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, 2016

OR

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

For the transition period from to

Commission File Number 001-35238

HORIZON PHARMA PUBLIC LIMITED COMPANY
(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction of incorporation or organization)

Not Applicable
(I.R.S. Employer Identification No.)

Connaught House, 1st Floor
1 Burlington Road, Dublin 4, D04 C5Y6, Ireland
(Address of principal executive offices)

011 353 1 772 2100
(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 registrant’s ordinary shares, nominal value $0.0001, outstanding as of November 2, 2016: 161,257,419.
### PART I. FINANCIAL INFORMATION

**Item 1.** Financial Statements  
- Condensed Consolidated Balance Sheets as of September 30, 2016 and as of December 31, 2015 (Unaudited)  
- Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2016 and 2015 (Unaudited)  
- Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2016 and 2015 (Unaudited)  
- Notes to Unaudited Condensed Consolidated Financial Statements  

**Item 2.** Management’s Discussion and Analysis of Financial Condition and Results of Operations  

**Item 3.** Quantitative and Qualitative Disclosures About Market Risk  

**Item 4.** Controls and Procedures  

### PART II. OTHER INFORMATION

**Item 1.** Legal Proceedings  

**Item 1A.** Risk Factors  

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

**Item 6.** Exhibits  

**Signatures**
# PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

**HORIZON PHARMA PLC**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(UNAUDITED)**  
(In thousands, except share data)

<table>
<thead>
<tr>
<th></th>
<th>As of September 30, 2016</th>
<th>As of December 31, 2015</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>$549,303</td>
<td>$859,616</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>5,271</td>
<td>1,860</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>362,899</td>
<td>210,437</td>
</tr>
<tr>
<td>Inventories, net</td>
<td>162,155</td>
<td>18,376</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>38,078</td>
<td>15,858</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td><strong>1,117,706</strong></td>
<td><strong>1,106,147</strong></td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>21,442</td>
<td>14,020</td>
</tr>
<tr>
<td>Developed technology, net</td>
<td><strong>1,877,158</strong></td>
<td><strong>1,609,049</strong></td>
</tr>
<tr>
<td>In-process research and development</td>
<td>66,000</td>
<td>66,000</td>
</tr>
<tr>
<td>Other intangible assets, net</td>
<td>6,453</td>
<td>7,061</td>
</tr>
<tr>
<td>Goodwill</td>
<td>248,736</td>
<td>253,811</td>
</tr>
<tr>
<td>Deferred tax assets, net</td>
<td>5,975</td>
<td>2,278</td>
</tr>
<tr>
<td>Other assets</td>
<td>6,201</td>
<td>222</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td><strong>$3,349,671</strong></td>
<td><strong>$3,058,588</strong></td>
</tr>
<tr>
<td><strong>LIABILITIES AND SHAREHOLDERS' EQUITY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CURRENT LIABILITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term debt—current portion</td>
<td>$4,000</td>
<td>$4,000</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>65,684</td>
<td>16,590</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>157,534</td>
<td>100,046</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>268,202</td>
<td>183,769</td>
</tr>
<tr>
<td>Accrued royalties—current portion</td>
<td>59,176</td>
<td>51,700</td>
</tr>
<tr>
<td>Deferred revenues—current portion</td>
<td>1,635</td>
<td>1,447</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td><strong>556,231</strong></td>
<td><strong>357,552</strong></td>
</tr>
<tr>
<td><strong>LONG-TERM LIABILITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exchangeable notes, net</td>
<td>294,089</td>
<td>282,889</td>
</tr>
<tr>
<td>Long-term debt, net, net of current</td>
<td>849,135</td>
<td>849,867</td>
</tr>
<tr>
<td>Accrued royalties, net of current</td>
<td>169,618</td>
<td>123,519</td>
</tr>
<tr>
<td>Deferred revenues, net of current</td>
<td>8,154</td>
<td>8,785</td>
</tr>
<tr>
<td>Deferred tax liabilities, net</td>
<td>95,583</td>
<td>113,400</td>
</tr>
<tr>
<td>Other long-term liabilities</td>
<td>14,883</td>
<td>9,431</td>
</tr>
<tr>
<td><strong>Total long-term liabilities</strong></td>
<td><strong>1,431,462</strong></td>
<td><strong>1,387,891</strong></td>
</tr>
<tr>
<td><strong>COMMITMENTS AND CONTINGENCIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SHAREHOLDERS’ EQUITY:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ordinary shares, $0.0001 nominal value; 300,000,000 shares authorized; 161,618,473 and 160,069,067 shares issued at September 30, 2016 and December 31, 2015, respectively, and 161,234,107 and 159,684,701 shares outstanding at September 30, 2016 and December 31, 2015, respectively</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Treasury stock, 384,366 ordinary shares at September 30, 2016 and December 31, 2015</td>
<td>(4,585)</td>
<td>(4,585)</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>2,086,873</td>
<td>2,001,552</td>
</tr>
<tr>
<td>Accumulated other comprehensive loss</td>
<td>(2,847)</td>
<td>(2,651)</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(717,479)</td>
<td>(681,187)</td>
</tr>
<tr>
<td><strong>Total shareholders’ equity</strong></td>
<td><strong>1,361,978</strong></td>
<td><strong>1,313,145</strong></td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES AND SHAREHOLDERS’ EQUITY</strong></td>
<td><strong>$3,349,671</strong></td>
<td><strong>$3,058,588</strong></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended September 30,</th>
<th>For the Nine Months Ended September 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2016</td>
<td>2015</td>
</tr>
<tr>
<td>Net sales</td>
<td>$208,702</td>
<td>$226,544</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>85,161</td>
<td>61,250</td>
</tr>
<tr>
<td>Gross profit</td>
<td>123,541</td>
<td>165,294</td>
</tr>
<tr>
<td>OPERATING EXPENSES:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>12,814</td>
<td>13,073</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>72,564</td>
<td>51,973</td>
</tr>
<tr>
<td>General and administrative</td>
<td>59,485</td>
<td>54,516</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>144,863</td>
<td>119,562</td>
</tr>
<tr>
<td>Operating (loss) income</td>
<td>(21,322)</td>
<td>45,732</td>
</tr>
<tr>
<td>OTHER INCOME (EXPENSE), NET:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(19,066)</td>
<td>(20,300)</td>
</tr>
<tr>
<td>Foreign exchange loss</td>
<td>(108)</td>
<td>(86)</td>
</tr>
<tr>
<td>Loss on induced conversion of debt and debt extinguishment</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Other income (expense), net</td>
<td>6,879</td>
<td>90</td>
</tr>
<tr>
<td>Total other income (expense), net</td>
<td>(12,295)</td>
<td>(20,476)</td>
</tr>
<tr>
<td>(Loss) income before (benefit) expense for income taxes</td>
<td>(33,617)</td>
<td>25,256</td>
</tr>
<tr>
<td>(BENEFIT) EXPENSE FOR INCOME TAXES</td>
<td>(27,747)</td>
<td>21,979</td>
</tr>
<tr>
<td>NET (LOSS) INCOME</td>
<td>(33,617)</td>
<td>25,256</td>
</tr>
<tr>
<td>NET (LOSS) INCOME PER ORDINARY SHARE—Basic</td>
<td>(0.04)</td>
<td>0.02</td>
</tr>
<tr>
<td>WEIGHTED AVERAGE ORDINARY SHARES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OUTSTANDING—Basic</td>
<td>161,038,827</td>
<td>159,035,580</td>
</tr>
<tr>
<td>NET (LOSS) INCOME PER ORDINARY SHARE—Diluted</td>
<td>$ (0.04)</td>
<td>0.02</td>
</tr>
<tr>
<td>WEIGHTED AVERAGE ORDINARY SHARES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OUTSTANDING—Diluted</td>
<td>161,038,827</td>
<td>166,830,800</td>
</tr>
<tr>
<td>OTHER COMPREHENSIVE LOSS, NET OF TAX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign currency translation adjustments</td>
<td>(110)</td>
<td>(48)</td>
</tr>
<tr>
<td>Unrealized loss on long-term investment</td>
<td>(110)</td>
<td>(29,448)</td>
</tr>
<tr>
<td>Other comprehensive loss</td>
<td>—</td>
<td>(110)</td>
</tr>
<tr>
<td>COMPREHENSIVE LOSS</td>
<td>$ (5,980)</td>
<td>(26,171)</td>
</tr>
</tbody>
</table>

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

For the Nine Months Ended September 30,

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CASH FLOWS FROM OPERATING ACTIVITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net (loss) income</td>
<td>$(36,292)</td>
<td>$15,538</td>
</tr>
<tr>
<td>Adjustments to reconcile net (loss) income to net cash provided by operating activities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization expense</td>
<td>154,465</td>
<td>94,025</td>
</tr>
<tr>
<td>Equity-settled share-based compensation</td>
<td>84,011</td>
<td>56,253</td>
</tr>
<tr>
<td>Royalty accretion</td>
<td>28,762</td>
<td>13,571</td>
</tr>
<tr>
<td>Royalty liability remeasurement</td>
<td>—</td>
<td>14,277</td>
</tr>
<tr>
<td>Loss on induced conversions of debt and debt extinguishment</td>
<td>—</td>
<td>21,581</td>
</tr>
<tr>
<td>Amortization of debt discount and deferred financing costs</td>
<td>13,469</td>
<td>13,328</td>
</tr>
<tr>
<td>Deferred income taxes</td>
<td>(35,158)</td>
<td>(144,014)</td>
</tr>
<tr>
<td>Foreign exchange loss and other adjustments</td>
<td>268</td>
<td>1,137</td>
</tr>
<tr>
<td>Changes in operating assets and liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>(142,448)</td>
<td>(135,370)</td>
</tr>
<tr>
<td>Inventories</td>
<td>23,842</td>
<td>12,819</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>(20,838)</td>
<td>417</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>49,695</td>
<td>38,213</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>83,009</td>
<td>35,136</td>
</tr>
<tr>
<td>Accrued expenses and accrued royalties</td>
<td>29,582</td>
<td>11,052</td>
</tr>
<tr>
<td>Deferred revenues</td>
<td>(443)</td>
<td>2,143</td>
</tr>
<tr>
<td>Payment of original issue discount upon repayment of 2014 Term Loan Facility</td>
<td>—</td>
<td>(3,000)</td>
</tr>
<tr>
<td>Other non-current assets and liabilities</td>
<td>(1,653)</td>
<td>2,122</td>
</tr>
<tr>
<td>Net cash provided by operating activities</td>
<td>230,271</td>
<td>59,228</td>
</tr>
</tbody>
</table>

| **CASH FLOWS FROM INVESTING ACTIVITIES:** |       |       |
| Payments for acquisitions, net of cash acquired | (520,405) | (1,022,361) |
| Proceeds from the liquidation of available-for-sale investments | — | 64,623 |
| Purchases of long-term investments | — | (71,813) |
| Purchases of property and equipment | (14,616) | (4,514) |
| Change in restricted cash | (3,411) | (122) |
| Net cash used in investing activities | (538,432) | (1,034,187) |

| **CASH FLOWS FROM FINANCING ACTIVITIES:** |       |       |
| Net proceeds from issuance of Exchangeable Senior Notes | — | 387,181 |
| Net proceeds from issuance of 2023 Senior Notes | — | 462,340 |
| Net proceeds from the 2015 Term Loan Facility | — | 391,506 |
| Repayment of the 2014 Term Loan Facility | — | (297,000) |
| Repayment of the 2015 Term Loan Facility | (3,000) | (1,000) |
| Net proceeds from the issuance of ordinary shares | — | 475,627 |
| Proceeds from the issuance of ordinary shares in connection with warrant exercises | — | 18,124 |
| Proceeds from the issuance of ordinary shares through ESPP programs | 3,235 | 1,541 |
| Proceeds from the issuance of ordinary shares in connection with stock option exercises | 3,384 | 4,602 |
| Payment of employee withholding taxes relating to share-based awards | (5,309) | (2,334) |
| Net cash (used in) provided by financing activities | (1,690) | 1,440,587 |

| Effect of foreign exchange rate changes on cash | (462) | (149) |

| **NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS** | (310,313) | 465,479 |
| **CASH AND CASH EQUIVALENTS, beginning of the period** | 859,616 | 218,807 |
| **CASH AND CASH EQUIVALENTS, end of the period** | $549,303 | $684,286 |
For the Nine Months Ended September 30,

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash paid for interest</td>
<td>$39,542</td>
<td>$21,417</td>
</tr>
<tr>
<td>Cash paid for income taxes</td>
<td>18,538</td>
<td>1,903</td>
</tr>
<tr>
<td>Fee paid for debt commitment</td>
<td>—</td>
<td>9,000</td>
</tr>
<tr>
<td>Cash paid for induced conversions</td>
<td>—</td>
<td>10,005</td>
</tr>
<tr>
<td>Cash paid for debt extinguishment</td>
<td>—</td>
<td>45,367</td>
</tr>
<tr>
<td>Conversion of Convertible Senior Notes to ordinary shares</td>
<td>$ —</td>
<td>$60,985</td>
</tr>
<tr>
<td>Purchases of property and equipment included in accounts payable and accrued expenses</td>
<td>1,101</td>
<td>1,130</td>
</tr>
</tbody>
</table>

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

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, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. The December 31, 2015 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by GAAP.

On September 19, 2014, the businesses of Horizon Pharma, Inc. (“HPI”) and Vidara Therapeutics International Public Limited Company (“Vidara”) were combined in a merger transaction (the “Vidara Merger”), accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with HPI treated as the acquiring company in the Vidara Merger for accounting purposes. As part of the Vidara Merger, a wholly owned subsidiary of Vidara merged with and into HPI, with HPI surviving the Vidara Merger as a wholly owned subsidiary of Vidara. Prior to the Vidara Merger, Vidara changed its name to Horizon Pharma plc (the “Company”). Upon the consummation of the Vidara Merger, the historical financial statements of HPI became the Company’s historical financial statements.

On May 7, 2015, the Company completed its acquisition of Hyperion Therapeutics Inc. (“Hyperion”) in which the Company acquired all of the issued and outstanding shares of Hyperion’s common stock for $46.00 per share in cash, or approximately $1.1 billion on a fully-diluted basis. Following completion of the acquisition, Hyperion became a wholly owned subsidiary of the Company and was renamed as Horizon Therapeutics, Inc.

On January 13, 2016, the Company completed its acquisition of Crealta Holdings LLC (“Crealta”) for approximately $539.7 million, including cash acquired of $24.9 million. Following completion of the acquisition, Crealta became a wholly owned subsidiary of the Company and was renamed as Horizon Pharma Rheumatology LLC.

The unaudited condensed consolidated financial statements presented herein include the results of operations of the acquired Hyperion and Crealta businesses from the applicable dates of acquisition. See Note 3 for further details of business acquisitions.

On May 18, 2016, the Company entered into a definitive agreement with Boehringer Ingelheim International GmbH (“Boehringer Ingelheim International”) to acquire certain rights to interferon gamma-1b, which Boehringer Ingelheim International currently commercializes under the trade names IMUKIN®, IMUKINE®, IMMUKIN® and IMMUKINE® in an estimated 30 countries, primarily in Europe and the Middle East. Under the terms of the agreement, the Company paid Boehringer Ingelheim International €5.0 million ($5.6 million when converted using a Euro-to-Dollar exchange rate of 1.1132) upon signing and will pay €20.0 million upon closing, for certain rights for interferon gamma-1b in all territories outside of the United States, Canada and Japan, as the Company currently holds marketing rights to interferon gamma-1b in these territories. The Company currently markets interferon gamma-1b as ACTIMMUNE® in the United States. The transaction is expected to close in the first half of 2017 and the Company is continuing to work with Boehringer Ingelheim International to enable the transfer of applicable marketing authorizations. Under the terms of a separate agreement, the Company also in-licensed certain U.S., European and Canadian intellectual property rights for interferon gamma-1b for the treatment of Friedreich’s ataxia (“FA”). Interferon gamma-1b is currently not indicated or approved for the treatment of FA.

On October 25, 2016, the Company completed its acquisition of Raptor Pharmaceutical Corp. (“Raptor”) in which the Company acquired all of the issued and outstanding shares of Raptor’s common stock for $9.00 per share in cash, or approximately $804.7 million on a fully-diluted basis. Following completion of the acquisition, Raptor became a wholly owned subsidiary of the Company and converted to a Delaware limited liability company, changing its name to Horizon Pharmaceutical LLC. The Company financed the transaction through $300.0 million aggregate principal amount of 8.75% Senior Notes due 2024 (the “2024 Senior Notes”), $375.0 million aggregate principal amount of loans pursuant to an amendment to the Company’s existing credit agreement and cash on hand. See Note 18 for additional details.

Unless otherwise indicated or the context otherwise requires, references to the “Company”, “we”, “us” and “our” refer to Horizon Pharma plc and its consolidated subsidiaries, including its predecessor, HPI. All references to “Vidara” are references to Horizon Pharma plc (formerly known as Vidara Therapeutics International Public Limited Company) and its consolidated subsidiaries prior to the effective time of the Vidara Merger on September 19, 2014.

The unaudited condensed consolidated financial statements presented herein include the accounts of the Company and its wholly owned subsidiaries. All inter-company transactions and balances have been eliminated.
Business Overview

The Company is a biopharmaceutical company focused on improving patients’ lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs. The Company markets eleven medicines through its orphan, rheumatology and primary care business units. The Company’s marketed medicines are ACTIMMUNE® (interferon gamma-1b), BUPHENYL® (sodium phenylbutyrate) Tablets and Powder, DUEXIS® (ibuprofen/lamotrigine), KRYSTEXXA® (pegloticase), MIGERGOT® (ergotamine tartrate & caffeine suppositories), PENNSAID® (diclofenac sodium topical solution) 2% w/w (“PENNSAID 2%”), PROCYSBI® (cysteamine bitartrate) delayed-release capsules, QUINSAIR™ (aerosolized form of levofloxacin), RAVICTI® (glycerol phenylbutyrate Oral Liquid), RAYOS® (prednisone) delayed-release tablets and VIMOVO® (naproxen/cismentazole magnesium).

The Company developed DUEXIS and RAYOS, known as LODOTRA® outside the United States, acquired the U.S. rights to VIMOVO from AstraZeneca AB (“AstraZeneca”) in November 2013, acquired certain rights to ACTIMMUNE as a result of the Vidara Merger in September 2014, acquired the U.S. rights to PENNSAID 2% from Nuvo Research Inc. (“Nuvo”) in October 2014, acquired RAVICTI and BUPHENYL, known as AMMONAPS® in certain European countries, as a result of the acquisition of Hyperion in May 2015, acquired KRystexxa and the U.S. rights to MIGERGOT as a result of the acquisition of Crealta in January 2016 and acquired PROCYSBI and QUINSAIR as a result of the acquisition of Raptor in October 2016.

The Company’s medicines are dispensed by retail and specialty pharmacies. Part of the Company’s commercial strategy for its primary care and rheumatology business units is to offer physicians the opportunity to have their patients fill prescriptions through pharmacies participating in the Company’s HorizonCares patient access program. This program does not involve the Company in the prescribing of medicines. The purpose of this program is solely to assist in ensuring that, when physicians determine that one of the Company’s medicines offers a potential clinical benefit to their patients and prescribe the medicine for an eligible patient, financial assistance may be available to reduce a commercial patient’s out-of-pocket costs. In the first nine months of 2016, this resulted in 99.9 percent of commercial patients having co-pay amounts of $10 or less when filling prescriptions for the Company’s medicines utilizing its patient access program. For commercial patients who are prescribed the Company’s primary care medicines or RAYOS, the HorizonCares program offers co-pay assistance when a third-party payer covers a prescription but requires an eligible patient to pay a co-pay or deductible, and offers full subsidization when a third-party payer rejects coverage for an eligible patient. For patients who are prescribed the Company’s orphan medicines, the Company’s patient access programs provide reimbursement support, a clinical nurse program, co-pay and other patient assistance. The aggregate commercial value of the Company’s patient access programs for the nine months ended September 30, 2016 was $1,275.2 million. All pharmacies that dispense prescriptions for the Company’s medicines, which the Company estimates to be about 20,000 during the first nine months of 2016, are fully independent, including those that participate in HorizonCares. The Company does not own or possess any option to purchase an ownership stake in any pharmacy that distributes its medicines, and the Company’s relationship with each pharmacy is non-exclusive and arm’s length. All of the Company’s medicines are dispensed through pharmacies independent of its business.

As an alternative means of ensuring access to its medicines, the Company has also begun pursuing business arrangements with pharmacy benefit managers (“PBMs”) and other payers to secure formulary status and reimbursement of the Company’s medicines, such as the Company’s recently announced arrangements with CVS Caremark and Prime Therapeutics LLC. While the Company believes that, if successful, this strategy would result in broader inclusion of certain of the Company’s primary care medicines on healthcare plan formularies, and therefore increase payer reimbursement and lower the Company’s cost of providing patient access programs, these arrangements generally require the Company to pay administrative and rebate payments to the PBMs and/or other payers.

The Company has a compliance program in place to address adherence with various laws and regulations relating to the selling, marketing and manufacturing of the Company’s medicines, as well as certain third-party relationships, including pharmacies. Specifically with respect to pharmacies, the compliance program utilizes a variety of methods and tools to monitor and audit pharmacies, including those that participate in the Company’s patient access programs, to confirm their activities, adjudication and practices are consistent with the Company’s compliance policies and guidance.

The Company markets its medicines in the United States through its field sales force, which numbered approximately 470 representatives as of September 30, 2016. The Company’s strategy is to use the commercial strength and infrastructure it has established in creating a global biopharmaceutical company to continue the successful commercialization of the Company’s existing medicine portfolio while also expanding and leveraging these capabilities by identifying, developing, acquiring and commercializing additional differentiated and accessible medicines that address unmet medical needs.

The Company is a public limited company formed under the laws of Ireland. The Company operates through a number of international and U.S. subsidiaries with principal business purposes to either perform research and development or manufacturing operations, serve as distributors of the Company’s medicines, hold intellectual property assets or provide services and financial support to the Company.
Recent Accounting Pronouncements

From time to time, the Company adopts, as of the specified effective date, new accounting pronouncements issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company’s financial position or results of operations upon adoption.

In May 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers (Subtopic 606). The new standard aims to achieve a consistent application of revenue recognition within the United States, resulting in a single revenue model to be applied by reporting companies under GAAP. Under the new model, recognition of revenue occurs when a customer obtains control of promised goods or services in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the new standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The new standard is required to be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. In March 2016 and April 2016, the FASB issued ASU No. 2016-08 and ASU No. 2016-10, respectively, which further clarify the implementation guidance on principal versus agent considerations contained in ASU No. 2014-09. In May 2016, the FASB issued ASU 2016-12, narrow-scope improvements and practical expedients which provides clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition. These standards will be effective for the Company beginning in the first quarter of 2018. Early adoption is permitted, but not before December 15, 2016, the original effective date of the standard. The Company has not yet selected a transition method nor has it determined the impact of the new standard on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. ASU No. 2014-15 is intended to define management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity’s ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). ASU No. 2014-15 provides guidance to an organization’s management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations in the financial statement footnotes. ASU No. 2014-15 is effective for annual reporting periods ending after December 15, 2016 and to annual and interim periods thereafter. Early adoption is permitted. The Company adopted ASU No. 2014-15 on April 1, 2016, and the adoption did not have a material impact on the consolidated financial statements and related disclosures.

In April 2015, the FASB issued ASU No. 2015-03, Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. In August 2015, the FASB issued ASU No. 2015-15, which further clarifies the implementation guidance of ASU No. 2015-03. The amendments in these ASUs are effective for the financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The Company adopted ASU No. 2015-03 on January 1, 2016. The following table summarizes the adjustments made to conform prior period classifications as a result of the new guidance (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>As of December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>As filed</td>
</tr>
<tr>
<td>Other non-current assets</td>
<td>$ 8,581</td>
</tr>
<tr>
<td>Exchangeable notes, net</td>
<td>$(283,675)</td>
</tr>
<tr>
<td>Long-term debt, net, net of current</td>
<td>$(857,440)</td>
</tr>
</tbody>
</table>

In April 2015, the FASB issued ASU No. 2015-05: Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement which provides guidance on a customer’s accounting for fees paid in a cloud computing arrangement. Under the new standard, customers will apply the same criteria as vendors to determine whether a cloud computing arrangement contains a software license or is solely a service contract. The amendments in this ASU, which may be applied prospectively or retrospectively, are effective for annual and interim periods beginning after December 15, 2015. The Company adopted ASU No. 2015-05 on January 1, 2016 and the adoption did not have a material impact on the consolidated financial statements and related disclosures.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Under this new guidance, entities that measure inventory using any method other than last-in, first-out or the retail inventory method will be required to measure inventory at the lower of cost and net realizable value. The amendments in this ASU, which should be applied prospectively, are effective for annual and interim periods beginning after December 15, 2016. Early adoption is permitted. The Company adopted ASU No. 2015-11 on April 1, 2016, and the adoption did not have a material impact on the consolidated financial statements and related disclosures.
In September 2015, the FASB issued ASU No. 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments (“ASC 805”). Under this guidance, an acquirer is required to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments in this ASU require that the acquirer record, in the same period’s financial statements, the effect on earnings of changes in depreciation, amortization or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The amendments in this ASU require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. The amendments in this ASU, which should be applied prospectively, are effective for annual and interim periods beginning after December 15, 2015. The Company adopted ASU No. 2015-16 on January 1, 2016, and the adoption did not have a material impact on the consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). Under ASU No. 2016-02, an entity will be required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. ASU No. 2016-02 offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessors and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. ASU No. 2016-02 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, with early adoption permitted. At adoption, this update will be applied using a modified retrospective approach. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2016-02 on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The updated guidance will change how companies account for certain aspects of share-based payments to employees. Entities will be required to recognize the income tax effects of awards in the statement of income when the awards vest or are settled. The guidance on accounting for an employee’s use of shares to satisfy the statutory income tax withholding obligation and for forfeitures is changing, and the update requires companies to present excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. The amendments in this update will be effective for annual periods beginning after December 15, 2016 and interim periods within those annual periods. Early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2016-09 on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The amendments in this ASU provide guidance on the following eight specific cash flow classification issues: (1) debt prepayment or debt extinguishment costs; (2) settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; (3) contingent consideration payments made after a business combination; (4) proceeds from the settlement of insurance claims; (5) proceeds from the settlement of corporate-owned life insurance policies, including bank-owned life insurance policies; (6) distributions received from equity method investees; (7) beneficial interests in securitization transactions; and (8) separately identifiable cash flows and application of the predominance principle. Current GAAP does not include specific guidance on these eight cash flow classification issues. The amendments of this ASU are effective for reporting periods beginning after December 15, 2017, with early adoption permitted. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2016-15 on its consolidated financial statements and related disclosures.

NOTE 2 – NET (LOSS) INCOME PER SHARE

The following table presents basic net (loss) income per share for the three and nine months ended September 30, 2016 and 2015 (in thousands, except share and per share data):

| Basic net (loss) income per share calculation: | For the Three Months Ended September 30, | For the Nine Months Ended September 30, |
| | 2016 | 2015 | 2016 | 2015 |
| Net (loss) income | $ (5,870) | $ 3,277 | $ (36,292) | $ 15,538 |
| Weighted average ordinary shares outstanding | 161,038,827 | 159,035,580 | 160,472,530 | 145,208,252 |
| Basic net (loss) income per share | $ (0.04) | $ 0.02 | $ (0.23) | $ 0.11 |
The following table presents diluted net (loss) income per share for the three and nine months ended September 30, 2016 and 2015 (in thousands, except share and per share data):

<table>
<thead>
<tr>
<th>Diluted net (loss) income per share calculation:</th>
<th>For the Three Months Ended September 30,</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net (loss) income</td>
<td>$ (5,870)</td>
<td>$ 3,277</td>
<td>$ (36,292)</td>
</tr>
<tr>
<td>Weighted average ordinary shares outstanding</td>
<td>161,038,827</td>
<td>166,830,800</td>
<td>160,472,530</td>
</tr>
<tr>
<td>Diluted net (loss) income per share</td>
<td>$(0.04)</td>
<td>$0.02</td>
<td>$(0.23)</td>
</tr>
</tbody>
</table>

Basic net (loss) income per share is computed by dividing net (loss) income by the weighted-average number of ordinary shares outstanding during the period. Diluted net income per share reflects the potential dilution beyond shares for basic net income per share that could occur if securities or other contracts to issue ordinary shares were exercised, converted into ordinary shares, or resulted in the issuance of ordinary shares that would have shared in the Company’s earnings.

The computation of diluted net (loss) income per share excluded 11.6 million and 14.2 million equity awards for the three and nine months ended September 30, 2016, respectively, and 5.6 million and 4.4 million equity awards for the three and nine months ended September 30, 2015, respectively, because their inclusion would have had an anti-dilutive effect on diluted net (loss) income per share.

The potentially dilutive impact of the March 2015 private placement of $400.0 million aggregate principal amount of 2.50% Exchangeable Senior Notes due 2022 (the “Exchangeable Senior Notes”) by Horizon Pharma Investment Limited (“Horizon Investment”), a wholly owned subsidiary of the Company, is determined using a method similar to the treasury stock method. Under this method, no numerator or denominator adjustments arise from the principal and interest components of the Exchangeable Senior Notes because the Company has the intent and ability to settle the Exchangeable Senior Notes’ principal and interest in cash. Instead, the Company is required to increase the diluted net (loss) income per share denominator by the variable number of shares that would be issued upon conversion if it settled the conversion spread obligation with shares. For diluted net (loss) income per share purposes, the conversion spread obligation is calculated based on whether the average market price of the Company’s ordinary shares over the reporting period is in excess of the exchange price of the Exchangeable Senior Notes. The calculated spread added to the denominator for the three and nine months ended September 30, 2015 was 1,298,616 and 775,807 ordinary shares, respectively. There was no calculated spread added to the denominator for the three and nine months ended September 30, 2016.

NOTE 3 – BUSINESS ACQUISITIONS

Raptor Acquisition

On October 25, 2016, the Company completed its acquisition of Raptor in which the Company acquired all of the issued and outstanding shares of Raptor’s common stock for $9.00 per share in cash or approximately $804.7 million on a fully-diluted basis. The acquisition added two medicines, PROCYSBI and QUINSAIR, to the Company’s medicine portfolio. Through the acquisition, the Company expects to leverage as well as expand the existing infrastructure of its orphan disease business. Following completion of the acquisition, Raptor became a wholly owned subsidiary of the Company and converted to a Delaware limited liability company, changing its name to Horizon Pharmaceutical LLC. The Company financed the transaction through $300.0 million of aggregate principal amount of 2024 Senior Notes, $375.0 million aggregate principal amount of loans pursuant to an amendment to the Company’s existing credit agreement and cash on hand. See Note 18 for additional details.

Acquisition of Additional Rights to Interferon Gamma-1b

On May 18, 2016, the Company entered into a definitive agreement with Boehringer Ingelheim International to acquire certain rights to interferon gamma-1b, which Boehringer Ingelheim International currently commercializes under the trade names IMUKIN, IMUKINE, IMMUKIN and IMMUKINE in an estimated 30 countries primarily in Europe and the Middle East. Under the terms of the agreement, the Company paid Boehringer Ingelheim International €5.0 million ($5.6 million when converted using a Euro-to-Dollar exchange rate of 1.1132) upon signing and will pay €20.0 million upon closing, for certain rights for interferon gamma-1b in all territories outside of the United States, Canada and Japan, as the Company currently holds marketing rights to interferon gamma-1b in these territories. The transaction is expected to close in the first half of 2017 and the Company is continuing to work with Boehringer Ingelheim International to enable the transfer of applicable marketing authorizations. The Company currently markets interferon gamma-1b as ACTIMMUNE in the United States. The €5.0 million ($5.6 million) upfront amount paid in May 2016 has been included in “other assets” in the Company’s condensed consolidated balance sheet as of September 30, 2016.
Crealta Acquisition

On January 13, 2016, the Company completed its acquisition of all the membership interests of Crealta. The acquisition added two medicines, KRYSTEXXA and MIGERGOT, to the Company’s medicine portfolio. The Crealta acquisition further diversified the Company’s portfolio of medicines and aligned with its focus of acquiring value-enhancing, clinically differentiated, long-life medicines that treat orphan diseases. The total consideration for the acquisition was approximately $539.7 million, including cash acquired of $24.9 million, and was composed of the following before and after the measurement period adjustments (in thousands):

<table>
<thead>
<tr>
<th>Before</th>
<th>Adjustments</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash</td>
<td>536,181</td>
<td>25</td>
</tr>
<tr>
<td>Net settlements on the exercise of stock options and unrestricted units</td>
<td>3,526</td>
<td>—</td>
</tr>
<tr>
<td>Total consideration</td>
<td>539,707</td>
<td>25</td>
</tr>
</tbody>
</table>

During the three and nine months ended September 30, 2016, the Company incurred $0.4 million and $12.1 million, respectively, in Crealta acquisition-related costs including advisory, legal, accounting, valuation, severance, retention bonuses and other professional and consulting fees. During the three and nine months ended September 30, 2016, $0.5 million and $11.5 million were accounted for as “general and administrative”, respectively, a net expense reduction of $0.1 million and a net expense of $0.2 million were accounted for as “research and development”, respectively, and zero and $0.4 million were accounted for as “costs of goods sold”, respectively, in the condensed consolidated statements of comprehensive loss.

Pursuant to ASC 805, the Company accounted for the Crealta acquisition as a business combination using the acquisition method of accounting. Identifiable assets and liabilities of Crealta, including identifiable intangible assets, were recorded based on their estimated fair values as of the date of the closing of the acquisition. The excess of the purchase price over the fair value of the net assets acquired was recorded as goodwill. Significant judgment was required in determining the estimated fair values of developed technology intangible assets, inventories and certain other assets and liabilities. Such preliminary valuation required estimates and assumptions including, but not limited to, estimating future cash flows and direct costs in addition to developing the appropriate discount rates and current market profit margins. The Company’s management believes the fair values recognized for the assets acquired and the liabilities assumed are based on reasonable estimates and assumptions. Accordingly, the unaudited purchase price adjustments are preliminary and are subject to further adjustments as additional information becomes available and as additional analyses are performed, and such further adjustments may be material.

During the nine months ended September 30, 2016, the Company recorded measurement period adjustments related to developed technology and inventory, which resulted in a net increase in goodwill of $0.3 million. The measurement period adjustments were the result of a net working capital true-up adjustment and the alignment of Crealta’s inventory and obsolescence reserve policy to the Company’s policy.

The following table summarizes the preliminary fair values assigned to the assets acquired and the liabilities assumed by the Company, along with the resulting goodwill before and after the measurement period adjustments (in thousands):

<table>
<thead>
<tr>
<th>(Liabilities assumed) and assets acquired:</th>
<th>Before</th>
<th>Adjustments</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accounts payable and accrued expenses</td>
<td>$ (4,543)</td>
<td>—</td>
<td>$ (4,543)</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>(1,424)</td>
<td>—</td>
<td>(1,424)</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>(20,835)</td>
<td>—</td>
<td>(20,835)</td>
</tr>
<tr>
<td>Other non-current liabilities</td>
<td>(6,900)</td>
<td>—</td>
<td>(6,900)</td>
</tr>
<tr>
<td>Contingent royalty liabilities</td>
<td>(51,300)</td>
<td>—</td>
<td>(51,300)</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>24,893</td>
<td>—</td>
<td>24,893</td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>10,014</td>
<td>—</td>
<td>10,014</td>
</tr>
<tr>
<td>Inventories</td>
<td>169,054 (1,700)</td>
<td>167,354</td>
<td></td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>1,382</td>
<td>—</td>
<td>1,382</td>
</tr>
<tr>
<td>Developed technology</td>
<td>417,300 1,400</td>
<td>418,700</td>
<td></td>
</tr>
<tr>
<td>Other non-current assets</td>
<td>275</td>
<td>—</td>
<td>275</td>
</tr>
<tr>
<td>Goodwill</td>
<td>1,791 325</td>
<td>2,116</td>
<td></td>
</tr>
<tr>
<td>Fair value of consideration paid</td>
<td>$ 539,707</td>
<td>25</td>
<td>$ 539,732</td>
</tr>
</tbody>
</table>
Inventories acquired included raw materials, work in process and finished goods for KRYSTEXXA and MIGERGOT. Inventories were recorded at their preliminary estimated fair values. The fair value of finished goods has been determined based on the estimated selling price, net of selling costs and a margin on the selling costs. The fair value of work in process has been determined based on estimated selling price, net of selling costs and costs to complete the manufacturing, and a margin on the selling and manufacturing costs. The fair value of raw materials was estimated to equal the replacement cost. A step up in the value of inventory of $163.6 million was originally recorded in connection with the acquisition and this was reduced to $161.9 million following the recording of $1.7 million in measurement period adjustments during the nine months ended September 30, 2016. During the three and nine months ended September 30, 2016, the Company amortized inventory step-up of $11.3 million and $27.9 million, respectively.

