for Par’s Generic Tablets, at Par’s sole cost and expense. Par shall reimburse Horizon USA for all reasonable out-of-pocket
costs and expenses incurred by Horizon USA and/or its Affiliates in performing activities under this Paragraph 7, within thirty (30) days after receipt of an invoice therefor from Horizon USA.

II. Effectiveness; Term

8. Term. Unless terminated sooner pursuant to Paragraph 9, the License continues until the last to expire of each of the Licensed Patents (including any extensions thereof) and/or regulatory exclusivities associated therewith.

9. Termination. This License Agreement may be terminated by written notice to Licensees if Par Co. or Par commits a material breach hereof that is not cured or is not curable within thirty (30) days after Horizon Inc.’s or Horizon USA’s notice of such breach.

   (a) Without limiting the foregoing, Licensors may terminate this Agreement immediately upon written notice to Licensees if Licensees or any of its Affiliates or Releases directly or indirectly, including through assistance granted to a third party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any of the Licensed Patents or their foreign equivalents. Notwithstanding the foregoing, nothing herein shall preclude Licensees or any of its Affiliates or Releases from engaging in any of the foregoing activities in the immediately preceding sentence, including asserting the invalidity, unenforceability and/or the non-infringement of any of the Licensed Patents in any future litigation or proceeding, to the extent concerning any product that is not the subject of the DUEXIS NDA and is not licensed under the License Agreement.

   (b) In addition, this License Agreement shall terminate automatically if the Dismissal Effective Date has not occurred within seventy-five (75) days after the Execution Date (or by such later date as may be mutually agreed by the Parties pursuant to the Settlement Agreement). For clarity, this License Agreement shall automatically terminate upon any termination of the Settlement Agreement.

   (c) All licenses and rights granted to Licensees in this License Agreement shall automatically terminate upon any termination of this License Agreement; provided, however, that Par shall be responsible for paying all Profit Share and any other amounts owed to Horizon USA under Paragraph 3(b) prior to termination.

10. Survival. The provisions of Paragraphs 4, 5, 10, 11, and 14-26 shall survive termination of this License Agreement for any reason.

III. Confidentiality

11. Restrictions; Obligations. The Parties hereby agree that, except as permitted herein or unless otherwise agreed to by the Parties in writing or required by law, the Parties, their Affiliates and their respective employees, officers, directors and other representatives shall not publish or otherwise disclose the contents of this License Agreement. The Parties may state publicly that the U.S. District Court Case has been settled on terms that are confidential, but no
public announcement concerning the terms or subject matter of this License Agreement shall be made, either directly or indirectly, by any Party without first obtaining the approval of the other Party and agreement upon the nature and text of such public announcement or disclosure, such agreement and approval not to be unreasonably withheld, delayed or conditioned; except a Party may make such public announcements that in the opinion of legal counsel for such Party are required by any applicable law, including the US Securities Act of 1933, as amended, the US Securities Exchange Act of 1934, as amended, any governamental law or regulation, or the rules of any recognized stock exchange. Without limiting the foregoing, Licensees acknowledge that Licensors intend to (a) issue a press release (which shall be in substantially the form exchanged and agreed by the Parties prior to execution of this License Agreement) and file a disclosure with the U.S. Securities and Exchange Commission (the “SEC”) upon execution of this Agreement and the Settlement Agreement announcing settlement of the U.S. District Court Case and entry into this Agreement and the Settlement Agreement, and outlining certain material terms thereof, and (b) publicly file copies of the Settlement Agreement and License Agreement with the SEC, which copies may be redacted by Licensors after consultation with Par and consistent with the terms of this Paragraph 11. In addition, and notwithstanding the foregoing, the Parties agree that a Party may disclose the contents of this License Agreement (i) to its Affiliates, (ii) to the extent necessary to enforce the License Agreement, (iii) to third parties in connection with due diligence or similar investigations by such third parties, and disclosure to potential third party investors in confidential financing documents, provided that, in each case under this subclause (iii), any such third party agrees to be bound by reasonable obligations of confidentiality consistent with those set forth in this Paragraph 11 and (iv) to the extent necessary to comply with applicable law or regulation; provided, however, that if a Party believes that the disclosure of all or portions of this License Agreement is required by applicable law, then that Party shall inform the other Party in sufficient time, if practicable, prior to any such disclosure to allow the other Party to seek a protective order or confidential treatment prior to any such disclosure; and provided further that such notice shall not be required for disclosure required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Each Party agrees that it shall cooperate fully with the other Party with respect to all disclosures regarding this License Agreement to any governamental or regulatory agencies or any court, including requests for confidential treatment of proprietary information of any Party included in such disclosure. If the Parties are unable to agree on the form or content of any required disclosure, such disclosure shall be limited to the minimum required, as determined by the disclosing Party in consultation with its legal counsel. Without limiting the foregoing, each Party shall consult with the other Party on the provisions of this License, together with any schedules or other attachments attached hereto, to be redacted in any filings made by any Party with the SEC or as otherwise required by law, regulation or the rules of any recognized stock exchange.

IV. Representations and Warranties

12. Mutual Representations. Each Party hereby represents and warrants to the other Party, as of the Execution Date, that:
(a) Such Party is validly existing and in good standing under the laws of the jurisdiction of its incorporation and has the corporate power and authority to enter into this License Agreement and to carry out the provisions hereof;

(b) Such Party has taken all corporate action necessary to authorize the execution and delivery of this License Agreement and the performance of its obligations under this License Agreement;

(c) This License Agreement has been duly executed by such Party and constitutes a valid and legally binding obligation of such Party, enforceable in accordance with its terms;

(d) The execution, delivery and performance of this License Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it;

(e) Such Party has been advised by its counsel of its rights and obligations under this License Agreement and enters into this License Agreement freely, voluntarily, and without duress; and

(f) Such Party is not relying on any promises, inducements, or representations other than those provided herein.

13. Horizon Representations. Licensors hereby represent and warrant that they (i) are the sole and exclusive owners of the Licensed Patents existing as of the Execution Date, (ii) have not obtained or been granted (and are not aware of any need or requirement to obtain or be granted) any Third-Party License and (iii) have the authority to grant the licenses hereunder. Horizon Inc. and Horizon USA, on behalf of itself and its Affiliates, will impose the license grants, covenants, and other obligations contained in this License Agreement on any third party to which Horizon Inc. or Horizon USA, or any of its Affiliates, may assign or otherwise transfer right, title or interest (excluding any license or sublicense) in or to any of the Licensed Patents, and will impose covenants contained herein, as appropriate, on any licensee or sublicensee of Licensors under the Licensed Patents in the Territory.

14. Limitations. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN PARAGRAPHS 12-13 OF THIS LICENSE AGREEMENT, NO PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO THE SUBJECT MATTER OF THIS LICENSE AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. PAR ACKNOWLEDGES THAT, NOTWITHSTANDING THE RIGHTS EFFECTIVE HEREIN AS OF THE DISMISSAL EFFECTIVE DATE OR GENERIC ENTRY DATE, PAR MIGHT NOT BE ABLE TO LEGALLY EXPLOIT SUCH RIGHTS WITH RESPECT TO PAR’S GENERIC

-9-
TABLET ON SUCH DATES, INCLUDING, FOR EXAMPLE, DUE TO EXCLUSIVITY GRANTED BY THE FDA TO OTHER ABBREVIATED NEW DRUG APPLICATION FILERS, LACK OF REGULATORY APPROVAL FOR PAR’S GENERIC TABLET BY THE FDA OR THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

V. Waiver

15. **Waiver.** A waiver by any Party of any of the terms and conditions of this License Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this License Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of any Party.

VI. Choice of Law and Remedies

16. **Choice of Law; Remedies.** This License Agreement shall be governed and interpreted in accordance with the laws of the State of Delaware, and all claims relating to or arising out of this Agreement, or the breach thereof, whether sounding in contract, tort or otherwise, shall likewise be governed by the laws of Delaware, excluding such State’s choice-of-law principles. The Court shall have exclusive jurisdiction (to the extent that it has subject matter jurisdiction) in all matters arising under this License Agreement, and the Parties hereto expressly consent and submit to the personal and subject matter jurisdiction of the Court. This License Agreement does not limit or restrict the remedies available to any Party for the breach of another Party, and the Parties expressly reserve any and all remedies available to them, at law or in equity, for breach of this License Agreement.