Other tangible assets and liabilities were valued at their respective carrying amounts as management believes that these amounts approximated their acquisition date fair values.

Other non-current liabilities represented an assumed $6.9 million probable contingent liability which was released to “Other income (expense)” in the condensed consolidated statement of comprehensive loss during the three months ended September 30, 2016. See Note 12 for further details.

Identifiable intangible assets and liabilities acquired include developed technology and contingent royalties. The preliminary estimated fair values of the developed technology and contingent royalties represent preliminary valuations performed with the assistance of an independent appraisal firm based on management’s estimates, forecasted financial information and reasonable and supportable assumptions.

Developed technology intangible assets reflect the estimated fair value of Crealta’s rights to its currently marketed medicines, KRYSTEXXA and MIGERGOT. The preliminary fair value of developed technology was determined using an income approach. The income approach explicitly recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on current sales projections and estimated direct costs for Crealta’s medicines. Indications of value were developed by discounting these benefits to their acquisition-date worth at a discount rate of 27% for KRYSTEXXA and 23% for MIGERGOT. The fair value of the KRYSTEXXA and MIGERGOT developed technologies were capitalized as of the Crealta acquisition date and are subsequently being amortized over approximately 12 and 10 years, respectively, which are the periods in which over 90% of the estimated cash flows are expected to be realized.

The Company has assigned a preliminary fair value of $51.3 million to a contingent liability for royalties potentially payable under previously existing agreements related to KRYSTEXXA and MIGERGOT. The royalties for KRYSTEXXA are payable under the terms of a license agreement with Duke University (“Duke”) and Mountain View Pharmaceuticals (“MVP”). See Note 12 for details of the percentages of royalties payable under such agreements. The initial fair value of this liability was determined using a discounted cash flow analysis incorporating the estimated future cash flows of royalty payments resulting from future sales. The discount rate used was the same as for the fair value of the developed technology.

The preliminary deferred tax liability recorded represents deferred tax liabilities assumed as part of the acquisition, net of deferred tax assets, related to net operating tax loss carryforwards of Crealta.

Goodwill represents the excess of the preliminary acquisition consideration over the estimated fair value of net assets acquired and was recorded in the condensed consolidated balance sheet as of the acquisition date. The Company does not expect any portion of this goodwill to be deductible for tax purposes.

**Hyperion Acquisition**

On May 7, 2015, the Company completed the acquisition of Hyperion in which it acquired all of the issued and outstanding shares of Hyperion’s common stock for $46.00 per share. The acquisition added two important medicines, RAVICTI and BUPHENYL, to the Company’s medicine portfolio. Through the acquisition, the Company leveraged as well as expanded the existing infrastructure of its orphan disease business. The total consideration for the acquisition was approximately $1.1 billion and was composed of the following (in thousands, except share and per share data):
During the three and nine months ended September 30, 2016, the Company recorded a net expense reduction of $0.2 million and $0.5 million, respectively, in Hyperion acquisition-related costs primarily due to a reduction in severance and other payroll-related payments required. During the three and nine months ended September 30, 2016, a net expense reduction of $0.2 million and $0.8 million were accounted for as “general and administrative”, respectively. Additionally, during the nine months ended September 30, 2016, an expense of $0.3 million was accounted for as “research and development” in the condensed consolidated statements of comprehensive loss.

During the three and nine months ended September 30, 2015, the Company incurred $4.6 million and $52.4 million, respectively, in Hyperion acquisition-related costs. During the three and nine months ended September 30, 2015, $2.7 million and $40.5 million were accounted for as “general and administrative expenses”, respectively, $1.9 million and $1.9 million were accounted for as “research and development”, respectively, and zero and $10.0 million were accounted for as “other expenses, net”, respectively, in the condensed consolidated statements of comprehensive loss.

Pursuant to ASC 805, the Company accounted for the Hyperion acquisition as a business combination using the acquisition method of accounting. Identifiable assets and liabilities of Hyperion, including identifiable intangible assets, were recorded based on their estimated fair values as of the date of the closing of the acquisition. The excess of the purchase price over the fair value of the net assets acquired was recorded as goodwill. Significant judgment was required in determining the estimated fair values of developed technology intangible assets and certain other assets and liabilities. Such a valuation required estimates and assumptions including, but not limited to, estimating future cash flows and direct costs in addition to developing the appropriate discount rates and current market profit margins. The Company’s management believes the fair values recognized for the assets acquired and the liabilities assumed are based on reasonable estimates and assumptions.

During the nine months ended September 30, 2016, the Company recorded an adjustment related to deferred tax liabilities which resulted in a decrease to goodwill of $7.2 million. In evaluating whether the Company’s previously issued consolidated financial statements were materially misstated, the Company considered the guidance in FASB ASC Topic 250, Accounting Changes and Error Corrections, ASC Topic 250-10-S99-1, Assessing Materiality, and ASC Topic 250-10-S99-2, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements. The adjustment was the result of a correction of an error in the Hyperion pre-acquisition deferred tax calculation. The Company concluded that this misstatement was not material, individually or in the aggregate, to any of the reporting periods impacted. As such, the correction for this error was made during the three months ended September 30, 2016.

The following table summarizes the final fair values assigned to the assets acquired and the liabilities assumed by the Company (in thousands):

<table>
<thead>
<tr>
<th>(Liabilities assumed) and assets acquired:</th>
<th>As Reported</th>
<th>Adjustment</th>
<th>As Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferred tax liabilities, net</td>
<td>($262,732)</td>
<td>$7,191</td>
<td>($255,541)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>(2,439)</td>
<td>(2,439)</td>
<td></td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>(9,792)</td>
<td>(9,792)</td>
<td></td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>(7,566)</td>
<td>(7,566)</td>
<td></td>
</tr>
<tr>
<td>Contingent royalties</td>
<td>(86,800)</td>
<td>(86,800)</td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>53,037</td>
<td>53,037</td>
<td></td>
</tr>
<tr>
<td>Short-term investments</td>
<td>39,049</td>
<td>39,049</td>
<td></td>
</tr>
<tr>
<td>Long-term investments</td>
<td>25,574</td>
<td>25,574</td>
<td></td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>11,858</td>
<td>11,858</td>
<td></td>
</tr>
<tr>
<td>Inventory</td>
<td>13,498</td>
<td>13,498</td>
<td></td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>2,533</td>
<td>2,533</td>
<td></td>
</tr>
<tr>
<td>Property and equipment</td>
<td>1,044</td>
<td>1,044</td>
<td></td>
</tr>
<tr>
<td>Other non-current assets</td>
<td>123</td>
<td>123</td>
<td></td>
</tr>
<tr>
<td>Developed technology</td>
<td>1,044,200</td>
<td>1,044,200</td>
<td></td>
</tr>
<tr>
<td>Goodwill</td>
<td>253,811</td>
<td>(7,191)</td>
<td>246,620</td>
</tr>
<tr>
<td>Fair value of consideration paid</td>
<td>$1,075,398</td>
<td>$1,075,398</td>
<td></td>
</tr>
</tbody>
</table>

Inventories acquired included raw materials and finished goods. Inventories were recorded at their current fair values. The fair value of finished goods has been determined based on the estimated selling price, net of selling costs and a margin on the selling costs. The fair value of raw materials was estimated to equal the replacement cost. A step up in the value of inventory of $8.7 million was recorded in connection with the acquisition and has subsequently been fully recognized in the condensed consolidated statements of comprehensive loss.

Other tangible assets and liabilities were valued at their respective carrying amounts as management believes that these amounts approximated their acquisition date fair values.
Identifiable intangible assets and liabilities acquired include developed technology and contingent royalties. The fair values of the developed technology and contingent royalties represent valuations performed with the assistance of an independent appraisal firm based on management’s estimates, forecasted financial information and reasonable and supportable assumptions.

Developed technology intangible assets reflect the estimated value of Hyperion’s rights to its currently marketed medicines, RAVICTI and BUPHENYL. The fair value of developed technology was determined using an income approach. The income approach explicitly recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on current sales projections and estimated direct costs for Hyperion’s medicines. Indications of value were developed by discounting these benefits to their acquisition-date worth at a discount rate of 8.5% that reflected the then-current return requirements of the market. The fair value of the RAVICTI and BUPHENYL developed technologies were capitalized as of the Hyperion acquisition date and are subsequently being amortized over 11 and 7 years, respectively, which are the periods in which over 90% of the estimated cash flows are expected to be realized.

Deferred tax assets and liabilities arise from acquisition accounting adjustments where book values of certain assets and liabilities differ from their tax bases. Deferred tax assets and liabilities are recorded at the currently enacted rates which will be in effect at the time when the temporary differences are expected to reverse in the country where the underlying assets and liabilities are located. Hyperion’s developed technology as of the acquisition date was located primarily in the United States where a U.S. tax rate of 39% is being utilized and a significant deferred tax liability is recorded. Upon consummation of the Hyperion acquisition, Hyperion became a member of the Company’s U.S. tax consolidation group. As such, its tax assets and liabilities were considered in determining the appropriate amount (if any) of valuation allowances that should be recognized in assessing the realizability of the group’s deferred tax assets. The Hyperion acquisition adjustments resulted in the recognition of significant net deferred tax liabilities. Per ASC Topic 740, Accounting for Uncertainty in Income Taxes, future reversals of existing taxable temporary differences provide objectively verifiable evidence that should be considered as a source of taxable income to realize a tax benefit for deductible temporary differences and carryforwards. Generally, the existence of sufficient taxable temporary differences will enable the use of the tax benefit of existing deferred tax assets. As of the first quarter of 2015, the Company had significant U.S. federal and state valuation allowances. These valuation allowances were released in the second quarter of 2015 to reflect the recognition of Hyperion’s deferred tax liabilities that will provide taxable temporary differences that will be realized within the carryforward period of the Company’s U.S. tax consolidation group’s available net operating losses and other deferred tax assets. Accordingly, the Company recorded an income tax benefit of $105.1 million in the second quarter of 2015 relating to the release of existing U.S. federal and state valuation allowances.

Goodwill represents the excess of the acquisition consideration over the estimated fair value of net assets acquired and was recorded in the condensed consolidated balance sheet as of the acquisition date. The Company does not expect any portion of this goodwill to be deductible for tax purposes.

Pro Forma Information

The table below represents the condensed consolidated financial information for the Company for the nine months ended September 30, 2015 on a pro forma basis, assuming that the Crealta and Hyperion acquisitions occurred as of January 1, 2015. The historical financial information has been adjusted to give effect to pro forma items that are directly attributable to the Crealta and Hyperion acquisitions, and are expected to have a continuing impact on the consolidated results. These items include, among others, adjustments to record the amortization of definite-lived intangible assets, interest expense, debt discount and deferred financing costs associated with the debt in connection with the acquisitions.

The Company does not believe that the pre-acquisition operating results for Crealta during January 2016 are material to the combined entity and as such the Company did not prepare an unaudited pro forma combined statement of operations for the nine months ended September 30, 2016.

13
Additionally, the following table sets forth unaudited financial information and has been compiled from historical financial statements and other information, but is not necessarily indicative of the results that actually would have been achieved had the transactions occurred on the dates indicated or that may be achieved in the future (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>As reported</th>
<th>Pro forma adjustments</th>
<th>Pro forma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>$512,506</td>
<td>$84,942</td>
<td>$597,448</td>
</tr>
<tr>
<td>Net income (loss)</td>
<td>15,538</td>
<td>(46,420)</td>
<td>(30,882)</td>
</tr>
</tbody>
</table>

The Company’s unaudited condensed consolidated statements of comprehensive loss for the nine months ended September 30, 2016 include KRYSTEXXA and MIGERGOT net sales as a result of the acquisition of Crealta of $61.6 million and $3.2 million, respectively, and RAVICTI and BUPHENYL net sales as a result of the acquisition of Hyperion of $118.6 million and $12.1 million, respectively. The Company’s unaudited condensed consolidated statements of comprehensive loss for the nine months ended September 30, 2015 include RAVICTI and BUPHENYL net sales as a result of the acquisition of Hyperion of $52.4 million and $7.8 million, respectively.

Crealta and Hyperion have been fully integrated into the Company’s business and as a result of these integration efforts, the Company cannot distinguish between these operations and those of the Company’s legacy business.

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 of finished goods or the purchase of raw materials and production supplies. The Company’s inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs.

The components of inventories as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2016</th>
<th>December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw materials</td>
<td>$3,660</td>
<td>$6,232</td>
</tr>
<tr>
<td>Work-in-process</td>
<td>114,049</td>
<td>631</td>
</tr>
<tr>
<td>Finished goods</td>
<td>44,446</td>
<td>11,513</td>
</tr>
<tr>
<td>Inventories, net</td>
<td>$162,155</td>
<td>$18,376</td>
</tr>
</tbody>
</table>

Work-in-process at September 30, 2016 included $101.7 million of stepped-up KRYSTEXXA and MIGERGOT inventory. Finished goods at September 30, 2016 included $32.3 million of stepped-up KRYSTEXXA and MIGERGOT inventory. The Company amortized $11.3 million and $27.9 million of the KRYSTEXXA and MIGERGOT inventory step-up during the three and nine months ended September 30, 2016, respectively.

NOTE 5 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2016</th>
<th>December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepaid income taxes</td>
<td>$13,413</td>
<td>$4</td>
</tr>
<tr>
<td>Medicine samples inventory</td>
<td>8,723</td>
<td>4,697</td>
</tr>
<tr>
<td>Prepaid co-pay expenses</td>
<td>2,022</td>
<td>1,881</td>
</tr>
<tr>
<td>Rabbi trust assets</td>
<td>2,740</td>
<td>773</td>
</tr>
<tr>
<td>Other prepaid expenses</td>
<td>11,180</td>
<td>8,503</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>$38,078</td>
<td>$15,858</td>
</tr>
</tbody>
</table>
NOTE 6 – PROPERTY AND EQUIPMENT

Property and equipment as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2016</th>
<th>December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software</td>
<td>$10,005</td>
<td>$1,360</td>
</tr>
<tr>
<td>Leasehold improvements</td>
<td>8,781</td>
<td>1,966</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>2,975</td>
<td>2,514</td>
</tr>
<tr>
<td>Machinery and equipment</td>
<td>2,843</td>
<td>2,946</td>
</tr>
<tr>
<td>Other</td>
<td>1,763</td>
<td>276</td>
</tr>
<tr>
<td></td>
<td>26,367</td>
<td>9,062</td>
</tr>
<tr>
<td>Less accumulated depreciation</td>
<td>(6,839)</td>
<td>(3,791)</td>
</tr>
<tr>
<td>Construction in process</td>
<td>—</td>
<td>3,492</td>
</tr>
<tr>
<td>Software implementation in process</td>
<td>1,914</td>
<td>5,257</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>$21,442</td>
<td>$14,020</td>
</tr>
</tbody>
</table>

The Company capitalizes development costs associated with internal use software, including external direct costs of materials and services and payroll costs for employees devoting time to a software project. Costs incurred during the preliminary project stage, as well as costs for maintenance and training, are expensed as incurred.

Software implementation in process as of September 30, 2016 and December 31, 2015 is related to new enterprise resource planning software being implemented by the Company. The software is being implemented on a phased basis starting January 2016 and depreciation is not recorded on capitalized costs relating to a phase which has not yet entered service. Once a particular phase of the project enters service, associated capitalized costs are moved from "software implementation in process" to "software" in the table above, and depreciation commences.

Depreciation expense was $1.2 million and $1.6 million for the three months ended September 30, 2016 and 2015, respectively, and was $3.3 million and $2.8 million for the nine months ended September 30, 2016 and 2015, respectively.

NOTE 7 – GOODWILL AND INTANGIBLE ASSETS

Goodwill

The gross carrying amount of goodwill as of September 30, 2016 was as follows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at December 31, 2015</td>
<td>$253,811</td>
</tr>
<tr>
<td>Acquired during the period</td>
<td>2,116</td>
</tr>
<tr>
<td>Adjustment relating to the prior year</td>
<td>(7,191)</td>
</tr>
<tr>
<td>Balance at September 30, 2016</td>
<td>$248,736</td>
</tr>
</tbody>
</table>

In May 2015, the Company recognized goodwill with a value of $253.8 million in connection with the Hyperion acquisition, which represented the excess of the purchase price over the fair value of the net assets acquired. During the nine months ended September 30, 2016, the Company recorded an adjustment related to deferred tax liabilities which resulted in a decrease to goodwill of $7.2 million. The adjustment was the result of a correction of an error in the Hyperion pre-acquisition deferred tax calculation. The Company concluded that this misstatement was not material, individually or in the aggregate, to any of the reporting periods impacted. As such, the correction for this error was made during the three months ended September 30, 2016.

In January 2016, the Company recognized goodwill with a preliminary value of $1.8 million in connection with the Crealta acquisition, which represented the excess of the purchase price over the fair value of the net assets acquired. During the nine months ended September 30, 2016, the Company recorded measurement period adjustments related to developed technology and inventory, which resulted in a net increase in goodwill of $0.3 million.

See Note 3 for further details of goodwill acquired in business acquisitions.

As of September 30, 2016, there were no accumulated goodwill impairment losses.
Intangible Assets

The Company’s intangible assets consist of developed technology related to ACTIMMUNE, BUPHENYL, KRYS
tEXXA, MIGERGOT, PENNSAID 2%, RAVICTI, RAYOS and VIMOVO in the United States, and AMMONAPS and LODOTRA in Europe, as well as in-process research and development (“IPR&D”) and customer relationships for ACTIMMUNE.

In May 2015, in connection with the acquisition of Hyperion, the Company capitalized $1,021.6 million of developed technology related to RAVICTI and $22.6 million of developed technology related to BUPHENYL.

In January 2016, in connection with the acquisition of Crealta, the Company capitalized $392.7 million of developed technology related to KRYS
tEXXA and $24.6 million of developed technology related to MIGERGOT. During the nine months ended September 30, 2016, the Company recorded a measurement period adjustment which increased the cost basis of MIGERGOT developed technology by $1.4 million, to $26.0 million.

See Note 3 for further details of intangible assets acquired in business acquisitions.

IPR&D is related to one research and development project for the application of ACTIMMUNE in the treatment of FA. The fair value of the IPR&D was recorded as an indefinite-lived intangible asset and is tested for impairment annually until completion or abandonment of research and development efforts associated with the project. IPR&D is not amortized until successful completion of the project. In June 2015, the Company initiated the Phase 3 Safety, Tolerability and Efficacy of ACTIMMUNE Dose Escalation in Friedreich's Ataxia Study (“STEADFAST study”) of ACTIMMUNE for the treatment of FA. The Company expects to have top-line results from the STEADFAST study in late December 2016.

After receiving the results from the STEADFAST study, the Company will assess the impact of the results on the accounting for the IPR&D intangible asset. Possible accounting treatments include the commencement of amortization of the intangible asset following approval by the FDA, or the recording of an impairment charge if the study is unsuccessful.

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. The Company does not believe there have been any circumstances or events that would indicate that the carrying value of any of its intangible assets was impaired at September 30, 2016 or December 31, 2015.

As of September 30, 2016 and December 31, 2015, amortizable intangible assets consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2016</th>
<th>December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cost Basis</td>
<td>Accumulated Amortization</td>
</tr>
<tr>
<td>Developed technology</td>
<td>$2,211,195</td>
<td>$(334,037)</td>
</tr>
<tr>
<td>Customer relationships</td>
<td>8,100</td>
<td>(1,647)</td>
</tr>
<tr>
<td>Total amortizable intangible assets</td>
<td>$2,219,295</td>
<td>$(335,684)</td>
</tr>
</tbody>
</table>

Amortization expense for the three months ended September 30, 2016 and 2015 was $50.8 million and $41.7 million, respectively, and was $151.2 million and $91.2 million for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, estimated future amortization expense was as follows (in thousands):

<table>
<thead>
<tr>
<th>Year</th>
<th>Amortization Expense</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016 (October to December)</td>
<td>$50,619</td>
</tr>
<tr>
<td>2017</td>
<td>203,086</td>
</tr>
<tr>
<td>2018</td>
<td>203,086</td>
</tr>
<tr>
<td>2019</td>
<td>190,094</td>
</tr>
<tr>
<td>2020</td>
<td>189,875</td>
</tr>
<tr>
<td>Thereafter</td>
<td>1,046,851</td>
</tr>
<tr>
<td>Total</td>
<td>$1,883,611</td>
</tr>
</tbody>
</table>
NOTE 8 – ACCRUED TRADE DISCOUNTS AND REBATES

Accrued trade discounts and rebates as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2016</th>
<th>December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accrued wholesaler fees and commercial rebates</td>
<td>$27,965</td>
<td>$21,112</td>
</tr>
<tr>
<td>Accrued co-pay and other patient assistance</td>
<td>173,229</td>
<td>114,201</td>
</tr>
<tr>
<td>Accrued government rebates and chargebacks</td>
<td>67,008</td>
<td>48,456</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>268,202</td>
<td>183,769</td>
</tr>
<tr>
<td>Invoiced wholesaler fees and commercial rebates, co-pay and other patient assistance, and government rebates and chargebacks in accounts payable</td>
<td>42,466</td>
<td>—</td>
</tr>
<tr>
<td>Total customer-related accruals and allowances</td>
<td>$310,668</td>
<td>$183,769</td>
</tr>
</tbody>
</table>

The following table summarizes changes in the Company’s customer-related accruals and allowances from December 31, 2015 to September 30, 2016 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Wholesaler Fees and Commercial Rebates</th>
<th>Co-Pay and Other Patient Assistance</th>
<th>Government Rebates and Chargebacks</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at December 31, 2015</td>
<td>$21,112</td>
<td>$114,201</td>
<td>$48,456</td>
<td>$183,769</td>
</tr>
<tr>
<td>Current provisions relating to sales in the nine months ended September 30, 2016</td>
<td>82,232</td>
<td>1,275,181</td>
<td>205,437</td>
<td>1,562,850</td>
</tr>
<tr>
<td>Adjustments relating to prior year sales</td>
<td>2,812</td>
<td>—</td>
<td>(7,043)</td>
<td>(4,231)</td>
</tr>
<tr>
<td>Payments relating to sales in the nine months ended September 30, 2016</td>
<td>(57,921)</td>
<td>(1,065,202)</td>
<td>(133,763)</td>
<td>(1,256,886)</td>
</tr>
<tr>
<td>Payments relating to sales in prior years</td>
<td>(20,644)</td>
<td>(114,201)</td>
<td>(41,413)</td>
<td>(176,258)</td>
</tr>
<tr>
<td>Crealta acquisition on January 13, 2016</td>
<td>492</td>
<td>—</td>
<td>932</td>
<td>1,424</td>
</tr>
<tr>
<td>Balance at September 30, 2016</td>
<td>$28,083</td>
<td>$209,979</td>
<td>$72,606</td>
<td>$310,668</td>
</tr>
</tbody>
</table>

NOTE 9 – ACCRUED EXPENSES

Accrued expenses as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2016</th>
<th>December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Litigation settlement</td>
<td>$65,000</td>
<td>—</td>
</tr>
<tr>
<td>Payroll-related expenses</td>
<td>35,004</td>
<td>47,205</td>
</tr>
<tr>
<td>Consulting and professional services</td>
<td>25,664</td>
<td>17,160</td>
</tr>
<tr>
<td>Accrued interest</td>
<td>16,223</td>
<td>10,637</td>
</tr>
<tr>
<td>Accrued other</td>
<td>15,643</td>
<td>25,044</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>$157,534</td>
<td>$100,046</td>
</tr>
</tbody>
</table>

Accrued expenses as of September 30, 2016 include $65.0 million in relation to a litigation settlement with Express Scripts, Inc. ("Express Scripts"). See Note 12 for further details of this settlement.
NOTE 10 – ACCRUED ROYALTIES
During the nine months ended September 30, 2016, changes to the liability for royalties for medicines acquired through business combinations consisted of the following (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance as of December 31, 2015</td>
<td>$175,219</td>
</tr>
<tr>
<td>Assumed KRYSTEXXA and MIGERGOT accrued royalties</td>
<td>1,401</td>
</tr>
<tr>
<td>Assumed KRYSTEXXA and MIGERGOT contingent royalty liabilities</td>
<td>51,300</td>
</tr>
<tr>
<td>Royalty payments</td>
<td>(27,888)</td>
</tr>
<tr>
<td>Accretion expense</td>
<td>28,762</td>
</tr>
<tr>
<td>Balance as of September 30, 2016</td>
<td>228,794</td>
</tr>
<tr>
<td>Less: Current portion</td>
<td>59,176</td>
</tr>
<tr>
<td>Accrued royalties, net of current</td>
<td>$169,618</td>
</tr>
</tbody>
</table>

The Company did not record any remeasurements of contingent royalty liabilities during the nine months ended September 30, 2016, as there were no triggering events during the period.

The top-line results from the STEADFAST study are expected in late December 2016. The Company may then seek approval of ACTIMMUNE for the treatment of FA from the FDA, which may result in a remeasurement of contingent royalty liabilities.

NOTE 11 – FAIR VALUE MEASUREMENTS
The following tables and paragraphs set forth the Company’s financial instruments that are measured at fair value on a recurring basis within the fair value hierarchy. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The following 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; and

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

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

As of September 30, 2016, the Company’s restricted cash included bank time deposits which were measured at fair value using Level 2 inputs and their carrying values were approximately equal to their fair values. Level 2 inputs, obtained from various third-party data providers, represent quoted prices for similar assets in active markets, or these inputs were derived from observable market data, or if not directly observable, were derived from or corroborated by other observable market data.

Other current assets recorded at fair value on a recurring basis are composed of investments held in a rabbi trust related to deferred compensation arrangements. Quoted prices for these investments, primarily in mutual funds, are available in active markets. Thus, the Company’s investments related to deferred compensation arrangements are classified as Level 1 measurements in the fair value hierarchy.

The Company transfers its financial assets and liabilities between the fair value hierarchies at the end of each reporting period. There were no transfers between the different levels of the fair value hierarchy in 2016 or 2015.
Assets and liabilities measured at fair value on a recurring basis

The following table sets forth the Company’s financial assets and liabilities at fair value on a recurring basis as of September 30, 2016 and December 31, 2015 (in thousands):

<table>
<thead>
<tr>
<th>September 30, 2016</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bank time deposits</td>
<td>$ —</td>
<td>$ 2,504</td>
<td>$ —</td>
<td>$ 2,504</td>
</tr>
<tr>
<td>Money market funds</td>
<td>430,000</td>
<td>—</td>
<td>—</td>
<td>430,000</td>
</tr>
<tr>
<td>Other current assets</td>
<td>2,740</td>
<td>—</td>
<td>—</td>
<td>2,740</td>
</tr>
<tr>
<td><strong>Total assets at fair value</strong></td>
<td>$ 432,740</td>
<td>$ 2,504</td>
<td>—</td>
<td>$ 435,244</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>December 31, 2015</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bank time deposits</td>
<td>$ —</td>
<td>$ 1,000</td>
<td>$ —</td>
<td>$ 1,000</td>
</tr>
<tr>
<td>Money market funds</td>
<td>280,053</td>
<td>—</td>
<td>—</td>
<td>280,053</td>
</tr>
<tr>
<td>Other current assets</td>
<td>773</td>
<td>—</td>
<td>—</td>
<td>773</td>
</tr>
<tr>
<td><strong>Total assets at fair value</strong></td>
<td>$ 280,826</td>
<td>$ 1,000</td>
<td>—</td>
<td>$ 281,826</td>
</tr>
</tbody>
</table>

NOTE 12 – COMMITMENTS AND CONTINGENCIES

Lease Obligations

The Company has the following lease agreements in place for real properties:

<table>
<thead>
<tr>
<th>Location</th>
<th>Approximate Square Footage</th>
<th>Lease Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dublin, Ireland</td>
<td>18,900</td>
<td>November 3, 2029</td>
</tr>
<tr>
<td>Lake Forest, Illinois (1)</td>
<td>160,000</td>
<td>March 31, 2024</td>
</tr>
<tr>
<td>Deerfield, Illinois (2)</td>
<td>53,500</td>
<td>June 30, 2018</td>
</tr>
<tr>
<td>Brisbane, California (3)</td>
<td>20,100</td>
<td>November 30, 2019</td>
</tr>
<tr>
<td>Mannheim, Germany</td>
<td>14,300</td>
<td>December 31, 2018</td>
</tr>
<tr>
<td>Chicago, Illinois</td>
<td>6,500</td>
<td>December 31, 2018</td>
</tr>
<tr>
<td>Reinach, Switzerland</td>
<td>3,500</td>
<td>May 31, 2020</td>
</tr>
</tbody>
</table>

(1) In connection with the Lake Forest, Illinois lease, the Company has provided a $2.1 million letter of credit to the landlord, through a commercial bank. The Company has two separate lease agreements in place for this property, one of which, consisting of approximately 15,000 square feet, was assumed by the Company as a result of its acquisition of Crealta in January 2016 and will expire on October 31, 2017.

(2) The Company vacated the premises in Deerfield, Illinois in January 2016.

(3) The Company vacated the premises in Brisbane, California in December 2015 and entered into a sublease agreement for the property with Raptor in January 2016. See Note 3 for details of the Company’s acquisition of Raptor in October 2016. Since the closing of the Raptor acquisition, this sublease has been between subsidiaries of the Company and the premises are no longer considered vacated.

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 an initial five years from the date of first launch of RAYOS/LODOTRA in a major country, as defined in the agreement, which was April 2009. Thereafter, the agreement automatically renews on a yearly basis until either party provides two years advance written notice of termination. In April 2016 the agreement automatically renewed, therefore the earliest the agreement can expire according to this advance notice procedure is April 15, 2019, and the minimum purchase commitment is in force until April 2019. At September 30, 2016, the minimum purchase commitment based on tablet pricing in effect under the agreement was $2.1 million through April 2019.
In May 2011, the Company entered into a manufacturing and supply agreement with Sanofi-Aventis U.S. LLC (“Sanofi-Aventis U.S.”), and 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 (“EU”) member states and Scandinavia. At September 30, 2016, the Company had a binding purchase commitment to Sanofi-Aventis U.S. for DUEXIS of $4.6 million, which is to be delivered through December 2016.

In July 2013, Vidara and Boehringer Ingelheim RCV GmbH & Co. KG (“Boehringer Ingelheim”) entered into an exclusive supply agreement, which the Company assumed as a result of the Vidara Merger and amended effective as of June 1, 2015. Under the agreement, Boehringer Ingelheim is required to manufacture and supply interferon gamma-1b (ACTIMMUNE) to the Company. The Company is required to purchase minimum quantities of finished medicine per annum through July 2020. As of September 30, 2016, the minimum binding purchase commitment to Boehringer Ingelheim was $13.7 million (converted using a Euro-to-Dollar exchange rate of 1.1240) through July 2020.

In October 2016, the Company committed to purchase additional units of ACTIMMUNE from Boehringer Ingelheim in 2017 at a cost of $7.3 million (converted using a Euro-to-Dollar exchange rate of 1.1240). These additional units of ACTIMMUNE are intended to cover anticipated demand if the results of the STEADFAST study of ACTIMMUNE for the treatment of FA are successful and the Company subsequently receives U.S. marketing approval for FA. Top-line results from the study are expected in late December 2016, and if the trial is not successful, the Company may have excess ACTIMMUNE inventory and/or purchase commitments.

In November 2013, the Company entered into a long-term manufacturing services and product agreement with Patheon Pharmaceuticals Inc. (“Patheon”) pursuant to which Patheon is obligated to manufacture VIMOVO for the Company through December 31, 2019. The Company agreed to purchase a specified percentage of VIMOVO requirements for the United States from Patheon. The Company must pay an agreed price for final, packaged VIMOVO supplied by Patheon as set forth in the Patheon manufacturing agreement, subject to adjustments, including certain unilateral adjustments by Patheon, such as annual adjustments for inflation and adjustments to account for certain increases in the cost of components of VIMOVO other than active materials. The Company issues 12-month forecasts of the volume of VIMOVO that the Company expects to order. The first six months of the forecast are considered binding firm orders. At September 30, 2016, the Company had a binding purchase commitment with Patheon for VIMOVO of $0.5 million through December 2016.

In October 2014, in connection with the acquisition of the U.S. rights to PENNSAID 2% from Nuvo, the Company and Nuvo entered into an exclusive supply agreement, which was amended in February 2016. Under the supply agreement, Nuvo is obligated to manufacture and supply PENNSAID 2% to the Company. The term of the supply agreement is through December 31, 2029, but the agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party. At least 90 days prior to the first day of each calendar month during the term of the supply agreement, the Company submits a binding written purchase order to Nuvo for PENNSAID 2% in minimum batch quantities. At September 30, 2016, the Company had a binding purchase commitment with Nuvo for PENNSAID 2% of $3.9 million through December 2016.

Purchase orders relating to the manufacture of RAVICTI and BUPHENYL of $3.6 million were outstanding at September 30, 2016.
In March 2007, Savient Pharmaceuticals, Inc. (as predecessor in interest to Crealta), entered into a commercial supply agreement with Bio-Technology General (Israel) Ltd (“BTG Israel”) for the production of the bulk KRYSTEXXA medicine (“bulk product”). The Company assumed this agreement as part of the Crealta acquisition and amended the agreement in September 2016 (the “September 2016 Amendment”). Under this agreement, the Company has agreed to purchase certain minimum annual order quantities and is obligated to purchase at least 80 percent of its annual world-wide bulk product requirements from BTG Israel. The term of the agreement runs until December 31, 2030, and will automatically renew for successive three year periods unless earlier terminated by either party upon three years prior written notice. The agreement may be terminated earlier by either party in the event of a force majeure, liquidation, dissolution, bankruptcy or insolvency of the other party, uncured material breach by the other party or after January 1, 2024, upon three years prior written notice. Under the agreement if the manufacture of the bulk product is moved out of Israel, the Company may be required to obtain the approval of the Israeli Office of the Chief Scientist (“OCS”) because certain KRYSTEXXA intellectual property was initially developed with a grant funded by the OCS and the Company may be required to pay the OCS additional amounts as a repayment for the OCS grant funding. In December 2015, Crealta received a notice of termination from BTG Israel and, as of the Crealta acquisition date, it had been considered probable that the manufacture of the KRYSTEXXA bulk product would be moved outside of Israel and the Company would have been required to pay additional amounts estimated at approximately $6.9 million. This estimated obligation was recorded as an assumed contingent liability as of the Crealta acquisition date (see Note 3 for further details) and was included in “Other long-term liabilities” in the condensed consolidated balance sheet. Following the execution of the September 2016 Amendment, the Company determined it would not move the manufacture of the KRYSTEXXA bulk product outside of Israel, and released the $6.9 million assumed contingent liability to “Other income (expense)” in the condensed consolidated statement of comprehensive loss during the three months ended September 30, 2016. The Company issues 18-month forecasts of the volume of KRYSTEXXA that the Company expects to order. The first six months of the forecast are considered binding firm orders. At September 30, 2016, the Company had a binding purchase commitment with BTG Israel for KRYSTEXXA of $0.2 million through December 2016, and $5.0 million per annum thereafter.

Royalty Agreements

RAYOS/LODOTRA

In connection with an August 2004 development and license agreement with SkyePharma AG, who subsequently entered into a business combination with Tribute Pharmaceuticals Canada Inc. to become known as Anlez Pharmaceuticals Inc. (“Anlez”), under this agreement, the Company is required to pay Anlez a flat 10% royalty on net sales of VIMOVO and other medicines sold by the Company, its affiliates or sublicensees during the royalty term that contain gastroprotective agents in a single fixed combination oral solid dosage form with nonsteroidal anti-inflammatory drugs, subject to minimum annual royalty obligations of $7.5 million. These minimum royalty obligations will continue for each year during which one of Anlez’s patents covers such medicines in the United States and there are no competing medicines in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing medicines. The Company’s obligation to pay royalties to Anlez will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such medicines in the United States, and (b) ten years after the first commercial sale of such medicines in the United States.

VIMOVO

The Company entered into a license agreement with Pozen Inc., who subsequently entered into a business combination with Tribute Pharmaceuticals Canada Inc. to become known as Anlez Pharmaceuticals Inc. (“Anlez”). Under this agreement, the Company is required to pay Anlez a flat 10% royalty on net sales of VIMOVO and other medicines sold by the Company, its affiliates or sublicensees during the royalty term that contain gastroprotective agents in a single fixed combination oral solid dosage form with nonsteroidal anti-inflammatory drugs, subject to minimum annual royalty obligations of $7.5 million. These minimum royalty obligations will continue for each year during which one of Anlez’s patents covers such medicines in the United States and there are no competing medicines in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing medicines. The Company’s obligation to pay royalties to Anlez will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such medicines in the United States, and (b) ten years after the first commercial sale of such medicines in the United States.

ACTIMMUNE

Under a license agreement, as amended, with Genentech Inc. (“Genentech”), who was the original developer of ACTIMMUNE, the Company is or was obligated to pay royalties to Genentech on its net sales of ACTIMMUNE as follows:

- Through November 25, 2014, a royalty of 45% of the first $3.7 million in net sales achieved in a calendar year, and 10% on all additional net sales in that year;
- For the period from November 26, 2014 through May 5, 2018, a royalty in the 20% to 30% range for the first tier in net sales and in the 1% to 9% range for the second tier; and
- From May 6, 2018 and for so long as the Company continues to commercially sell ACTIMMUNE, an annual royalty in the low single digits as a percentage of annual net sales.

21
Under the terms of an assignment and option agreement with Connetics, the Company is obligated to pay royalties to Connetics on the Company’s net sales of ACTIMMUNE as follows:

- 0.25% of net sales of ACTIMMUNE, rising to 0.5% once cumulative net sales of ACTIMMUNE in the United States surpass $1.0 billion; and
- in the event the Company develops and receives regulatory approval for ACTIMMUNE in the indication of scleroderma, the Company will be obligated to pay a royalty of 4% on all net sales of ACTIMMUNE recorded for use in that indication.

RAVICTI

Under the terms of an asset purchase agreement with Ucyclyd, the Company is obligated to pay to Ucyclyd tiered mid to high single-digit royalties on its global net sales of RAVICTI. Under the terms of a license agreement with Brusilow, the Company is obligated to pay low single-digit royalties to Brusilow on net sales of RAVICTI that are covered by a valid claim of a licensed patent.

BUPHENYL

Under the terms of an amended and restated collaboration agreement with Ucyclyd, the Company is obligated to pay to Ucyclyd tiered mid to high single-digit royalties on its net sales in the United States of BUPHENYL to urea cycle disorder patients outside of the U.S. Food and Drug Administration (“FDA”) approved labeled age range for RAVICTI.

KRISTEXXA

Under the terms of a license agreement with Duke and MVP, the Company is obligated to pay Duke a mid-single digit royalty on its global net sales of KRISTEXXA and a low-double digit royalty on any global sublicense revenue. The Company is also obligated to pay MVP a mid-single digit royalty on its net sales of KRISTEXXA outside of the United States and a low-double digit royalty on any sublicense revenue outside of the United States.

The royalty obligations described above are included in accrued royalties on the Company’s condensed consolidated balance sheets.

For all of the royalty agreements entered into by the Company, a total expense of $11.2 million and $32.6 million was recorded in cost of goods sold for the three and nine months ended September 30, 2016, respectively. The total expense recorded in cost of goods sold for the three and nine months ended September 30, 2015 was $6.6 million and $28.0 million, 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. In addition, the Company from time to time has billing disputes with vendors in which amounts invoiced are not in accordance with the terms of their contracts.

In November 2015, Express Scripts filed suit against the Company in Delaware Superior Court, Newcastle County, asserting claims for breach of contract, breach of the implied covenant of good faith and fair dealing, unjust enrichment, and declaratory relief arising from the parties’ 2012 Preferred Savings Grid Rebate Program Agreement. The Company filed a counter-claim against Express Scripts for breach of contract, breach of the implied covenant of good faith and fair dealing, and declaratory relief arising from Express Scripts’ breach of the rebate agreement. In September 2016, the Company entered into a settlement agreement and mutual release with Express Scripts pursuant to which the Company and Express Scripts were released from any and all claims relating to the litigation without admitting any fault or wrongdoing and the Company agreed to pay Express Scripts $65.0 million. The settlement amount will be paid to Express Scripts in installments, with 50 percent of the installment due in the fourth quarter of 2016, 25 percent in the first quarter of 2017 and 25 percent in the second quarter of 2017. The full amount of this settlement has been accounted for as a reduction of “net sales” in the condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2016.

In November 2015, the Company received a subpoena from the U.S. Attorney’s Office for the Southern District of New York requesting documents and information related to its patient access programs and other aspects of its marketing and commercialization activities. The Company is unable to predict how long this investigation will continue or its outcome, but it anticipates that it may incur significant costs in connection with the investigation, regardless of the outcome. The Company may also become subject to similar investigations by other governmental agencies. The investigation by the U.S. Attorney’s Office and any additional investigations of the Company’s patient access programs and sales and marketing activities may result in damages, fines, penalties or other administrative sanctions against the Company.

22
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. In connection with the federal securities class action litigation (described in Note 13 below), the Company has received notice from the Underwriter Defendants (as defined below) of their intention to seek indemnification and has received, but not yet paid, several invoices from the Underwriter Defendants. The Company may record charges in the future as a result of these indemnification obligations.

In accordance with its memorandum and articles of association, 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 into, 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. In connection with the federal securities class action litigation (described in Note 13 below), the Company has paid legal fees and costs on behalf of itself and the current and former officers and directors of the Company who are named as defendants in that litigation. The Company also has a director and officer insurance policy that enables it to recover a portion of any amounts paid for future potential claims. Certain of the Company’s officers and directors had also entered into separate indemnification agreements with HPI prior to the Vidara Merger.

NOTE 13 – LEGAL PROCEEDINGS

On July 15, 2013, the Company received a Paragraph IV Patent Certification from Watson Laboratories, Inc.—Florida, known as Actavis Laboratories FL, Inc. (“Actavis FL”), advising that Actavis FL had filed an Abbreviated New Drug Application (“ANDA”) with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. On August 26, 2013, the Company, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Actavis FL, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc. seeking an injunction to prevent the approval of the ANDA.

On October 1, 2015, the Company’s subsidiary Horizon Pharma Switzerland GmbH, as well as Jagotec, entered into a license and settlement agreement (the “Actavis settlement agreement”) with Actavis FL relating to the Company’s and Jagotec’s patent infringement litigation against Actavis FL. In accordance with legal requirements, the Company, Jagotec and Actavis FL agreed to submit the Actavis settlement agreement to the U.S. Federal Trade Commission (“FTC”) and the U.S. Department of Justice (“DOJ”) for review. The parties submitted the Actavis settlement agreement to the FTC and DOJ for review and no issues were raised by either. The parties agreed to file stipulations of dismissal with the court regarding the litigation and the court entered the stipulation and closed the case on December 4, 2015. The Actavis settlement agreement provides for a full settlement and release by each party of all claims that relate to the litigation or under the patents with respect to Actavis FL’s generic version of RAYOS tablets.

Under the Actavis settlement agreement, the Company and Jagotec granted Actavis FL a non-exclusive license to manufacture and commercialize Actavis FL’s generic version of RAYOS tablets in the United States after the generic entry date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Actavis FL’s generic version of RAYOS tablets during certain limited periods prior to the generic entry date. The Company and Jagotec also agreed that during the 180 days after the generic entry date, the license granted to Actavis FL would be exclusive with respect to any third-party generic version of RAYOS tablets.

Under the Actavis settlement agreement, the generic entry date is December 23, 2022; however, Actavis FL may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party RAYOS patent litigation, the entry of other generic versions of RAYOS tablets or certain substantial reductions in RAYOS prescriptions over specified periods of time.

The Company and Jagotec also agreed not to sue or assert any claim against Actavis FL for infringement of any patent or patent application owned or controlled by the Company or Jagotec during the term of the Actavis settlement agreement based on Actavis FL’s generic version of RAYOS tablets in the United States. In turn, Actavis FL agreed not to challenge the validity or enforceability of the licensed patents.

If the Company or Jagotec enter into any similar agreements with other parties with respect to generic versions of RAYOS tablets, the Company and Jagotec agreed to amend the Actavis settlement agreement to provide Actavis FL with terms that are no less favorable than those provided to such other parties with respect to the license terms, generic entry date, permitted pre-market activities and notice provisions.
On November 13, 2014, the Company received a Paragraph IV Patent Certification from Watson Laboratories, Inc. ("Watson Laboratories") advising that Watson Laboratories had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On December 23, 2014, the Company filed suit in the United States District Court for the District of New Jersey against Watson Laboratories, Actavis, Inc., and Actavis plc (collectively "Actavis") seeking an injunction to prevent the approval of the ANDA. Since then, Watson Laboratories, Inc. changed its name to Actavis Laboratories UT, Inc., and remains the current holder of the ANDA. The lawsuit alleged that Actavis had infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market a generic version of PENNSAID 2% prior to the expiration of certain of the Company’s patents listed in the FDA’s Orange Book ("Orange Book"). The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Actavis’ ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid.

On June 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patent No. 9,066,913. On August 11, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patent No. 9,101,591. On September 17, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patent No. 9,132,110. All three patents, U.S. Patent Nos. 9,066,913, 9,101,591, and 9,132,110 are listed in the Orange Book and have claims that cover PENNSAID 2%. These three cases have since been consolidated with the case filed against Actavis on December 23, 2014.

On October 27, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patent Nos. 9,168,304 and 9,168,305. On February 5, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patent No. 9,220,784. All three patents, U.S. Patent Nos. 9,168,304, 9,168,305, and 9,220,784 are listed in the Orange Book and have claims that cover PENNSAID 2%.

On August 18, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patent Nos. 9,339,551, 9,339,552, 9,370,501, and 9,375,412. All four patents, U.S. Patent Nos. 9,339,551, 9,339,552, 9,370,501, and 9,375,412, are listed in the Orange Book and have claims that cover PENNSAID 2%. All of the litigation against Actavis remains pending. No trial date for any of the Actavis actions has been set by the court.

The Company received from Actavis a Paragraph IV Patent Certification Notice Letter dated September 27, 2016, against Orange Book listed U.S. Patent Nos. 9,415,029, advising that Actavis had filed an ANDA with the FDA for a generic version of PENNSAID 2%.

On December 2, 2014, the Company received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,741,956 from Paddock Laboratories, LLC ("Paddock") advising that Paddock had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On January 9, 2015, the Company received from Paddock another Paragraph IV Patent Certification against newly Orange Book listed U.S. Patent No. 8,871,809. On January 13, 2015 and January 14, 2015, the Company filed suits in the United States District Court for the District of New Jersey and the United States District Court for the District of Delaware, respectively, against Paddock seeking an injunction to prevent the approval of the ANDA. The lawsuits alleged that Paddock has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of certain of the Company’s patents listed in the Orange Book.

On May 6, 2015, the Company entered into a settlement and license agreement (the “Perrigo settlement agreement”) with Perrigo Company plc and its subsidiary Paddock (collectively, “Perrigo”), relating to the Company’s patent infringement litigation against Perrigo. The Perrigo settlement agreement provides for a full settlement and release by both the Company and Perrigo of all claims that were or could have been asserted in the litigation and that arise out of the issues that were the subject of the litigation or Perrigo’s generic version of PENNSAID 2%. The Perrigo settlement agreement also contemplated the filing of a joint stipulation of dismissal by the parties. This stipulation of dismissal was entered by the district court on May 13, 2015.

Under the Perrigo settlement agreement, the Company granted Perrigo a non-exclusive license to manufacture and commercialize Perrigo’s generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Perrigo’s generic version of PENNSAID 2% during certain limited periods prior to the license effective date.

Under the Perrigo settlement agreement, the license effective date is January 10, 2029; however, Perrigo may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in the Company’s PENNSAID 2% shipments over specified periods of time.
Under the Perrigo settlement agreement, the Company also agreed not to sue or assert any claim against Perrigo for infringement of any patent or patent application owned or controlled by the Company during the term of the license granted in the Perrigo settlement agreement based on the manufacture, use, sale, offer for sale, or importation of Perrigo’s generic version of PENNSAID 2% in the United States.

In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, the Company may be required to supply Perrigo PENNSAID 2% as its authorized distributor of generic PENNSAID 2%, with the Company receiving specified percentages of any net sales by Perrigo. The Company also agreed that if it enters into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, the Company will amend the Perrigo settlement agreement to provide Perrigo with terms that are no less favorable than those provided to such other parties.

On February 2, 2015, the Company received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 from Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (collectively, “Taro”) advising that Taro had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On March 13, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Taro seeking an injunction to prevent the approval of the ANDA.

On September 9, 2015, certain subsidiaries of the Company (the “Horizon Subsidiaries”) entered into a settlement and license agreement with Taro (the “Taro settlement agreement”) relating to the Horizon Subsidiaries’ patent infringement litigation against Taro. In accordance with legal requirements, the Horizon Subsidiaries and Taro submitted the Taro settlement agreement to the FTC and DOJ for review, and no issues have been raised by the FTC and DOJ. The Horizon Subsidiaries and Taro have also filed stipulations of dismissal with the courts regarding the litigation, with these dismissals being entered by the district court on November 3, 2015. The Taro settlement agreement provides for a full settlement and release by both us and Taro of all claims that were or could have been asserted in the Litigation and that arise out of the issues that were subject of the litigation or Taro’s generic version of PENNSAID 2%.

Under the Taro settlement agreement, the Horizon Subsidiaries granted Taro a non-exclusive license to manufacture and commercialize Taro’s generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Taro’s generic version of PENNSAID 2% during certain limited periods prior to the license effective date.

Under the Taro settlement agreement, the license effective date is January 10, 2029; however, Taro may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in the Company’s PENNSAID 2% shipments over specified periods of time.

Under the Taro settlement agreement, the Horizon Subsidiaries also agreed not to sue or assert any claim against Taro for infringement of any patent or patent application owned or controlled by the Horizon Subsidiaries during the term of the license granted in the Taro settlement agreement based on the manufacture, use, sale, offer for sale, or importation of Taro’s generic version of PENNSAID 2% in the United States.

The Horizon Subsidiaries also agreed that if they enter into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, the Horizon Subsidiaries will amend the Taro settlement agreement to provide Taro with terms that are no less favorable than those provided to the other parties.

On March 18, 2015, the Company received a Paragraph IV Patent Certification against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 from Lupin Limited advising that Lupin Limited had filed an ANDA with the FDA for generic version of PENNSAID 2%. On April 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Lupin Limited and Lupin Pharmaceuticals Inc. (collectively, “Lupin”), seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Lupin has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of certain of the Company’s patents listed in the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Lupin’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid.

On June 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patent No. 9,066,913. On August 11, 2015, the Company filed an amended complaint in the United States District Court for the District of New Jersey against Lupin that added U.S. Patent No. 9,101,591 to the litigation with respect to U.S. Patent No. 9,066,913. On September 17, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patent No. 9,132,110. All three patents, U.S. Patent Nos. 9,066,913, 9,101,591, and 9,132,110 are listed in the Orange Book and have claims that cover PENNSAID 2%.
On October 27, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patent Nos. 9,066,913. On August 11, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent No. 9,101,591. On September 17, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent No. 9,132,110. All three patents, U.S. Patent Nos. 9,066,913, 9,101,591, and 9,132,110 are listed in the Orange Book and have claims that cover PENNSAID 2%. All of the infringement actions brought against Lupin remain pending. The court has not yet set a trial date for the Lupin actions.

On June 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent No. 9,066,913. On August 11, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent No. 9,101,591. On September 17, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent No. 9,132,110. All three patents, U.S. Patent Nos. 9,066,913, 9,101,591, and 9,132,110 are listed in the Orange Book and have claims that cover PENNSAID 2%.

On October 27, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent Nos. 9,168,304 and 9,168,305. On February 5, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent No. 9,220,784. On August 18, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patent No. 9,220,784. All seven patents, U.S. Patent Nos. 9,168,304, 9,168,305, 9,220,784, 9,339,551, 9,339,552, 9,370,501, and 9,375,412 are listed in the Orange Book and have claims that cover PENNSAID 2%. All of the infringement actions brought against Teligent remain pending. The court has not yet set a trial date for the Teligent actions.

The Company entered into a settlement and license agreement with Teligent (the “Teligent settlement agreement”), effective May 9, 2016, relating to the patent infringement litigation against Teligent. In accordance with legal requirements, the Company and Teligent submitted the Teligent settlement agreement to the FTC and DOJ for review, and no issues have been raised by the FTC and DOJ. The Company and Teligent have also filed stipulations of dismissal with the district court regarding the litigation, with these dismissals having been entered by the district court on May 2, 2016. The Teligent settlement agreement provides for a full settlement and release by both the Company and Teligent of all claims that were or could have been asserted in the litigation and that arise out of the issues that were subject of the litigation or Teligent’s generic version of PENNSAID 2%.

Under the Teligent settlement agreement, the Company granted Teligent a non-exclusive license to manufacture and commercialize Teligent’s generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Teligent’s generic version of PENNSAID 2% during certain limited periods prior to the license effective date.

Under the Teligent settlement agreement, the license effective date is January 10, 2029; however, Teligent may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in the Company’s PENNSAID 2% shipments over specified periods of time.

Under the Teligent settlement agreement, the Company also agreed not to sue or assert any claim against Teligent for infringement of any patent or patent application owned or controlled by the Company during the term of the license granted in the Teligent settlement agreement based on the manufacture, use, sale, offer for sale, or importation of Teligent’s generic version of PENNSAID 2% in the United States.

In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, the Company may be required to supply Teligent PENNSAID 2% as an authorized distributor of generic PENNSAID 2%, with the Company receiving specified percentages of any net sales by Teligent. The Company also agreed that if it enters into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, the Company will amend the Teligent settlement agreement to provide Teligent with terms that are no less favorable than those provided to the other parties.
The Company received from Amneal Pharmaceuticals LLC ("Amneal") a Paragraph IV Patent Certification dated April 2, 2015 against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 advising that Amneal had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On May 15, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Amneal has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of certain of the Company’s patents listed in the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Amneal’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid.

On June 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent No. 9,066,913. On August 11, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent No. 9,101,591. On September 17, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent No. 9,132,110. All three patents, U.S. Patent Nos. 9,066,913, 9,101,591, and 9,132,110 are listed in the Orange Book and have claims that cover PENNSAID 2%.

On October 27, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent Nos. 9,168,304 and 9,168,305. On February 5, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent No. 9,220,784. All three patents, U.S. Patent Nos. 9,168,304, 9,168,305, and 9,220,784 are listed in the Orange Book and have claims that cover PENNSAID 2%.

On April 18, 2016, the Company entered into a settlement and license agreement (the “Amneal settlement agreement”) with Amneal relating to the Company’s patent infringement litigation against Amneal. In accordance with legal requirements, the Company and Amneal submitted the Amneal settlement agreement to the FTC and DOJ for review, and no issues have been raised by the FTC and DOJ. The Company and Amneal have also filed a stipulation of dismissal with the court regarding the litigation. The Amneal settlement agreement provides for a full settlement and release by both the Company and Amneal of all claims that were or could have been asserted in the litigation and that arise out of the issues that were the subject of the litigation or Amneal’s generic version of PENNSAID 2%.

Under the Amneal settlement agreement, the Company granted Amneal a non-exclusive license to manufacture and commercialize Amneal’s generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Amneal’s generic version of PENNSAID 2% during certain limited periods prior to the license effective date.

Under the Amneal settlement agreement, the license effective date is January 10, 2029; however, Amneal may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation or the entry of other third-party generic versions of PENNSAID 2%.

Under the Amneal settlement agreement, the Company also agreed not to sue or assert any claim against Amneal for infringement of any patent or patent application owned or controlled by the Company during the term of the license granted in Amneal settlement agreement based on the manufacture, use, sale, offer for sale, or importation of Amneal’s generic version of PENNSAID 2% in the United States.

In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, the Company may be required to supply Amneal PENNSAID 2% as a non-exclusive, authorized distributor of generic PENNSAID 2%, with the Company receiving specified percentages of any net sales by Amneal. The Company also agreed that if it enters into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, the Company will amend the Amneal settlement agreement to provide Amneal with terms that are no less favorable than those provided to the other parties.

The Company received from Apotex Inc. (“Apotex”) a Paragraph IV Patent Certification Notice Letter dated April 1, 2016, against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, 8,871,809, 9,066,913, 9,101,591, 9,132,110, 9,168,304, 9,168,305 and 9,220,784 advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%. The Company also received from Apotex a second Paragraph IV Patent Certification Notice Letter dated June 30, 2016, against Orange Book listed U.S. Patent Nos. 9,339,551 and 9,339,552, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%. The Company also received from Apotex a third Paragraph IV Patent Certification Notice Letter dated September 21, 2016, against Orange Book listed U.S. Patent No. 9,415,029, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%.
Currently, patent litigation is pending in the United States District Court for the District of New Jersey against four generic companies intending to market VIMOVO prior to the expiration of certain of the Company’s patents listed in the Orange Book. These cases are in the United States District Court for the District of New Jersey. They are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy’s Laboratories Inc. and Dr. Reddy’s Laboratories Ltd. (collectively, “Dr. Reddy’s”); (ii) Lupin; (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, “Mylan”); and (iv) Actavis FL and Actavis Pharma, Inc. (collectively, “Actavis Pharma”). Patent litigation in the United States District Court for the District of New Jersey against a fifth generic company, Anchen Pharmaceuticals Inc. (“Anchen”), was dismissed on June 9, 2014 after Anchen recertified under Paragraph III. The Company understands that Dr. Reddy’s has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy’s is now able to commercialize VIMOVO under AstraZeneca’s Nexium patent rights. The settlement agreement, however, has no effect on the AraZeal VIMOVO patents, which are still the subject of patent litigations. As part of the Company’s acquisition of the U.S. rights to VIMOVO, the Company has taken over and is responsible for the patent litigations that include the AraZeal patents licensed to the Company under the amended and restated collaboration and license agreement for the United States with AraZeal.

The VIMOVO cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, January 4, 2013, May 10, 2013, June 28, 2013, October 23, 2013, May 13, 2015 and November 24, 2015 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907, 8,557,285, 8,852,636, and 8,858,996 (the “’996 patent”). On June 18, 2015, the Company amended the complaints to add a charge of infringement of U.S. Patent No. 8,865,190 (the “’190 patent”). On January 7, 2016, Actavis Pharma asserted a counterclaim for declaratory judgment of invalidity and non-infringement of U.S. Patent No. 8,945,621 (the “’621 patent”). On January 25, 2016, the Company filed a new case against Actavis Pharma including allegations of infringement of U.S. Patent Nos. 9,161,920 and 9,198,888. This case was subsequently consolidated with the Actavis Pharma case involving the ’996 patent, the ’190 patent and U.S. Patent No. 8,852,636. On August 10, 2016, the Company amended the complaints against Dr. Reddy’s, Lupin, and Mylan to add charges of infringement of U.S. Patent Nos. 9,161,920 and 9,198,888. On February 19, 2016, Mylan asserted a counterclaim for declaratory judgment of invalidity and non-infringement of U.S. Patent No. 9,220,698. On August 11, 2016, the Company filed new complaints asserting the ’621 patent and U.S. Patent Nos. 9,220,698, and 9,345,695 against the defendants.

The cases asserting U.S. Patent Nos. 8,557,285 and 6,926,907 have been consolidated for discovery. The court has issued a claim construction order for these cases and set a trial date for December 7, 2016. On May 12, 2016, the court granted Dr. Reddy’s motion for summary judgment of non-infringement of U.S. Patent No. 6,926,907 with respect to one of Dr. Reddy’s two ANDAs.

The cases asserting the ’996 patent, the ’190 patent and U.S. Patent Nos. 8,852,636, 9,161,920 and 9,198,888 have been consolidated for discovery. The court has not issued a claim construction order or set a pretrial schedule.

On August 23, 2016, the court entered an order denying Mylan’s motion to consolidate the cases asserting U.S. Patent Nos. 8,557,285 and 6,926,907 (“Case I”) with the cases asserting the ’996 patent, the ’190 patent and U.S. Patent Nos. 8,852,636, 9,161,920, and 9,198,888 (“Case II”). The court ordered the parties to submit a proposed scheduling order for Case II no later than 14 days from the date of the order denying the motion to consolidate. On September 9, 2016, the VIMOVO Generics proposed a schedule for Case II while plaintiffs are seeking a stay of Case I at trial.

The Company understands the cases arise from Paragraph I Patent Certification notice letters providing notice of the filing of ANDAs with the FDA seeking regulatory approval to market generic versions of VIMOVO before the expiration of the patent-in-suit. The Company understands the Dr. Reddy’s notice letters were dated March 11, 2011, November 20, 2012 and April 20, 2015; the Lupin notice letters were dated June 10, 2011 and March 12, 2014; the Mylan notice letters were dated May 16, 2013, February 9, 2015, January 26, 2016, February 26, 2016, July 19, 2016 and September 22, 2016; the Actavis Pharma notice letters were dated March 29, 2013, November 5, 2013, October 9, 2015, December 10, 2015, March 1, 2016, April 6, 2016, July 22, 2016 and September 8, 2016; and the Anchen notice letter was dated September 16, 2011.

On February 24, 2015, Dr. Reddy’s filed a Petition for inter partes review (“IPR”) of U.S. Patent No. 8,557,285, one of the patents in litigation in the above referenced VIMOVO cases. On October 9, 2015, the United States Patent and Trademark Office (the “U.S. PTO”) denied such Petition for IPR.

On May 21, 2015, the Coalition for Affordable Drugs VII LLC (“Coalition for Affordable Drugs”) filed a Petition for IPR of U.S. Patent No. 6,926,907, one of the patents in litigation in the above referenced VIMOVO cases. On December 8, 2015, the U.S. PTO denied such Petition for IPR.

On June 5, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of the ’996 patent, one of the patents in litigation in the above referenced VIMOVO cases. On December 17, 2015, the U.S. PTO denied such Petition for IPR.
On August 7, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of U.S. Patent No. 8,852,636, one of the patents in litigation in the above referenced VIMOVO cases. On February 11, 2016, the U.S. PTO denied such Petition for IPR.

On August 12, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of the '621 patent, one of the patents in litigation in the above referenced VIMOVO cases. On February 22, 2016, the Patent Trial and Appeal Board (the “PTAB”) issued a decision to institute the IPR. The PTAB hearing for the '621 patent is set for November 16, 2016. The PTAB must issue a final written decision on the IPR of the '621 patent no later than February 22, 2017.

On August 19, 2015, Lupin filed Petitions for IPR of the '996 patent, the '190 patent and U.S. Patent No. 8,852,636, all patents in litigation in the above referenced VIMOVO cases. On March 1, 2016, the PTAB issued decisions to institute the IPRs for the '996 patent” and the '190 patent. On March 1, 2016, the PTAB denied the Petition for IPR for U.S. Patent No. 8,852,636. The PTAB hearings for the '996 patent and '190 patent are set for November 29, 2016. The PTAB must issue a final written decision on the IPRs of the '996 patent and the ’190 patent no later than March 1, 2017.

On March 17, 2014, Hyperion received notice from Par Pharmaceutical, Inc. (“Par Pharmaceutical”) that it had filed an ANDA with the FDA seeking approval for a generic version of the Company’s medicine RAVICTI. The ANDA contained a Paragraph IV Patent Certification alleging that two of the patents covering RAVICTI, U.S. Patent No. 8,404,215, titled “Methods of therapeutic monitoring of nitrogen scavenging drugs,” which expires in March 2032 (the “'215 patent”), and U.S. Patent No. 8,642,012, titled “Methods of treatment using ammonia scavenging drugs,” which expires in September 2030 (the “'012 patent”), are invalid and/or will not be infringed by Par Pharmaceutical’s manufacture, use or sale of the medicine for which the ANDA was submitted. Par Pharmaceutical did not challenge the validity, enforceability, or infringement of the Company’s primary composition of matter patent for RAVICTI, U.S. Patent No. 5,968,979 titled “Triglycerides and ethyl esters of phenylalkanoic acid and phenylalkanoic acid useful in treatment of various disorders,” which would have expired on February 7, 2015, but as to which Hyperion was granted an interim term of extension until February 7, 2016 and to which the U.S. PTO has granted a final term extension of 1,267 days. Hyperion filed suit in the United States District Court for the Eastern District of Texas, Marshall Division, against Par Pharmaceutical on April 23, 2014 seeking an injunction to prevent the approval of Par Pharmaceutical’s ANDA and/or to prevent Par Pharmaceutical from selling a generic version of RAVICTI, and the Company has taken over and is responsible for this patent litigation. On September 15, 2015, the Company received notice from Par Pharmaceutical that it had filed a Paragraph IV Patent Certification alleging that U.S. Patent No. 9,095,559 (the “'559 patent”) is invalid and/or will not be infringed by Par Pharmaceutical’s manufacture, use or sale of the medicine for which the ANDA was submitted. On March 14, 2016, the Company received notice from Par Pharmaceutical that it had filed a Paragraph IV Patent Certification alleging that U.S. Patent No. 9,254,278 (the “'278 patent”) is invalid and/or will not be infringed by Par Pharmaceutical’s manufacture, use or sale of the medicine for which the ANDA was submitted. On June 3, 2016, the Company received notice from Par Pharmaceutical that it had filed a Paragraph IV Patent Certification alleging that U.S. Patent No. 9,326,966 (the “'966 patent”) is invalid and/or will not be infringed by Par Pharmaceutical’s manufacture, use or sale of the medicine for which the ANDA was submitted. The Company filed suit in the United States District Court for the District of New Jersey against Par Pharmaceutical on June 30, 2016 (“the Par New Jersey action”), seeking an injunction to prevent the approval of Par Pharmaceutical’s ANDA and/or to prevent Par Pharmaceutical from selling a generic version of RAVICTI prior to the expiration of the patents. The subject patents are listed in the Orange Book. The court has not yet set a trial date for the Par New Jersey action.

On April 29, 2015, Par Pharmaceutical filed Petitions for IPR of the ’215 patent and the ‘012 patent. The PTAB issued decisions instituting such IPRs on November 4, 2015. On December 14, 2015, the District Court Judge Roy Payne issued a stay pending a final written decision from the PTAB with respect to the IPRs of the ’215 patent and the '012 patent. On September 29, 2016, the PTAB issued a final written decision holding all the claims of the ’215 patent unpatentable. The Company is considering whether to appeal the PTAB’s decision concerning the ’215 patent to the Federal Circuit. On November 3, 2016, the PTAB issued a final written decision holding all of the claims of the ‘012 patent patentable.

On September 4, 2015, the Company received notice from Lupin of Lupin’s Paragraph IV Patent Certification against the ‘215 patent and the ‘012 patent, advising that Lupin had filed an ANDA with the FDA for a generic version of RAVICTI. On November 6, 2015, the Company also received Notice of Lupin’s Paragraph IV Patent Certification against the ‘559 patent. Lupin has not advised the Company as to the timing or status of the FDA’s review of its filing. On October 19, 2015 the Company filed suit in the United States District Court for the District of New Jersey against Lupin seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Lupin has infringed the ‘215 patent, the ‘012 patent and the ‘559 patent by filing an ANDA seeking approval from the FDA to market generic versions of RAVICTI prior to the expiration of the patents. The subject patents are listed in the Orange Book. On April 6, 2016, the Company filed an Amended Complaint in the United States District Court for the District of New Jersey against Lupin alleging that Lupin has infringed the ‘559 patent by filing an ANDA seeking approval from the FDA to market generic versions of RAVICTI prior to expiration of the ‘559 patent. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Lupin’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. On April 18, 2016, the Company received notice from Lupin of Lupin’s Paragraph IV Patent Certification against the ‘278 patent. On July 6, 2016, the Company received notice from Lupin of Lupin’s Paragraph IV Patent Certification against the ‘966 patent. The Company filed suit in the United States District Court for the District of New Jersey against Lupin on July 21, 2016, seeking an injunction to prevent the approval of Lupin’s ANDA and/or to prevent Lupin from selling a generic version of RAVICTI. The lawsuit alleges that Lupin has infringed the ‘278 patent and the ‘966 patent by filing an ANDA seeking approval from the FDA to market generic versions of RAVICTI prior to the expiration of the patents. The subject patents are listed in the Orange Book. The court has not yet set a trial date for the Lupin New Jersey actions.

On April 1, 2016, Lupin filed a Petition to request an IPR of the ‘559 patent. On September 30, 2016, the PTAB issued a decision to institute the IPR for the ‘559 patent. The PTAB must issue a final written decision on the IPR of the ‘559 patent no later than September 30, 2017.

In November 2015, Express Scripts filed suit against the Company in Delaware Superior Court, New Castle County, asserting claims for breach of contract, breach of the implied covenant of good faith and fair dealing, unjust enrichment, and declaratory relief arising from the parties’ 2012 Preferred Savings Grid Rebate Program Agreement. The Company filed a counter-claim against Express Scripts for breach of contract, breach of the implied covenant of good faith and fair dealing, and declaratory relief arising from Express Scripts’ breach of the rebate agreement. In September 2016, the Company entered into a settlement agreement and mutual release with Express Scripts pursuant to which the Company and Express Scripts were released from any and all claims relating to the litigation without admitting any fault or wrongdoing and the Company agreed to pay Express Scripts $65.0 million.

Beginning on March 8, 2016, two federal securities class action lawsuits (captioned Schaffer v. Horizon Pharma plc, et al., Case No. 16-cv-01763-JMF and Banie v. Horizon Pharma plc, et al., Case No. 16-cv-01789-JMF) were filed in the United States District Court for the Southern District of New York against the Company and certain of the Company’s current and former officers (the “Officer Defendants”). On March 24, 2016, the court consolidated the two actions under Schaffer v. Horizon Pharma plc, et al. On March 24, 2016, the court consolidated the two actions under Schaffer v. Horizon Pharma plc, et al. On June 3, 2016, the court appointed Locals 302 and 612 of the International Union of Operating Engineers-Employers Construction Industry Retirement Trust and the Carpenters Pension Trust Fund for Northern California as lead plaintiffs and Labaton Sucharow LLP as lead counsel. On July 25, 2016, lead plaintiffs and additional named plaintiff Automotive Industries Pension Trust Fund filed their consolidated complaint, which they subsequently amended on October 7, 2016, including additional current and former officers, the Company’s Board of Directors (the “Director Defendants”), and underwriters involved with the Company’s April 2015 public offering (the “Underwriter Defendants”) as defendants. The plaintiffs allege that certain of the Company and the Officer Defendants violated sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by making false and/or misleading statements about, among other things: (a) the Company’s financial performance, (b) the Company’s business prospects and drug-pricing practices, (c) the Company’s sales and promotional practices, and (d) the Company’s design, implementation, performance, and risks associated with the Company’s Prescriptions-Made-Easy program. The plaintiffs allege that certain of the Company, the Director Defendants and the Underwriter Defendants violated sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended, (the “Securities Act”) in connection with the Company’s April 2015 public offering. The plaintiffs seek, among other things, an award of damages allegedly sustained by plaintiffs and the putative class, including a reasonable allowance for costs and attorney’s fees. The defendants’ deadline to answer or otherwise respond to the amended consolidated complaint is November 14, 2016.
Between October 5 and October 7, 2016, two complaints (captioned Lavrenov v. Raptor Pharmaceutical Corp., et al., Case No. 16-cv-00901, and Jordan v. Raptor Pharmaceutical Corp., et al., Case No. 16-cv-00913) were filed in the United States District Court for the District of Delaware. Both actions were filed against Raptor and each member of Raptor’s board of directors. The Company and Misneach Corporation, a wholly owned subsidiary of the Company, were named as defendants in the Lavrenov action, but not the Jordan action. The actions were brought by purported stockholders of Raptor, on their own behalf and as a putative class of Raptor stockholders, and assert causes of action under Sections 14 and 20 of the Securities Exchange Act of 1934, as amended. The Lavrenov action also asserts breach of fiduciary duty and aiding and abetting claims under Delaware law. The complaints allege, among other things, that the process leading up to the Raptor acquisition was inadequate and that the Schedule 14D-9 filed by Raptor with the Securities and Exchange Commission (the “SEC”) omits certain material information, which allegedly renders the information disclosed materially misleading. The complaints seek, among other things, to enjoin the Raptor acquisition, or in the event the Raptor acquisition is consummated, to recover money damages. On October 17, 2016, Raptor filed an amended Schedule 14D-9 with the SEC. Plaintiffs did not file a motion to preliminarily enjoin the Raptor acquisition, which was completed on October 25, 2016.

NOTE 14 – DEBT AGREEMENTS

The Company’s outstanding debt balances as of September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2016</th>
<th>December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015 Term Loan Facility</td>
<td>$395,000</td>
<td>$398,000</td>
</tr>
<tr>
<td>2023 Senior Notes</td>
<td>475,000</td>
<td>475,000</td>
</tr>
<tr>
<td>Exchangeable Senior Notes</td>
<td>400,000</td>
<td>400,000</td>
</tr>
<tr>
<td>Total face value</td>
<td>1,270,000</td>
<td>1,273,000</td>
</tr>
<tr>
<td>Debt discount</td>
<td>(115,615)</td>
<td>(127,885)</td>
</tr>
<tr>
<td>Deferred financing fees</td>
<td>(7,161)</td>
<td>(8,359)</td>
</tr>
<tr>
<td>Total long-term debt</td>
<td>1,147,224</td>
<td>1,136,756</td>
</tr>
<tr>
<td>Less: current maturities</td>
<td>4,000</td>
<td>4,000</td>
</tr>
<tr>
<td>Long-term debt, net of current maturities</td>
<td>$1,143,224</td>
<td>$1,132,756</td>
</tr>
</tbody>
</table>

The Company adopted ASU No. 2015-03, Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs on January 1, 2016. The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. See Note 1 for further details of the impact this adoption has had on the financial statements.