VII. Assignment

17. **Assignment.** This License Agreement and the rights herein shall not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, that the prior written consent of the other Party shall not be required for a Party to assign or transfer this License Agreement in its entirety in connection with a sale of substantially all of such Party’s assets or business or of the portion of such Party’s assets or business to which this License Agreement relates, or pursuant to a merger, consolidation, reorganization or similar transaction related to such Party (each, an “Acquisition Transaction”); and provided further that in the event of an assignment or transfer of this License Agreement by Horizon Inc. and/or Horizon USA in connection with an Acquisition Transaction (whether this Agreement is actually assigned or is assumed by the acquiring party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such Acquisition Transaction (if other than one of the Parties to this Agreement) shall not be included in the intellectual property licensed by Licensors hereunder or otherwise subject to this Agreement.
VIII. Costs

18. Costs. Each Party shall each bear their own costs and legal fees associated with the negotiation and preparation of this License Agreement.

IX. Severability

19. Severability. When possible, each provision of this License Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this License Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this License Agreement.

X. Integration

20. Entire Agreement. The Settlement Agreement and its Exhibits, which include this License Agreement, shall constitute the entire agreement among the Parties with respect to the subject matter hereof and supersede all prior agreements and understandings, both oral and written, among the Parties with respect to such subject matter, including, without limitation, the [...***...].

X. Amendment

21. Amendment. No amendment, modification or supplement of any provisions of this License Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

XI. Descriptive Headings

22. Captions. The captions and descriptive headings of this License Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this License Agreement.

XII. No Presumption Against Drafting Party

23. No Presumption. This License Agreement and its wording are the result of mutual arm’s length negotiation, and in the event of a dispute concerning the meaning of any term contained herein, no adverse inference or presumption shall be drawn against the Party who drafted such term.

XIII. Third Party Benefit

24. Third Party Benefit. None of the provisions of this License Agreement shall be for the benefit of or enforceable by any third party.

***Confidential Treatment Requested**
XIV. Notice

25. Notice. Any notice or other communication to be given under this Agreement by a Party to the other Party shall be in writing and shall be (a) personally delivered, (b) mailed by registered or certified mail, postage prepaid with return receipt requested, (c) delivered by overnight express delivery service or same-day local courier service, or (d) delivered by facsimile transmission (followed by a copy by the preceding (a), (b) or (c)), to the address of the other Party as set forth below, or to such other address as may be designated by the Parties from time to time in accordance with this Paragraph 25. Notices delivered personally, by overnight express delivery service or by local courier service shall be deemed given as of actual receipt. Mailed notices shall be deemed given five (5) business days after mailing. Notices delivered by facsimile transmission shall be deemed given upon receipt by the sender of the transmission confirmation if transmitted before 5:00 p.m. (recipient’s local time) on a business day, and otherwise on the following business day.

If to Horizon Inc.: Horizon Pharma, Inc.
520 Lake Cook Road, Suite 520
Deerfield, Illinois 60015
Attn: Timothy P. Walbert
Fax: (847) 572-1372

If to Horizon USA: Horizon Pharma USA, Inc.
520 Lake Cook Road, Suite 520
Deerfield, Illinois 60015
Attn: Timothy P. Walbert
Fax: (847) 572-1372

If to Par Co.: Par Pharmaceutical Companies, Inc.
300 Tice Boulevard
Woodcliff Lake, New Jersey 07677
Attn: General Counsel
Fax: (201) 802-4600

If to Par: Par Pharmaceutical, Inc.
One Ram Ridge Road
Spring Valley, New York 10977
Attn: General Counsel
Fax: (201) 802-4600

XV. Counterparts

26. Counterparts. This License Agreement may be executed in any number of signature page counterparts transmitted via facsimile, any one of which need not contain the signature of more than one Party but all such counterparts taken together shall constitute one and the same License Agreement.
IN WITNESS WHEREOF, each of the Parties has caused this License Agreement to be executed by its duly authorized representative as of the day and year first above written.

HORIZON PHARMA, INC.
By: /s/ Robert De Vaere
   Name: Robert De Vaere
   Title: Executive VP, CFO

HORIZON PHARM USA, INC.
By: /s/ Robert De Vaere
   Name: Robert De Vaere
   Title: Executive VP, CFO

PAR PHARMACEUTICAL COMPANIES, INC.
By: /s/ Thomas J. Haughey
   Name: Thomas J. Haughey
   Title: President

PAR PHARMACEUTICAL, INC.
By: /s/ Thomas J. Haughey
   Name: Thomas J. Haughey
   Title: President

-13-
"Affiliate" means, with respect to Licensors, any Person that directly or indirectly controls, is controlled by, or is under common control with any one of the Licensors; and with respect to Par, (a) for so long as Par is controlled directly or indirectly by investment funds affiliated with TPG Capital, L.P., Sky Growth Holdings Corporation, a Delaware corporation, to the extent it remains an indirect parent company of Par and including any successor entity to Sky Growth Holdings Corporation to the extent such successor is an indirect parent company of Par ("SGHC"), and any Person directly or indirectly controlled by SGHC or Par and (b) at any time that Par is not directly or indirectly controlled by investment funds affiliated with TPG Capital, L.P., any Person that directly or indirectly controls, is controlled by, or is under common control with Par. For purposes of the foregoing definition, “control” (including, with correlative meaning, the terms “controlled by”, and “under common control with”) means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through ownership of interests representing equity securities, or partnership interests or by contract, or otherwise, and ownership of more than fifty percent (50%) of such equity securities or partnership interests in a Person shall, without limitation, be deemed to be control for purposes of this definition.

“Baseline Amount” means US$[...***...].

“Control” means, with respect to any patents or other intellectual property rights, possession by an entity of the ability (whether by ownership, license or otherwise) to grant access to, to grant use of, or to grant a license or a sublicense of or under such patents or intellectual property rights without violating the terms of any agreement or other arrangement with any third party.

“DUEXIS NDA” means New Drug Application 022519, and all associated amendments and supplements.

“DUEXIS Product” means the product or products that are the subject of the DUEXIS NDA.

“GAAP” means generally accepted accounting principles in effect in the United States from time to time, consistently applied.

“Generic Equivalent Product” means a pharmaceutical product that (i) is the Therapeutic Equivalent of DUEXIS® or sold as an authorized generic version of ibuprofen (800mg)/famotidine (26.6 mg) tablets that is the subject of, and pursuant to, the DUEXIS NDA and (ii) has been approved for sale in the Territory by the FDA.

“Licensed Patents” means the Asserted Patents and the ’451 Patent and any other patents owned or Controlled by Horizon Inc. or Horizon USA as of the Execution Date or thereafter during the term of this Agreement that would, absent the license granted hereunder, be infringed by the manufacture, use, sale, offer for sale or import of Par’s Generic Tablets in the Territory, including all continuations, continuations-in-part, divisional, reissues and reexaminations and all extensions in the Territory, associated therewith.
“Market Decline” means the [...***...].

“Marketing Cost Allowance” means [...***...].

“Net Profits” means [...***...].

“Net Sales of DUEXIS Products” has the same meaning as “Net Sales of Par’s Generic Tablets” except that (i) references to “Licensees or their Affiliates” shall be changed to “Licensors or their Affiliates or their respective licensees or sublicensees;” (ii) references to “Par’s Generic Tablets” shall be changed to “DUEXIS Products;” and (iii) the deduction set forth in clause (vi) of such definition shall be changed to “amounts paid to patients through co-pay assistance programs.”