2015 Senior Secured Credit Facility

On May 7, 2015, HPI, the Company and certain of its subsidiaries entered into a credit agreement with Citibank, N.A., as administrative and collateral agent, and the lenders from time to time party thereto (as amended by the 2016 Amendment described below in Note 18, the “credit agreement”) providing for (i) the six-year $400.0 million term loan facility (the “2015 Term Loan Facility”); (ii) an uncommitted accordion facility subject to the satisfaction of certain financial and other conditions; and (iii) one or more uncommitted refinancing loan facilities with respect to loans thereunder (collectively the “2015 Senior Secured Credit Facility”). The initial borrower under the 2015 Term Loan Facility is HPI. The credit agreement allows for the Company and certain other subsidiaries of the Company to become borrowers under the accordion or refinancing facilities. Loans under the 2015 Term Loan Facility bear interest, at each borrower’s option, at a rate equal to either the London Inter-Bank Offer Rate (“LIBOR”), plus an applicable margin of 3.5% per year (subject to a 1.0% LIBOR floor), or the adjusted base rate plus 2.5%. The adjusted base rate is defined as the greater of (a) LIBOR (using one-month interest period) plus 1%, (b) prime rate, (c) fed funds plus ½ of 1%, and (d) 2%. The Company borrowed the full $400.0 million available under the 2015 Term Loan Facility on May 7, 2015 as a LIBOR-based borrowing. In connection with the financing for the acquisition of Raptor, the credit agreement was amended to add a $375.0 million incremental term loan facility and change the interest rate margins applicable to the 2015 Term Loan Facility, as further described in Note 18.

The obligations under the credit agreement and any swap obligations and cash management obligations owing to a lender (or an affiliate of a lender) thereunder are and will be guaranteed by the Company and each of the Company’s existing and subsequently acquired or organized direct and indirect subsidiaries (other than certain immaterial subsidiaries, subsidiaries whose guarantee would result in material adverse tax consequences and subsidiaries whose guarantee is prohibited by applicable law). The obligations under the credit agreement and any such swap and cash management obligations are secured, subject to customary permitted liens and other agreed upon exceptions, by a perfected security interest in (i) all tangible and intangible assets of the borrowers, (ii) all of the capital stock of each borrower, and (iii) all of the capital stock of each subsidiary thereunder, limited, in the case of the stock of certain non-U.S. subsidiaries of the borrowers, to 65% of the capital stock of such subsidiaries.
The borrowers are permitted to make voluntary prepayments at any time without payment of a premium. HPI is required to make mandatory prepayments of loans under the 2015 Term Loan Facility (without payment of a premium) with (a) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (b) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions), (c) net cash proceeds from issuances of debt (other than certain permitted debt), and (d) beginning with the fiscal year ending December 31, 2016, 50% of the Company’s excess cash flow (subject to decrease to 25% or 0% if the Company’s first lien leverage ratio is less than 2.25:1 and 1.75:1, respectively). The loans under the 2015 Term Loan Facility will amortize in equal quarterly installments in an aggregate annual amount equal to 1% of the original principal amount thereof, with any remaining balance payable on the final maturity date of the loans under the 2015 Term Loan Facility.

The credit agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions, and customary events of default.

The Company was, as of September 30, 2016, and is currently in compliance with this credit agreement.

As of September 30, 2016, the fair value of the 2015 Term Loan Facility was approximately $391.1 million, categorized as a Level 2 instrument, as defined in Note 11.

See Note 18 for further details on changes to the 2015 Senior Secured Credit Facility.

2023 Senior Notes

On April 29, 2015, Horizon Pharma Financing Inc. (“Horizon Financing”) a wholly owned subsidiary of the Company, completed a private placement of $475.0 million aggregate principal amount of 6.625% Senior Notes due 2023 (the “2023 Senior Notes”) to certain investment banks acting as initial purchasers who subsequently resold the 2023 Senior Notes to qualified institutional buyers as defined in Rule 144A under the Securities Act, and in offshore transactions to non-U.S. persons in reliance on Regulation S under the Securities Act.

In connection with the closing of the Hyperion acquisition on May 7, 2015, Horizon Financing merged with and into HPI and, as a result, the 2023 Senior Notes became HPI’s general unsecured senior obligations and the Company and all of the Company’s direct and indirect subsidiaries that are guarantors under the 2015 Senior Secured Credit Facility fully and unconditionally guaranteed on a senior unsecured basis HPI’s obligations under the 2023 Senior Notes.

The 2023 Senior Notes accrue interest at an annual rate of 6.625% payable semiannually in arrears on May 1 and November 1 of each year, beginning on November 1, 2015. The 2023 Senior Notes will mature on May 1, 2023, unless earlier exchanged, repurchased or redeemed.

Except as described below, the 2023 Senior Notes may not be redeemed before May 1, 2018. Thereafter, some or all of the 2023 Senior Notes may be redeemed at any time at specified redemption prices, plus accrued and unpaid interest to the redemption date. At any time prior to May 1, 2018, some or all of the 2023 Senior Notes may be redeemed at a price equal to 100% of the aggregate principal amount thereof, plus a make-whole premium and accrued and unpaid interest to the redemption date. Also prior to May 1, 2018, up to 35% of the aggregate principal amount of the 2023 Senior Notes may be redeemed at a redemption price of 106.625% of the aggregate principal amount thereof, plus accrued and unpaid interest, with the net proceeds of certain equity offerings.

In addition, the 2023 Senior Notes may be redeemed in whole but not in part at a redemption price equal to 100% of the principal amount plus accrued and unpaid interest and additional amounts, if any, to, but excluding, the redemption date, if on the next date on which any amount would be payable in respect of the 2023 Senior Notes, HPI or any guarantor is or would be required to pay additional amounts as a result of certain tax-related events.

If the Company undergoes a change of control, HPI will be required to make an offer to purchase all of the 2023 Senior Notes at a price in cash equal to 101% of the aggregate principal amount thereof plus accrued and unpaid interest to, but not including, the repurchase date. If the Company or certain of its subsidiaries engages in certain asset sales, HPI will be required under certain circumstances to make an offer to purchase the 2023 Senior Notes at 100% of the principal amount thereof, plus accrued and unpaid interest to the repurchase date.

The indenture governing the 2023 Senior Notes contains covenants that limit the ability of the Company and its restricted subsidiaries to, among other things, pay dividends or distributions, repurchase equity, prepay junior debt and make certain investments, incur additional debt and issue certain preferred stock, incur liens on assets, engage in certain asset sales, merge, consolidate with or merge or sell all or substantially all of their assets, enter into transactions with affiliates, designate subsidiaries as unrestricted subsidiaries, and allow to exist certain restrictions on the ability of restricted subsidiaries to pay dividends or make other payments to the Company. Certain of the covenants will be suspended during any period in which the notes receive investment grade ratings. The indenture also includes customary events of default.
The Company was, as of September 30, 2016, and is currently in compliance with the indenture governing the 2023 Senior Notes.

As of September 30, 2016, the fair value of the 2023 Senior Notes was approximately $446.5 million, categorized as a Level 2 instrument, as defined in Note 11.

**Exchangeable Senior Notes**

On March 13, 2015, Horizon Investment completed a private placement of $400.0 million aggregate principal amount of Exchangeable Senior Notes to several investment banks acting as initial purchasers who subsequently resold the Exchangeable Senior Notes to qualified institutional buyers as defined in Rule 144A under the Securities Act. The net proceeds from the offering of the Exchangeable Senior Notes were approximately $387.2 million, after deducting the initial purchasers’ discount and offering expenses payable by Horizon Investment.

The Exchangeable Senior Notes are fully and unconditionally guaranteed, on a senior unsecured basis, by the Company (the “Guarantee”). The Exchangeable Senior Notes and the Guarantee are Horizon Investment’s and the Company’s senior unsecured obligations. The Exchangeable Senior Notes accrue interest at an annual rate of 2.50% payable semiannually in arrears on March 15 and September 15 of each year, beginning on September 15, 2015. The Exchangeable Senior Notes will mature on March 15, 2022, unless earlier exchanged, repurchased or redeemed. The initial exchange rate is 34.8979 ordinary shares of the Company per $1,000 principal amount of the Exchangeable Senior Notes (equivalent to an initial exchange price of approximately $28.66 per ordinary share). The exchange rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date or upon a tax redemption, Horizon Investment will increase the exchange rate for a holder who elects to exchange its Exchangeable Senior Notes in connection with such a corporate event or a tax redemption in certain circumstances.

Other than as described below, the Exchangeable Senior Notes may not be redeemed by the Company.

**Issuer Redemptions:**

Optional Redemption for Changes in the Tax Laws of a Relevant Taxing Jurisdiction: Horizon Investment may redeem the Exchangeable Senior Notes at its option, prior to March 15, 2022, in whole but not in part, in connection with certain tax-related events.

Provisional Redemption on or After March 20, 2019: On or after March 20, 2019, Horizon Investment may redeem for cash all or a portion of the Exchangeable Senior Notes if the last reported sale price of ordinary shares of the Company has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which Horizon Investment provide written notice of redemption. The redemption price will be equal to 100% of the principal amount of the Exchangeable Senior Notes to be redeemed, plus accrued and unpaid interest to, but not including, the redemption date; provided that if the redemption date occurs after a regular record date and on or prior to the corresponding interest payment date, Horizon Investment will pay the full amount of accrued and unpaid interest due on such interest payment date to the record holder of the Exchangeable Senior Notes on the regular record date corresponding to such interest payment date, and the redemption price payable to the holder who presents an Exchangeable Senior Note for redemption will be equal to 100% of the principal amount of such Exchangeable Senior Note.
**Holder Exchange Rights:**

Holders may exchange all or any portion of their Exchangeable Senior Notes at their option at any time prior to the close of business on the business day immediately preceding December 15, 2021 only upon satisfaction of one or more of the following conditions:

1. **Exchange upon Satisfaction of Sale Price Condition** – During any calendar quarter commencing after the calendar quarter ending on June 30, 2015 (and only during such calendar quarter), if the last reported sale price of ordinary shares of the Company for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the applicable exchange price on each applicable trading day.

2. **Exchange upon Satisfaction of Trading Price Condition** – During the five business day period after any ten consecutive trading day period in which the trading price per $1,000 principal amount of Exchangeable Senior Notes for each trading day of such period was less than 98% of the product of the last reported sale price of ordinary shares of the Company and the applicable exchange rate on such trading day.

3. **Exchange upon Notice of Redemption** – Prior to the close of business on the business day immediately preceding December 15, 2021, if Horizon Investment provides a notice of redemption, at any time prior to the close of business on the second scheduled trading day immediately preceding the redemption date.

As of September 30, 2016, none of the above conditions had been satisfied and no exchange of Exchangeable Senior Notes had been triggered. On or after December 15, 2021, a holder may exchange all or any portion of its Exchangeable Senior Notes at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date regardless of the foregoing conditions.

Upon exchange, Horizon Investment will settle exchanges of the Exchangeable Senior Notes by paying or causing to be delivered, as the case may be, cash, ordinary shares or a combination of cash and ordinary shares, at its election.

The Company recorded the Exchangeable Senior Notes under the guidance in Topic ASC 470-20, Debt with Conversion and Other Options, and separated them into a liability component and equity component. The carrying amount of the liability component of $268.9 million was determined by measuring the fair value of a similar liability that does not have an associated equity component. The carrying amount of the equity component of $119.1 million represented by the embedded conversion option was determined by deducting the fair value of the liability component of $268.9 million from the initial proceeds of $387.2 million ascribed to the convertible debt instrument as a whole. The initial debt discount of $131.1 million is being charged to interest expense over the life of the Exchangeable Senior Notes using the effective interest rate method.

As of September 30, 2016, the fair value of the Exchangeable Senior Notes was approximately $386.8 million, categorized as a Level 2 instrument, as defined in Note 11.

**2014 Senior Secured Credit Facility**

On June 17, 2014, the Company entered into a credit agreement with a group of lenders and Citibank, N.A., as administrative and collateral agent to provide the Company with $300.0 million in financing through a five-year senior secured credit facility (the “2014 Senior Secured Credit Facility”). Loans under the five-year $300.0 million term loan facility (“2014 Term Loan Facility”) bore interest, at each borrower’s option, at a rate equal to either the LIBOR, plus an applicable margin of 8.0% per year (subject to a 1.0% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 7.0% per year. The Company borrowed the full $300.0 million available on the 2014 Term Loan Facility on September 19, 2014 as a LIBOR-based borrowing.

On May 7, 2015, the Company repaid the entire $300.0 million outstanding amount under the 2014 Senior Secured Credit Facility in connection with the closing of the Hyperion acquisition and recognized a $56.8 million loss on debt extinguishment as a result of the early repayment.

**Convertible Senior Notes**

On November 22, 2013, the Company issued $150.0 million aggregate principal amount of 5.00% Convertible Senior Notes due 2018 ("Convertible Senior Notes"), and received net proceeds of $143.6 million, after deducting fees and expenses of $6.4 million.
During 2015, the Company entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes ("2015 Conversions") which were on substantially the same terms as prior conversion agreements entered into by the Company. Under the 2015 Conversions, the applicable holders agreed to convert an aggregate principal amount of $61.0 million of Convertible Senior Notes held by them and the Company agreed to settle such conversions by issuing an aggregate of 11,368,921 ordinary shares. In addition, pursuant to such conversion agreements, the Company made an aggregate cash payment of $10.0 million to the applicable holders for additional exchange consideration and $0.9 million for accrued and unpaid interest, and recognized a non-cash charge of $10.1 million related to the extinguishment of debt as a result of the note conversions. Following the closings under the 2015 Conversions, there were no Convertible Senior Notes remaining outstanding.

NOTE 15 – SHAREHOLDERS' EQUITY

During the nine months ended September 30, 2016, the Company issued an aggregate of:

- 496,012 ordinary shares in connection with the exercise of stock options and received $3.4 million in proceeds;
- 619,696 ordinary shares in net settlement of vested restricted stock units;
- 13,584 ordinary shares in net settlement of vested performance stock units; and
- 261,780 ordinary shares pursuant to employee stock purchase plans and received $3.2 million in proceeds.

During the nine months ended September 30, 2016, warrants to purchase an aggregate of 207,110 ordinary shares of the Company were exercised in cashless exercises, resulting in the issuance of 161,259 ordinary shares. As of September 30, 2016, there were outstanding warrants to purchase 1,374,410 ordinary shares of the Company.

During the nine months ended September 30, 2016, the Company made payments of $5.3 million for employee withholding taxes relating to share-based awards.

In May 2016, the Company’s board of directors authorized a share repurchase program pursuant to which the Company may repurchase up to 5,000,000 of its ordinary shares. The timing and amount of repurchases, including whether the Company decides to repurchase any shares pursuant to the authorization, will depend on a variety of factors, including the price of the Company’s ordinary shares, alternative investment opportunities, the Company’s cash resources, restrictions under the Company’s credit agreement, and market conditions. As of September 30, 2016, the Company had not purchased any of its ordinary shares under this repurchase program.

NOTE 16 – SHARE-BASED INCENTIVE PLANS

Employee Stock Purchase Plan

2014 Employee Stock Purchase Plan. On May 17, 2014, HPI’s board of directors adopted the 2014 Employee Stock Purchase Plan (the “2014 ESPP”). On September 18, 2014, at a special meeting of the stockholders of HPI (the “Special Meeting”), HPI’s stockholders approved the 2014 ESPP. Upon consummation of the Vidara Merger, the Company assumed the 2014 ESPP. As described below, effective as of May 3, 2016, the number of ordinary shares authorized for issuance under the 2014 ESPP was reduced by 5,000,000 shares.

As of September 30, 2016, an aggregate of 4,076,279 ordinary shares were authorized and available for future issuance under the 2014 ESPP.

Share-Based Compensation Plans

2005 Stock Plan. In October 2005, HPI adopted the 2005 Stock Plan (the “2005 Plan”). Upon the signing of the underwriting agreement related to HPI's initial public offering, on July 28, 2011, no further option grants were made under the 2005 Plan. All stock awards granted under the 2005 Plan prior to July 28, 2011 continue to be governed by the terms of the 2005 Plan. Upon consummation of the Vidara Merger, the Company assumed the 2005 Plan.

2011 Equity Incentive Plan. In July 2010, HPI’s board of directors adopted the 2011 Equity Incentive Plan (the “2011 EIP”). In June 2011, HPI’s stockholders approved the 2011 EIP, and it became effective upon the signing of the underwriting agreement related to HPI's initial public offering on July 28, 2011. Upon consummation of the Vidara Merger, the Company assumed the 2011 EIP, and upon the effectiveness of the Horizon Pharma Public Limited Company 2014 Equity Incentive Plan (the “2014 EIP”), no additional stock awards were or will be made under the 2011 Plan, although all outstanding stock awards granted under the 2011 Plan continue to be governed by the terms of the 2011 Plan.

35
2014 Equity Incentive Plan and 2014 Non-Employee Equity Plan. On May 17, 2014, HPI’s board of directors adopted the 2014 EIP and the Horizon Pharma Public Limited Company 2014 Non-Employee Equity Plan (the “2014 Non-Employee Equity Plan”). At the Special Meeting, HPI’s stockholders approved the 2014 EIP and 2014 Non-Employee Equity Plan. Upon consummation of the Vidara Merger, the Company assumed the 2014 EIP and 2014 Non-Employee Equity Plan, which serve as successors to the 2011 EIP.

The 2014 EIP provides for the grant of incentive and nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other stock awards that may be settled in cash, shares or other property to the employees of the Company (or a subsidiary company). The number of ordinary shares of the Company that were initially authorized for issuance under the 2014 EIP was no more than 22,052,130, which number consisted of (i) 15,500,000 ordinary shares of the Company; plus (ii) the number of shares available for issuance pursuant to the grant of future awards under the 2011 EIP; plus (iii) any shares subject to outstanding stock awards granted under the 2011 EIP and the 2005 Plan that expire or terminate for any reason prior to exercise or settlement or are forfeited, redeemed or repurchased because of the failure to meet a contingency or condition required to vest such shares; less (iv) 10,000,000 shares, which is the additional number of shares which were previously approved as an increase to the share reserve of the 2011 EIP. On March 23, 2015, the compensation committee of the Company’s board of directors approved amending the 2014 EIP subject to shareholder approval to, among other things, increase the aggregate number of shares authorized for issuance under the 2014 EIP by an additional 14,000,000 shares. On May 6, 2015, the shareholders of the Company approved such amendment to the 2014 EIP. On February 25, 2016, the compensation committee of the Company’s board of directors approved, subject to shareholder approval, amending the 2014 EIP to, among other things, increase the aggregate number of shares authorized for issuance under the 2014 EIP beyond those remaining available for future grant under the 2014 EIP by an additional 6,000,000 shares and also approved a reduction in the number of shares authorized under our 2014 Non-Employee Equity Plan and 2014 ESPP by 1,000,000 shares and 5,000,000 shares, respectively, contingent on shareholder approval of the amendment to the 2014 EIP. On May 3, 2016, the shareholders of the Company approved the amendment to the 2014 EIP. The Company’s board of directors has authority to suspend or terminate the 2014 EIP at any time.

The 2014 Non-Employee Equity Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other forms of stock awards that may be settled in cash, shares or other property to the non-employee directors and consultants of the Company (or a subsidiary company). The total number of ordinary shares of the Company that were initially authorized for issuance under the 2014 Non-Employee Equity Plan is 2,500,000. As described above, effective as of May 3, 2016, the number of ordinary shares authorized for issuance under the 2014 Non-Employee Equity Plan was reduced by 1,000,000 shares. The Company’s board of directors has authority to suspend or terminate the 2014 Non-Employee Equity Plan at any time.

As of September 30, 2016, an aggregate of 7,442,963 and 963,567 ordinary shares were authorized and available for future grants under the 2014 EIP and 2014 Non-Employee Equity Plan, respectively.

### Stock Options

The following table summarizes stock option activity during the nine months ended September 30, 2016:

<table>
<thead>
<tr>
<th></th>
<th>Options</th>
<th>Weighted Average Exercise Price</th>
<th>Weighted Average Contractual Term Remaining (in years)</th>
<th>Aggregate Intrinsic Value (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2015</td>
<td>13,385,791</td>
<td>$17.73</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granted</td>
<td>1,741,192</td>
<td>$18.13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercised</td>
<td>(496,012)</td>
<td>$6.89</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forfeited</td>
<td>(1,012,082)</td>
<td>$18.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expired</td>
<td>(58,879)</td>
<td>$12.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outstanding as of September 30, 2016</td>
<td>13,560,010</td>
<td>$18.18</td>
<td>7.79</td>
<td>46,036</td>
</tr>
<tr>
<td>Exercisable as of September 30, 2016</td>
<td>6,393,796</td>
<td>$15.20</td>
<td>6.88</td>
<td>36,202</td>
</tr>
</tbody>
</table>

Stock options typically have a contractual term of 10 years from grant date.
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 share 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 share 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, 2016 and 2015, and assumptions used to value stock options, are as follows:

<table>
<thead>
<tr>
<th>For the Nine Months Ended September 30,</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dividend yield</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Risk-free interest rate</td>
<td>1.3% - 1.8%</td>
<td>1.3% - 2.0%</td>
</tr>
<tr>
<td>Weighted average expected volatility</td>
<td>73.8%</td>
<td>77.1%</td>
</tr>
<tr>
<td>Expected life (in years)</td>
<td>6.1</td>
<td>6.0</td>
</tr>
<tr>
<td>Weighted average grant-date fair value per share of options granted</td>
<td>$11.78</td>
<td>$16.20</td>
</tr>
</tbody>
</table>

**Dividend yield**

The Company has never paid dividends and does not anticipate paying any dividends in the near future. Additionally, the 2015 Senior Secured Credit Facility, as amended by the 2016 Amendment (described in Note 14 above and Note 18 below), as well as the 2023 Senior Notes and the 2024 Senior Notes (described in Note 18 below), contain covenants that restrict the Company from issuing dividends.

**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 share price volatility of comparable companies to be representative of future share price volatility, as the Company did not have sufficient trading history for its ordinary shares.

**Expected Term**

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

**Forfeitures**

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

**Restricted Stock Units**

The following table summarizes restricted stock unit activity for the nine months ended September 30, 2016:

<table>
<thead>
<tr>
<th></th>
<th>Number of Units</th>
<th>Weighted Average Grant-Date Fair Value Per Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2015</td>
<td>3,361,746</td>
<td>$18.71</td>
</tr>
<tr>
<td>Granted</td>
<td>763,519</td>
<td>$17.09</td>
</tr>
<tr>
<td>Vested</td>
<td>(910,322)</td>
<td>$17.40</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(329,428)</td>
<td>$17.71</td>
</tr>
<tr>
<td>Outstanding as of September 30, 2016</td>
<td>2,885,515</td>
<td>$18.80</td>
</tr>
</tbody>
</table>

The grant-date fair value of restricted stock units is the closing price of the Company’s shares on the date of grant.
Performance Stock Units

The following table summarizes performance stock unit ("PSU") activity for the nine months ended September 30, 2016:

<table>
<thead>
<tr>
<th></th>
<th>Number of Units</th>
<th>Weighted Average Grant-Date Fair Value Per Unit</th>
<th>Average Illiquidity Discount</th>
<th>Recorded Weighted Average Fair Value Per Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2015</td>
<td>13,049,000</td>
<td>$7.99</td>
<td>8.2%</td>
<td>$7.34</td>
</tr>
<tr>
<td>Granted</td>
<td>260,000</td>
<td>$7.99</td>
<td>0.0%</td>
<td>$7.99</td>
</tr>
<tr>
<td>Vested</td>
<td>(20,000)</td>
<td>$14.32</td>
<td>15.4%</td>
<td>$12.25</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(960,000)</td>
<td>$14.32</td>
<td>15.4%</td>
<td>$12.25</td>
</tr>
<tr>
<td>Outstanding as of September 30, 2016</td>
<td>12,329,000</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In January 2016, the compensation committee of the Company’s board of directors approved the grant of 260,000 PSUs to certain members of the Company’s senior leadership team.

In 2014, the Company granted 25,000 PSUs. All other outstanding PSUs were granted in 2015 and 2016 and may vest if the Company’s total compounded annual shareholder rate of return ("TSR") over three performance measurement periods summarized below equals or exceeds a minimum of 15%.

<table>
<thead>
<tr>
<th>Vesting Tranche</th>
<th>Percent of Total PSU Award</th>
<th>Beginning of Performance Measurement Period</th>
<th>End of Performance Measurement Period</th>
<th>Length of Performance Measurement Period (Years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tranche One</td>
<td>33.3%</td>
<td>March 23, 2015</td>
<td>December 22, 2017</td>
<td>2.75</td>
</tr>
<tr>
<td>Tranche Two</td>
<td>33.3%</td>
<td>March 23, 2015</td>
<td>March 22, 2018</td>
<td>3.00</td>
</tr>
<tr>
<td>Tranche Three</td>
<td>33.3%</td>
<td>March 23, 2015</td>
<td>June 22, 2018</td>
<td>3.25</td>
</tr>
</tbody>
</table>

These outstanding PSUs granted in 2015 and 2016 will vest in amounts ranging from 25% to 100% based on the achievement of the following TSR over the three performance periods:

<table>
<thead>
<tr>
<th>TSR Achieved</th>
<th>Vesting Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>15%</td>
<td>25 %</td>
</tr>
<tr>
<td>30%</td>
<td>50 %</td>
</tr>
<tr>
<td>45%</td>
<td>75 %</td>
</tr>
<tr>
<td>60%</td>
<td>100 %</td>
</tr>
</tbody>
</table>

The TSR will be based on the volume weighted average trading price ("VWAP") of the Company’s ordinary shares over the 20 trading days ending on the last day of each of the three performance measurement periods versus the VWAP of the Company’s ordinary shares over the 20 trading days ended March 23, 2015 of $21.50. These PSUs are subject to a post vesting holding period of one year for 50% of the PSUs and two years for 50% of the PSUs for those who were members of the executive committee at the date of grant, and one year for 50% of the PSUs for all others who were not executive committee members at the date of grant.

The Company accounts for the PSUs as equity-settled awards in accordance with ASC 718. Because the value of the outstanding PSUs granted in 2015 and 2016 is dependent upon the attainment of a level of TSR, it requires the impact of the market condition to be considered when estimating the fair value of the PSUs. As a result, the Monte Carlo model is applied and the most significant valuation assumptions used include:

<table>
<thead>
<tr>
<th>For the Nine Months Ended September 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Valuation date stock price</td>
</tr>
<tr>
<td>Expected volatility</td>
</tr>
<tr>
<td>Risk free rate</td>
</tr>
</tbody>
</table>
The average estimated fair value of each outstanding PSU granted under the 2014 EIP is as follows (allocated between groupings based on grant-date classification):

<table>
<thead>
<tr>
<th></th>
<th>Number of Units</th>
<th>Weighted Average Fair Value Per Unit</th>
<th>Average Illiquidity Discount</th>
<th>Recorded Weighted Average Fair Value Per Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive committee members</td>
<td>9,173,000</td>
<td>$15.18</td>
<td>18.3%</td>
<td>$12.40</td>
</tr>
<tr>
<td>Non-executive committee members</td>
<td>3,131,000</td>
<td>$13.55</td>
<td>7.3%</td>
<td>$12.56</td>
</tr>
<tr>
<td></td>
<td>12,304,000</td>
<td>$14.76</td>
<td>15.7%</td>
<td>$12.44</td>
</tr>
</tbody>
</table>

During the nine months ended September 30, 2016, the Company recorded $36.1 million of expense related to PSUs.

**Cash Long-Term Incentive Program**

On November 5, 2014, the compensation committee of the Company’s board of directors approved a performance cash long-term incentive program for the members of the Company’s executive committee and executive leadership team, including its executive officers (the “Cash Bonus Program”). Participants in the Cash Bonus Program will be eligible for a specified cash bonus. The Cash Bonus Program pool funding of approximately $16.0 million was determined based on the Company’s actual TSR over the period from November 5, 2014 to May 6, 2015, and the bonus will be earned and payable only if the TSR for the period from November 5, 2014 to November 4, 2017 is greater than 15%. The portion of the total bonus pool payable to individual participants is based on allocations established by the Company’s compensation committee. Participants must remain employed by the Company through November 4, 2017 unless a participant’s earlier departure from employment is due to death, disability, termination without cause or a change in control transaction. Bonus payments under the Cash Bonus Program, if any, will be made after November 4, 2017.

The Company accounts for the Cash Bonus Program under the liability method in accordance with ASC 718. Because vesting of the bonus pool is dependent upon the attainment of a VWAP of $18.37 or higher over the 20 trading days ending November 4, 2017, the Cash Bonus Program will be considered to be subject to a “market condition” for the purposes of ASC 718. ASC 718 requires the impact of the market condition to be considered when estimating the fair value of the bonus pool. As of September 30, 2016 and December 31, 2015, the estimated fair value was $5.1 million and $6.0 million, respectively. For the nine months ended September 30, 2016, the Company recorded an expense of $0.9 million to the unaudited condensed consolidated statement of comprehensive loss as a result of the valuation of the Cash Bonus Program. The most significant valuation assumptions used as of September 30, 2016 include:

- Valuation Date Stock Price - $18.13.
- Expected Volatility - The expected volatility assumption of 88.0% is based on the Company’s historical volatility over the 1.09 year period ending September 30, 2016, based upon daily stock price observations.
- Risk Free Rate – 0.60%, which is based upon the yield on U.S. Treasury Separate Trading of Registered Interest and Principal Securities with a remaining term of 1.09 years as of September 30, 2016.

**Share-Based Compensation Expense**

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, 2016 and 2015 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>For the Nine Months Ended September 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2016</td>
</tr>
<tr>
<td>Research and development</td>
<td>$6,845</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>19,306</td>
</tr>
<tr>
<td>General and administrative</td>
<td>58,770</td>
</tr>
<tr>
<td>Total share-based compensation expense</td>
<td>$84,921</td>
</tr>
</tbody>
</table>

No material income tax benefit has been recognized relating to share-based compensation expense and no tax benefits have been realized from exercised stock options, due to the Company’s net loss position. As of September 30, 2016, the Company estimates that pre-tax unrecognized compensation expense of $220.5 million for all unvested share-based awards, including stock options, restricted stock units and PSUs, will be recognized through the third quarter of 2020. The Company expects to satisfy the exercise of stock options and future distribution of shares for restricted stock units and PSUs by issuing new ordinary shares which have been reserved under the 2014 EIP.
NOTE 17 – 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 valuation allowances 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 period in which the change is enacted.

The following table presents the (benefit) expense for income taxes for the three and nine months ended September 30, 2016 and 2015 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended September 30,</th>
<th>For the Nine Months Ended September 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2016</td>
<td>2015</td>
</tr>
<tr>
<td>(Loss) income before (benefit) expense for income taxes</td>
<td>$ (33,617)</td>
<td>$ 25,256</td>
</tr>
<tr>
<td>(Benefit) expense for income taxes</td>
<td>(27,747)</td>
<td>21,979</td>
</tr>
<tr>
<td>Net (loss) income</td>
<td>$ (5,870)</td>
<td>$ 3,277</td>
</tr>
</tbody>
</table>

In the course of preparing the condensed consolidated balance sheet and the condensed consolidated statements of comprehensive loss as of and for the three and nine months ended September 30, 2016, the Company determined that deferred tax liabilities were understated by $2.4 million and accrued expenses were understated by $1.1 million, each as of December 31, 2015, and the benefit for income taxes was overstated by $3.5 million for the year ended December 31, 2015. The Company concluded that these misstatements were not material, individually or in the aggregate, to any of the reporting periods. As such, the correction for this error was made during the three months ended September 30, 2016.

During the three and nine months ended September 30, 2016, the Company recorded a benefit for income taxes of $27.7 million and $31.9 million, respectively, compared to an expense of $22.0 million and a benefit of $136.8 million during the three and nine months ended September 30, 2015, respectively. The benefit for income taxes recorded during the three and nine months ended September 30, 2016 was attributable to pre-tax losses incurred in higher tax rate jurisdictions which exceeded pre-tax income in lower tax rate jurisdictions during the periods, as well as certain discrete factors and events, including the tax benefit recorded as a result of the $65.0 million litigation settlement with Express Scripts. The benefit for income taxes recorded during the nine months ended September 30, 2015 was primarily attributable to the release of valuation allowances in the United States due to the recognition of significant deferred tax liabilities as a result of the Hyperion acquisition as well as the ability to recognize a tax benefit for the Company’s U.S. tax consolidation group losses then projected to be incurred during 2015.

Deferred tax assets and liabilities arise from acquisition accounting adjustments where book values of certain assets and liabilities differ from their tax bases. Deferred tax assets and liabilities are recorded at the currently enacted rates which will be in effect at the time when the temporary differences are expected to reverse in the country where the underlying assets and liabilities are located.

NOTE 18 – SUBSEQUENT EVENTS

Raptor Acquisition

On October 25, 2016, the Company completed its acquisition of Raptor pursuant to which the Company acquired all of the issued and outstanding shares of Raptor common stock at a price of $9.00 per share in cash or approximately $804.7 million on a fully diluted basis. The Raptor acquisition expands the Company’s product portfolio by adding two orphan disease medicines, PROCYSBI and QUINSAIR.

In connection with the Raptor acquisition, the Company expects to pay an estimated $19.2 million of transaction fees for legal, advisory and other fees.

The final determination of the purchase price allocation is expected to be completed as soon as practicable after consummation of the Raptor acquisition. Due to the limited time between the acquisition date and the filing of this Quarterly Report on Form 10-Q, it is not practicable for the Company to disclose: (i) the allocation of purchase price to assets acquired and liabilities assumed as of the date of close, and (ii) pro forma revenues and earnings of the combined company for the period ended September 30, 2016.
2024 Senior Notes

On October 25, 2016, HPI and Horizon Pharma USA, Inc., a wholly-owned subsidiary of the Company (“HPUSA” and, together with HPI, the “2024 Issuers”), completed a private placement of $300.0 million aggregate principal amount of 2024 Senior Notes to certain investment banks acting as initial purchasers who subsequently resold the 2024 Senior Notes to qualified institutional buyers as defined in Rule 144A under the Securities Act.

The 2024 Senior Notes are the 2024 Issuers’ general unsecured senior obligations and the Company and all of the Company’s direct and indirect subsidiaries that are guarantors under the 2015 Senior Secured Credit Facility and the 2016 Incremental Loan Facility (as defined below) fully and unconditionally guaranteed on a senior unsecured basis the 2024 Issuers’ obligations under the 2024 Senior Notes.

The 2024 Senior Notes accrue interest at an annual rate of 8.75% payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2017. The 2024 Senior Notes will mature on November 1, 2024, unless earlier exchanged, repurchased or redeemed.

Except as described below, the 2024 Senior Notes may not be redeemed before November 1, 2019. Thereafter, some or all of the 2024 Senior Notes may be redeemed at any time at specified redemption prices, plus accrued and unpaid interest to the redemption date. At any time prior to November 1, 2019, some or all of the 2024 Senior Notes may be redeemed at a price equal to 100% of the aggregate principal amount thereof, plus a make-whole premium and accrued and unpaid interest to the redemption date. Also prior to November 1, 2019, up to 33% of the aggregate principal amount of the 2024 Senior Notes may be redeemed at a redemption price of 108.75% of the aggregate principal amount thereof, plus accrued and unpaid interest, with the net proceeds of certain equity offerings. In addition, the 2024 Senior Notes may be redeemed in whole but not in part at a redemption price equal to 100% of the principal amount plus accrued and unpaid interest and additional amounts, if any, to, but excluding, the redemption date, if on the next date on which any amount would be payable in respect of the 2024 Senior Notes, the 2024 Issuers or any guarantor is or would be required to pay additional amounts as a result of certain tax-related events.

If the Company undergoes a change of control, the 2024 Issuers will be required to make an offer to purchase all of the 2024 Senior Notes at a price in cash equal to 101% of the aggregate principal amount thereof plus accrued and unpaid interest to, but not including, the repurchase date. If the Company or certain of its subsidiaries engages in certain asset sales, the 2024 Issuers will be required under certain circumstances to make an offer to purchase the 2024 Senior Notes at 100% of the principal amount thereof, plus accrued and unpaid interest to the repurchase date.

The indenture governing the 2024 Senior Notes contains covenants that limit the ability of the Company and its restricted subsidiaries to, among other things, pay dividends or distributions, repurchase equity, prepay junior debt and make certain investments, incur additional debt and issue certain preferred stock, incur liens on assets, engage in certain asset sales, merge, consolidate with or merge or sell all or substantially all of their assets, enter into transactions with affiliates, designate subsidiaries as unrestricted subsidiaries, and allow to exist certain restrictions on the ability of restricted subsidiaries to pay dividends or make other payments to the Company. Certain of the covenants will be suspended during any period in which the notes receive investment grade ratings. The indenture also includes customary events of default.

2016 Amendment to Credit Agreement

On October 25, 2016, HPI and HPUSA (together, in such capacity, the “Incremental Borrowers”) entered into an amendment to the credit agreement (the “2016 Amendment”) with Citibank, N.A., as administrative and collateral agent, and Bank of America, N.A., as the incremental B-1 lender thereunder, pursuant to which the Incremental Borrowers borrowed $375.0 million aggregate principal amount of loans (the “2016 Incremental Loan Facility”). The 2016 Incremental Loan Facility was incurred as a separate class of term loans under the credit agreement with the same terms of loans under the 2015 Term Loan Facility, except as described below.

Loans under the 2016 Incremental Loan Facility bear interest, at each Incremental Borrowers’ option, at a rate equal to either LIBOR plus an applicable margin of 4.50% per year (subject to a LIBOR floor of 1.0%), or the adjusted base rate plus 3.50%. The terms of the loans under the 2015 Term Loan Facility (the “2015 Loans”) provided for an amendment such that the effective yield of the 2015 Loans would not be less than the effective yield of the loans under the 2016 Incremental Loan Facility (the “Incremental Loans”) minus 0.50%. Consequently, the issuance of the Incremental Loans resulted in an increase of the interest rate applicable to the 2015 Loans, as of October 25, 2016, to LIBOR plus 4.00%, subject to a LIBOR floor of 1.0% (an initial interest rate of 5.00%). Borrowers under the credit agreement are permitted to make voluntary prepayments of the loans under the credit agreement at any time without payment of a premium, except that with respect to the Incremental Loans, a 1% premium will apply to a repayment of the Incremental Loans in connection with a repricing of, or any amendment to the credit agreement in a repricing of, such loans effected on or prior to the date that is twelve months following October 25, 2016.
ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

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

OVERVIEW

Unless otherwise indicated or the context otherwise requires, references to the “Company”, “we”, “us” and “our” refer to Horizon Pharma plc and its consolidated subsidiaries, including its predecessor, Horizon Pharma, Inc., or HPI. All references to “Vidara” are references to Horizon Pharma plc (formerly known as Vidara Therapeutics International Public Limited Company) and its consolidated subsidiaries prior to the effective time of the merger of the businesses of HPI and Vidara on September 19, 2014, or the Vidara Merger. The disclosures in this report relating to the pre-Vidara Merger business of Horizon Pharma plc, unless noted as being the business of Vidara prior to the Vidara Merger, pertain to the business of HPI prior to the Vidara Merger.

OUR BUSINESS

We are a biopharmaceutical company focused on improving patients’ lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs. We market eleven medicines through our orphan, rheumatology and primary care business units. Our marketed medicines are ACTIMMUNE® (interferon gamma-1b), BUPHENYL® (sodium phenylbutyrate) Tablets and Powder, DUEXIS® (ibuprofen/famotidine), KRISTEXXA® (pegloticase), MIGERGOT® (ergotamine tartrate & caffeine suppositories), PENNSAID® (diclofenac sodium topical solution) 2% w/w, or PENNSAID 2%, PROCYSBI® (cysteamine bitartrate) delayed-release capsules, QUINSAIR™ (aerosolized form of levofloxacin), RAVICTI® (glycerol phenylbutyrate) Oral Liquid, RAYOS® (prednisone) delayed-release tablets and VIMOVO® (naproxen/esomeprazole magnesium).

We developed DUEXIS and RAYOS, known as LODOTRA® outside the United States, acquired the U.S. rights to VIMOVO from AstraZeneca AB in November 2013, acquired certain rights to ACTIMMUNE as a result of the Vidara Merger in September 2014, acquired the U.S. rights to PENNSAID 2% from Nuvo Research Inc. in October 2014, acquired RAVICTI and BUPHENYL, known as AMMONAPS® in certain European countries, as a result of our acquisition of Hyperion Therapeutics Inc., or Hyperion, in May 2015, acquired KRISTEXXA and the U.S. rights to MIGERGOT as a result of our acquisition of Crealta Holdings LLC., or Crealta, in January 2016 and acquired PROCYSBI and QUINSAIR as a result of our acquisition of Raptor Pharmaceutical Corp., or Raptio, in October 2016.

On May 18, 2016, we entered into a definitive agreement with Boehringer Ingelheim International GmbH, or Boehringer Ingelheim International, to acquire certain rights to interferon gamma-1b, which Boehringer Ingelheim International currently commercializes under the trade names IMUKIN®, IMMUKINE®, IMMUKIN® and IMMUKINE® in an estimated 30 countries primarily in Europe and the Middle East. Under the terms of the agreement, we paid Boehringer Ingelheim International €5.0 million ($5.6 million when converted using a Euro-to-Dollar exchange rate of 1.1132) upon signing and will pay €20.0 million upon closing, for certain rights for interferon gamma-1b in all territories outside of the United States, Canada and Japan, as we currently hold marketing rights to interferon gamma-1b in these territories. We currently market interferon gamma-1b as ACTIMMUNE in the United States. The transaction is expected to close in the first half of 2017 and we are continuing to work with Boehringer Ingelheim International to enable the transfer of applicable marketing authorizations. Under the terms of a separate agreement, we also in-licensed certain U.S., European and Canadian intellectual property rights for interferon gamma-1b for the treatment of Friedreich's ataxia, or FA, a degenerative neuro-muscular disorder. Interferon gamma-1b is currently not indicated or approved for the treatment of FA.

In February 2015, we submitted an investigational new drug application to the U.S. Food and Drug Administration for ACTIMMUNE in the treatment of FA. In June 2015, we commenced the Phase 3 Safety, Tolerability and Efficacy of ACTIMMUNE Dose Escalation in Friedreich's Ataxia Study, or STEADFAST, study, of ACTIMMUNE for the treatment of FA. Top-line results from the STEADFAST study are expected in late December 2016, at which time we will make a determination on the next steps for the development of ACTIMMUNE in the treatment of FA.
On October 25, 2016, we completed our acquisition of Raptor in which we acquired all of the issued and outstanding shares of Raptor’s common stock for $9.00 per share in cash, or approximately $804.7 million on a fully-diluted basis. Following completion of the acquisition, Raptor became our wholly owned subsidiary and converted to a Delaware limited liability company, changing its name to Horizon Pharmaceutical LLC. We financed the transaction through $300.0 million aggregate principal amount of 8.75% Senior Notes due 2024, or the 2024 Senior Notes, $375.0 million aggregate principal amount of loans pursuant to an amendment to our existing credit agreement and cash on hand.

Our medicines are dispensed by retail and specialty pharmacies. Part of our commercial strategy for our primary care and rheumatology business units is to offer physicians the opportunity to have their patients fill prescriptions through pharmacies participating in our HorizonCares patient access program. This program does not involve us in the prescribing of medicines. The purpose of this program is solely to assist in ensuring that, when physicians determine that one of our medicines offers a potential clinical benefit to their patients and prescribe the medicine for an eligible patient, financial assistance may be available to reduce a commercial patient’s out-of-pocket costs. In the first nine months of 2016, this resulted in 99.9 percent of commercial patients having co-pay amounts of $10 or less when filling prescriptions for our medicines utilizing our patient access program. For commercial patients who are prescribed our primary care medicines or RAYOS, the HorizonCares program offers co-pay assistance when a third-party payer covers a prescription but requires an eligible patient to pay a co-pay or deductible, and offers full subsidization when a third-party payer rejects coverage for an eligible patient. For patients who are prescribed our orphan medicines, our patient access programs provide reimbursement support, a clinical nurse program, co-pay and other patient assistance. The aggregate commercial value of our patient access programs for the nine months ended September 30, 2016 was $1.275.2 million. All pharmacies that dispense prescriptions for our medicines, which we estimate to be about 20,000 during the first nine months of 2016, are fully independent, including those that participate in HorizonCares. We do not own or possess any option to purchase an ownership stake in any pharmacy that distributes our medicines, and our relationship with each pharmacy is non-exclusive and arm’s length. All of our medicines are dispensed through pharmacies independent of our business.

As an alternative means of ensuring access to our medicines, we have also begun pursuing business arrangements with pharmacy benefit managers, or PBMs, and other payers to secure formulary status and reimbursement of our medicines, such as our recently announced arrangements with CVS Caremark and Prime Therapeutics LLC. While we believe that, if successful, this strategy would result in broader inclusion of certain of our primary care medicines on healthcare plan formularies, and therefore increase payer reimbursement and lower our cost of providing patient access programs, these arrangements generally require us to pay administrative and rebate payments to the PBMs and/or other payers.

We have a compliance program in place to address adherence with various laws and regulations relating to the selling, marketing and manufacturing of our medicines, as well as certain third-party relationships, including pharmacies. Specifically with respect to pharmacies, the compliance program utilizes a variety of methods and tools to monitor and audit pharmacies, including those that participate in our patient access programs, to confirm their activities, adjudication and practices are consistent with our compliance policies and guidance.

We market our medicines in the United States through our field sales force, which numbered approximately 470 representatives as of September 30, 2016. Our strategy is to use the commercial strength and infrastructure we have established in creating a global biopharmaceutical company to continue the successful commercialization of our existing medicine portfolio while also expanding and leveraging these capabilities by identifying, developing, acquiring and commercializing additional differentiated and accessible medicines that address unmet medical needs.
RESULTS OF OPERATIONS
Comparison of Three Months Ended September 30, 2016 and 2015

The 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, 2016, compared to the three months ended September 30, 2015.

For the Three Months Ended September 30, 2016 2015 Increase / (Decrease) (in thousands)
Net sales $208,702 $226,544 $(17,842) (8%)
Cost of goods sold 85,161 61,250 23,911
Gross profit 123,541 165,294 (41,753) (25,054)
Operating expenses:
Research and development 12,814 13,073 (259) (2%)
Sales and marketing 72,564 51,973 20,591
General and administrative 59,485 54,516 4,969
Total operating expenses 144,863 119,562 25,301
Operating (loss) income $(21,322) 45,732 $(67,054)
Other income (expense), net:
Interest expense, net $(19,066) $(20,300) $(1,234)
Foreign exchange loss (108) (86) (22)
Other income (expense), net 6,879 (90) 6,969
Total other income (expense), net $(12,295) $(20,476) $(8,181)
(Loss) income before (benefit) expense for income taxes $(33,617) 25,256 $(58,873)
(Benefit) expense for income taxes $(27,747) 21,979 $(49,726)
Net (loss) income $(5,870) $3,277 $(9,147)

Net sales. Net sales decreased $17.8 million, or 7.9%, to $208.7 million during the three months ended September 30, 2016, from $226.5 million during the three months ended September 30, 2015. Excluding the $65.0 million litigation settlement with Express Scripts, Inc., or Express Scripts, as discussed further below, non-GAAP adjusted net sales increased by $47.2 million, or 20.8%, from the same quarter in the prior year.

The following table presents a summary of total net sales attributed to geographic sources for the three months ended September 30, 2016 and 2015 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amount</td>
<td>% of Total Net Sales</td>
</tr>
<tr>
<td>United States</td>
<td>$ 204,302</td>
<td>98%</td>
</tr>
<tr>
<td>Rest of world</td>
<td>4,400</td>
<td>2%</td>
</tr>
<tr>
<td>Total Net Sales</td>
<td>$ 208,702</td>
<td></td>
</tr>
</tbody>
</table>

The following table reflects the components of net sales for the three months ended September 30, 2016 and 2015:

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended September 30, 2016</th>
<th>Change</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(in thousands)</td>
<td>$</td>
<td>%</td>
</tr>
<tr>
<td>PENNSAID 2%</td>
<td>$ 80,199</td>
<td>$ 43,892</td>
<td>83%</td>
</tr>
<tr>
<td>DUEXIS</td>
<td>47,615</td>
<td>56,902</td>
<td>(16)%</td>
</tr>
<tr>
<td>RAVICTI</td>
<td>42,176</td>
<td>33,427</td>
<td>26%</td>
</tr>
<tr>
<td>VIMOVO</td>
<td>32,839</td>
<td>46,855</td>
<td>(30)%</td>
</tr>
<tr>
<td>KRYSTEXXA</td>
<td>25,542</td>
<td>—</td>
<td>25,542</td>
</tr>
<tr>
<td>ACTIMMUNE</td>
<td>24,915</td>
<td>28,737</td>
<td>(13)%</td>
</tr>
<tr>
<td>RAYOS</td>
<td>13,419</td>
<td>11,670</td>
<td>15%</td>
</tr>
<tr>
<td>BUPHENYL</td>
<td>4,341</td>
<td>3,962</td>
<td>10%</td>
</tr>
<tr>
<td>LODOTRA</td>
<td>1,502</td>
<td>1,099</td>
<td>37%</td>
</tr>
<tr>
<td>MIGERGOT</td>
<td>1,154</td>
<td>—</td>
<td>1,154</td>
</tr>
<tr>
<td>Litigation settlement</td>
<td>(65,000)</td>
<td>—</td>
<td>(65,000)</td>
</tr>
<tr>
<td>Total Net Sales</td>
<td>$ 208,702</td>
<td>$ 226,544</td>
<td>(17,842)</td>
</tr>
</tbody>
</table>

* Percentage change is not meaningful.
The decrease in net sales during the three months ended September 30, 2016 was primarily due to the $65.0 million litigation settlement with Express Scripts, along with decreases in net sales of DUEXIS and VIMOVO, offset by growth in net sales of PENNSAID 2% and RAVICTI and the recognition of KRYSTEXXA sales following the acquisition of Crealta in January 2016.

**PENNSAID 2%**. Net sales increased $36.3 million, or 83%, to $80.2 million during the three months ended September 30, 2016, from $43.9 million during the three months ended September 30, 2015. Net sales increased by approximately $24.0 million due to higher net pricing and $12.3 million resulting from prescription volume growth.

**DUEXIS**. Net sales decreased $9.3 million, or 16%, to $47.6 million during the three months ended September 30, 2016, from $56.9 million during the three months ended September 30, 2015. Net sales decreased by approximately $17.5 million due to lower net pricing resulting from higher co-pay and other patient assistance, offset by an increase of approximately $8.2 million resulting from prescription volume growth.

**RAVICTI**. Net sales increased $8.8 million, or 26%, to $42.2 million during the three months ended September 30, 2016, from $33.4 million during the three months ended September 30, 2015. Net sales increased by approximately $7.6 million resulting from prescription volume growth and $1.2 million due to higher net pricing.

**VIMOVO**. Net sales decreased $14.0 million, or 30%, to $32.8 million during the three months ended September 30, 2016, from $46.8 million during the three months ended September 30, 2015. Net sales decreased by approximately $7.6 million due to lower net pricing resulting from higher co-pay and other patient assistance, and approximately $6.4 million resulting from prescription volume decreases.

**KRYSTEXXA**. Net sales were $25.5 million during the three months ended September 30, 2016. We began recognizing KRYSTEXXA sales following the acquisition of Crealta in January 2016.

**ACTIMMUNE**. Net sales decreased $3.8 million, or 13%, to $24.9 million during the three months ended September 30, 2016, from $28.7 million during the three months ended September 30, 2015. Net sales decreased by approximately $3.3 million resulting from prescription volume decreases and approximately $0.5 million due to lower net pricing resulting from higher co-pay and other patient assistance.

**RAYOS**. Net sales increased $1.7 million, or 15%, to $13.4 million during the three months ended September 30, 2016, from $11.7 million during the three months ended September 30, 2015. Net sales increased by approximately $2.4 million resulting from prescription volume growth, offset by a decrease of approximately $0.7 million due to lower net pricing resulting from higher co-pay and other patient assistance.

**BUPHENYL**. Net sales increased $0.4 million, or 10%, to $4.3 million during the three months ended September 30, 2016, from $3.9 million during the three months ended September 30, 2015. Net sales increased by approximately $1.1 million resulting from prescription volume growth, offset by a decrease of approximately $0.7 million due to lower net pricing resulting from higher co-pay and other patient assistance.

**LODOTRA**. Net sales increased $0.4 million, or 37%, to $1.5 million during the three months ended September 30, 2016, from $1.1 million during the three months ended September 30, 2015. The increase was the result of increased medicine shipments to our European distribution partner, Mundipharma International Corporation Limited, or Mundipharma. LODOTRA shipments to Mundipharma are not linear or directly tied to Mundipharma’s in-market sales and can therefore fluctuate significantly from quarter to quarter.

**MIGERGOT**. Net sales were $1.2 million during the three months ended September 30, 2016. We began recognizing MIGERGOT sales following the acquisition of Crealta in January 2016.

In September 2016, we entered into a settlement agreement and mutual release with Express Scripts pursuant to which we and Express Scripts were released from any and all claims relating to our then ongoing litigation without admitting any fault or wrongdoing and we agreed to pay Express Scripts $65.0 million. This settlement has been accounted for as a reduction of “net sales” in the condensed consolidated statement of comprehensive loss for the three months ended September 30, 2016.
The table below reconciles our gross to net sales for the three months ended September 30, 2016 and 2015 (in millions):

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amount</td>
<td>% of Gross Sales</td>
</tr>
<tr>
<td>Gross sales</td>
<td>$865.9</td>
<td>100.0%</td>
</tr>
<tr>
<td>Adjustments to gross sales:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prompt pay discounts</td>
<td>(16.7)</td>
<td>(1.9)%</td>
</tr>
<tr>
<td>Medicine returns</td>
<td>(9.1)</td>
<td>(1.1)%</td>
</tr>
<tr>
<td>Co-pay and other patient assistance</td>
<td>(458.4)</td>
<td>(52.9)%</td>
</tr>
<tr>
<td>Wholesaler fees and commercial rebates</td>
<td>(30.2)</td>
<td>(3.5)%</td>
</tr>
<tr>
<td>Government rebates and chargebacks</td>
<td>(77.8)</td>
<td>(9.0)%</td>
</tr>
<tr>
<td>Litigation settlement</td>
<td>(65.0)</td>
<td>(7.5)%</td>
</tr>
<tr>
<td>Total adjustments</td>
<td>(657.2)</td>
<td>(75.9)%</td>
</tr>
<tr>
<td>Net sales</td>
<td>$208.7</td>
<td>24.1%</td>
</tr>
</tbody>
</table>

During the three months ended September 30, 2016, co-pay and other patient assistance, as a percentage of gross sales, increased to 52.9% from 47.2% during the three months ended September 30, 2015. The increase was primarily due to the rollout of our HorizonCares program to all sales territories which helped ensure patient access to our medicines in the face of increased control by certain PBMs and payers.

Cost of Goods Sold. Cost of goods sold increased $23.9 million to $85.2 million during the three months ended September 30, 2016, from $61.3 million during the three months ended September 30, 2015. As a percentage of net sales, cost of goods sold was 40.8% during the three months ended September 30, 2016, compared to 27.0% during the three months ended September 30, 2015. The large increase in costs of goods as a percentage of net sales was due to a decrease in net sales in the three months ended September 30, 2016 as a result of a litigation settlement with Express Scripts. The increase in cost of goods sold was primarily attributable to an increase in intangible amortization expense of $9.1 million, a $4.4 million increase in medicine costs associated with higher sales, a $7.2 million increase in inventory step-up amortization and higher royalty accretion expense of $3.2 million.

The increase in intangible amortization of $9.1 million during the three months ended September 30, 2016 compared to the prior year period was due to the amortization of developed technology related to KRUSTEXXA and MIGERGOT (acquired in January 2016).

The increase in inventory step-up amortization of $7.2 million during the three months ended September 30, 2016 compared to the prior year period was due to $11.3 million recorded during the three months ended September 30, 2016 related to KRUSTEXXA and MIGERGOT inventory step-up (acquired in January 2016) compared to $4.1 million expense recorded during the three months ended September 30, 2015 related to RAVICTI and BUPHENYL inventory step-up (acquired in May 2015).

Research and Development Expenses. Research and development expenses decreased $0.3 million to $12.8 million during the three months ended September 30, 2016, from $13.1 million during the three months ended September 30, 2015. The decrease in research and development expenses during the three months ended September 30, 2016 was primarily associated with a decrease of $2.2 million in acquisition-related research and development expenses offset by increases in employee and other costs of $1.9 million. During the fourth quarter of 2016, we anticipate investing additional amounts in clinical development, regulatory and commercial functions for a potential launch of ACTIMMUNE for FA. We expect to have top-line results from the STEADFAST study in late December 2016.

Sales and Marketing Expenses. Sales and marketing expenses increased $20.6 million to $72.6 million during three months ended September 30, 2016, from $52.0 million during the three months ended September 30, 2015. The increase in sales and marketing expenses was in line with the significant growth in gross sales and an increase in the number of sales representatives over the same period last year. The increase was primarily attributable to an increase of $11.5 million in employee costs and an increase of $9.6 million in marketing and commercialization expenses, offset by a decrease of $0.5 million in expenses relating to the distribution of medicine samples. As of September 30, 2016, we had approximately 470 sales representatives, a decrease from approximately 500 sales representatives as of June 30, 2016, and this is not expected to be a continuing trend. During the fourth quarter of 2016, we anticipate investing additional amounts in expanding our managed care organization to account for a broader contracting strategy with PBMs and payers, including the addition of national and regional account managers expected to provide long-term durability to our primary care medicines. Additionally, during the fourth quarter of 2016, we anticipate investing in marketing, medical education and commercial infrastructure to support long-term growth of KRUSTEXXA, including new patient access managers to focus on account support of additional KRUSTEXXA treatment sites.
General and Administrative Expenses. General and administrative expenses increased $5.0 million to $59.5 million during the three months ended September 30, 2016, from $54.5 million during the three months ended September 30, 2015. The increase was primarily attributable to an increase of $2.8 million in share-based compensation expenses and $9.4 million related to our growth in headcount and operating costs following the Crealta acquisition, offset by a decrease of $7.2 million in acquisition-related general and administrative expenses.

Interest Expense, Net. Interest expense, net, decreased $1.2 million to $19.1 million during the three months ended September 30, 2016, from $20.3 million during the three months ended September 30, 2015. The decrease was primarily due to a decrease in amortization of debt discount during the three months ended September 30, 2016.

Other Income (Expense) net. Other income (expense), net during the three months ended September 30, 2016 was primarily related to the release of a contingent liability of $6.9 million which was recorded as part of acquisition accounting for Crealta. In December 2015, it was considered probable that the manufacture of the active pharmaceutical ingredient, or API, for KRYSTEXXA would be moved out of Israel based on a notice of termination provided by its contract manufacturer, therefore triggering a repayment obligation to Israel’s Office of the Chief Scientist. As a result, Crealta recorded a charge of $6.9 million to cost of goods sold and a corresponding reserve to non-current liabilities. This reserve was then recorded in “Other non-current liabilities” as part of the acquisition accounting for Crealta. Following the execution of an amendment to our agreement with such contract manufacturer and our subsequent determination that the manufacture of the KRYSTEXXA API would not be moved outside of Israel, the contingent liability was released to “Other income (expense)” during the three months ended September 30, 2016.

(Benefit) expense for Income Taxes. During the three months ended September 30, 2016, we recorded a benefit for income taxes of $27.7 million compared to an expense of $22.0 million during the three months ended September 30, 2015. The benefit for income taxes during the three months ended September 30, 2016 was primarily attributable to pre-tax losses incurred in higher tax rate jurisdictions which exceeded pre-tax income in lower tax rate jurisdictions as well as the tax impact of certain discrete factors and events, including the tax benefit recorded as a result of the $65.0 million litigation settlement with Express Scripts.

Comparison of Nine Months Ended September 30, 2016 and 2015

The 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, 2016, compared to the nine months ended September 30, 2015.

<table>
<thead>
<tr>
<th>For the Nine Months Ended September 30,</th>
<th>Increase / (Decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2016</td>
</tr>
<tr>
<td>Net sales</td>
<td>$670,770</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>243,520</td>
</tr>
<tr>
<td>Gross profit</td>
<td>427,250</td>
</tr>
<tr>
<td>Operating expenses</td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>36,746</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>227,697</td>
</tr>
<tr>
<td>General and administrative</td>
<td>179,866</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>444,309</td>
</tr>
<tr>
<td>Operating (loss) income</td>
<td>(17,059)</td>
</tr>
<tr>
<td>Other income (expense), net:</td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(57,752)</td>
</tr>
<tr>
<td>Foreign exchange loss</td>
<td>(266)</td>
</tr>
<tr>
<td>Loss on induced conversion of debt and debt extinguishment</td>
<td>(77,624)</td>
</tr>
<tr>
<td>Other income (expense), net</td>
<td>6,839</td>
</tr>
<tr>
<td>Total other income (expense), net</td>
<td>(51,179)</td>
</tr>
<tr>
<td>Loss before benefit for income taxes</td>
<td>(68,238)</td>
</tr>
<tr>
<td>Benefit for income taxes</td>
<td>(31,946)</td>
</tr>
<tr>
<td>Net (loss) income</td>
<td>(36,292)</td>
</tr>
</tbody>
</table>

Net sales. Net sales increased $158.3 million, or 30.9%, to $670.8 million during the nine months ended September 30, 2016, from $512.5 million during the nine months ended September 30, 2015. Excluding the $65.0 million settlement with Express Scripts, as discussed further below, non-GAAP adjusted net sales increased by $223.3 million, or 43.6%, from the same nine month period in the prior year.
The following table presents a summary of total net sales attributed to geographic sources for the nine months ended September 30, 2016 and 2015 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amount</td>
<td>% of Total Net Sales</td>
</tr>
<tr>
<td>United States</td>
<td>$660,608</td>
<td>98%</td>
</tr>
<tr>
<td>Rest of world</td>
<td>10,162</td>
<td>2%</td>
</tr>
<tr>
<td>Total Net Sales</td>
<td>$670,770</td>
<td></td>
</tr>
</tbody>
</table>

The following table reflects the components of net sales for the nine months ended September 30, 2016 and 2015:

<table>
<thead>
<tr>
<th>Product</th>
<th>Nine Months Ended September 30,</th>
<th>Change</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2016 (in thousands)</td>
<td>2015</td>
<td>$</td>
</tr>
<tr>
<td>PENNSAID 2%</td>
<td>$207,857</td>
<td>$91,583</td>
<td>$116,274</td>
</tr>
<tr>
<td>DUEXIS</td>
<td>122,780</td>
<td>129,981</td>
<td>(7,201)</td>
</tr>
<tr>
<td>RAVICTI</td>
<td>118,599</td>
<td>52,420</td>
<td>66,179</td>
</tr>
<tr>
<td>VIMOVO</td>
<td>89,710</td>
<td>119,628</td>
<td>(29,918)</td>
</tr>
<tr>
<td>ACTIMMUNE</td>
<td>80,465</td>
<td>79,369</td>
<td>1,096</td>
</tr>
<tr>
<td>KRYSTEXXA</td>
<td>61,570</td>
<td>--</td>
<td>61,570</td>
</tr>
<tr>
<td>RAYOS</td>
<td>36,062</td>
<td>29,191</td>
<td>6,871</td>
</tr>
<tr>
<td>BUPHENYL</td>
<td>12,134</td>
<td>7,822</td>
<td>4,312</td>
</tr>
<tr>
<td>LODOTRA</td>
<td>3,397</td>
<td>2,512</td>
<td>885</td>
</tr>
<tr>
<td>MIGERGOT</td>
<td>3,196</td>
<td>--</td>
<td>3,196</td>
</tr>
<tr>
<td>Litigation settlement</td>
<td>(65,000)</td>
<td>--</td>
<td>(65,000)</td>
</tr>
<tr>
<td>Total Net Sales</td>
<td>$670,770</td>
<td>$512,506</td>
<td>$158,264</td>
</tr>
</tbody>
</table>

* Percentage change is not meaningful.

The increase in net sales during the nine months ended September 30, 2016 was primarily due to the growth in net sales of PENNSAID 2%, the full-period recognition of RAVICTI sales in 2016, compared to a partial period recognition in 2015 following the acquisition of Hyperion in May 2015, and the recognition of KRYSTEXXA sales following the acquisition of Crealta in January 2016, offset by the $65.0 million litigation settlement with Express Scripts along with lower net sales of VIMOVO and DUEXIS.

PENNSAID 2%. Net sales increased $116.3 million, or 127%, to $207.9 million during the nine months ended September 30, 2016, from $91.6 million during the nine months ended September 30, 2015. Net sales increased by approximately $65.8 million resulting from prescription volume growth and approximately $50.5 million due to higher net pricing.

DUEXIS. Net sales decreased $7.2 million, or 6%, to $122.8 million during the nine months ended September 30, 2016, from $130.0 million during the nine months ended September 30, 2015. Net sales decreased by approximately $48.7 million due to lower net pricing resulting from higher co-pay and other patient assistance, offset by an increase of approximately $41.5 million resulting from prescription volume growth.

RAVICTI. Net sales increased $66.2 million, or 126%, to $118.6 million during the nine months ended September 30, 2016, from $52.4 million during the nine months ended September 30, 2015. We began recognizing RAVICTI sales following the closing of the Hyperion acquisition on May 7, 2015, therefore only a partial period of RAVICTI sales were recognized during the nine months ended September 30, 2015, compared with full-period recognition of sales during the nine months ended September 30, 2016.

VIMOVO. Net sales decreased $29.9 million, or 25%, to $89.7 million during the nine months ended September 30, 2016, from $119.6 million during the nine months ended September 30, 2015. Net sales decreased by approximately $35.8 million due to lower net pricing resulting from higher co-pay and other patient assistance, offset by an increase of approximately $5.9 million resulting from prescription volume growth.

ACTIMMUNE. Net sales increased $1.1 million, or 1%, to $80.5 million during the nine months ended September 30, 2016, from $79.4 million during the nine months ended September 30, 2015. Net sales increased by approximately $8.5 million due to higher net pricing, offset by a decrease of approximately $7.4 million resulting from prescription volume decreases.

KRYSTEXXA. Net sales were $61.6 million during the nine months ended September 30, 2016. We began recognizing KRYSTEXXA sales following the acquisition of Crealta in January 2016.
**RAYOS.** Net sales increased $6.9 million, or 24%, to $36.1 million during the nine months ended September 30, 2016, from $29.2 million during the nine months ended September 30, 2015. Net sales increased by approximately $8.4 million resulting from prescription volume growth, offset by a decrease of approximately $1.5 million due to lower net pricing resulting from higher co-pay and other patient assistance.

**BUPHENYL.** Net sales increased $4.3 million, or 55%, to $12.1 million during the nine months ended September 30, 2016, from $7.8 million during the nine months ended September 30, 2015. We began recognizing BUPHENYL sales following the closing of the Hyperion acquisition on May 7, 2015, therefore only a partial period of BUPHENYL sales were recognized during the nine months ended September 30, 2015, compared with full-period recognition of sales during the nine months ended September 30, 2016.

**LODOTRA.** Net sales increased $0.9 million, or 35%, to $3.4 million during the nine months ended September 30, 2016, from $2.5 million during the nine months ended September 30, 2015. The increase was the result of increased medicine shipments to our European distribution partner, Mundipharma. LODOTRA shipments to Mundipharma are not linear or directly tied to Mundipharma’s in-market sales and can therefore fluctuate significantly from quarter to quarter.

**MIGERGOT.** Net sales were $3.2 million during the nine months ended September 30, 2016. We began recognizing MIGERGOT sales following the acquisition of Crealta in January 2016.

In September 2016, we entered into a settlement agreement and mutual release with Express Scripts pursuant to which we and Express Scripts were released from any and all claims relating to our then ongoing litigation without admitting any fault or wrongdoing and we agreed to pay Express Scripts $65.0 million. This settlement has been accounted for as a reduction of “net sales” in the condensed consolidated statement of comprehensive loss for the nine months ended September 30, 2016.

The table below reconciles our gross to net sales for the nine months ended September 30, 2016 and 2015 (in millions):

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount</td>
<td>$2,350.5</td>
<td>$1,378.3</td>
</tr>
<tr>
<td>% of Gross Sales</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Adjustments to gross sales:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prompt pay discounts</td>
<td>(46.8)</td>
<td>(26.8)</td>
</tr>
<tr>
<td>% of Gross Sales</td>
<td>(2.0)%</td>
<td>(1.9)%</td>
</tr>
<tr>
<td>Medicine returns</td>
<td>(9.3)</td>
<td>(11.6)</td>
</tr>
<tr>
<td>% of Gross Sales</td>
<td>(0.4)%</td>
<td>(0.8)%</td>
</tr>
<tr>
<td>Co-pay and other patient assistance</td>
<td>(1,275.2)</td>
<td>(673.5)</td>
</tr>
<tr>
<td>% of Gross Sales</td>
<td>(54.3)%</td>
<td>(48.9)%</td>
</tr>
<tr>
<td>Wholesaler fees and commercial rebates</td>
<td>(85.0)</td>
<td>(44.3)</td>
</tr>
<tr>
<td>% of Gross Sales</td>
<td>(3.6)%</td>
<td>(3.2)%</td>
</tr>
<tr>
<td>Government rebates and chargebacks</td>
<td>(198.4)</td>
<td>(109.6)</td>
</tr>
<tr>
<td>% of Gross Sales</td>
<td>(8.4)%</td>
<td>(8.0)%</td>
</tr>
<tr>
<td>Litigation settlement</td>
<td>(65.0)</td>
<td>—</td>
</tr>
<tr>
<td>% of Gross Sales</td>
<td>(2.8)%</td>
<td>—</td>
</tr>
<tr>
<td>Total adjustments</td>
<td>(1,679.7)</td>
<td>(865.8)</td>
</tr>
<tr>
<td>% of Gross Sales</td>
<td>(71.5)%</td>
<td>(62.8)%</td>
</tr>
<tr>
<td>Net sales</td>
<td>$670.8</td>
<td>$512.5</td>
</tr>
<tr>
<td>% of Gross Sales</td>
<td>28.5%</td>
<td>37.2%</td>
</tr>
</tbody>
</table>

During the nine months ended September 30, 2016, co-pay and other patient assistance, as a percentage of gross sales, increased to 54.3% from 48.9% during the nine months ended September 30, 2015. The increase was primarily due to the rollout of our HorizonCares program to all sales territories which helped ensure patient access to our medicines in the face of increased control by certain PBMs and payers. During the nine months ended September 30, 2016, we recorded a net expense reduction of $4.2 million in accrued wholesaler fees and commercial rebates and government rebates and chargebacks resulting from the receipt of lower than estimated invoices related to the year ended December 31, 2015.

**Cost of Goods Sold.** Cost of goods sold increased $91.6 million to $243.5 million during the nine months ended September 30, 2016, from $151.9 million during the nine months ended September 30, 2015. As a percentage of net sales, cost of goods sold was 36.3% during the nine months ended September 30, 2016 compared to 29.6% during the nine months ended September 30, 2015. The increase in costs of goods as a percentage of net sales was due to a decrease in net sales in the nine months ended September 30, 2016 as a result of a settlement with Express Scripts. The increase in cost of goods sold was primarily attributable to an increase in intangible amortization expense of $60.0 million, a $17.2 million increase in inventory step-up amortization, higher royalty accretion expense of $15.2 million and a $13.5 million increase in medicine costs associated with higher sales, offset by a decrease related to the remeasurement of royalties acquired through business combinations of $14.3 million, recorded during the nine months ended September 30, 2015.

The increase in intangible amortization of $60.0 million during the nine months ended September 30, 2016 compared to the prior year period was due to a $33.9 million increase in amortization expense related to RAVICTI and BUPHENYL intangible assets (acquired in May 2015) and $26.1 million amortization of developed technology related to KRYSTEXXA and MIGERGOT (acquired in January 2016).
The increase in inventory step-up amortization of $17.2 million during the nine months ended September 30, 2016 compared to the prior year period was due to $27.9 million recorded during the nine months ended September 30, 2016 related to KRYSTEXXA and MIGERGOT inventory step-up (acquired in January 2016) compared to $7.5 million recorded during the nine months ended September 30, 2015 related to RAVICTI and BUPHENYL inventory step-up (acquired in May 2015) and $3.2 million related to ACTIMMUNE inventory step-up (acquired in September 2014).

**Research and Development Expenses.** Research and development expenses increased $8.6 million to $36.8 million during the nine months ended September 30, 2016, from $28.2 million during the nine months ended September 30, 2015. The increase in research and development expenses during the nine months ended September 30, 2016 was primarily associated with an increase of $4.1 million in employee costs, including an increase of $2.1 million in share-based compensation to research and development employees, an increase of $2.8 million in general research and development costs, an increase of $1.4 million in regulatory submission fees and a $2.0 million upfront fee paid for a license of a patent, offset by a decrease of $1.7 million in acquisition-related research and development expenses.

**Sales and Marketing Expenses.** Sales and marketing expenses increased $70.6 million to $227.7 million during nine months ended September 30, 2016, from $157.1 million during the nine months ended September 30, 2015. The increase in sales and marketing expenses was in line with the significant growth in gross sales and an increase in the number of sales representatives over the same period and was primarily attributable to an increase of $36.1 million in employee costs, including $3.7 million related to share-based compensation resulting from increased staffing of our field sales force, an increase of $31.2 million in marketing and commercialization expenses and an increase of $3.3 million in expenses relating to the distribution of medicine samples.

**General and Administrative Expenses.** General and administrative expenses increased $21.9 million to $179.9 million during the nine months ended September 30, 2016, from $158.0 million during the nine months ended September 30, 2015. The increase was attributable to $21.3 million of share-based compensation expense, $37.7 million related to our growth in headcount and operating costs following the Hyperion and Crealta acquisitions, offset by a decrease of $37.1 million in acquisition-related general and administrative expenses.