“Net Sales of Par’s Generic Tablets” means the aggregate gross amounts invoiced for the sale of Par’s Generic Tablets by Licensees or their Affiliates in arm’s-length transactions with third parties in the Territory, less all applicable deductions set forth in clauses (i) – (vi) below, in each case to the extent specifically related to such sales of Par’s Generic Tablets and taken by Licensees or its Affiliates, or otherwise paid for, or accrued by, Licensees or their Affiliates in accordance with GAAP and in the ordinary course of business:

(i) cash discounts, quantity discounts, promotional discounts, stocking or other promotional allowances;

(ii) sales and excise taxes, customs and any other taxes, all to the extent added to the sale price and paid and not refundable in accordance with applicable law (but not including taxes assessed against the income derived from such sale);

(iii) returns, recalls and returned goods allowances;

(iv) retroactive corrections, including price adjustments (including those on customer inventories following price changes) and corrections for billing errors or shipping errors;

(v) chargebacks, rebates, administrative fees, any other allowances actually granted or allowed to any Person, including group purchasing organizations, managed health care organizations and to governments, including their agencies, or to trade customers, in each case that are not Affiliates of a Party; and

(vi) redistribution center (RDC) fees and information service agreement (ISA) fees.

***Confidential Treatment Requested
“Person” means an individual, corporation, partnership, limited liability company, firm, association, joint venture, estate, trust, governmental or administrative body or agency, or any other entity.

“Profit Share” means [...] percent ([... [%] of [...]).

[...] means the average [...] of the DUEXIS Product in any [...] following the Execution Date, as calculated by dividing (i) all [...] of the DUEXIS Product for the [...] month period ending the most recently ended [...] by (ii) [...] of [...].

“Territory” means the United States of America, including its territories, possessions and commonwealths.

“Therapeutic Equivalent” has the meaning given to it by the FDA in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, as may be amended from time to time.
AMENDMENT TO
MANUFACTURING AND SUPPLY AGREEMENT

This Amendment (the “Amendment”) is effective as of September 25, 2013 (“Amendment Effective Date”) by and between sanofi-aventis U.S. LLC, with offices at 55 Corporate Drive, Bridgewater, NJ 08807 (“Sanofi”), and Horizon Pharma USA, Inc., with offices at 520 Lake Cook Road, Suite 520, Deerfield, IL 60015 (hereinafter “Horizon”, and together with Sanofi, the “Parties”).

WHEREAS, the Parties entered into a Manufacturing and Supply Agreement (as amended, the “Agreement”), effective as of May 25, 2011 (the “Effective Date”); and

WHEREAS, as of the date hereof Sanofi and Horizon wish to amend the terms of the Agreement as set forth below.

NOW, THEREFORE, in consideration of mutual covenants the Parties agree as follows:

1. Article 6. FORECASTS AND ORDERS: Section 6.1 (Organization of the Production Site); Section 6.2 (Communication of Forecasts and Purchase Orders by Horizon); and Section 6.3(b) (Confirmation by sanofi-aventis). Article 6 is hereby modified by making the “Organizational Change” rights, duties, and obligations of both parties set out therein, only applicable and effective starting [...***...].

2. 2014 Purchase Orders.
   a. 3x3 Count. Upon the full execution of this Amendment, Horizon shall issue a Purchase Order for the calendar year 2014, for [...***...] 3x3 ct blisters of Product.
   b. 90 Count. Upon the full execution of this Amendment, Horizon shall issue a Purchase Order for the calendar year 2014, for [...***...] 90 ct bottles of Product.

3. Exhibit 1. Exhibit 1 to the Agreement is hereby replaced in its entirety with the attached Exhibit 1.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives as of the date first above written.

SANOFI-AVENTIS US LLC

By /s/ Kenneth J. Bruss
Name Kenneth J. Bruss
Title KCIA Site Head
Date 10/7/2013

HORIZON PHARMA USA, INC.

By /s/ Jeffrey W. Sherman, MD
Name Jeffrey W. Sherman, MD
Title Chief Medical Officer
Date 24 Sep 2013

***Confidential Treatment Requested
### Table 1 – 2013 selling prices

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Base Selling Price</th>
<th>API Cost &amp; API Freight</th>
<th>Total Selling Price</th>
<th>Base Selling Price</th>
<th>API Cost &amp; API Freight</th>
<th>Total Selling Price</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>90ct Bottle</strong></td>
<td>As Per table 1.1</td>
<td>As Per table 1.1</td>
<td>As Per table 1.1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latin America Bulk -per 1000 tablets</td>
<td>[...***... ]</td>
<td>[...***... ]</td>
<td>[...***... ]</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Price based on blister material as non-child proof Aclar,
1. Such pricing is subject to adjustment pursuant to Articles 5 and 9 of the Agreement.
2. Such pricing is based on and applies to annual production for the given Contract Year.
3. Such pricing includes packaging in a round 90ct bottle or single one count (1ct) blister packaged in a (15 x 1ct) per specifications in Exhibit 2. Pricing for other SKUs, such samples and blister packaging shall be agreed in writing by the Parties.
4. Such pricing is exclusive of all taxes

### Table 1.1 – DUEXIS 90count Bottle Pricing Schedule for volumes < [...***... ]

<table>
<thead>
<tr>
<th>Calendar Year</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
</table>

*API price shall be adjusted [...***...] beginning in [...***...] as per section 9.3(b) of the Agreement.

***Confidential Treatment Requested
1. General.

(a) Successor to and Continuation of Prior Plan. The Plan is intended as the successor to and continuation of the Horizon Pharma, Inc. 2005 Stock Plan (the “Prior Plan”). Following the Effective Date, no additional stock awards shall be granted under the Prior Plan. Any shares remaining available for issuance pursuant to the exercise of options or issuance or settlement of stock awards under the Prior Plan as of the Effective Date (the “Prior Plan’s Available Reserve”) shall become available for issuance pursuant to Stock Awards granted hereunder. From and after the Effective Date, all outstanding stock awards granted under the Prior Plan shall remain subject to the terms of the Prior Plan; provided, however, any shares subject to outstanding stock awards granted under the Prior Plan that expire or terminate for any reason prior to exercise or settlement or are forfeited because of the failure to meet a contingency or condition required to vest such shares (the “Returning Shares”) shall become available for issuance pursuant to Awards granted hereunder. All Awards granted on or after the Effective Date of this Plan shall be subject to the terms of this Plan.

(b) Eligible Award Recipients. The persons eligible to receive Awards are Employees, Directors and Consultants.


(d) Purpose. The Company, by means of the Plan, seeks to secure and retain the services of the group of persons eligible to receive Awards as set forth in Section 1(b), to provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and to provide a means by which such eligible recipients may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Awards.

2. Administration.

(a) Administration by Board. The Board shall administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) Powers of Board. The Board shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine from time to time (A) which of the persons eligible under the Plan shall be granted Awards; (B) when and how each Award shall be granted; (C) what type or combination of types of Award shall be granted; (D) the provisions of each Award granted (which need not be identical), including the time or times when a person shall be permitted to receive cash or Common Stock pursuant to a Stock Award; (E) the number of shares of Common Stock with respect to which a Stock Award shall be granted to each such person; and (F) the Fair Market Value applicable to a Stock Award.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Stock Award Agreement or in the written terms of a Performance Cash Award, in a manner and to the extent it shall deem necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate the time at which an Award may first be exercised or the time during which an Award or any part thereof will vest in accordance with the Plan, notwithstanding the provisions in the Award stating the time at which it may first be exercised or the time during which it will vest.
(v) To suspend or terminate the Plan at any time. Suspension or termination of the Plan shall not impair rights and obligations under any Award granted while the Plan is in effect except with the written consent of the affected Participant.

(vi) To amend the Plan in any respect the Board deems necessary or advisable. However, except as provided in Section 9(a) relating to Capitalization Adjustments, to the extent required by applicable law or listing requirements, stockholder approval shall be required for any amendment of the Plan that either (A) materially increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan or materially reduces the price at which shares of Common Stock may be issued or purchased under the Plan, (D) materially extends the term of the Plan, or (E) expands the types of Awards available for issuance under the Plan. Except as provided above, rights under any Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of (A) Section 162(m) of the Code regarding the exclusion of performance-based compensation from the limit on corporate deductibility of compensation paid to Covered Employees, (B) Section 422 of the Code regarding incentive stock options or (C) Rule 16b-3.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; provided however, that except with respect to amendments that disqualify or impair the status of an Incentive Stock Option, a Participant’s rights under any Award shall not be impaired by any such amendment unless (A) the Company requests the consent of the affected Participant, and (B) such Participant consents in writing. Notwithstanding the foregoing, subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Awards without the affected Participant’s consent if necessary to maintain the qualified status of the Award as an Incentive Stock Option or to bring the Award into compliance with Section 409A of the Code.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees, Directors or Consultants who are foreign nationals or employed outside the United States.

(xi) To effect, at any time and from time to time, with the consent of any adversely affected Participant, (A) the reduction of the exercise price (or strike price) of any outstanding Option or SAR under the Plan; (B) the cancellation of any outstanding Option or SAR under the Plan and the grant in substitution therefor of (1) a new Option or SAR under the Plan or another equity plan of the Company covering the same or a different number of shares of Common Stock, (2) a Restricted Stock Award, (3) a Restricted Stock Unit Award, (4) an Other Stock Award, (5) cash and/or (6) other valuable consideration (as determined by the Board, in its sole discretion); or (C) any other action that is treated as a repricing under generally accepted accounting principles.

(c) Delegation to Committee.

(i) General. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee shall have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board shall thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Committee may, at any time, abolish the subcommittee and/or revest in the Committee any powers delegated to the subcommittee. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(ii) Section 162(m) and Rule 16b-3 Compliance. The Committee may consist solely of two or more Outside Directors, in accordance with Section 162(m) of the Code, or solely of two or more Non-Employee Directors, in accordance with Rule 16b-3.

(d) Effect of Board’s Decision. All determinations, interpretations and constructions made by the Board in good faith shall not be subject to review by any person and shall be final, binding and conclusive on all persons.
3. Shares Subject to the Plan.

(a) **Share Reserve.** Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock of the Company that may be issued pursuant to Stock Awards after the Effective Date shall not exceed (i) the number of shares subject to the Prior Plan’s Available Reserve, (ii) plus an additional one million six hundred thousand six hundred seventy-three (1,600,673) shares, plus (iii) an additional number of shares in an amount not to exceed one million three hundred seventeen thousand five hundred thirty-four (1,317,534) shares (which number consists of the Returning Shares, if any, as such shares become available from time to time), plus (iv) two hundred thousand (200,000) shares that may be issued pursuant to Inducement Awards under Section 3(g) of the Plan. In addition, the number of shares of Common Stock available for issuance under the Plan shall automatically increase on January 1st of each year for a period of nine (9) years commencing on January 1, 2012 and ending on (and including) January 1, 2021, in an amount equal to the lesser of (i) five percent (5%) of the total number of shares of Common Stock outstanding on December 31st of the preceding calendar year, or (ii) one million four hundred seventy-four thousand three hundred forty-nine (1,474,349) shares. Notwithstanding the foregoing, the Board may act prior to the first day of any calendar year, to provide that there shall be no increase in the share reserve for such calendar year or that the increase in the share reserve for such calendar year shall be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence. For clarity, the limitation in this Section 3(a) is a limitation in the number of shares of Common Stock that may be issued pursuant to the Plan. Accordingly, this Section 3(a) does not limit the granting of Stock Awards except as provided in Section 7(a). Shares may be issued in connection with a merger or acquisition as permitted by, as applicable, NASDAQ Marketplace Rule 4350(i)(1)(A)(iii), NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable stock exchange rules, and such issuance shall not reduce the number of shares available for issuance under the Plan. Furthermore, if a Stock Award or any portion thereof (i) expires or otherwise terminates without all of the shares covered by such Stock Award having been issued or (ii) is settled in cash (i.e., the Participant receives cash rather than stock), such expiration, termination or settlement shall not reduce (or otherwise offset) the number of shares Common Stock that may be available for issuance under the Plan.

(b) **Additions to the Share Reserve.** The Share Reserve also shall be increased from time to time by a number of shares equal to the number of shares of Common Stock that (i) are issuable pursuant to options outstanding under the Prior Plan as of the Effective Date and (ii) but for the termination of the Prior Plan as of the Effective Date, would otherwise have reverted to the share reserve of the Prior Plan pursuant to the provisions thereof.

(c) **Reversion of Shares to the Share Reserve.** If any shares of common stock issued pursuant to a Stock Award are forfeited back to the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited shall revert to and again become available for issuance under the Plan. Any shares reacquired by the Company pursuant to Section 8(g) or as consideration for the exercise of an Option shall again become available for issuance under the Plan. Notwithstanding the foregoing, any Inducement Shares that become available for issuance pursuant to this subsection 3(c) will only become available for issuance pursuant to Inducement Awards.

(d) **Incentive Stock Option Limit.** Notwithstanding anything to the contrary in this Section 3 and, subject to the provisions of Section 9(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options shall be two million one hundred six thousand one hundred forty-nine (2,106,149) shares of Common Stock plus the amount of any increase in the number of shares that may be available for issuance pursuant to Stock Awards pursuant to Section 3(a).

(e) **Section 162(m) Limitation on Annual Grants.** Subject to the provisions of Section 9(a) relating to Capitalization Adjustments and except with respect to Inducement Awards, at such time as the Company may be subject to the applicable provisions of Section 162(m) of the Code, a maximum of one million fifty-three thousand seven hundred forty-nine (1,053,749) shares of Common Stock subject to Options, Stock Appreciation Rights and Other Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least one hundred percent (100%) of the Fair Market Value on the date any such Stock Award is granted may be granted to any Participant during any calendar year. Notwithstanding the foregoing, if any additional Options, Stock Appreciation Rights or Other Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least one hundred percent (100%) of the Fair Market Value on the date the Stock Award are granted to any Participant during any calendar year, compensation attributable to the exercise of such additional Stock Awards shall not satisfy the requirements to be considered “qualified performance-based compensation” under Section 162(m) of the Code unless such additional Stock Award is approved by the Company’s stockholders.

(f) **Source of Shares.** The stock issuable under the Plan shall be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

(g) **Inducement Shares.** This subsection 3(g) will apply with respect to the two hundred thousand (200,000) shares of Common Stock reserved under this Plan by action of the Board (or a committee thereof) to be used exclusively for the grant of Inducement Awards in compliance with NASDAQ Listing Rule 5635(c)(4) (the “Inducement Shares”). Notwithstanding anything to
the contrary in this Plan, an Inducement Award may be granted only to an Employee who has not previously been an Employee or a non-Employee Director of the Company or an Affiliate, or following a bona fide period of non-employment, as an inducement material to the individual’s entering into employment with the Company within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules. In addition, notwithstanding any other provision of the Plan to the contrary, all such Inducement Awards must be granted by a Committee consisting of the majority of the Company’s independent directors or the Company’s independent compensation committee, in either case in accordance with NASDAQ Listing Rule 5635(c)(4) (each an “Inducement Committee”).

4. Eligibility.

(a) Eligibility for Specific Stock Awards. Incentive Stock Options may be granted only to employees of the Company or a “parent corporation” or “subsidiary corporation” thereof (as such terms are defined in Sections 424(e) and (f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants; provided, however, Nonstatutory Stock Options and SARs may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any “parent” of the Company, as such term is defined in Rule 405 promulgated under the Securities Act, unless the stock underlying such Stock Awards is treated as “service recipient stock” under Section 409A of the Code because the Stock Awards are granted pursuant to a corporate transaction (such as a spin off transaction) or unless such Stock Awards comply with the distribution requirements of Section 409A of the Code.

(b) Ten Percent Stockholders. A Ten Percent Stockholder shall not be granted an Incentive Stock Option unless the exercise price of such Option is at least one hundred ten percent (110%) of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five (5) years from the date of grant.