**Interest Expense, Net.** Interest expense, net, increased $8.0 million to $57.8 million during the nine months ended September 30, 2016, from $49.8 million during the nine months ended September 30, 2015. The increased interest expense, net, was primarily due to full-period recognition during the nine months ended September 30, 2016 of the interest on higher borrowings to fund the acquisition of Hyperion in May 2015, including our $475.0 million aggregate principal amount of 6.625% Senior Notes due 2023, the six-year $400.0 million term loan facility, the 2015 Term Loan Facility, and our lower prior year borrowings under our prior five-year $300.0 million term loan facility, or 2014 Term Loan Facility.

**Loss on Induced Conversion of Debt and Debt Extinguishment.** The loss on induced conversion of debt and debt extinguishment during the nine months ended September 30, 2015 of $77.6 million was composed of $20.7 million related to the induced conversions of our 5.00% Convertible Senior Notes due 2018, or the Convertible Senior Notes, and $56.9 million related to the extinguishment of the 2014 Term Loan Facility. The loss on induced conversions consisted of $10.0 million for cash inducement payments, a $10.1 million charge for the extinguishment of debt and $0.6 million of expenses. The loss on extinguishment of the 2014 Term Loan Facility consisted of a $45.4 million early redemption premium and an $11.5 million charge for the extinguishment of debt.

**Other Income (Expense) net.** Other income (expense), net during the nine months ended September 30, 2016 was primarily related to the release of a contingent liability of $6.9 million which was recorded as part of acquisition accounting for Crealta. In December 2015, it was considered probable that the manufacture of the API for KRYSTEXXA would be moved out of Israel based on a notice of termination provided by its contract manufacturer, therefore triggering a repayment obligation to Israel’s Office of the Chief Scientist. As a result, Crealta recorded a charge of $6.9 million to cost of goods sold and a corresponding reserve to non-current liabilities. This reserve was then recorded in “Other non-current liabilities” as part of the acquisition accounting for Crealta. Following the execution of an amendment to our agreement with such contract manufacturer and our subsequent determination that the manufacture of the KRYSTEXXA API would not be moved outside of Israel, the contingent liability was released to “Other income (expense)” during the nine months ended September 30, 2016. Other income (expense), net during the nine months ended September 30, 2015 totaled $10.2 million, which primarily related to the fees for the Hyperion acquisition financing commitment.
Benefit for Income Taxes. During the nine months ended September 30, 2016, we recorded a benefit for income taxes of $31.9 million compared to $136.8 million during the nine months ended September 30, 2015. The benefit for income taxes during the nine months ended September 30, 2016 was primarily attributable to pre-tax losses incurred in higher tax rate jurisdictions which exceeded pre-tax income in lower tax rate jurisdictions. In addition, during the nine months ended September 30, 2016, we recognized certain discrete items which contributed to the overall tax benefit recognized, including the tax benefit recorded as a result of the $65.0 million litigation settlement with Express Scripts. The benefit for income taxes during the nine months ended September 30, 2015 was primarily attributable to the release of $105.1 million in valuation allowances in the United States due to the recognition of significant deferred tax liabilities as a result of the Hyperion acquisition.

NON-GAAP FINANCIAL MEASURES

EBITDA, or earnings before interest, taxes, depreciation and amortization, and adjusted EBITDA are used and provided by us as non-GAAP financial measures. We provide certain other financial measures such as non-GAAP adjusted net sales, non-GAAP net income and non-GAAP earnings per share which include adjustments to GAAP figures. The exclusion of the $65.0 million litigation settlement from GAAP net sales is the only adjustment reflected in non-GAAP adjusted net sales for the three and nine months ended September 30, 2016. Adjusted EBITDA and non-GAAP net income are intended to provide additional information on our performance, operations and profitability. Adjustments to our GAAP figures as well as EBITDA exclude acquisition-related expenses, an upfront fee for a license of a patent, the Express Scripts litigation settlement amount and loss on debt extinguishment, as well as non-cash items such as share-based compensation, inventory step-up, depreciation and amortization, remeasurement of royalties for medicines acquired through business combinations, royalty accretion, non-cash interest expense, the reversal of a pre-acquisition reserve upon the signing of a contract and other non-cash adjustments. Certain other special items or substantive events may also be included in the non-GAAP adjustments periodically when their magnitude is significant within the periods incurred. We maintain an established non-GAAP cost policy that guides the determination of what costs will be excluded in non-GAAP measures. We believe that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of our financial and operating performance. The non-GAAP financial measures are included with the intent of providing investors with a more complete understanding of our historical and expected financial results and trends and to facilitate comparisons between periods and with respect to projected information. In addition, these non-GAAP financial measures are among the indicators our management uses for planning and forecasting purposes and measuring our performance. For example, adjusted EBITDA is used by us as one measure of management performance under certain incentive compensation arrangements. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. The non-GAAP financial measures used by us may be calculated differently from, and therefore may not be comparable to, non-GAAP financial measures used by other companies.

Beginning in the second quarter of 2016, we modified the method of calculating non-GAAP income tax expense to align with guidance issued by the SEC on May 17, 2016. The new methodology calculates the income tax component of non-GAAP net income for each period by adjusting the GAAP tax expense (benefit) for the estimated tax impact of each non-GAAP adjustment based on the statutory income tax rate of the applicable jurisdictions for each non-GAAP adjustment. This new methodology does not reflect any use of net operating loss carryforwards that we potentially may have been able to use if our actual earnings for these periods had been the non-GAAP net income. Previously, we had calculated the income tax component of non-GAAP net income by using the estimated cash taxes that we expected to pay for the period. The non-GAAP net income and diluted net income per share amounts shown in the GAAP to non-GAAP reconciliation tables below are based on the new methodology.

Reconciliations of reported GAAP net sales to non-GAAP adjusted net sales, reported GAAP net (loss) income to EBITDA, adjusted EBITDA and non-GAAP net income, and the related per share amounts, are as follows (in thousands, except share and per share amounts):

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended September 30,</th>
<th>For the Nine Months Ended September 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2016</td>
<td>2015</td>
</tr>
<tr>
<td>GAAP Net Sales</td>
<td>$208,702</td>
<td>$226,544</td>
</tr>
<tr>
<td>Litigation settlement</td>
<td>65,000</td>
<td>---</td>
</tr>
<tr>
<td>Non-GAAP Adjusted Net Sales</td>
<td>$273,702</td>
<td>$226,544</td>
</tr>
<tr>
<td></td>
<td>For the Three Months Ended September 30</td>
<td>For the Nine Months Ended September 30</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------------------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>GAAP Net (Loss) Income</td>
<td>$ (5,870) 3,277</td>
<td>$ (36,292) 15,538</td>
</tr>
<tr>
<td>Depreciation</td>
<td>1,183 1,578</td>
<td>3,266 2,808</td>
</tr>
<tr>
<td>Amortization and accretion:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intangible amortization expense</td>
<td>50,757 41,707 151,199 91,217</td>
<td></td>
</tr>
<tr>
<td>Amortization of deferred revenue</td>
<td>(212) (490) (631) (753)</td>
<td></td>
</tr>
<tr>
<td>Accretion of royalty liabilities</td>
<td>9,734 6,551 28,762 13,571</td>
<td></td>
</tr>
<tr>
<td>Amortization of inventory step-up adjustment</td>
<td>11,305 4,140 27,853 10,635</td>
<td></td>
</tr>
<tr>
<td>Interest expense, net (including amortization of debt discount and deferred financing costs)</td>
<td>19,066 20,300 57,752 49,780</td>
<td></td>
</tr>
<tr>
<td>(Benefit) expense for income taxes</td>
<td>(27,747) 21,979 (31,946) (136,788)</td>
<td></td>
</tr>
<tr>
<td><strong>EBITDA</strong></td>
<td><strong>58,216 99,042</strong></td>
<td><strong>199,963 46,008</strong></td>
</tr>
<tr>
<td>Non-GAAP adjustments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remeasurement of royalties for medicines acquired through business combinations</td>
<td>— — — 14,277</td>
<td></td>
</tr>
<tr>
<td>Acquisition-related costs</td>
<td>5,159 14,498 16,456 64,841</td>
<td></td>
</tr>
<tr>
<td>Upfront fee for license of global patent</td>
<td>— — 2,000 —</td>
<td></td>
</tr>
<tr>
<td>Loss on induced conversion of debt and debt extinguishment</td>
<td>— — — 77,624</td>
<td></td>
</tr>
<tr>
<td>Share-based compensation</td>
<td>29,312 26,457 84,921 57,796</td>
<td></td>
</tr>
<tr>
<td>Royalties for medicines acquired through business combinations (1)</td>
<td>(9,564) (8,854) (27,159) (20,890)</td>
<td></td>
</tr>
<tr>
<td>Litigation settlement</td>
<td>65,000 — 65,000</td>
<td></td>
</tr>
<tr>
<td>Reversal of pre-acquisition reserve upon signing of contract</td>
<td>(6,900) — (6,900) —</td>
<td></td>
</tr>
<tr>
<td>Total of non-GAAP adjustments</td>
<td>83,007 32,101 134,318 193,648</td>
<td></td>
</tr>
<tr>
<td><strong>Adjusted EBITDA</strong></td>
<td><strong>$ 141,223 $ 131,143</strong></td>
<td><strong>$ 334,281 $ 239,656</strong></td>
</tr>
<tr>
<td>------------------------</td>
<td>------</td>
<td>------</td>
</tr>
<tr>
<td>$ (5,870)</td>
<td>$ 3,277</td>
<td>$ (36,292)</td>
</tr>
</tbody>
</table>

**Non-GAAP Adjustments:**

- **Remeasurement of royalties for medicines acquired through business combinations**
- **Acquisition-related costs**
- **Upfront fee for license of global patent**
- **Loss on induced conversion of debt and debt extinguishment**
- **Amortization and accretion:**
  - Intangible amortization expense
  - Amortization of debt discount and deferred financing costs
  - Accretion of royalty liabilities
  - Amortization of inventory step-up adjustment
  - Share-based compensation
  - Depreciation expense
  - Royalties for medicines acquired through business combinations
  - Reversal of pre-acquisition reserve upon signing of contract

**Income tax effect:**

<table>
<thead>
<tr>
<th>Income tax effect of pre-tax non-GAAP adjustments</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>$ (39,180)</td>
<td>$ (25,018)</td>
<td></td>
</tr>
</tbody>
</table>

**Other non-GAAP income tax adjustments:**

<table>
<thead>
<tr>
<th>Other non-GAAP income tax adjustments</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>$ (105,133)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total non-GAAP adjustments**

<table>
<thead>
<tr>
<th>Total non-GAAP adjustments</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>$ 121,343</td>
<td>$ 66,539</td>
<td></td>
</tr>
</tbody>
</table>

**Non-GAAP Earnings Per Share:**

- Weighted average ordinary shares – Basic
  | 2016 | 2015 |
  | 161,038,827 | 159,035,580 |
  | 160,472,530 | 145,208,252 |

- **Non-GAAP Earnings Per Share – Basic**
  | GAAP (loss) earnings per share – Basic | $ (0.04) | $ 0.02 | $ (0.23) | $ 0.11 |
  | Non-GAAP adjustments | 0.76 | 0.42 | 1.78 | 0.93 |
  | Non-GAAP earnings per share – Basic | $ 0.72 | $ 0.44 | $ 1.55 | $ 1.04 |

- **Weighted average ordinary shares – Diluted**
  | Weighted average ordinary shares – Basic | 2016 | 2015 |
  | 161,038,827 | 159,035,580 | 160,472,530 | 145,208,252 |

- **Non-GAAP Earnings Per Share – Diluted**
  | GAAP (loss) earnings per share – Diluted | $ (0.04) | $ 0.02 | $ (0.23) | $ 0.10 |
  | Non-GAAP adjustments | 0.75 | 0.40 | 1.77 | 0.88 |
  | Diluted earnings per share effect of ordinary share equivalents | (0.01) | | | |
  | Non-GAAP earnings per share – Diluted | $ 0.70 | $ 0.42 | $ 1.51 | $ 0.98 |

(1) Royalties for medicines acquired through business combinations relate to ACTIMMUNE, BUPHENYL, KRYSTEXXA, MIGERGOT, RAVICTI and VIMOVO.

(2) Adjustment to the GAAP tax (benefit) expense for the estimated tax impact of each non-GAAP adjustment based on the statutory tax rate of the applicable jurisdictions for each non-GAAP adjustment.

(3) Other non-GAAP income tax adjustments in the nine months ended September 30, 2015 of $105.1 million related to the release of certain valuation allowances in connection with the Hyperion acquisition.
LIQUIDITY, FINANCIAL POSITION AND CAPITAL RESOURCES

We have incurred losses since our inception in June 2005 and, as of September 30, 2016, we had an accumulated deficit of $717.5 million. We expect that our sales and marketing expenses will continue to increase as a result of our commercialization of our medicines, but we believe these cost increases will be more than offset by higher net sales and gross profits. We achieved operating profitability in the year ended December 31, 2015. While we have incurred operating losses of $21.3 million and $17.1 million for the three and nine months ended September 30, 2016, respectively, excluding the non-recurring $65.0 million litigation settlement with Express Scripts during the three months ended September 30, 2016, we achieved operating profitability during such periods and we expect our current operations to continue to achieve operating profitability in 2016, absent unusual or non-recurring items.

Our cash position as of September 30, 2016 does not reflect our use of approximately $207.6 million of cash on hand to fund our acquisition of Raptor on October 25, 2016.

We have financed our operations to date through equity financings, debt financings and the issuance of convertible notes, along with cash flows from operations during the last several quarters. As of September 30, 2016, we had $549.3 million in cash and cash equivalents and total debt with a book value of $1,147.2 million and face value of $1,270.0 million. We believe our existing cash and cash equivalents and our expected cash flows from our operations will be sufficient to fund our business needs for at least the next 12 months. Part of our strategy is to expand and leverage our commercial capabilities by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs. To the extent we enter into transactions to acquire medicines or businesses in the future, we will most likely need to finance a significant portion of those acquisitions through additional debt, equity or convertible debt financings.

In March 2015, April 2015 and June 2015, we entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes which were on substantially the same terms as prior conversion agreements entered into by us. Under these conversion agreements, the applicable holders agreed to convert an aggregate principal amount of $61.0 million of Convertible Senior Notes held by them and we agreed to settle such conversions by issuing an aggregate of 11,368,921 ordinary shares. In addition, pursuant to such conversion agreements, we made an aggregate cash payment of $10.0 million to the applicable holders for additional exchange consideration and $0.9 million for accrued and unpaid interest. Following these conversions, there were no Convertible Senior Notes remaining outstanding.

On March 13, 2015, Horizon Pharma Investment Limited, a wholly owned subsidiary of Horizon Pharma plc, or Horizon Investment, completed a private placement of $475.0 million aggregate principal amount of Exchangeable Senior Notes to several investment banks acting as initial purchasers who subsequently resold the Exchangeable Senior Notes to qualified institutional buyers as defined in Rule 144A under the Securities Act. The net proceeds from the offering of the Exchangeable Senior Notes were approximately $387.2 million, after deducting the initial purchasers’ discount and offering expenses payable by Horizon Investment.

We have fully and unconditionally guaranteed the Exchangeable Senior Notes and the Guarantee are Horizon Investment’s and our senior unsecured obligations. The Exchangeable Senior Notes accrue interest at an annual rate of 2.50% payable semiannually in arrears on March 15 and September 15 of each year, beginning on September 15, 2015. The Exchangeable Senior Notes will mature on March 15, 2022, unless earlier exchanged, repurchased or redeemed. The initial exchange rate is 34.8979 of our ordinary shares per $1,000 principal amount of the Exchangeable Senior Notes (equivalent to an initial exchange price of approximately $28.66 per ordinary share).

On April 21, 2015, we closed an underwritten public offering of 17,652,500 of our ordinary shares at a price to the public of $28.25 per share, or the 2015 Offering. The net proceeds to us from the 2015 Offering were approximately $475.6 million, after deducting underwriting discounts and other offering expenses payable by us.

On April 29, 2015, Horizon Pharma Financing Inc., our then wholly owned subsidiary, or Horizon Financing, completed a private placement of $475.0 million aggregate principal amount of 2023 Senior Notes to certain investment banks acting as initial purchasers who subsequently resold the 2023 Senior Notes to qualified institutional buyers as defined in Rule 144A under the Securities Act and in offshore transactions to non-U.S. Persons in reliance on Regulation S under the Securities Act. The net proceeds from the 2023 Senior Notes were approximately $462.3 million.

In connection with the closing of the Hyperion acquisition on May 7, 2015, Horizon Financing merged with and into HPI and, as a result, the 2023 Senior Notes became HPI’s general unsecured senior obligations and we and all of our direct and indirect subsidiaries that are guarantors under the 2015 Senior Secured Credit Facility (as described below) fully and unconditionally guaranteed on a senior unsecured basis HPI’s obligations under the 2023 Senior Notes.

The 2023 Senior Notes accrue interest at an annual rate of 6.625% payable semiannually in arrears on May 1 and November 1 of each year, beginning on November 1, 2015. The 2023 Senior Notes will mature on May 1, 2023, unless earlier exchanged, repurchased or redeemed.
Except as described below, the 2023 Senior Notes may not be redeemed before May 1, 2018. Thereafter, some or all of the 2023 Senior Notes may be redeemed at any time at specified redemption prices, plus accrued and unpaid interest to the redemption date. At any time prior to May 1, 2018, some or all of the 2023 Senior Notes may be redeemed at a price equal to 100% of the aggregate principal amount thereof, plus a make-whole premium and accrued and unpaid interest to, but not including, the redemption date. Also prior to May 1, 2018, up to 35% of the aggregate principal amount of the 2023 Senior Notes may be redeemed at a redemption price of 106.625% of the aggregate principal amount thereof, plus accrued and unpaid interest, with the net proceeds of certain equity offerings; provided that: (1) at least 65% of the aggregate principal amount of notes originally issued under the indenture (excluding notes held by the parent and its subsidiaries) remains outstanding immediately after the occurrence of such redemption; and (2) the redemption occurs with 180 days of the date of closing such equity offering. In addition, the 2023 Senior Notes may be redeemed in whole but not in part at a redemption price equal to 100% of the principal amount plus accrued and unpaid interest and additional amounts, if any, to, but excluding, the redemption date, if on the next date on which any amount would be payable in respect of the 2023 Senior Notes, HPI or any guarantor is or would be required to pay additional amounts as a result of certain tax-related events.

If we undergo a change of control, HPI will be required to make an offer to purchase all of the 2023 Senior Notes at a price in cash equal to 101% of the aggregate principal amount thereof plus accrued and unpaid interest to, but not including, the repurchase date. If we or certain of our subsidiaries engage in certain asset sales, HPI will be required under certain circumstances to make an offer to purchase the 2023 Senior Notes at 100% of the principal amount thereof, plus accrued and unpaid interest to the repurchase date.

On May 7, 2015, we, HPI, and certain of our subsidiaries entered into a credit agreement with Citibank N.A., as administrative agent and collateral agent, and the lenders from time to time party thereto, or, as amended, the credit agreement, providing for (i) the six-year $400.0 million 2015 Term Loan Facility; (ii) an uncommitted accordion facility subject to the satisfaction of certain financial and other conditions; and (iii) one or more uncommitted refinancing loan facilities with respect to loans thereunder, or the 2015 Senior Secured Credit Facility. The initial borrower under the 2015 Term Loan Facility is HPI. The credit agreement allows for us and certain of our other subsidiaries to become borrowers under the accordion or refinancing facilities. Until October 25, 2016, loans under the 2015 Term Loan Facility bore interest, at each borrower’s option, at a rate equal to either the London Inter-Bank Offer Rate, or LIBOR, plus an applicable margin of 3.50% per year (subject to a 1.0% LIBOR floor), or the adjusted base rate plus 2.50%. The issuance of the Incremental Loans (as defined below) resulted in an increase of the interest rate applicable to the loans under the 2015 Term Loan Facility, as of October 25, 2016, to LIBOR plus an applicable margin of 4.00% per year (subject to a 1.0% LIBOR floor), or the adjusted base rate plus 3.00%. The adjusted base rate is defined as the greater of (a) LIBOR (using one-month interest period) plus 1%, (b) prime rate, (c) fed funds plus ½ of 1% and (d) 2%. We borrowed the full $400.0 million available under the 2015 Term Loan Facility on May 7, 2015 as a LIBOR-based borrowing. The net proceeds from the 2015 Term Loan Facility were approximately $391.7 million.

The obligations under the credit agreement and any swap obligations and cash management obligations owing to a lender (or an affiliate of a lender) thereunder are and will be guaranteed by our and each of our existing and subsequently acquired or organized direct and indirect subsidiaries (other than certain immaterial subsidiaries, subsidiaries whose guarantee would result in material adverse tax consequences and subsidiaries whose guarantee is prohibited by applicable law). The obligations under the credit agreement and any such swap and cash management obligations are secured, subject to customary permitted liens and other agreed upon exceptions, by a perfected security interest in (i) all tangible and intangible assets of the borrowers and the guarantors, except for certain customary excluded assets, and (ii) all of the capital stock owned by the borrowers and guarantors thereunder (limited, in the case of the stock of certain non-U.S. subsidiaries of the borrowers, to 65% of the capital stock of such subsidiaries).

We are permitted to make voluntary prepayments at any time without payment of a premium. We are required to make mandatory prepayments of loans under the 2015 Term Loan Facility (without payment of a premium) with (a) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (b) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions), (c) net cash proceeds from issuances of debt (other than certain permitted debt), and (d) beginning with the fiscal year ending December 31, 2016, 50% of our excess cash flow (subject to decrease to 25% or 0% if our first lien leverage ratio is less than 2.25:1 and 1.75:1, respectively). The loans under the 2015 Term Loan Facility will amortize in equal quarterly installments in an aggregate annual amount equal to 1% of the original principal amount thereof, with any remaining balance payable on the final maturity date of the loans under the 2015 Term Loan Facility.

We used the net proceeds from the 2015 Offering, the offering of the 2023 Senior Notes, borrowings under the 2015 Term Loan Facility and existing cash to fund our acquisition of Hyperion, repay the $300.0 million outstanding amounts under the 2014 Term Loan Facility plus the related $45.4 million make-whole fee, and pay prepayment premiums, fees and expenses in connection with the foregoing.
On October 25, 2016, HPI and Horizon Pharma USA, Inc., our wholly-owned subsidiary, or HPUSA, and, together with HPI, the 2024 Issuers, completed a private placement of $300.0 million aggregate principal amount of 2024 Senior Notes to certain investment banks acting as initial purchasers who subsequently resold the 2024 Senior Notes to qualified institutional buyers as defined in Rule 144A under the Securities Act.

The 2024 Senior Notes are the 2024 Issuers’ general unsecured senior obligations and we and all of our direct and indirect subsidiaries that are guarantors under the 2015 Senior Secured Credit Facility and the 2016 Incremental Loan Facility (as defined below) fully and unconditionally guaranteed on a senior unsecured basis the 2024 Issuers’ obligations under the 2024 Senior Notes.

The 2024 Senior Notes accrue interest at an annual rate of 8.75% payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2017. The 2024 Senior Notes will mature on November 1, 2024, unless earlier exchanged, repurchased or redeemed.

Except as described below, the 2024 Senior Notes may not be redeemed before November 1, 2019. Thereafter, some or all of the 2024 Senior Notes may be redeemed at any time at specified redemption prices, plus accrued and unpaid interest to the redemption date. At any time prior to November 1, 2019, some or all of the 2024 Senior Notes may be redeemed at a price equal to 100% of the aggregate principal amount thereof, plus a make-whole premium and accrued and unpaid interest to the redemption date. Also prior to November 1, 2019, up to 35% of the aggregate principal amount of the 2024 Senior Notes may be redeemed at a redemption price of 108.75% of the aggregate principal amount thereof, plus accrued and unpaid interest, with the net proceeds of certain equity offerings. In addition, the 2024 Senior Notes may be redeemed in whole but not in part at a redemption price equal to 100% of the principal amount plus accrued and unpaid interest and additional amounts, if any, to, but excluding, the redemption date, if on the next date on which any amount would be payable in respect of the 2024 Senior Notes, the 2024 Issuers or any guarantor is or would be required to pay additional amounts as a result of certain tax-related events.

If we undergo a change of control, the 2024 Issuers will be required to make an offer to purchase all of the 2024 Senior Notes at a price in cash equal to 101% of the aggregate principal amount thereof plus accrued and unpaid interest to, but not including, the repurchase date. If we or certain of our subsidiaries engage in certain asset sales, the 2024 Issuers will be required under certain circumstances to make an offer to purchase the 2024 Senior Notes at 100% of the principal amount thereof, plus accrued and unpaid interest to the repurchase date.

On October 25, 2016, HPI and HPUSA, together, in such capacity, the Incremental Borrowers, entered into an amendment to the credit agreement, or the 2016 Amendment, with Citibank, N.A., as administrative and collateral agent, and Bank of America, N.A., as the incremental B-1 lender thereunder, pursuant to which the Incremental Borrowers borrowed $375.0 million aggregate principal amount of loans, or the 2016 Incremental Loan Facility. The 2016 Incremental Loan Facility was incurred as a separate class of term loans under the credit agreement with the same terms of loans under the 2015 Term Loan Facility, except as described below.

Loans under the 2016 Incremental Loan Facility bear interest, at each Incremental Borrowers’ option, at a rate equal to either LIBOR plus an applicable margin of 4.50% per year (subject to a LIBOR floor of 1.0%), or the adjusted base rate plus 3.50%. The terms of the loans under the 2015 Term Loan Facility, or the 2015 Loans, provided for an amendment such that the effective yield of the 2015 Loans would not be less than the effective yield of the loans under the 2016 Incremental Loan Facility, or the Incremental Loans, minus 0.50%. Consequently, the issuance of the Incremental Loans resulted in an increase of the interest rate applicable to the 2015 Loans, as of October 25, 2016, to LIBOR plus 4.00%, subject to a LIBOR floor of 1.0% (an initial interest rate of 5.00%). Borrowers under the credit agreement are permitted to make voluntary prepayments of the loans under the credit agreement at any time without payment of a premium, except that with respect to the Incremental Loans, a 1% premium will apply to a repayment of the Incremental Loans in connection with a re-pricing of, any amendment to the credit agreement in a re-pricing of, such loans effected on or prior to the date that is twelve months following October 25, 2016.

We used the net proceeds of the offering of the 2024 Senior Notes, borrowings under the 2016 Incremental Facility and existing cash to fund our acquisition of Raptor, plus the related fees and expenses in connection with the foregoing.

We have a significant amount of debt outstanding on a consolidated basis. This substantial level of debt could have important consequences to our business, including, but not limited to: making it more difficult for us to satisfy our obligations; requiring a substantial portion of our cash flows from operations to be dedicated to the payment of principal and interest on our indebtedness, therefore reducing our ability to use our cash flows to fund acquisitions, capital expenditures, and future business opportunities; limiting our ability to obtain additional financing, including borrowing additional funds; increasing our vulnerability to, and reducing our flexibility to respond to, general adverse economic and industry conditions; limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; and placing us at a disadvantage as compared to our competitors, to the extent that they are not as highly leveraged. We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness.
In addition, the indentures governing the 2024 Senior Notes and 2023 Senior Notes and the credit agreement related to the 2015 Senior Secured Credit Facility and 2016 Incremental Facility impose various covenants that limit our ability and/or our restricted subsidiaries’ ability to, among other things, pay dividends or distributions, repurchase equity, prepay junior debt and make certain investments, incur additional debt and issue certain preferred stock, incur liens on assets, engage in certain asset sales or merger transactions, enter into transactions with affiliates, designate subsidiaries as unrestricted subsidiaries; and allow to exist certain restrictions on the ability of restricted subsidiaries to pay dividends or make other payments to us.

During the nine months ended September 30, 2016, we issued an aggregate of:

• 496,012 ordinary shares in connection with the exercise of stock options and received $3.4 million in proceeds;
• 619,696 ordinary shares in net settlement of vested restricted stock units;
• 13,584 ordinary shares in net settlement of vested performance stock units; and
• 261,780 ordinary shares pursuant to employee stock purchase plans and received $3.2 million in proceeds.

During the nine months ended September 30, 2016, warrants to purchase an aggregate of 207,110 of our ordinary shares were exercised in cashless exercises, resulting in the issuance of 161,259 ordinary shares. As of September 30, 2016, there were outstanding warrants to purchase 1,374,410 of our ordinary shares.

During the nine months ended September 30, 2016, we made payments of $5.5 million for employee withholding taxes relating to share-based awards.

In May 2016, our board of directors authorized a share repurchase program pursuant to which we may repurchase up to 5,000,000 of our ordinary shares. The timing and amount of repurchases, including whether we decide to repurchase any shares pursuant to the authorization, will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, our cash resources, restrictions under our credit agreement, and market conditions. As of September 30, 2016, we had not purchased any of our ordinary shares under this repurchase program.

Sources and Uses of Cash

The following table provides a summary of our cash position and cash flows as of and for the nine months ended September 30, 2016 and 2015 (in thousands):

<table>
<thead>
<tr>
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<th>2016</th>
<th>2015</th>
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<td>Cash and cash equivalents</td>
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<td>$684,286</td>
</tr>
<tr>
<td>Cash provided by (used in):</td>
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<td></td>
</tr>
<tr>
<td>Operating activities</td>
<td>230,271</td>
<td>59,228</td>
</tr>
<tr>
<td>Investing activities</td>
<td>(538,432)</td>
<td>(1,034,187)</td>
</tr>
<tr>
<td>Financing activities</td>
<td>(1,690)</td>
<td>1,440,587</td>
</tr>
</tbody>
</table>

Operating Cash Flows

During the nine months ended September 30, 2016, net cash provided by operating activities was $230.3 million compared to $59.2 million during the nine months ended September 30, 2015. The increase in net cash provided by operating activities was primarily attributable to higher cash collections from accounts receivable balances as a result of an increase in sales of medicines, partially offset by higher cash outlays for contractual allowances, patient access programs and government rebates and chargebacks. The payment of the $65.0 million litigation settlement with Express Scripts was not made during the nine months ended September 30, 2016 and therefore had no impact on operating cash flows. This settlement amount will be paid to Express Scripts in installments, with 50 percent of the installment due in the fourth quarter of 2016, 25 percent in the first quarter of 2017 and 25 percent in the second quarter of 2017.

Cash provided by operating activities was negatively impacted during the nine months ended September 30, 2016 due to cash payments of $39.5 million for interest payments made on our 2015 Term Loan Facility, 2023 Senior Notes and Exchangeable Senior Notes, $27.5 million for costs related to acquisitions, $18.5 million of cash paid for income taxes and $2.0 million of cash paid for an upfront fee for a license of a global patent. During the nine months ended September 30, 2015, we made cash payments of $55.4 million for induced conversions and debt extinguishment and related expenses, $49.2 million for costs related to acquisitions, $21.4 million for interest payments, $11.2 million for employee and director-related excise taxes due to the Vidara Merger, $9.0 million for fees relating to a debt commitment and $1.9 million for income taxes.

57
Investing Cash Flows

During the nine months ended September 30, 2016 and 2015, net cash used in investing activities was $538.4 million and $1,034.2 million, respectively. The net cash used in investing activities during the nine months ended September 30, 2016 was primarily associated with $514.8 million of payments for the acquisition of Crealta, net of cash acquired, a $5.6 million (£5.0 million) initial payment for certain intellectual property rights to interferon gamma-1b for the treatment of FA and $14.6 million of payments for purchases of property and equipment. The net cash used in investing activities during the nine months ended September 30, 2015 was primarily associated with payments for the acquisition of Hyperion in May 2015 of $1,022.4 million, net of cash acquired, and payments of $71.8 million for purchases of long-term investments, offset by $64.6 million in proceeds from the liquidation of available-for-sale investments.

Financing Cash Flows

During the nine months ended September 30, 2016, net cash used in financing activities was $1.7 million compared to net cash provided by financing activities of $1,440.6 million during the nine months ended September 30, 2015. The decrease in net cash provided by financing activities during the nine months ended September 30, 2016 was primarily attributable to the absence of any new financings being completed during the nine months ended September 30, 2016, as the financings to fund the acquisition of Raptor did not close until October 25, 2016. Net cash provided by financing activities during the nine months ended September 30, 2015 was primarily attributable to $475.6 million of net proceeds from the 2015 Offering, $462.3 million of net proceeds from the issuance of the 2023 Senior Notes, $391.5 million of net proceeds from the 2015 Term Loan Facility, $387.2 million of net proceeds received from borrowings under the Exchangeable Senior Notes, and was negatively impacted by the repayment of $297.0 million and $1.0 million of the 2014 Term Loan Facility and 2015 Term Loan Facility, respectively.

Financial Condition as of September 30, 2016 compared to December 31, 2015

Accounts receivable, net. Accounts receivable, net, increased $152.5 million, from $210.4 million as of December 31, 2015 to $362.9 million as of September 30, 2016. The increase is due to growth in gross sales of our medicines, from December 2015 to September 2016.

Inventories, net. Inventories, net, increased $143.8 million, from $18.4 million as of December 31, 2015 to $162.2 million as of September 30, 2016. This increase is primarily due to $134.0 million of stepped-up KRYSTEXXA and MIGERGOT inventory at September 30, 2016 recorded as a result of the Crealta acquisition in January 2016.

Prepaid expenses and other current assets. Prepaid expenses and other current assets increased $22.2 million, from $15.9 million as of December 31, 2015 to $38.1 million as of September 30, 2016. The increase is primarily due to $13.4 million of quarterly estimated income tax installments paid as of September 30, 2016, an increase of $4.0 million in medicine samples inventory and an additional $2.0 million of rabbit trust assets held at September 30, 2016.

Developed technology, net. Developed technology, net, increased $268.1 million, from $1,609.1 million as of December 31, 2015 to $1,877.2 million as of September 30, 2016. The increase is due to $418.7 million of KRYSTEXXA and MIGERGOT developed technology acquired in the Crealta acquisition, offset by amortization of developed technology on our medicines acquired through acquisitions of $150.6 million during the nine months ended September 30, 2016.

Other assets. Other assets increased $6.0 million, from $0.2 million as of December 31, 2015 to $6.2 million as of September 30, 2016. This increase is primarily due to an upfront payment of $5.6 million (£5.0 million) to Boehringer Ingelheim International upon the signing of a definitive agreement to acquire worldwide rights to interferon gamma-1b.

Accounts payable. Accounts payable increased $49.1 million, from $16.6 million as of December 31, 2015 to $65.7 million as of September 30, 2016. This increase is primarily due to $42.5 million of trade discounts and rebates included within accounts payable as of September 30, 2016 and timing of payments.

Accrued expenses. Accrued expenses increased $57.5 million, from $100.0 million as of December 31, 2015 to $157.5 million as of September 30, 2016. This is due to an accrued litigation settlement amount of $65.0 million as of September 30, 2016, following the litigation settlement with Express Scripts, an increase of $8.5 million in consulting and professional services fee accruals, an increase of $5.6 million in accrued interest, offset by decreases in payroll-related accrued expenses of $12.2 million and other accrued expenses of $9.4 million.

Accrued trade discounts and rebates. Accrued trade discounts and rebates increased $84.4 million, from $183.8 million as of December 31, 2015 to $268.2 million as of September 30, 2016. This is due to a $59.0 million increase in accrued co-pay and other patient assistance, a $18.5 million increase in accrued government rebates and chargebacks and a $6.9 million increase in accrued wholesaler fees and commercial rebates. These increases are in line with the increase in gross sales during the period.
Accrued royalties, net of current. Accrued royalties, net of current, increased $46.1 million, from $123.5 million as of December 31, 2015 to $169.6 million as of September 30, 2016. This increase is primarily due to KRYSTEXXA and MIGERGOT contingent royalties of $47.9 million at September 30, 2016 as a result of the Crealta acquisition in January 2016.

Deferred tax liabilities, net. Deferred tax liabilities, net, decreased $17.8 million, from $113.4 million as of December 31, 2015 to $95.6 million as of September 30, 2016. The decrease was as a result of the tax benefit recorded in the condensed consolidated statement of comprehensive loss during the nine months ended September 30, 2016 and the correction of an error in the Hyperion pre-acquisition deferred tax calculation, as described in Note 3 “Business Acquisitions” in the notes to our condensed consolidated financial statements included in this report, offset by the recording of deferred tax liabilities in connection with the acquisition of Crealta in January 2016.

Other long-term liabilities. Other long-term liabilities increased $5.5 million, from $9.4 million as of December 31, 2015 to $14.9 million as of September 30, 2016. The increase is primarily due to an increase of $2.0 million in long-term deferred compensation plan liabilities and $1.7 million of increased tax liabilities.

Contractual Obligations

During the nine months ended September 30, 2016, there were no material changes outside of the ordinary course of business to our contractual obligations as previously disclosed in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, except for the changes described below.

On October 25, 2016, we completed a private placement of $300.0 million aggregate principal amount of the 2024 Senior Notes. The 2024 Senior Notes will accrue interest at an annual rate of 8.75% payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2017. The 2024 Senior Notes will mature on November 1, 2024, unless earlier exchanged, repurchased or redeemed.