Each Option or SAR shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. All Options shall be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates shall be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, then the Option shall be a Nonstatutory Stock Option. The provisions of separate Options or SARs need not be identical; provided, however, that each Option Agreement or Stock Appreciation Right Agreement shall conform to (through incorporation of provisions hereof by reference in the applicable Award Agreement or otherwise) the substance of each of the following provisions:

(a) Term. Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, no Option or SAR shall be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Award Agreement.

(b) Exercise Price. Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, the exercise price (or strike price) of each Option or SAR shall be not less than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Option or SAR is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise price (or strike price) lower than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option or SAR if such Option or SAR is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Sections 409A and, if applicable, 424(a) of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

(c) Purchase Price for Options. The purchase price of Common Stock acquired pursuant to the exercise of an Option shall be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board shall have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to utilize a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) if the option is a Nonstatutory Stock Option, by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; provided, however, that the Company shall accept a cash or other
payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued; provided, further, that shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are reduced to pay the exercise price pursuant to the “net exercise,” (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that may be acceptable to the Board.

(d) Exercise and Payment of a SAR. To exercise any outstanding Stock Appreciation Right, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such Stock Appreciation Right. The appreciation distribution payable on the exercise of a Stock Appreciation Right will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the Stock Appreciation Right) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such Stock Appreciation Right, and with respect to which the Participant is exercising the Stock Appreciation Right on such date, over (B) the strike price that will be determined by the Board at the time of grant of the Stock Appreciation Right. The appreciation distribution in respect to a Stock Appreciation Right may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Stock Appreciation Right Agreement evidencing such Stock Appreciation Right.

(e) Transferability of Options and SARs. The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board shall determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs shall apply:

(i) Restrictions on Transfer. An Option or SAR shall not be transferable except by will or by the laws of descent and distribution and shall be exercisable during the lifetime of the Participant only by the Participant; provided, however, that the Board may, in its sole discretion, permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws upon the Participant’s request. Except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Notwithstanding the foregoing, an Option or SAR may be transferred pursuant to a domestic relations order; provided, however, that if an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(iii) Beneficiary Designation. Notwithstanding the foregoing, the Participant may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company and any broker designated by the Company to effect Option exercises, designate a third party who, in the event of the death of the Participant, shall thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant’s estate shall be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise.

(f) Vesting Generally. The total number of shares of Common Stock subject to an Option or SAR may vest and therefore become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of Performance Goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) Termination of Continuous Service. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant’s Continuous Service terminates (other than for Cause or upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Participant’s Continuous Service (or such longer or shorter period specified in the applicable Award Agreement), or (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the time specified herein or in the Award Agreement (as applicable), the Option or SAR shall terminate.

(h) Extension of Termination Date. If the exercise of an Option or SAR following the termination of the Participant’s Continuous Service (other than for Cause or upon the Participant’s death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR shall terminate on the earlier of (i) the expiration of a total period of three (3) months (that need not be consecutive) after the
termination of the Participant’s Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement. In addition, unless otherwise provided in a Participant’s Award Agreement, if the immediate sale of any Common Stock received upon exercise of an Option or SAR following the termination of the Participant’s Continuous Service (other than for Cause) would violate the Company’s insider trading policy, then the Option or SAR shall terminate on the earlier of (i) the expiration of a period equal to the applicable post-termination exercise period after the termination of the Participant’s Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company’s insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement.

(i) **Disability of Participant.** Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant’s Continuous Service terminates as a result of the Participant’s Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination of Continuous Service (or such longer or shorter period specified in the Award Agreement), or (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the time specified herein or in the Award Agreement (as applicable), the Option or SAR (as applicable) shall terminate.

(j) **Death of Participant.** Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if (i) a Participant’s Continuous Service terminates as a result of the Participant’s death, or (ii) the Participant dies within the period (if any) specified in the Award Agreement for exercisability after the termination of the Participant’s Continuous Service (for a reason other than death), then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant’s estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant’s death, but only within the period ending on the earlier of (i) the date eighteen (18) months following the date of death (or such longer or shorter period specified in the Award Agreement), or (ii) the expiration of the term of such Option or SAR as set forth in the Award Agreement. If, after the Participant’s death, the Option or SAR is not exercised within the time specified herein or in the Award Agreement (as applicable), the Option or SAR shall terminate.

(k) **Termination for Cause.** Except as explicitly provided otherwise in a Participant’s Award Agreement or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant’s Continuous Service is terminated for Cause, the Option or SAR shall terminate immediately upon such Participant’s termination of Continuous Service, and the Participant shall be prohibited from exercising his or her Option or SAR from and after the time of such termination of Continuous Service.

(l) **Non-Exempt Employees.** No Option or SAR, whether or not vested, granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, shall be first exercisable for any shares of Common Stock until at least six months following the date of grant of the Option or SAR. Notwithstanding the foregoing, consistent with the provisions of the Worker Economic Opportunity Act, (i) in the event of the Participant’s death or Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant’s retirement (as such term may be defined in the Participant’s Award Agreement or in another applicable agreement or in accordance with the Company’s then current employment policies and guidelines), any such vested Options and SARs may be exercised earlier than six months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay.

6. **Provisions of Stock Awards other than Options and SARs.**

(a) **Restricted Stock Awards.** Each Restricted Stock Award Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. To the extent consistent with the Company’s Bylaws, at the Board’s election, shares of Common Stock may be (i) held in book entry form subject to the Company’s instructions until any restrictions relating to the Restricted Stock Award lapse; or (ii) evidenced by a certificate, which certificate shall be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical; provided, however, that each Restricted Stock Award Agreement shall conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) **Consideration.** A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal
consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) Termination of Participant’s Continuous Service. If a Participant’s Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) Transferability. Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement shall be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board shall determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(v) Dividends. A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

(b) Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical; provided, however, that each Restricted Stock Unit Award Agreement shall conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by theParticipant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

(vi) Termination of Participant’s Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant’s termination of Continuous Service.

(c) Performance Awards.

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award that may vest or may be exercised contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Stock Award may, but need not, require the completion of a specified period of Continuous Service. The length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance
Goals have been attained shall be conclusively determined by the Committee, in its sole discretion. Except with respect to Inducement Awards, the maximum number of shares covered by an Award that may be granted to any Participant in a calendar year attributable to Stock Awards described in this Section 6(c)(i) (whether the grant, vesting or exercise is contingent upon the attainment during a Performance Period of the Performance Goals) shall not exceed six hundred thirty-one thousand eight hundred forty-four (631,844) shares of Common Stock. The Board may provide for or, subject to such terms and conditions as the Board may specify, may permit a Participant to elect for, the payment of any Performance Stock Award to be deferred to a specified date or event. In addition, to the extent permitted by applicable law and the applicable Award Agreement, the Board may determine that cash may be used in payment of Performance Stock Awards.

(ii) Performance Cash Awards. A Performance Cash Award is a cash award that may be paid contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Cash Award may also require the completion of a specified period of Continuous Service. At the time of grant of a Performance Cash Award, the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained shall be conclusively determined by the Committee, in its sole discretion. In any calendar year, the Committee may not grant a Performance Cash Award that has a maximum value that may be paid to any Participant in excess of 3 million dollars ($3,000,000). The Board may provide for or, subject to such terms and conditions as the Board may specify, may permit a Participant to elect for, the payment of any Performance Cash Award to be deferred to a specified date or event. The Committee may specify the form of payment of Performance Cash Awards, which may be cash or other property, or may provide for a Participant to have the option for his or her Performance Cash Award, or such portion thereof as the Board may specify, to be paid in whole or in part in cash or other property.

(iii) Board Discretion. The Board retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for a Performance Period.