On October 25, 2016, we entered into the 2016 Incremental Facility and the Incremental Borrowers borrowed the entire $375.0 million available under the 2016 Incremental Facility. Loans under the 2016 Incremental Loan Facility bear interest, at each Incremental Borrowers’ option, at a rate equal to either LIBOR plus an applicable margin of 4.50% per year (subject to a LIBOR floor of 1.0%), or the adjusted base rate plus 3.50%. The terms of the 2015 Term Loan Facility provided for an amendment such that the effective yield of the 2015 Term Loan Facility would not be less than the effective yield of the 2016 Incremental Loans minus 0.50%. Consequently, the issuance of the 2016 Incremental Loans resulted in an increase of the interest rate applicable to the 2015 Term Loan Facility, as of October 25, 2016, to LIBOR plus 4.00%, subject to a LIBOR floor of 1.0% (an initial interest rate of 5.00%). Thus, loans under the 2015 Term Loan Facility bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.00% per annum (subject to a 1.00% LIBOR floor), or the adjusted base rate plus 3.00%. The adjusted base rate is defined as the greater of (a) LIBOR (using one-month interest period) plus 1%, (b) prime rate, (c) fed funds plus ½ of 1% and (d) 2%.

In October 2016, we committed to purchase additional units of ACTIMMUNE from Boehringer Ingelheim in 2017 at a cost of $7.3 million. These additional units of ACTIMMUNE are intended to cover anticipated demand if the results of the STEADFAST study of ACTIMMUNE for the treatment of FA are successful and we subsequently receive U.S. marketing approval for FA. Top-line results from the study are expected in late December 2016, and if the trial is not successful, we may have excess ACTIMMUNE inventory and/or purchase commitments.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements in accordance with U.S. GAAP principles requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenue and expenses. Certain of these policies are considered critical as these most significantly impact a company’s financial condition and results of operations and require the most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Actual results may vary from these estimates. A summary of our significant accounting policies is included in Note 2 to our Annual Report on Form 10-K for the year ended December 31, 2015. There have been no significant changes in our application of our critical accounting policies during the nine months ended September 30, 2016.

OFF-BALANCE SHEET ARRANGEMENTS

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities, other than the indemnification agreements discussed in Note 12, “Commitments and Contingencies” in the 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. We are subject to interest rate fluctuation exposure through our borrowings under the 2015 Term Loan Facility and our investment in money market accounts which bear a variable interest rate. The terms of the 2015 Term Loan Facility provided for an amendment such that the effective yield of the 2015 Term Loan Facility would not be less than the effective yield of the 2016 Incremental Loans minus 0.50%. Consequently, the issuance of the 2016 Incremental Loans resulted in an increase of the interest rate applicable to the 2015 Term Loan Facility, as of October 25, 2016, to LIBOR plus 4.00%, subject to a LIBOR floor of 1.0% (an initial interest rate of 5.00%). Thus, loans under the 2015 Term Loan Facility bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.00% per annum (subject to a 1.00% LIBOR floor), or the adjusted base rate plus 3.00%. The adjusted base rate is defined as the greater of (a) LIBOR (using one-month interest period) plus 1%, (b) prime rate, (c) fed funds plus ½ of 1% and (d) 2%. Since drawing the full $400.0 million available in May 2015, our borrowings had been based on LIBOR. Since current LIBOR rates are below the 1.0% LIBOR floor, the interest rate on our borrowings has been 5.00% per annum.

An increase in the LIBOR of 100 basis points above the 1.0% LIBOR floor would increase our interest expense related to the 2015 Term Loan Facility by $4.0 million per year.

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 purchase cost of ACTIMMUNE under our contract with Boehringer Ingelheim RCV GmbH & Co. KG as well as our sales contracts relating to LODOTRA are principally denominated in Euros and are subject to foreign currency risk. We also incur certain operating expenses in currencies other than the U.S. dollar in relation to our Irish operations and foreign subsidiaries, including Horizon Pharma Switzerland GmbH; therefore, we are subject to volatility in cash flows due to fluctuations in foreign currency exchange rates, particularly changes in the Euro. Following the acquisition of Raptor, we are subject to increased foreign currency risk for our operations in Europe due to an increased level of sales and operating expenses denominated in Euros. 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 medicines to pharmacies, hospitals and other customers. For the nine months ended September 30, 2016, our top five customers, AmerisourceBergen, Cardinal Health, Inc., CVS Health, McKesson Corporation and Rochester Drug Company accounted for approximately 85% of total consolidated gross sales. For the nine months ended September 30, 2015, our top five customers, American Specialty Pharmacy, Inc., AmerisourceBergen, Cardinal Health, Inc., McKesson Corporation and Rochester Drug Company accounted for approximately 82% of total consolidated gross sales.

In addition, five customers, AmerisourceBergen, Cardinal Health, Inc., CVS Health, McKesson Corporation and Rochester Drug Company accounted for approximately 95% of our total outstanding accounts receivable balances at September 30, 2016. Five customers, American Specialty Pharmacy, Inc., AmerisourceBergen, Cardinal Health, Inc., McKesson Corporation and Rochester Drug also accounted for approximately 90% of our total outstanding accounts receivable balances at September 30, 2015. Historically, we have not experienced any significant 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 Rules 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, 2016, the end of the period covered by this report.

Changes in Internal Control Over Financial Reporting. We are in the process of implementing new enterprise resource planning software, SAP, as part of a plan to integrate and upgrade our systems and processes. The implementation of this global software is scheduled to continue in phases over a number of years. During the first nine months of 2016, we migrated certain areas of our business to SAP, including financial reporting, financial planning and analysis, supply chain and treasury. As the phased implementation of this system occurs, we are experiencing certain changes to our processes and procedures which, in turn, result in changes to our internal control over financial reporting. While we expect SAP to strengthen our internal financial controls by automating certain manual processes and standardizing business processes and reporting across our organization, management will continue to evaluate and monitor our internal controls as processes and procedures in each of the affected areas evolve.

During the three months ended September 30, 2016, other than continuing changes to our internal control processes resulting from new enterprise resource planning software, as discussed above, there have been no material changes to our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f), that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.
ITEM 1. LEGAL PROCEEDINGS

For a description of our legal proceedings, see Note 13, Legal Proceedings, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q.

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 ordinary shares. 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 ordinary shares 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, 2015, as filed with the SEC.

Risks Related to Our Business and Industry

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

Our current medicines, and other medicines or medicine candidates that we may develop or acquire, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. We have a limited history of commercializing medicines and most of our medicines have not been on the market for an extensive period of time, which subjects us to numerous risks as we attempt to increase our market share. We believe that the degree of market acceptance and our ability to generate revenues from our medicines will depend on a number of factors, including:

- timing of market introduction of our medicines as well as competitive medicines;
- efficacy and safety of our medicines;
- continued projected growth of the markets in which our medicines compete;
- prevalence and severity of any side effects;
- if and when we are able to obtain regulatory approvals for additional indications for our medicines;
- acceptance by patients, primary care physicians and key specialists, including rheumatologists, orthopedic surgeons, pain specialists, podiatrists, medical geneticists and specialists in pediatric immunology, allergy, infectious diseases and hematology/oncology;
- availability of coverage and adequate reimbursement and pricing from government and other third-party payers;
- potential or perceived advantages or disadvantages of our medicines 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 medicines, both in absolute terms and relative to alternative treatments;
- impact of past and limitation of future medicine price increases;
- our ability to maintain a continuous supply of medicine for commercial sale;
- the effect of current and future healthcare laws;
- the performance of third-party distribution partners, over which we have limited control; and
- medicine labeling or medicine insert requirements of the U.S. Food and Drug Administration, or FDA, or other regulatory authorities.
With respect to DUEXIS and VIMOVO, studies indicate that physicians do not commonly co-prescribe gastrointestinal, or GI, protective agents to high-risk patients taking nonsteroidal anti-inflammatory drugs, or NSAIDs. We believe this is due in part to a lack of awareness among physicians prescribing NSAIDs regarding the risk of NSAID-induced upper GI ulcers, in addition to the inconvenience of prescribing two separate medications and patient compliance issues associated with multiple prescriptions. If physicians remain unaware of, or do not otherwise believe in, the benefits of combining GI protective agents with NSAIDs, our market opportunity for DUEXIS and VIMOVO will be limited. Some physicians may also be reluctant to prescribe DUEXIS or VIMOVO due to the inability to vary the dose of ibuprofen and naproxen, respectively, or if they believe treatment with NSAIDs or GI protective agents other than those contained in DUEXIS and VIMOVO, including those of its competitors, would be more effective for their patients. With respect to each of DUEXIS, PENNSAID 2% w/w, or PENNSAID 2%, RAYOS/LODOTRA, VIMOVO and BUPHENYL, their higher cost compared to the generic or branded forms of their active ingredients alone may limit adoption by physicians, patients and healthcare payers. With respect to ACTIMMUNE, while it is the only FDA-approved treatment for chronic granulomatous disease, or CGD, and severe, malignant osteopetrosis, or SMO, they are very rare conditions and, as a result, our ability to grow ACTIMMUNE sales will depend on our ability to further penetrate this limited market and obtain marketing approval for additional indications. With respect to RAVICTI, which is also approved to treat a very limited patient population, our ability to grow sales will depend in large part on our ability to transition urea cycle disorder, or UCD, patients from BUPHENYL or generic equivalents, which are comparatively much less expensive, to RAVICTI. With respect to KRYSTEXXA, our ability to grow sales will be affected by the success of our sales and marketing strategies and life cycle management, including studies designed to test reduction of immunogenicity in KRYSTEXXA which could expand the patient population and usage of KRYSTEXXA. With respect to MIGERGOT, our ability to sustain sales will depend on the management of inventory levels and the continued awareness of its benefits among physicians. With respect to PROCYSBI, which is approved to treat a very limited patient population, our ability to grow sales will depend in large part on our ability to transition patients from the first-generation therapy to PROCYSBI, to identify additional patients with nephropathic cystinosis, and expand commercialization in Europe. Unless QUINSAIR is approved for marketing in additional countries, our ability to drive growth of this medicine will largely depend on expanding its use in Europe and Canada. If our current medicines or any other medicine that we may seek approval for or acquire 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 (including, possibly, the value of our ordinary shares).

Our future prospects are highly dependent on our ability to successfully formulate and execute commercialization strategies for each of our medicines. Failure to do so would adversely impact our financial condition and prospects.*

A substantial majority of our resources are focused on the commercialization of our current medicines. Our ability to generate significant medicine revenues and to achieve commercial success in the near-term will initially depend almost entirely on our ability to successfully commercialize these medicines in the United States.

With respect to our orphan medicines, ACTIMMUNE, BUPHENYL, PROCYSBI, QUINSAIR and RAVICTI, and with respect to our rheumatology medicine KRYSTEXXA, our commercialization strategy includes efforts to increase awareness of the rare conditions that each medicine is designed to treat, enhancing efforts to identify target patients and in certain cases pursue opportunities for label expansion and more effective use through clinical trials. In addition, our strategy with respect to ACTIMMUNE includes pursuing label expansion for additional indications, such as Friedreich’s ataxia, or FA, and price increases but we cannot be certain that our pricing strategy will not result in downward pressure on sales or that we will be able to successfully complete clinical trials and obtain regulatory approvals in additional indications. With respect to RAVICTI and PROCYSBI, our strategy includes accelerating the transition of patients from first-generation therapies, and increasing the diagnosis of the associated rare conditions through patient and physician outreach. Part of our success in our strategy for RAVICTI will also depend on obtaining approval of RAVICTI for the treatment of UCD in patients less than two years of age. On June 29, 2016, we submitted a supplemental new drug application, or sNDA, with the FDA for RAVICTI to expand the age range for chronic management of UCDs from two years of age and older to two months of age and older. Subject to positive data from on-going studies, we have targeted an sNDA submission in the first quarter of 2018 in relation to UCD patients during the first two months of life, however, we cannot guarantee that on-going studies will be positive or that we will be able to expand the labeling for RAVICTI on our anticipated timeline or at all. Our strategy with respect to KRYSTEXXA includes the expansion of our sales force, the planned enhancement of the KRYSTEXXA marketing campaign with improved immunogenicity data, continued volume growth and pricing optimization.

With respect to our primary care medicines DUEXIS, PENNSAID 2% and VIMOVO, our strategy has included bringing pricing in-line with other branded NSAIDs, thereby significantly increasing the value we realize per prescription, and also increasing sales and marketing support to drive volume growth in prescriptions. We cannot guarantee that this strategy will continue to be effective generally, due to negative reactions to price increases or otherwise. More recently, we have begun entering into rebate agreements with pharmacy benefit managers, or PBMs, for certain of our primary care medicines where we believe the rebates and costs justify expanded formulary access for patients. However, we cannot guarantee that we will be able to secure additional rebate agreements on commercially reasonable terms. For each of our primary care medicines, we expect that our commercial success will depend on our sales and marketing efforts in the United States.

63
Our strategy for RAYOS in the United States is to solely focus on the rheumatology indications approved for RAYOS where our Phase 3 clinical trial data supports our commercial plans.

Our overall commercialization strategy also includes plans to expand our sales and market efforts in Europe and other countries outside the United States for certain of our orphan and rheumatology medicines. In November 2015, we received approval of the Committee for Medicinal Products for Human Use of the European Medicines Agency, or EMA, for RAVICTI for use as an adjunctive therapy for chronic management of adult and pediatric UCD patients greater than two months of age. This authorizes us to market RAVICTI in all 28 Member States of the European Union, or EU, and will form the basis for recognition by the Member States of the European Economic Area, namely Norway, Iceland and Liechtenstein, for the medicine to be placed on the market. In June 2016, we partnered with Clinigen Group plc’s Idis managed access division to initiate a managed access program in selected European countries. While we expect to commercially launch RAVICTI in Europe in 2017, we cannot guarantee we will be able to successfully implement our commercial plans for RAVICTI in Europe. With respect to PROCYSBI and QUINSAIR, which are approved for marketing in the EU, we intend to continue evaluating commercial launches in additional EU countries as well as pursuing early access programs. Although LODOTRA is approved for marketing in countries outside the United States, to date it has only been marketed in a limited number of countries.

If any of our commercial strategies are unsuccessful or we fail to successfully modify our strategies over time due to changing market conditions, our ability to increase market share for our medicines, grow revenues and sustain profitability will be harmed.

In order to increase adoption and sales of our medicines, we will need to continue developing our commercial organization as well as recruit and retain qualified sales representatives.*

Part of our strategy is to continue to build a biopharmaceutical company to successfully execute the commercialization of our medicines in the U.S. market, and in selected markets in Europe where we have commercial rights. We may not be able to successfully commercialize our medicines in the United States or in any other territories where we have commercial rights. Prior to our commercial launch of DUEXIS in the United States in December 2011, we did not have any experience commercializing medicines on our own. In order to commercialize any approved medicines, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Although we had expanded our sales force to approximately 470 sales representatives as of September 30, 2016, consisting of approximately 15 orphan disease sales representatives, 90 rheumatology sales specialists and 365 primary care sales representatives, we currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market our medicines and any additional medicines we may acquire will be expensive and time-consuming. We also cannot 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 for our primary care and rheumatology business units 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 and VIMOVO to a generic or over-the-counter brand of their active ingredients. We have faced similar challenges for RAYOS, BUPHENYL and PENNSAID 2% with respect to generic brands. While we believe the profile of our representatives is better suited for this evolving environment, we cannot be certain that our representatives will be able to successfully protect our market for DUEXIS, PENNSAID 2%, RAYOS, BUPHENYL and VIMOVO 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 medicines, we may receive less revenue than if we commercialized these medicines 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 may not be able to commercialize our medicines and medicine candidates and execute on our business plan.
If we are unable to effectively train and equip our sales force, our ability to successfully commercialize our medicines will be harmed.*

As we recently acquired additional medicines through acquisition transactions, the members of our sales force may have limited experience promoting these medicines. To the extent we have retained the sales forces promoting recently-acquired medicines, we may not be successful in continuing to retain these employees and we otherwise have limited experience marketing these medicines under our commercial organization. As a result, we are required to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense our medicines. In addition, we must train our sales force to ensure that a consistent and appropriate message about our medicines is being delivered to our potential customers. Our sales representatives may also experience challenges promoting multiple medicines when we call on physicians and their office staff. We have experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire, requiring us to train new sales representatives. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate physicians about the benefits of our medicines and their proper administration and label indication, as well as our patient access programs, our efforts to successfully commercialize our medicines could be put in jeopardy, which could have a material adverse effect on our financial condition, share price and operations.

If we cannot successfully implement our patient access programs or enter into formulary and reimbursement agreements with pharmacy benefit managers in the face of increasing pressure to reduce the price of medications, the adoption of our medicines by physicians, patients and payers may decline.*

There continues to be immense pressure from healthcare payers and PBMs to use less expensive generics or over-the-counter brands instead of branded medicines. For example, some of the largest PBMs placed DUEXIS and VIMOVO on their formulary exclusion lists beginning in January 2015. Additional healthcare plans, including those that contract with these PBMs but use different formularies, may also choose to exclude our medicines from their formularies or restrict coverage to situations where a generic or over-the-counter medicine has been tried first. Many payers and PBMs also require patients to make co-payments for branded medicines, including many of our medicines, in order to incentivize the use of generic or other lower-priced alternatives instead. Legislation enacted in most states in the United States allows, or in some instances mandates, that a pharmacist dispenses an available generic equivalent when filling a prescription for a branded medicine, in the absence of specific instructions from the prescribing physician. Because our medicines (other than BUPHENYL) do not currently have FDA-approved generic equivalents in the United States, we do not believe our medicines should be subject to mandatory generic substitution laws. However, we understand that some pharmacies may attempt to obtain physician authorization to switch prescriptions for DUEXIS or VIMOVO to prescriptions for multiple generic medicines with similar active pharmaceutical ingredients, or APIs, to ensure payment for the medicine if the physician’s prescription for the branded medicine is not immediately covered by the payer, despite such substitution being off-label in the case of DUEXIS and VIMOVO. If these limitations in coverage and other incentives result in patients refusing to fill prescriptions or being dissatisfied with the out-of-pocket costs of their medications, or if pharmacies otherwise seek and receive physician authorization to switch prescriptions, not only would we lose sales on prescriptions that are ultimately not filled, but physicians may be dissuaded from writing prescriptions for our medicines in the first place in order to avoid potential patient non-compliance or dissatisfaction over medication costs, or to avoid spending the time and effort of responding to pharmacy requests to switch prescriptions.

Part of our commercial strategy to increase adoption and access to our medicines in the face of these incentives to use generic alternatives is to offer physicians the opportunity to have patients fill prescriptions through independent pharmacies participating in our HorizonCares patient access program. Through HorizonCares, financial assistance may be available to reduce eligible patients’ out-of-pocket costs for prescriptions filled. Because of this assistance, eligible patients’ out-of-pocket cost for our medicines when dispensed through HorizonCares may be significantly lower than such costs when our medicines are dispensed outside of the HorizonCares program. However, to the extent physicians do not direct prescriptions currently filled through traditional pharmacies, including those associated with or controlled by PBMs, to pharmacies participating in our HorizonCares program, we may experience a significant decline in DUEXIS, VIMOVO and PENNSAID 2% prescriptions as a result of formulary exclusions, co-payment requirements or other incentives to use lower-priced alternatives to our medicines. Our ability to increase utilization of our patient access programs will depend on physician and patient awareness and comfort with the programs, and we have limited ability to influence whether physicians use our patient access programs to prescribe our medicines or whether patients will agree to receive our medicines through the HorizonCares program. In addition, the HorizonCares program is not available to federal health care program (such as Medicare and Medicaid) beneficiaries. We have also begun to pursue the additional strategy of contracting with PBMs and other payers to secure formulary status and reimbursement for certain of our primary care medicines, which generally require us to pay administrative fees and rebates to the PBMs and other payers for qualifying prescriptions. While we recently announced a business relationship with one of the largest PBMs, CVS Caremark, that has resulted in DUEXIS and VIMOVO being removed from the CVS Caremark 2017 exclusion list, as well as a rebate agreement with another PBM, Prime Therapeutics LLC, or Prime Therapeutics, and we believe these agreements will secure formulary status for certain of our medicines, we cannot guarantee that we will be able to agree to terms with other PBMs and other payers, or that such terms will be commercially reasonable to us. If we are unable to increase adoption of HorizonCares for filling prescriptions of our medicines or to secure formulary status and reimbursement through arrangements with PBMs and other payers, our ability to maintain or increase prescriptions for our medicines could be impaired.
There has been recent negative publicity regarding the use of specialty pharmacies and drug pricing. Our patient access programs are not involved in the prescribing of medicines and are solely to assist in ensuring that when a physician determines one of our medicines offers a potential clinical benefit to their patients and they prescribe one for an eligible patient, financial assistance may be available to reduce the patient’s out-of-pocket costs. In addition, all pharmacies that fill prescriptions for our medicines are fully independent, including those that participate in HorizonCares. We do not own or possess any option to purchase an ownership stake in any pharmacy that distributes our medicines, and our relationship with each pharmacy is non-exclusive and arm’s length. All of our sales are processed through pharmacies independent of us. Despite this, the recent negative publicity regarding specialty pharmacies may result in physicians being less willing to participate in our patient access programs and thereby limit our ability to increase patient access and adoption of our medicines.

We may also encounter difficulty in forming and maintaining relationships with pharmacies that participate in our patient access programs. We currently depend on a limited number of pharmacies participating in HorizonCares to fulfill patient prescriptions under the HorizonCares program. If these HorizonCares participating pharmacies are unable to process and fulfill the volume of patient prescriptions directed to them under the HorizonCares program, our ability to maintain or increase prescriptions for our medicines will be impaired. The commercialization of our medicines and our operating results could be affected should any of the HorizonCares participating pharmacies choose not to continue participation in our HorizonCares program or by any adverse events at any of those HorizonCares participating pharmacies. For example, pharmacies that dispense our medicines could lose contracts that they currently maintain with managed care organizations, or MCOs, including PBMs. Pharmacies often enter into agreements with MCOs. They may be required to abide by certain terms and conditions to maintain access to MCO networks, including terms and conditions that could limit their ability to participate in patient access programs like ours. Failure to comply with the terms of their agreements with MCOs could result in a variety of penalties, including termination of their agreement, which could negatively impact the ability of those pharmacies to dispense our medicines and collect reimbursement from MCOs for such medicines.

The HorizonCares program may implicate certain state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud. We have a compliance program in place to address adherence with various laws and regulations relating to the selling, marketing and manufacturing of our medicines, as well as certain third-party relationships, including pharmacies. Specifically with respect to pharmacies, the compliance program utilizes a variety of methods and tools to monitor and audit pharmacies, including those that participate in the HorizonCares program, to confirm their activities, adjudication and practices are consistent with our compliance policies and guidance. Despite our compliance efforts, to the extent the HorizonCares program is found to be inconsistent with applicable laws or the pharmacies that participate in our patient access programs do not comply with applicable laws, we may be required to restructure or discontinue such programs, terminate our relationship with certain pharmacies, or be subject to other significant penalties. In November 2015, we received a subpoena from the U.S. Attorney’s Office for the Southern District of New York requesting documents and information related to our patient access programs and other aspects of our marketing and commercialization activities. We are unable to predict how long this investigation will continue or its outcome, but we anticipate that we may incur significant costs in connection with the investigation, regardless of the outcome. We may also become subject to similar investigations by other governmental agencies. The investigation by the U.S. Attorney’s Office and any additional investigations of our patient access programs and sales and marketing activities may result in damages, fines, penalties or other administrative sanctions against us.

Even if we are successful in increasing the use of our patient access programs, these programs may become too costly for us to maintain if we are unable to maintain or enhance payer reimbursement of our medicines. The aggregate commercial value of our patient access programs for the nine months ended September 30, 2016 was $1,275.2 million. If additional formularies place our medicines on their exclusion lists or increase the co-payments applicable to our medicines, our cost of ensuring that patients have low-cost access to our medicines will increase and our profitability could decline. If the cost of maintaining our patient access programs increases relative to our sales revenues, we could be forced to reduce the amount of patient financial assistance that we offer or otherwise scale back or eliminate such programs, which could in turn have a negative impact on physicians’ willingness to prescribe and patients’ willingness to fill prescriptions of our medicines. As an alternative means of ensuring access to our medicines, we have also begun pursuing business arrangements with PBMs and other payers to secure formulary status and reimbursement of our medicines, such as our recently announced arrangements with CVS Caremark and Prime Therapeutics. While we believe that, if successful, this strategy would result in broader inclusion of certain of our primary care medicines on healthcare plan formularies, and therefore increase payer reimbursement and lower our cost of providing patient access programs, these arrangements generally require us to pay administrative and rebate payments to the PBMs and/or other payers. To the extent that we enter into arrangements with PBMs and other payers, we will owe rebate payments not only on prescriptions under plans that currently exclude certain of our medicines from their formulary and for which we provide significant patient assistance to ensure access, but also on prescriptions that are reimbursed by applicable healthcare plans. If our arrangements with PBMs and other payers do not result in increased prescriptions and reductions in our costs to provide our patient access programs that are sufficient to offset the administrative fees and rebate payments to the PBMs and/or other payers, our financial results may be harmed.
If we are unable to successfully implement our commercial plans and facilitate adoption by patients and physicians of any approved medicines through our sales, marketing and commercialization efforts, then we will not be able to generate sustainable revenues from medicine sales which will have a material adverse effect on our business and prospects.

We are solely dependent on third parties to commercialize certain of our medicines outside the United States. Failure of these third parties or any other third parties to successfully commercialize our medicines and medicine candidates in the applicable jurisdictions could have a material adverse effect on our business.*

We rely on Mundipharma International Corporation Limited, or Mundipharma, for commercialization of LODOTRA in various European countries and certain Asian, Latin American, Middle Eastern, African and other countries. We rely on other third-party distributors for commercialization of BUPHENYL (known as AMMONAPS in certain European countries) in certain territories outside the United States for which we currently have rights. We have limited contractual rights to force these third parties to invest significantly in commercialization of LODOTRA or BUPHENYL in our markets. In the event that Mundipharma or our current ex-U.S. distributors for BUPHENYL or any other third-party with any future commercialization rights to any of our medicines or medicine candidates fail to adequately commercialize those medicines or medicine candidates because they lack adequate financial or other resources, decide to focus on other initiatives or otherwise, our ability to successfully commercialize our medicines or medicine candidates in the applicable jurisdictions would be limited, which would adversely affect our business, financial condition, results of operations and prospects. We have had disagreements with Mundipharma under our European agreements and may continue to have disagreements, which could harm commercialization of LODOTRA in Europe or result in the termination of our agreements with Mundipharma. We also rely on Mundipharma’s ability to obtain regulatory approval for LODOTRA in certain Asian, Latin American, Middle Eastern, African and other countries. In addition, our agreements with Mundipharma and our agreements with our current ex-U.S. distributors for BUPHENYL 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 these third parties terminated their agreements, 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 or BUPHENYL outside the United States would be materially harmed.

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

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution and other possible activities relating to our medicines and our medicine candidates are, and 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 medicine approval, subject us to administrative or judicially imposed sanctions.

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

Applications for regulatory approval, including a marketing authorization application for marketing new drugs in Europe, must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable medicine candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the medicine candidate, the disease or the condition that the medicine candidate is designed to target and the regulations applicable to any particular medicine 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 medicine candidate for many reasons, including because they:

- may not deem a medicine 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 medicine 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 medicine 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 medicine 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, medicine candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the medicine 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 medicine candidates. We cannot predict when or whether regulatory approval will be obtained for any medicine candidate we develop.

Hyperion Therapeutics, Inc., or Hyperion, submitted a New Drug Submission, or NDS, to Health Canada, or HC, for approval to market RAVICTI in Canada. In March 2016, HC issued a Notice of Compliance for RAVICTI for use as an adjunctive therapy for chronic management of adult and pediatric patients two years of age and older with UCDs, and we launched RAVICTI in Canada in November 2016. However, if we are unable to obtain any further approvals for RAVICTI outside the United States, Canada and Europe, or determine that commercializing RAVICTI outside the United States, Canada and Europe is not economically viable, the market potential of RAVICTI may be limited.

On October 27, 2016, the FDA expressed its recommendation that an additional clinical trial should be conducted, and noted that if Raptor submits an NDA without conducting an additional clinical trial, the FDA will review the submission to determine whether it is acceptable for filing. The FDA stated in its meeting minutes dated September 22, 2016 that it recognizes that there is an unmet medical need for cystic fibrosis, or CF, patients. The FDA also stated that although a discussion about the design of a new trial may be helpful, the FDA was willing to reevaluate the existing data and the analysis presented at the meeting to determine if there is enough evidence to support the filing of an NDA. The FDA stated that it will further discuss some of the issues and will provide feedback to Raptor. In addition, the FDA may request additional information. On October 27, 2016, the FDA expressed its recommendation that an additional clinical trial should be conducted, and noted that if Raptor submits an NDA without conducting an additional clinical trial, the FDA will review the submission to determine whether it is acceptable for filing. We intend to further evaluate a potential NDA for QUINSAIR and it is possible that we will determine that based on the FDA’s guidance, further pursuit of U.S. approval of QUINSAIR as a treatment of Pseudomonas aeruginosa in adults with cystic fibrosis is not warranted.

Prior to our acquisition of Raptor, Raptor planned to pursue a Phase 3 clinical trial of QUINSAIR for use in the indication of bronchiectasis, or BE, not associated with cystic fibrosis. On September 8, 2016, Raptor met the Medicines and Healthcare Products Regulatory Agency, or the MHRA, to discuss non-clinical and clinical development aspects of QUINSAIR for the treatment of BE. On September 29, 2016, Raptor received a written response from the MHRA, which included answers to questions on trial design, among other responses. Raptor has also submitted the protocol to the FDA and has not received comments. Raptor was also exploring further clinical development of QUINSAIR for the treatment of pulmonary nontuberculous mycobacteria, or NTM, infection, based on third-party data generated pertaining to the susceptibility of certain pathogens to treatment with levofloxacin and other fluoroquinolone molecules. No clinical data have been generated with QUINSAIR in patients with BE or with NTM infections, either by Raptor, by us or by other parties. This creates uncertainty regarding the potential efficacy of QUINSAIR in these indications.
We will evaluate all development opportunities, including all obligations to use commercial reasonable efforts to further develop QUINSAIR. However, we may determine not to pursue such further development.

The ultimate approval and commercial marketing of any of our medicines in additional indications or geographies is subject to substantial uncertainty. Failure to gain additional regulatory approvals would limit the potential revenues and value of our medicines and could cause our share price to decline.

The amount of our product sales in the European Economic Area, or the EEA, is dependent in part upon the pricing and reimbursement decisions adopted in each of the EEA countries, which may not be at acceptable levels to us.*

One or more EEA countries may not support pricing within our target pricing and reimbursement range for our medicines due to budgetary decisions made by regional, national and local health authorities and third-party payers in the EEA, which would negatively affect our revenues. The pricing and reimbursement process in EEA countries can be lengthy, involved and difficult to predict. Failure to timely complete the pricing and reimbursement process in the EEA countries will delay our ability to market PROCYSBI, to bring QUINSAIR to market in the EEA and to derive revenues from those countries.

We may be subject to penalties and litigation and large incremental expenses if we fail to comply with regulatory requirements or experience problems with our medicines.*

Even after we achieve regulatory approvals, we are subject to ongoing obligations and continued regulatory review with respect to many operational aspects including our manufacturing processes, labeling, packaging, distribution, storage, adverse event monitoring and reporting, dispensation, advertising, promotion and recordkeeping. These requirements include submissions of safety and other post-marketing information and reports, ongoing maintenance of product registration and continued compliance with current good manufacturing practices, or cGMPs, good clinical practices, or GCPs, good pharmacovigilance practice, good distribution practices and good laboratory practices, or GLPs. If we, our medicines or medicine candidates, or the third-party manufacturing facilities for our medicines or medicine candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose injunctions or restrictions on the marketing, manufacturing or distribution of a product, suspend or withdraw product approvals, revoke necessary licenses or suspend product reimbursement;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- suspend any ongoing clinical trials or delay or prevent the initiation of clinical trials;
- delay or refuse to approve pending applications or supplements to approved applications we have filed;
- refuse to permit drugs or precursor or intermediary chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions or additional requirements on operations, including costly new manufacturing quality or pharmacovigilance requirements;
- seize or detain products or require us to initiate a product recall; and/or
- commence criminal investigations and prosecutions.

Moreover, existing regulatory approvals and any future regulatory approvals that we obtain will be subject to limitations on the approved indicated uses and patient populations for which our medicines may be marketed, the conditions of approval, requirements for potentially costly, post-market testing and requirements for surveillance to monitor the safety and efficacy of the medicines. In the EEA, the advertising and promotion of pharmaceuticals is strictly regulated. The direct-to-consumer promotion of prescription pharmaceuticals is not permitted, and some countries in the EEA require the notification and/or prior authorization of promotional or advertising materials directed at healthcare professionals. The FDA, EMA and other authorities in the EEA countries strictly regulate the promotional claims that may be made about prescription products, and our product labeling, advertising and promotion are subject to continuing regulatory review. Physicians nevertheless may prescribe our medicines to their patients in a manner that is inconsistent with the approved label or that is off-label. Positive clinical trial results in any of our medicine development programs increase the risk that approved pharmaceutical forms of the same active pharmaceutical ingredients may be used off-label in those indications. Our investigational medicine candidate RP103 is comprised of the same API as PROCYSBI. If we are found to have improperly promoted off-label uses of approved medicines, we may be subject to significant sanctions, civil and criminal fines and injunctions prohibiting us from engaging in specified promotional conduct.
In addition, engaging in improper promotion of our medicines for off-label uses in the United States can subject us to false claims litigation under federal and state statutes. These false claims statutes in the United States include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims or causing to present such false or fraudulent claims for payment by a federal program such as Medicare or Medicaid. Growth in false claims litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay civil money penalties, settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs.

The regulations, policies or guidance of regulatory agencies may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our medicine candidates or further restrict or regulate post-approval activities. For example, the Food and Drug Administration Safety and Innovation Act requires the FDA to issue new guidance describing its policy regarding internet and social media promotion of regulated medical products, and the FDA may soon specify new restrictions on this type of promotion. In January 2014, the FDA released draft guidance on how drug companies can fulfill their regulatory requirements for post-marketing submission of interactive promotional media, and though the guidance provided insight into how the FDA views a company’s responsibility for certain types of social media promotion, there remains a substantial amount of uncertainty. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are unable to achieve and maintain regulatory compliance, we will not be permitted to market our drugs, which would materially adversely affect our business, results of operations and financial condition.

Our limited history of commercial operations makes evaluating our business and future prospects difficult and may increase the risk of any investment in our ordinary shares.*

We face considerable risks and difficulties as a company with limited commercial operating history, particularly as a global 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, including our limited history commercializing our current medicines, makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. For example, we may underestimate the resources we will require to successfully integrate recent or future medicine or company acquisitions, or to commercialize our medicines, or not realize the benefits we expect to derive from our recent or future acquisitions. In addition, we have a limited history implementing our commercialization strategy focused on patient access, and we cannot guarantee that we will be able to successfully implement this strategy or that it will represent a viable strategy over the long term.
We have rights to medicines in certain jurisdictions but have no control over third parties that have rights to commercialize those medicines in other jurisdictions, which could adversely affect our commercialization of these medicines.*

Boehringer Ingelheim International GmbH, or Boehringer Ingelheim International, currently has certain rights to commercialize interferon gamma 1b, known as IMUKIN, outside the United States, Canada and Japan. On May 18, 2016, we entered into a definitive agreement with Boehringer Ingelheim International to acquire such rights to IMUKIN, or the IMUKIN Acquisition. The transaction is expected to close in the first half of 2017 and we are continuing to work with Boehringer Ingelheim International to enable the transfer of applicable marketing authorizations. AstraZeneca AB, or AstraZeneca, has retained its existing rights to VIMOVO in territories outside of the United States, including the right to use the VIMOVO name and related trademark. While we have the worldwide rights to BUPHENYL, the marketing and distribution rights are licensed to Swedish Orphan Biovitrum AB, or SOBI, through the end of 2016. Similarly, Nuvo Research Inc., or Nuvo, has retained its rights to PENNSAID 2% in territories outside of the United States and has announced its intention to seek commercialization partners outside the United States. We have little or no control over Boehringer Ingelheim International’s activities with respect to IMUKIN outside the United States, Canada and Japan, over AstraZeneca’s activities with respect to VIMOVO outside of the United States, over SOBI’s activities with respect to BUPHENYL in Europe, certain Asian, Latin American, Middle Eastern, North African and other countries or over Nuvo’s or its future commercial partners’ activities with respect to PENNSAID 2% outside of the United States, even though those activities could impact our ability to successfully commercialize ACTIMMUNE, VIMOVO, BUPHENYL and PENNSAID 2%. For example, AstraZeneca or its assignees or Nuvo or its assignees can make statements or use promotional materials with respect to VIMOVO or PENNSAID 2%, respectively, outside of the United States that are inconsistent with our positioning of the medicines in the United States, and could sell VIMOVO or PENNSAID 2%, respectively, in foreign countries, including Canada, at prices that are dramatically lower than the prices we charge in the United States. These activities and decisions, while occurring outside of the United States, could harm our commercialization strategy in the United States, in particular because AstraZeneca is continuing to market VIMOVO outside the United States under the same VIMOVO brand name that we are using in the United States. In addition, medicine recalls or safety issues with ACTIMMUNE, VIMOVO, BUPHENYL or PENNSAID 2% outside the United States, even if not related to the commercial medicine we sell in the United States, could result in serious damage to the brand in the United States and impair our ability to successfully market ACTIMMUNE, VIMOVO, BUPHENYL and PENNSAID 2%. We also rely on Boehringer Ingelheim International, AstraZeneca, SOBI and Nuvo or their assignees to provide us with timely and accurate safety information regarding the use of ACTIMMUNE, VIMOVO, BUPHENYL or PENNSAID 2%, respectively, outside of the United States (and outside of Canada and Japan with regards to Boehringer Ingelheim International), as we have or will have limited access to this information ourselves.