(iv) Section 162(m) Compliance. Unless otherwise permitted in compliance with the requirements of Section 162(m) of the Code with respect to an Award intended to qualify as “performance-based compensation” thereunder, the Committee shall establish the Performance Goals applicable to, and the formula for calculating the amount payable under, the Award no later than the earlier of (a) the date ninety (90) days after the commencement of the applicable Performance Period, or (b) the date on which twenty-five percent (25%) of the Performance Period has elapsed, and in either event at a time when the achievement of the applicable Performance Goals remains substantially uncertain. Prior to the payment of any compensation under an Award intended to qualify as “performance-based compensation” under Section 162(m) of the Code, the Committee shall certify the extent to which any Performance Goals and any other material terms under such Award have been satisfied (other than in cases where such relate solely to the increase in the value of the Common Stock). Notwithstanding satisfaction of any completion of any Performance Goals, to the extent specified at the time of grant of an Award to “covered employees” within the meaning of Section 162(m) of the Code, the number of shares of Common Stock, Options, cash or other benefits granted, issued, retainable and/or vested under an Award on account of satisfaction of such Performance Goals may be reduced by the Committee on the basis of such further considerations as the Committee, in its sole discretion, shall determine.

(d) Other Stock Awards. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than 100% of the Fair Market Value of the Common Stock at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Board shall have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. Covenants of the Company.

(a) Availability of Shares. During the terms of the Stock Awards, the Company shall keep available at all times the number of shares of Common Stock reasonably required to satisfy such Stock Awards.

(b) Securities Law Compliance. The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; provided, however, that this undertaking shall not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A
Participant shall not be eligible for the grant of a Stock Award or the subsequent issuance of Common Stock pursuant to the Stock Award if such grant or issuance would be in violation of any applicable securities law.

(c) No Obligation to Notify or Minimize Taxes. The Company shall have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company shall have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of a Stock Award or a possible period in which the Stock Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of a Stock Award to the holder of such Stock Award.

8. Miscellaneous.

(a) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Stock Awards shall constitute general funds of the Company.

(b) Corporate Action Constituting Grant of Stock Awards. Corporate action constituting a grant by the Company of a Stock Award to any Participant shall be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Stock Award is communicated to, or actually received or accepted by, the Participant.

(c) Stockholder Rights. No Participant shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Stock Award unless and until (i) such Participant has satisfied all requirements for exercise of the Stock Award pursuant to its terms, if applicable, and (ii) the issuance of the Common Stock subject to such Stock Award has been entered into the books and records of the Company.

(d) No Employment or Other Service Rights. Nothing in the Plan, any Stock Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto shall confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Stock Award was granted or shall affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant’s agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(e) Incentive Stock Option $100,000 Limitation. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds one hundred thousand dollars ($100,000), the Options or portions thereof that exceed such limit (according to the order in which they were granted) shall be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(f) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Participant’s knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Stock Award for the Participant’s own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, shall be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(g) Withholding Obligations. Unless prohibited by the terms of a Stock Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation or any social security deduction obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; provided, however, that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax and social security contribution required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); (iii) withholding cash from an Award settled in
cash; (iv) withholding payment from any amounts otherwise payable to the Participant; or (v) by such other method as may be set forth in the Award Agreement.

(h) Electronic Delivery. Any reference herein to a “written” agreement or document shall include any agreement or document delivered electronically or posted on the Company’s intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(i) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant’s termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(j) Compliance with Section 409A. To the extent that the Board determines that any Award granted hereunder is subject to Section 409A of the Code, the Award Agreement evidencing such Award shall incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code. To the extent applicable, the Plan and Award Agreements shall be interpreted in accordance with Section 409A of the Code. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded and a Participant holding an Award that constitutes “deferred compensation” under Section 409A of the Code is a “specified employee” for purposes of Section 409A of the Code, no distribution or payment of any amount shall be made upon a “separation from service” before a date that is six (6) months following the date of such Participant’s “separation from service” (as defined in Section 409A of the Code without regard to alternative definitions thereunder) or, if earlier, the date of the Participant’s death.

9. Adjustments upon Changes in Common Stock; Other Corporate Events.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board shall appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a) and 3(g), (ii) the class(es) and maximum number of securities by which the share reserve is to increase automatically each year pursuant to Section 3(a); (iii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(d), (iv) the class(es) and maximum number of securities that may be awarded to any person pursuant to Sections 3(e) and 6(c)(i), and (v) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive.

(b) Dissolution or Liquidation. Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company’s right of repurchase) shall terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company’s repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service, provided, however, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent upon its completion.

(a) Corporate Transaction. The following provisions shall apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Stock Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of a Stock Award.

(i) Stock Awards May Be Assumed. In the event of a Corporate Transaction, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation’s parent company) may assume or continue any or all Stock Awards outstanding under the Plan or may substitute similar stock awards for Stock Awards outstanding under the Plan (including but not limited to, awards to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction), and any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to Stock Awards may be assigned by the Company to the successor of the Company (or the successor's parent company, if any), in connection with such Corporate Transaction. A surviving corporation or acquiring corporation (or its parent) may choose to assume or continue only a portion of a Stock Award or substitute a similar stock award for only a portion of a Stock Award, or may choose to assume or continue
the Stock Awards held by some, but not all Participants. The terms of any assumption, continuation or substitution shall be set by the Board.

(ii) **Stock Awards Held by Current Participants.** In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Stock Awards or substitute similar stock awards for such outstanding Stock Awards, then with respect to Stock Awards that have not been assumed, continued or substituted and that are held by Participants whose Continuous Service has not terminated prior to the effective time of the Corporate Transaction (referred to as the “*Current Participants*”), the vesting of such Stock Awards (and, with respect to Options and Stock Appreciation Rights, the time when such Stock Awards may be exercised) shall be accelerated in full to a date prior to the effective time of such Corporate Transaction (contingent upon the effectiveness of the Corporate Transaction) as the Board shall determine (or, if the Board shall not determine such a date, to the date that is five (5) days prior to the effective time of the Corporate Transaction), and such Stock Awards shall terminate if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and any reacquisition or repurchase rights held by the Company with respect to such Stock Awards shall lapse (contingent upon the effectiveness of the Corporate Transaction).

(iii) **Stock Awards Held by Persons other than Current Participants.** In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Stock Awards or substitute similar stock awards for such outstanding Stock Awards, then with respect to Stock Awards that have not been assumed, continued or substituted and that are held by persons other than Current Participants, such Stock Awards shall terminate if not exercised (if applicable) prior to the effective time of the Corporate Transaction; *provided, however*, that any reacquisition or repurchase rights held by the Company with respect to such Stock Awards shall not terminate and may continue to be exercised notwithstanding the Corporate Transaction.

(iv) **Payment for Stock Awards in Lieu of Exercise.** Notwithstanding the foregoing, in the event a Stock Award will terminate if not exercised prior to the effective time of a Corporate Transaction, the Board may provide, in its sole discretion, that the holder of such Stock Award may not exercise such Stock Award but will receive a payment, in such form as may be determined by the Board, equal in value, at the effective time, to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award (including, at the discretion of the Board, any unvested portion of such Stock Award), over (B) any exercise price payable by such holder in connection with such exercise.

(b) **Change in Control.** A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration shall occur. 

10. **Termination or Suspension of the Plan.**

(a) **Plan Term.** The Board may suspend or terminate the Plan at any time. Unless terminated sooner by the Board, the Plan shall automatically terminate on the day before the tenth (10th) anniversary of the earlier of (i) the date the Plan is adopted by the Board, or (ii) the date the Plan is approved by the stockholders of the Company. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) **No Impairment of Rights.** Suspension or termination of the Plan shall not impair rights and obligations under any Award granted while the Plan is in effect except with the written consent of the affected Participant.

11. **Effective Date of Plan.**

The Plan shall become effective on the IPO Date, but no Award shall be exercised (or, in the case of a Restricted Stock Award, Restricted Stock Unit Award, or Other Stock Award shall be granted) unless and until the Plan has been approved by the stockholders of the Company, which approval shall be within twelve (12) months before or after the date the Plan is adopted by the Board.

12. **Choice of Law.**

The laws of the State of California shall govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state’s conflict of laws rules.
13. Definitions. As used in the Plan, the following definitions shall apply to the capitalized terms indicated below:

(a) “Affiliate” means, at the time of determination, any “parent” or “subsidiary” of the Company as such terms are defined in Rule 405 promulgated under the Securities Act. The Board shall have the authority to determine the time or times at which “parent” or “subsidiary” status is determined within the foregoing definition.

(b) “Award” means a Stock Award or a Performance Cash Award.

(c) “Award Agreement” means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award.

(d) “Board” means the Board of Directors of the Company.

(e) “Capitalization Adjustment” means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards No. 123 (revised). Notwithstanding the foregoing, the conversion of any convertible securities of the Company shall not be treated as a Capitalization Adjustment.

(f) “Cause” shall have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term shall mean, with respect to a Participant, the occurrence of any of the following events that has a material negative impact on the business or reputation of the Company: (i) such Participant’s repeated failure to perform one or more essential duties and responsibilities to the Company; (ii) such Participant’s failure to follow the lawful directives of manager(s); (iii) such Participant’s material violation of any Company policy; (iv) such Participant’s commission of any act of fraud, embezzlement, dishonesty or any other willful misconduct or gross misconduct; (v) such Participant’s unauthorized use or disclosure of any proprietary information, confidential information or trade secrets of the Company or any other party to whom he or she owes an obligation of nondisclosure as a result of his or her relationship with the Company; or (vi) such Participant’s willful breach of any of obligations under any written agreement or covenant with the Company or violation of any statutory duty owed to the Company. The determination that a termination of the Participant’s Continuous Service is either for Cause or without Cause shall be made by the Company, in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant shall have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(g) “Change in Control” means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company’s then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company’s securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (C) solely because the level of Ownership held by any Exchange Act Person (the “Subject Person”) exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;
the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur, except for a liquidation into a parent corporation;

(iv) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(v) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the “Incumbent Board”) cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing or any other provision of this Plan, (A) the term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, and (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Awards subject to such agreement; provided, however, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply.

(h) “Code” means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(i) “Committee” means a committee of one or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(j) “Common Stock” means the common stock of the Company.

(k) “Company” means Horizon Pharma, Inc., a Delaware corporation.

(l) “Consultant” means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, shall not cause a Director to be considered a “Consultant” for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company’s securities to such person.

(m) “Continuous Service” means that the Participant’s service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders service, provided that there is no interruption or termination of the Participant’s service with the Company or an Affiliate, shall not terminate a Participant’s Continuous Service; provided, however, if the Entity for which a Participant is rendering service ceases to qualify as an Affiliate, as determined by the Board, in its sole discretion, such Participant’s Continuous Service shall be considered to have terminated on the date such entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party’s sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of (i) any leave of absence approved by the Board or Chief Executive Officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence shall be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company’s leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(n) “Corporate Transaction” means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;
(ii) a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(o) “Covered Employee” shall have the meaning provided in Section 162(m)(3) of the Code.

(p) “Director” means a member of the Board.

(q) “Disability” means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than twelve (12) months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and shall be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(r) “Effective Date” means the effective date of the Plan as set forth in Section 11.

(s) “Employee” means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, shall not cause a Director to be considered an “Employee” for purposes of the Plan.

(t) “Entity” means a corporation, partnership, limited liability company or other entity.


(v) “Exchange Act Person” means any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that “Exchange Act Person” shall not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities.

(w) “Fair Market Value” means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on the NASDAQ Global Market or the NASDAQ Global Select Market, the Fair Market Value of a share of Common Stock, unless otherwise determined by the Board, shall be the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the last market trading day prior to the day of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the last market trading day prior to the day of determination, then the Fair Market Value shall be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value shall be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(x) “Incentive Stock Option” means an option granted pursuant to Section 5 of the Plan that is intended to be, and qualifies as, an “incentive stock option” within the meaning of Section 422 of the Code.

(y) “Inducement Award” means a Stock Award granted pursuant to Section 3(g) of the Plan.
“IPO Date” means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering.

“Non-Employee Director” means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act (“Regulation S-K”)), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a “non-employee director” for purposes of Rule 16b-3.

“Nonstatutory Stock Option” means any option granted pursuant to Section 5 of the Plan that does not qualify as an Incentive Stock Option.

“Officer” means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

“Option” means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

“Option Agreement” means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement shall be subject to the terms and conditions of the Plan.

“Optionholder” means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

“Other Stock Award” means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 6(d).

“Other Stock Award Agreement” means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement shall be subject to the terms and conditions of the Plan.

“Outside Director” means a Director who either (i) is not a current employee of the Company or an “affiliated corporation” (within the meaning of Treasury Regulations promulgated under Section 162(m) of the Code), is not a former employee of the Company or an “affiliated corporation” who receives compensation for prior services (other than benefits under a tax-qualified retirement plan) during the taxable year, has not been an officer of the Company or an “affiliated corporation,” and does not receive remuneration from the Company or an “affiliated corporation,” either directly or indirectly, in any capacity other than as a Director, or (ii) is otherwise considered an “outside director” for purposes of Section 162(m) of the Code.

“Own,” “Owned,” “Owner,” “Ownership” A person or Entity shall be deemed to “Own,” to have “Owned,” to be the “Owner” of, or to have acquired “Ownership” of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

“Participant” means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

“Performance Cash Award” means an award of cash granted pursuant to the terms and conditions of Section 6(c)(ii).

“Performance Criteria” means the one or more criteria that the Board shall select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that shall be used to establish such Performance Goals may be based on any one of, or combination of, the following as determined by the Board: (i) earnings (including earnings per share and net earnings); (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) total stockholder return; (v) return on equity or average stockholder's equity; (vi) return on assets, investment, or capital employed; (vii) stock price; (viii) margin (including gross margin); (ix) income (before or after taxes); (x) operating income; (xi) operating income after taxes; (xii) pre-tax profit; (xiii) operating cash flow; (xiv) sales or revenue targets; (xv) increases in revenue or product revenue; (xvi) expenses and cost reduction goals; (xvii) improvement in or attainment of working capital levels; (xviii) economic value added (or an equivalent metric); (xix) market share; (xx) cash flow; (xxi) cash flow per share; (xxii) share price performance; (xxiii) debt reduction; (xxiv) implementation or completion of projects or processes; (xxv) customer satisfaction; (xxvi)

---

15
stockholders’ equity; (xxvii) capital expenditures; (xxiii) debt levels; (xxix) operating profit or net operating profit; (xxx) workforce diversity; (xxxi) growth of net income or operating income; (xxxii) billings; and (xxxiii) to the extent that an Award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the Board.

(nn) “Performance Goals” means, for a Performance Period, the one or more goals established by the Board for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Board (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, the Board shall appropriately make adjustments in the method of calculating the attainment of Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated Performance Goals; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; and (5) to exclude the effects of any “extraordinary items” as determined under generally accepted accounting principles.

(oo) “Performance Period” means the period of time selected by the Board over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant’s right to and the payment of a Stock Award or a Performance Cash Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(pp) “Performance Stock Award” means a Stock Award granted under the terms and conditions of Section 6(c)(i).

(qq) “Plan” means this Horizon Pharma, Inc. 2011 Equity Incentive Plan.

(rr) “Restricted Stock Award” means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(ss) “Restricted Stock Award Agreement” means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement shall be subject to the terms and conditions of the Plan.

(tt) “Restricted Stock Unit Award” means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(uu) “Restricted Stock Unit Award Agreement” means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement shall be subject to the terms and conditions of the Plan.

(vv) “Rule 16b-3” means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(ww) “Securities Act” means the Securities Act of 1933, as amended.

(xx) “Stock Appreciation Right” or “SAR” means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(yy) “Stock Appreciation Right Agreement” means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement shall be subject to the terms and conditions of the Plan.

.zz) “Stock Award” means any right to receive Common Stock granted under the Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award or any Other Stock Award.

(aaa) “Stock Award Agreement” means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement shall be subject to the terms and conditions of the Plan.
“Subsidiary” means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%).

“Ten Percent Stockholder” means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Affiliate.
Pursuant to your Stock Option Grant Notice ("Grant Notice") and this Option Agreement, Horizon Pharma, Inc. (the “Company”) has granted you an option under its 2011 Equity Incentive Plan (the “Plan”) to purchase the number of shares of the Company’s Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. Defined terms not explicitly defined in this Option Agreement but defined in the Plan shall have the same definitions as in the Plan.

The details of your option are as follows:

1. **Vesting.** Subject to the limitations contained herein, your option will vest as provided in your Grant Notice, provided that vesting will cease upon the termination of your Continuous Service.

2. **Number of Shares and Exercise Price.** The number of shares of Common Stock subject to your option and your exercise price per share referenced in your Grant Notice may be adjusted from time to time for Capitalization Adjustments.

3. **Exercise Restriction for Non-Exempt Employees.** In the event that you are an Employee eligible for overtime compensation under the Fair Labor Standards Act of 1938, as amended (i.e., a “Non-Exempt Employee”), you may not exercise your option until you have completed at least six (6) months of Continuous Service measured from the Date of Grant specified in your Grant Notice, notwithstanding any other provision of your option.

4. **Method of Payment.** Payment of the exercise price is due in full upon exercise of all or any part of your option. You may elect to make payment of the exercise price in cash or by check or in any other manner permitted by your Grant Notice, which may include one or more of the following:
   a. Provided that at the time of exercise the Common Stock is publicly traded and quoted regularly in a source the Board deems reliable, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds.
   b. Provided that at the time of exercise the Common Stock is publicly traded and quoted regularly in a source the Board deems reliable, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. Notwithstanding the foregoing, you may not exercise your option by tender to the Company of Common Stock to the extent such tender would violate the provisions of any law, regulation or agreement restricting the redemption of the Company’s stock.

5. **Whole Shares.** You may exercise your option only for whole shares of Common Stock.

6. **Securities Law Compliance.** Notwithstanding anything to the contrary contained herein, you may not exercise your option unless the shares of Common Stock issuable upon such exercise are then registered under the Securities Act or, if such shares of Common Stock are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations.

7. **Term.** You may not exercise your option before the commencement of its term or after its term expires. The term of your option commences on the Date of Grant and expires upon the earliest of the following:
   a. immediately upon the termination of your Continuous Service for Cause;
   b. three (3) months after the termination of your Continuous Service for any reason other than Cause, Disability or death, provided that if during any part of such three (3)-month period you may not exercise your option solely because of the condition set forth in the preceding paragraph relating to “Securities Law Compliance,” your option shall not expire until the earlier of the Expiration Date or until it shall have been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service;
c. twelve (12) months after the termination of your Continuous Service due to your Disability;

d. eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause;

e. the Expiration Date indicated in your Grant Notice; or

f. the day before the tenth (10th) anniversary of the Date of Grant.

If your option is an Incentive Stock Option, note that to obtain the US federal income tax advantages associated with an Incentive Stock Option, the Code requires that at all times beginning on the date of grant of your option and ending on the day three (3) months before the date of your option’s exercise, you must be an employee of the Company or an Affiliate, except in the event of your death or your permanent and total disability, as defined in Section 22(e)(3) of the Code. The Company has provided for extended exercisability of your option under certain circumstances for your benefit but cannot guarantee that your option will necessarily be treated as an Incentive Stock Option if you continue to provide services to the Company or an Affiliate as a Consultant or Director after your employment terminates or if you otherwise exercise your option more than three (3) months after the date your employment with the Company or an Affiliate terminates.

8. Exercise.

a. You may exercise the vested portion of your option (and the unvested portion of your option if your Grant Notice so permits) during its term by delivering a Notice of Exercise (in a form designated by the Company) together with the exercise price to the Secretary of the Company, or to such other person as the Company may designate, during regular business hours, together with such additional documents as the Company may then require.

b. By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (1) the exercise of your option, (2) the lapse of any substantial risk of forfeiture to which the shares of Common Stock are subject at the time of exercise, or (3) the disposition of shares of Common Stock acquired upon such exercise.

c. If your option is an Incentive Stock Option, by exercising your option you agree that you will notify the Company in writing within fifteen (15) days after the date of any disposition of any of the shares of the Common Stock issued upon exercise of your option that occurs within two (2) years after the date of your option grant or within one (1) year after such shares of Common Stock are transferred upon exercise of your option.

9. Transferability. Your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, shall thereafter be entitled to exercise your option. In addition, if permitted by the Company you may transfer your option to a trust if you are considered to be the sole beneficial owner (determined under Section 671 of the Code and applicable state law) while the option is held in the trust, provided that you and the trustee enter into a transfer and other agreements required by the Company.

10. Option not a Service Contract. Your option is not an employment or service contract, and nothing in your option shall be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option shall obligate the Company or an Affiliate, their respective stockholders, Boards of Directors, Officers or Employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

11. Withholding Obligations.

a. At the time you exercise your option, in whole or in part, or at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a “cashless exercise” pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations and social security deduction obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

b. Upon your request and subject to approval by the Company, in its sole discretion, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax and social security contribution required to be
withheld by law (or such lower amount as may be necessary to avoid classification of your option as a liability for financial accounting purposes). Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

c. You may not exercise your option unless the tax withholding obligations and the social security contribution obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company shall have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein unless such obligations are satisfied.

12. **Tax Consequences.** You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You shall not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your option or your other compensation. In particular, you acknowledge that this option is exempt from Section 409A of the Code only if the exercise price per share specified in the Grant Notice is at least equal to the “fair market value” per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with the option.

13. **Notices.** Any notices provided for in your option or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company.

14. **Governing Plan Document.** Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of your option and those of the Plan, the provisions of the Plan shall control.
Horizon Pharma, Inc. (the “Company”), pursuant to its 2011 Equity Incentive Plan (the “Plan”), hereby grants to Optionholder an option to purchase the number of shares of the Company’s Common Stock set forth below. This option is subject to all of the terms and conditions as set forth herein and in the Option Agreement, the Plan, and the Notice of Exercise, all of which are attached hereto and incorporated herein in their entirety.

Optionholder: ____________________________________
Date of Grant: ________________________________
Vesting Commencement Date: ____________________
Number of Shares Subject to Option: ____________
Exercise Price (Per Share): ______________________
Total Exercise Price: ____________________________
Expiration Date: _______________________________

Type of Grant: □ Incentive Stock Option1 □ Nonstatutory Stock Option

Exercise Schedule: Same as Vesting Schedule

Vesting Schedule: [1/4th of the shares vest one year after the Vesting Commencement Date; the balance of the shares vest in a series of thirty-six (36) successive equal monthly installments measured from the first anniversary of the Vesting Commencement Date.]

Payment: By one or a combination of the following items (described in the Option Agreement):
☐ By cash or check
☐ Pursuant to a Regulation T Program if the Shares are publicly traded
☐ By delivery of already-owned shares if the Shares are publicly traded

Additional Terms/Acknowledgements: The undersigned Optionholder acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice, the Option Agreement and the Plan. Optionholder further acknowledges that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between Optionholder and the Company regarding the acquisition of stock in the Company and supersede all prior oral and written agreements on that subject with the exception of (i) options previously granted and delivered to Optionholder under the Plan, and (ii) the following agreements only:

Other Agreements: ____________________________

1 If this is an Incentive Stock Option, it (plus other outstanding Incentive Stock Options) cannot be first exercisable for more than $100,000 in value (measured by exercise price) in any calendar year. Any excess over $100,000 is a Nonstatutory Stock Option.
Horizon Pharma, Inc.  

By: ___________________________  

Signature  

Title: ___________________________  

Date: ___________________________  

Optionholder:  

By: ___________________________  

Signature  

Date: ___________________________  

Attachments: Option Agreement, 2011 Equity Incentive Plan and Notice of Exercise
Attachment III

NOTICE OF EXERCISE
I, Timothy P. Walbert, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: November 8, 2013

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

I, Robert J. De Vaere, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: November 8, 2013

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

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

1. the Company’s Quarterly Report on Form 10-Q for the period ended September 30, 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: November 8, 2013

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

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

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

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

1. the Company’s Quarterly Report on Form 10-Q for the period ended September 30, 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: November 8, 2013

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

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

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