We rely on third parties to manufacture commercial supplies of all of our medicines, and we currently intend to rely on third parties to manufacture commercial supplies of any other approved medicines. The commercialization of any of our medicines could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of medicine 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 medicines and medicine candidates must be approved by the applicable regulatory authorities. We do not control the manufacturing processes of third-party manufacturers and are currently completely dependent on our third-party manufacturing partners. In addition, we are required to obtain AstraZeneca’s consent prior to engaging any third-party manufacturers for esomeprazole, one of the APIs in VIMOVO, other than the third-party manufacturer(s) used by AstraZeneca or its affiliates or licensees. To the extent such manufacturers are unwilling or unable to manufacture esomeprazole for us on commercially acceptable terms, we cannot guarantee that AstraZeneca would consent to our use of alternate sources of supply.

We rely on an exclusive supply agreement with Boehringer Ingelheim RCV GmbH & Co. KG, or Boehringer Ingelheim, for manufacturing and supply of ACTIMMUNE. However, Boehringer Ingelheim also currently manufactures interferon gamma-1b to supply its own commercial needs in its licensed territory, and this may lead to capacity allocation issues and supply constraints to our company. On May 18, 2016, we entered into a definitive agreement with Boehringer Ingelheim International to acquire their rights to interferon gamma-1b, which is expected to close in the first half of 2017, and we are continuing to work with Boehringer Ingelheim International to enable the transfer of applicable marketing authorizations. ACTIMMUNE is manufactured by starting with cells from working cell bank samples which are derived from a master cell bank. We and Boehringer Ingelheim separately store multiple vials of the master cell bank. In the event of catastrophic loss at our or Boehringer Ingelheim’s storage facility, it is possible that we could lose multiple cell banks and have the manufacturing capacity of ACTIMMUNE severely impacted by the need to substitute or replace the cell banks. In addition, a key excipient used in PENNSAID 2% as a penetration enhancer is dimethyl sulfoxide, or DMSO. We and Nuvo, our exclusive supplier of PENNSAID 2%, rely on a sole proprietary form of DMSO for which we maintain a substantial safety stock. However, should this supply become inadequate, damaged, destroyed or unusable, we and Nuvo may not be able to qualify a second source. We rely on NOF Corporation, or NOF, as our exclusive supplier of the PEGylation agent that is a critical raw material in the manufacture of KRSTEXXA. If NOF failed to supply such PEGylation agent, it may lead to KRSTEXXA supply constraints.
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. For example, Pharmaceuticals International, Inc., or PIL, our manufacturer of BUPHENYL, was found to be non-compliant for cGMPs by the MHRA, which could restrict PIL from supplying BUPHENYL in the EU. However, BUPHENYL was considered to be critical to public health and as a result, the MHRA issued a certificate of cGMP compliance for PIL which is valid until June 30, 2017. 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 medicines 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 medicines, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our medicines. To the extent any third-party manufacturers that we engage with respect to our medicines are different from those currently being used for commercial supply in the United States, the FDA will need to approve the facilities of those third-party manufacturers used in the manufacture of our medicines prior to our sale of any medicine using these facilities.

Although we have entered into supply agreements for the manufacture of our medicines, 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. LLC, or Sanofi-Aventis U.S., either we or Sanofi-Aventis U.S. may terminate the agreement upon an uncured breach by the other party or without cause upon two years prior written notice. Under our master manufacturing services and medicine agreement with Patheon Pharmaceuticals Inc., or Patheon, for finished VIMOVO medicine, either we or Patheon may terminate the agreement for uncured material breach by the other party or upon the other party’s bankruptcy or insolvency, we may terminate the agreement if any regulatory authority takes any action or raises any objection that prevents us from commercializing the VIMOVO medicine and Patheon may terminate the agreement if we assign our rights or obligations under the agreement to a competitor of Patheon or to a party that, in the reasonable opinion of Patheon, is not a credit worthy substitute for us, or in certain other circumstances where we assign the agreement without Patheon’s consent. Our manufacturing agreement with Boehringer Ingelheim has a term that runs until July 31, 2020, but the agreement may be terminated earlier by either us or Boehringer Ingelheim for an uncured material breach by the other party or upon the other party’s bankruptcy or insolvency. Under our manufacturing and supply agreement with Jagotec AG, or 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 may have to qualify a new back-up manufacturer. The term of our supply agreement with Nuvo for PENNSAID 2% is through December 31, 2029, but the agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party. With respect to BUPHENYL, our supply agreement with PIL is in place until April 1, 2017, however, the agreement may be terminated earlier by either party. The term of our manufacturing agreement with Halo Pharmaceutical, Inc., for RAVICTI runs until July 4, 2018, however, the agreement may be terminated earlier in the case of breach by either party if the other party is in material breach of any provision of the agreement and the other party fails to remedy such a breach within thirty days, or by us at any time for any reason. Our master services agreement with Lyne Laboratories, Inc., or Lyne, for RAVICTI runs until February 1, 2017, with provision for 12 monthly auto renewals thereafter, unless 6 months’ written notice is provided by either party. The agreement may be terminated earlier, on 30 days’ notice, in case of breach by either party. The term of our commercial supply agreement with Bio-Technology General (Israel) Ltd., or BTG Israel, for KRUSTEXXA bulk product runs until December 31, 2030, and will automatically renew for successive three year periods unless earlier terminated by either party upon three years prior written notice. The agreement may be terminated earlier by either party in the event of a force majeure, liquidation, dissolution, bankruptcy or insolvency of the other party, uncured material breach by the other party or after January 1, 2024, upon three years prior written notice. We currently rely on single source suppliers for cysteamine API and for PROCYSBI drug product. We also rely on single source suppliers for the QUINSAIR API and drug product and the base units, nebulizers and hand-held devices used for the administration of QUINSAIR.
Our supply agreement with Cambrex Profarmaco Milano, or Cambrex, for cysteamine API runs until November 3, 2020, and will automatically renew for successive two year periods after such initial term. The agreement may be terminated earlier by either party for any uncured material breach or upon one year advance notice by either party provided such notice is given at least one year prior to the expiration of the then-current term. We are also able to terminate the agreement in the event of certain supply failures by Cambrex or if we determined that the products incorporating the cysteamine API will not be marketed or the FDA or EMA withdraws approval or fails to approve such products then in development. Our supply agreement for QUINSAIR API runs, with respect to the United States, until the seventh anniversary after the first commercial sale in the United States, with respect to Europe, until the fifth anniversary after the first commercial sale in Europe, in each case subject to early termination under specified circumstances. Our commercial supply agreement with PARI Pharma GmbH, or PARI, for base units, nebulizers and hand-held devices used for the administration of QUINSAIR may be terminated by either party for any uncured material breach by the other party or its obligations under the agreement, upon the filing of an application for commencement of bankruptcy or similar proceeding against the other party, or if we cease development and commercialization of applicable products for a certain number of years. We rely on safety stock to mitigate the risk of our current suppliers electing to cease producing bulk drug medicine or ceasing to do so at acceptable prices and quality. However, we can provide no assurance that such safety stocks would be sufficient to avoid supply shortfalls in the event we have to identify and qualify new contract manufacturers.

In addition, we do not have the capability to package any of our medicines for distribution. Under our master manufacturing services agreement with Patheon, we have entered into an agreement for packaging of RAYOS/LODOTRA. Valeant Pharmaceuticals International, Inc. manufactures and supplies DUEXIS to us in final, packaged form for the United States as well as any additional countries as may be agreed to by the parties. Patheon supplies final, packaged VIMOVO medicine pursuant to the master manufacturing services and product agreement we executed in connection with our acquisition of the U.S. rights to VIMOVO. Boehringer Ingelheim supplies final, packaged ACTIMMUNE to us and Nuvo supplies final, packaged PENNSAID 2% to us, in each case under exclusive supply agreements. We have clinical and commercial supplies of BUPHENYL finished medicine manufactured for us by PII on a purchase order basis. We have clinical and commercial supplies of RAVICTI finished drug medicine manufactured by Lyne under a commercial supply agreement and have an agreement in place with Halo Pharmaceutical, Inc. to serve as a finished drug medicine supplier for RAVICTI in the EU. Sigma Tau PharmaSource Inc. supplies final, packaged KRYSTEXXA to us for the United States. G & W Laboratories, Inc. manufactures and supplies MIGERGOT to us in final, packaged form for the United States.

The manufacture of medicines requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medicines 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 medicine, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in the medicines or in the manufacturing facilities in which our medicines are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that issues relating to the manufacture of any of our medicines will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize our medicines in the United States or provide any medicine candidates to patients in clinical trials would be jeopardized.

Any delay or interruption in our ability to meet commercial demand for our medicines will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these medicines. 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 medicines or medicine candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.
We have experienced recent growth and expanded the size of our organization substantially in connection with our recent acquisition transactions, and we may experience difficulties in managing this growth as well as potential additional growth in connection with future medicine or company acquisitions.*

As of December 31, 2010 and prior to the commercial launch of DUEXIS, we employed approximately 40 full-time employees as a consolidated entity. As of September 30, 2016, we employed approximately 870 full-time employees, including approximately 470 sales representatives, representing a substantial change to the size of our organization over a relatively short period of time. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire in connection with the commercialization of our medicines, requiring us to hire and train new sales representatives. Our management, personnel, systems and facilities currently in place may not be adequate to support this recent and anticipated growth, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses.

As our commercialization plans and strategies continue to develop, we will need to continue to recruit and train sales and marketing personnel and expect to need to expand the size of our employee base for managerial, operational, financial and other resources as a result of our recent acquisitions. Our ability to manage any future growth effectively may require us to, among other things:

• continue to manage and expand the sales and marketing efforts for our existing medicines;
• enhance our operational, financial and management controls, reporting systems and procedures;
• expand our international resources;
• successfully identify, recruit, hire, train, maintain, motivate and integrate additional employees;
• establish and increase our access to commercial supplies of our medicines and medicine 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.

In particular, the merger of our business with the business of Vidara Therapeutics International Public Limited Company, or Vidara, is subject to numerous uncertainties and risks and will continue to require significant efforts and expenditures. For example, we have transitioned from a standalone public Delaware corporation to being part of a combined company organized in Ireland. This combination as well as our other recent acquisitions have resulted in many changes, including significant changes in the corporate business and legal entity structure, the integration of other companies and their personnel with us, and changes in systems. We are currently undertaking numerous complex transition activities associated with our recent acquisitions, and we may encounter unexpected difficulties or incur unexpected costs, including:

• difficulties in achieving growth prospects from combining third party businesses with our business;
• difficulties in the integration of operations and systems;
• difficulties in the assimilation of employees and corporate cultures;
• challenges in preparing financial statements and reporting timely results at both a statutory level for multiple entities and jurisdictions and at a consolidated level for public reporting;
• challenges in keeping existing physician prescribers and patients and increasing adoption of acquired medicines;
• difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects from the combination;
• potential unknown liabilities, adverse consequences and unforeseen increased expenses associated with the transaction; and
• challenges in attracting and retaining key personnel.

If any of these factors impair our ability to continue to integrate our operations with those of any companies or businesses we acquire, we may not be able to realize the business opportunities, growth prospects and anticipated tax synergies from combining the businesses. In addition, we may be required to spend additional time or money on integration that otherwise would be spent on the development and expansion of our business.
As a result of our acquisition of Raptor and our plans to launch RAVICTI in Europe, we also expect to continue expanding our operations and to add commercial personnel in Europe. We may not be successful in integrating Raptor’s existing European operations and personnel with our own or in otherwise growing our commercial operations outside the United States, and could encounter other challenges in growing our commercial presence in Europe, including due to risks associated with political and economic instability, operating under different legal requirements and tax complexities. If we are unable to manage our commercial growth outside of the United States, our opportunities to expand sales in other countries will be limited or we may experience greater costs with respect to our ex-U.S. commercial operations.

Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities and toward managing these growth and integration 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.

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

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and international markets, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Additional consolidations 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, medicines that are more effective and/or less costly than our medicines.

DUEXIS and VIMOVO face competition from other NSAIDs, including Celebrex®, which was marketed by Pfizer Inc., and is also a generic medicine known as celecoxib and marketed by other pharmaceutical companies. DUEXIS and VIMOVO also face significant competition from the separate use of NSAIDs for pain relief and GI protective medications to reduce the risk of NSAID-induced upper GI ulcers. Both NSAIDs and GI protective medications are available in generic form and may be less expensive to use separately than DUEXIS or VIMOVO. PENNSAID 2% faces competition from generic versions of diclofenac sodium topical solutions that are priced significantly less than the price we charge for PENNSAID 2%, and Voltaren Gel, marketed by Endo Pharmaceuticals Solutions Inc., which is the market leader in the topical NSAID category. Legislation enacted in most states in the United States allows, or in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded medicine, 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, PENNSAID 2% or VIMOVO, those prescriptions may not result in sales. If physicians do not complete prescriptions through our HorizonCares program or otherwise provide prescribing instructions prohibiting the substitution of generic ibuprofen and famotidine separately as a substitution for DUEXIS or generic naproxen and branded Nexium® (esomeprazole) as a substitute for VIMOVO or generic diclofenac sodium topical solutions as a substitute for PENNSAID 2%, sales of DUEXIS, PENNSAID 2% and VIMOVO may suffer despite any success we may have in promoting DUEXIS, PENNSAID 2% or VIMOVO to physicians. In addition, other medicine candidates that contain ibuprofen and famotidine in combination or naproxen and esomeprazole in combination, while not currently known or FDA approved, may be developed and compete with DUEXIS or VIMOVO, respectively, in the future. While KRYSYTEXXA faces limited direct competition, a number of competitors have drugs in Phase 1 or Phase 2 trials. On December 22, 2015, AstraZeneca secured approval from the FDA for ZURAMPIC (lesinurad) 200mg tablets in combination with a xanthine oxidase inhibitor, or XOI, for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid (sUA) levels with an XOI alone. In April 2016, the U.S. rights to ZURAMPIC were licensed to Ironwood Pharmaceuticals Inc. Although ZURAMPIC is not a direct competitor because it has not been approved for refractory gout, this therapy could be used prior to use of KRYSYTEXXA and if effective, could reduce the target patient population for KRYSYTEXXA. PROSCYSBI faces competition from Cystagon (immediate-release cysteamine bitartrate capsules) for the treatment of cystinosis and Cystaran (cysteamine ophthalmic solution) for treatment of corneal crystal accumulation in patients with cystinosis. QUINSAIR faces competition from Tobramycin solution, which is available as a generic medicine for treatment of chronic Pseudomonas aeruginosa lung infections in patients with CF, TOBI Podhaler, Cayston and colistimethate.
We have also entered into settlement and license agreements that may allow certain of our competitors to sell generic versions of certain of our medicines in the United States, subject to the terms of such agreements. On August 21, 2013, we entered into a settlement agreement, or the Par settlement agreement, and license agreement, or the Par license agreement, with Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., collectively Par, relating to our patent infringement litigation with Par. Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances), or the License, to manufacture and commercialize Par’s generic version of DUEXIS in the United States after the generic entry date (as defined below) and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par’s generic version of DUEXIS prior to the generic entry date. Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier under 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.

On May 6, 2015, we entered into a settlement and license agreement, or the Perrigo settlement agreement, with Perrigo Company plc and its subsidiary Paddock Laboratories, LLC, or collectively Perrigo, relating to patent infringement litigation with Perrigo. Under the Perrigo settlement agreement, we granted Perrigo a non-exclusive license to manufacture and commercialize Perrigo’s generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Perrigo’s generic version of PENNSAID 2% during certain limited periods prior to the license effective date. Under the Perrigo settlement agreement, the license effective date is January 10, 2029; however, Perrigo may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in our PENNSAID 2% shipments over specified periods of time. In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, we may be required to supply PENNSAID 2% to Perrigo as our authorized distributor of generic PENNSAID 2%, with us receiving specified percentages of any net sales by Perrigo. We also agreed that if we enter into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, we will amend the Perrigo settlement agreement to provide Perrigo with terms that are no less favorable than those provided to the other parties.

On September 9, 2015, we entered into a settlement and license agreement, or the Taro settlement agreement, with Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd., or collectively Taro, relating to patent infringement litigation with Taro. Under the Taro settlement agreement, we granted Taro a non-exclusive license to manufacture and commercialize Taro’s generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Taro’s generic version of PENNSAID 2% during certain limited periods prior to the license effective date. Under the Taro settlement agreement, the license effective date is January 10, 2029; however, Taro may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in our PENNSAID 2% shipments over specified periods of time. We also agreed that if we enter into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, we will amend the Taro settlement agreement to provide Taro with terms that are no less favorable than those provided to the other parties.

On October 1, 2015, we, as well as Jagotec, entered into a license and settlement agreement, or the Actavis settlement agreement, with Actavis Laboratories FL, Inc. (formerly known as Watson Laboratories, Inc. – Florida), or Actavis FL, relating to patent infringement litigation with Actavis FL. Under the Actavis settlement agreement, we and Jagotec granted Actavis FL a non-exclusive license to manufacture and commercialize Actavis FL’s generic version of RAYOS tablets in the United States after the generic entry date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Actavis FL’s generic version of RAYOS tablets during certain limited periods prior to the generic entry date. We and Jagotec also agreed that during the 180 days after the generic entry date, the license granted to Actavis FL would be exclusive with respect to any third-party generic version of RAYOS tablets. Under the Actavis settlement agreement, the generic entry date is December 23, 2022; however, Actavis FL may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party RAYOS patent litigation, the entry of other generic versions of RAYOS tablets or certain substantial reductions in RAYOS prescriptions over specified periods of time. If we or Jagotec enter into any similar agreements with other parties with respect to generic versions of RAYOS tablets, we and Jagotec agreed to amend the Actavis settlement agreement to provide Actavis FL with terms that are no less favorable than those provided to the other parties with respect to the license terms, generic entry date, permitted pre-market activities and notice provisions.
On April 18, 2016, we entered into a settlement and license agreement, or the Amneal settlement agreement, with Amneal Pharmaceuticals LLC, or Amneal, relating to patent infringement litigation with Amneal. Under the Amneal settlement agreement, we granted Amneal a non-exclusive license to manufacture and commercialize Amneal’s generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Amneal’s generic version of PENNSAID 2% during certain limited periods prior to the license effective date. Under the Amneal settlement agreement, the license effective date is January 10, 2029; however, Amneal may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation or the entry of other third-party generic versions of PENNSAID 2%. In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, we may be required to supply PENNSAID 2% to Amneal as our non-exclusive, authorized distributor of generic PENNSAID 2%, with us receiving specified percentages of any net sales by Amneal. We also agreed that if we enter into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, we will amend the Amneal settlement agreement to provide Amneal with terms that are no less favorable than those provided to the other parties.

On May 9, 2016, we entered into a settlement and license agreement, or the Teligent settlement agreement, with Teligent, Inc., formerly known as IGI Laboratories, Inc., or Teligent, relating to patent infringement litigation with Teligent. Under the Teligent settlement agreement, we granted Teligent a non-exclusive license to manufacture and commercialize Taro’s generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Teligent’s generic version of PENNSAID 2% during certain limited periods prior to the license effective date. Under the Teligent settlement agreement, the license effective date is January 10, 2029; however, Teligent may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in our PENNSAID 2% shipments over specified periods of time. We also agreed that if we enter into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, we will amend the Teligent settlement agreement to provide Taro with terms that are no less favorable than those provided to the other parties.

Patent litigation is currently pending in the United States District Court for the District of New Jersey against several companies intending to market a generic version of PENNSAID 2% prior to the expiration of certain of our patents listed in the FDA’s Orange Book, or the Orange Book. These cases are collectively known as the PENNSAID 2% cases, and involve the following sets of defendants: (i) Actavis Laboratories UT, Inc., formerly known as Watson Laboratories, Inc., Actavis, Inc. and Actavis plc, or collectively Actavis; and (ii) Lupin Limited and Lupin Pharmaceuticals, Inc., or collectively Lupin. These cases arise from Paragraph IV Patent Certification notice letters from each of Actavis and Lupin advising each had filed an Abbreviated New Drug Application, or ANDA, with the FDA seeking approval to market a generic version of PENNSAID 2% before the expiration of the patents-in-suit. No trial date has been set by the court in these actions.

We received from Actavis a Paragraph IV Patent Certification Notice Letter dated September 27, 2016, against Orange Book listed U.S. Patent No. 9,415,029 advising that Actavis had filed an ANDA with the FDA for a generic version of PENNSAID 2%.

We received from Apotex Inc., or Apotex, a Paragraph IV Patent Certification Notice Letter dated April 1, 2016, against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, 8,871,809, 9,066,913, 9,101,591, 9,132,110, 9,168,304, 9,168,305 and 9,220,784, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%. We also received from Apotex a second Paragraph IV Patent Certification Notice Letter dated June 30, 2016, against Orange Book listed U.S. Patent Nos. 9,339,551 and 9,339,552, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%. We also received from Apotex a third Paragraph IV Patent Certification Notice Letter dated September 21, 2016, against Orange Book listed U.S. Patent No. 9,415,029, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%.

Patent litigation is currently pending in the United States District Court for the District of New Jersey against several companies intending to market a generic version of VIMOVO before the expiration of certain of our patents listed in the Orange Book. These cases are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy’s Laboratories Inc. and Dr. Reddy’s Laboratories Ltd., or collectively Dr. Reddy’s; (ii) Lupin; (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc., or collectively Mylan; and (iv) Actavis FL and Actavis Pharma, Inc., or collectively Actavis Pharma. The cases arise from Paragraph IV Patent Certification notice letters from each of Dr. Reddy’s, Lupin, Mylan and Actavis Pharma advising each had filed an ANDA with the FDA seeking approval to market generic versions of VIMOVO before the expiration of the patents-in-suit.

Patent litigation is currently pending in the United States District Court for the Eastern District of Texas against Par Pharmaceutical, Inc., or Par Pharmaceutical, and in the United States District Court for the District of New Jersey against Par Pharmaceutical and against Lupin, who are each intending to market generic versions of RAVICTI prior to the expiration of certain of our patents listed in the Orange Book. These cases are collectively known as the RAVICTI cases and arise from Paragraph IV Patent Certification notice letters from each of Par Pharmaceutical and Lupin advising each had filed an ANDA with the FDA seeking approval to market a generic version of RAVICTI before the expiration of the patents-in-suit.
If we are unsuccessful in any of the VIMOVO cases or PENNSAID 2% cases, we will likely face generic competition with respect to VIMOVO and/or PENNSAID 2% and sales of VIMOVO and/or PENNSAID 2% will be substantially harmed. If we are unsuccessful in any of the RAVICTI cases, RAVICTI would likely face generic competition in the United States when its orphan exclusivity expires (currently scheduled to occur in February 2020), and its sales would likely materially decline.

ACTIMMUNE is the only medicine currently approved by the FDA specifically for the treatment of CGD and SMO. While there are additional or alternative approaches used to treat patients with CGD and SMO, there are currently no medicines on the market that compete directly with ACTIMMUNE. A widely accepted protocol to treat CGD in the United States is the use of concomitant “triple prophylactic therapy” comprising ACTIMMUNE, an oral antibiotic agent and an oral antifungal agent. However, the FDA-approved labeling for ACTIMMUNE does not discuss this “triple prophylactic therapy,” and physicians may choose to prescribe one or both of the other modalities in the absence of ACTIMMUNE. Because of the immediate and life-threatening nature of SMO, the preferred treatment option for SMO is often to have the patient undergo a bone marrow transplant which, if successful, will likely obviate the need for further use of ACTIMMUNE in that patient. Likewise, the use of bone marrow transplants in the treatment of patients with CGD is becoming more prevalent, which could have a material adverse effect on sales of ACTIMMUNE and its profitability. We are aware of a number of research programs investigating the potential of gene therapy as a possible cure for CGD. Additionally, other companies may be pursuing the development of medicines and treatments that target the same diseases and conditions which ACTIMMUNE is currently approved to treat. As a result, it is possible that our competitors may develop new medicines that manage CGD or SMO more effectively, cost less or possibly even cure CGD or SMO. In addition, U.S. healthcare legislation passed in March 2010 authorized the FDA to approve biological products, known as biosimilars, that are similar to or interchangeable with previously approved biological products, like ACTIMMUNE, based upon potentially abbreviated data packages. Biosimilars are likely to be sold at substantially lower prices than branded medicines because the biosimilar manufacturer would not have to recoup the research and development and marketing costs associated with the branded medicine. Though we are not currently aware of any biosimilar under development, the development and commercialization of any competing medicines or the discovery of any new alternative treatment for CGD or SMO could have a material adverse effect on sales of ACTIMMUNE and its profitability.

BUPHENYL’s composition of matter patent protection and orphan drug exclusivity have expired. Because BUPHENYL has no regulatory exclusivity or listed patents, there is nothing to prevent a competitor from submitting an ANDA for a generic version of BUPHENYL and receiving FDA approval. In November 2011, Ampongen Pharmaceuticals, LLC received FDA approval for a generic version of NaPBA tablets, which may compete with RAVICTI and BUPHENYL in treating UCD. In March 2013, SigmaPharm Laboratories, LLC received FDA approval for a generic version of NaPBA powder, which competes with BUPHENYL and may compete with RAVICTI in treating UCD. In July 2013, Lucane Pharma, or Lucane, received marketing approval from the EMA for taste-masked NaPBA and has announced a distribution partnership in Canada. In January 2015, Lucane announced it had received marketing approval for its taste-masked NaPBA in Canada. We believe Lucane is also seeking approval via an ANDA in the United States. If this ANDA is approved, this formulation may compete with RAVICTI and BUPHENYL in treating UCD in the United States. Generic versions of BUPHENYL to date have been priced at a discount relative to BUPHENYL or RAVICTI, and physicians, patients, or payers may decide that this less expensive alternative is preferable to BUPHENYL and RAVICTI. If this occurs, sales of BUPHENYL and/or RAVICTI could be materially reduced, but we would nevertheless be required to make royalty payments to Ucyclyd Pharma, Inc., or Ucyclyd, and another external party, at the same royalty rates. While Ucyclyd and its affiliates are generally contractually prohibited from developing or commercializing new medicines, anywhere in the world, for the treatment of UCD or hepatic encephalopathy, or HE, which are chemically similar to RAVICTI, they may still develop and commercialize medicines that compete with RAVICTI. For example, medicines approved for indications other than UCD and HE may still compete with RAVICTI if physicians prescribe such medicines off-label for UCD or HE. We are also aware that Orphan Europe SARL, or Orphan Europe, is conducting a clinical trial of carglumic acid to treat some of the UCD enzyme deficiencies for which RAVICTI was approved. Promethera Biosciences SA has successfully completed Phase I/II trials of its cell-based therapy for the treatment of UCD and plans to conduct a Phase III clinical trial. Carglumic acid is approved for maintenance therapy for chronic hyperammonemia and to treat hyperammonemic crises in N-acetylglutamate synthase deficiency, a rare UCD subtype, and is sold under the name Carbaglu. If the results of this trial are successful and Orphan Europe is able to complete development and obtain approval of Carbaglu to treat additional UCD enzyme deficiencies, RAVICTI would face additional competition from this compound.

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

In addition, established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to acquire novel compounds that could make our medicines 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 and acquire medicines that are superior to other medicines in the market;
-   attract qualified clinical, regulatory, and sales and marketing personnel;
obtain patent and/or other proprietary protection for our medicines and technologies;
• obtain required regulatory approvals; and
• successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicine candidates.

If we are unable to maintain or realize the benefits of orphan drug exclusivity, we may face increased competition with respect to certain of our medicines. *

Under the Orphan Drug Act of 1983, the FDA may designate a medicine as an orphan drug if it is a drug intended to treat a rare disease or condition affecting fewer than 200,000 people in the United States. A company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years from the date of its approval. RAVICTI, KRYSSTEXXA and PROSCYSBI have been granted orphan drug exclusivity by the FDA, which we expect will provide orphan drug marketing exclusivity in the United States until May 2020, February 2018 and December 2020, respectively, with exclusivity for PROCYSBI extending to 2022 for patients ages two to six years. However, despite orphan drug exclusivity, the FDA can still approve another drug containing the same active ingredient and used for the same orphan indication if it determines that a subsequent drug is safer, more effective or makes a major contribution to patient care, and orphan exclusivity can be lost if the orphan drug manufacturer is unable to ensure that a sufficient quantity of the orphan drug is available to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective. In addition, orphan drug exclusivity does not prevent the FDA from approving competing drugs for the same or similar indication containing a different active ingredient. If orphan drug exclusivity is lost and we were unable to successfully enforce any remaining patents covering RAVICTI, KRYSSTEXXA or PROCYSBI, we could be subject to generic competition and revenues from RAVICTI, KRYSSTEXXA or PROCYSBI could decrease materially. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as RAVICTI, KRYSSTEXXA or PROCYSBI despite orphan drug exclusivity, we may face increased competition and lose market share with respect to these medicines. KRYSSTEXXA does not have orphan drug exclusivity in the EU or other regions of the world. RAVICTI will benefit from a period of 10 years of orphan market exclusivity in the EU, concurrently applied to each of the approved six sub-types of the UCDs. This will run concurrently with its marketing exclusivity status. PROCYSBI received marketing authorization in September 2013 from the European Commission, or EC, for marketing in the EU as an orphan medicinal product for the management of proven nephropathic cystinosis. PROCYSBI received seven years of market exclusivity, through 2020 for patients six years and older as an orphan drug in the United States and ten years of market exclusivity, through 2023, as an orphan drug in Europe. QUINSAIR received 10 years of market exclusivity in the EU, beginning with its March 2015 marketing authorization. Orphan market exclusivity may be reduced to six years in the EU if the orphan drug designation criteria are no longer met after five years, including where it is shown that the product is sufficiently profitable. As in the United States, loss of orphan marketing exclusivity in the EU may result in early generic competition, which could substantially reduce our revenues from EU sales of these medicines.

Our business operations may subject us to numerous commercial disputes, claims and/or lawsuits and such litigation may be costly and time-consuming and could materially and adversely impact our financial position and results of operations.*

Operating in the pharmaceutical industry, particularly the commercialization of medicines, involves numerous commercial relationships, complex contractual arrangements, uncertain intellectual property rights, potential product liability and other aspects that create heightened risks of disputes, claims and lawsuits. In particular, we may face claims related to the safety of our medicines, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture-related matters. For example, the active ingredient in QUINSAIR, levofloxacin, is currently subject to several product liability claims. Any commercial dispute, claim or lawsuit may divert management’s attention away from our business, we may incur significant expenses in addressing or defending any commercial dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results.

We are currently in litigation with multiple generic drug manufacturers regarding intellectual property infringement. For example, we are currently involved in Hatch Waxman litigation with generic drug manufacturers related to VIMOVO, PENNSAID 2% and RAVICTI.

Similarly, from time to time we are involved in disputes with distributors, PBMs and licensing partners regarding our rights and performance of obligations under contractual arrangements. For example, we were recently in litigation with Express Scripts, Inc., or Express Scripts, related to alleged breach of contract claims and in which Express Scripts was seeking payment for rebates relating to DUEXIS, RAYOS and VIMOVO. We counterclaimed against Express Scripts, contesting the amount owed and contending Express Scripts had breached the rebate agreement. In September 2016, we entered into a settlement agreement and mutual release with Express Scripts pursuant to which we and Express Scripts were released from any and all claims relating to the litigation without admitting any fault or wrongdoing and we agreed to pay Express Scripts $65.0 million.
A variety of risks associated with operating our business and marketing our medicines internationally could materially adversely affect our business.*

In addition to our U.S. operations, we have operations in Ireland, Bermuda, the Grand Duchy of Luxembourg, or Luxembourg, the Netherlands, France, Switzerland, Germany, Canada, the Grand Cayman Islands and in Israel (through Andromeda). Moreover, Grünenthal S.A. is in the registration process for the commercialization of DUEXIS in Latin America. BUPHENYL is currently marketed in various territories outside the United States by third-party distributors. RAVICTI received marketing authorization from the EMA in November 2015 and we plan to begin commercializing RAVICTI in Europe in 2017. PROCYSBI received marketing authorization from the EMA in September 2013 and is marketed in various countries within the European Economic Area. QUINSAIR received marketing authorization from the EMA in March 2015 and is also marketed in several countries within the European Economic Area. QUINSAIR received marketing authorization from HC in June 2015 and we anticipate launching in Canada in the fourth quarter of 2016. 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 medicines;
- compliance with Irish laws and the maintenance of our Irish tax residency with respect to our overall corporate structure and administrative operations, including the need to generally hold meetings of our board of directors and make decisions in Ireland, which may make certain corporate actions more cumbersome, costly and time-consuming;
- difficulties in staffing and managing foreign operations;
- in certain circumstances, including with respect to the commercialization of LODOTRA in Europe and certain Asian, Latin American, Middle Eastern and African countries, commercialization of BUPHENYL in select countries throughout Europe, the Middle East, and the Asia-Pacific region, commercialization of RAVICTI in select countries throughout Europe and commercialization of DUEXIS in Latin America, increased dependence on the commercialization efforts and regulatory compliance of third-party distributors or strategic partners;
- compliance with German laws with respect to our Horizon Pharma GmbH subsidiary through which Horizon Pharma Switzerland GmbH 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, or the FCPA;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the United Kingdom’s Bribery Act 2010, or the U.K. Bribery Act. The FCPA and similar anti-corruption laws generally prohibit offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to non-U.S. government officials in order to improperly influence any act or decision, secure any other improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the company and to devise and maintain an adequate system of internal accounting controls. The U.K. Bribery Act prohibits giving, offering, or promising bribes to any person, including non-U.K. government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the U.K. Bribery Act, companies which carry on a business or part of a business in the United Kingdom, or U.K., may be held liable for bribes given, offered or promised to any person, including non-U.K. government officials and private persons, by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability is strict, with no element of a corrupt state of mind, but a defense of having in place adequate procedures designed to prevent bribery is available. Furthermore, under the U.K. Bribery Act there is no exception for facilitation payments. As described above, our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, any dealings with these prescribers and purchasers may be subject to regulation under the FCPA. Recently the SEC and the U.S. Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd–Frank Wall Street Reform and Consumer Protection Act, private individuals who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We are engaged in ongoing efforts that are designed to ensure our compliance with these laws, including due diligence, training, policies, procedures and internal controls. However, there is no certainty that all employees and third-party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of manufacturers and other third-party agents, although we may be liable for their actions. Violation of these laws may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

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 or acquire other medicine candidates or medicines, our business and prospects would be limited.

A key element of our strategy is to develop or acquire and commercialize a portfolio of other medicines or medicine candidates in addition to our current medicines, through business or medicine acquisitions. Because we do not engage in proprietary drug discovery, 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 approved or clinically enabled medicine candidates for therapeutic indications that complement or augment our current medicines, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring promising medicines or medicine 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 medicine or medicine 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 suitable medicines or medicine candidates from third parties or acquire businesses at valuations and on other terms acceptable to us, or if we are unable to raise capital required to acquire businesses or new medicines, our business and prospects will be limited.
Moreover, any medicine candidate we acquire may require additional, time-consuming development or regulatory efforts prior to commercial sale or prior to expansion into other indications, including preclinical studies if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All medicine candidates are prone to the risk of failure that is inherent in pharmaceutical medicine development, including the possibility that the medicine 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 medicines that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

In addition, if we fail to successfully commercialize and further develop our medicines, there is a greater likelihood that we will fail to successfully develop a pipeline of other medicine candidates to follow our existing medicines or be able to acquire other medicines to expand our existing portfolio, and our business and prospects would be harmed.

Our recent medicine and company acquisitions and any other strategic transactions that we may pursue in the future could have a variety of negative consequences, and we may not realize the benefits of such transactions or attempts to engage in such transactions.*

We have recently completed multiple medicine and company acquisitions and our strategy is to engage in additional strategic transactions with third parties, such as acquisitions of companies or divisions of companies and asset purchases of medicines, medicine candidates or technologies that we believe will complement or augment our existing business. We may also consider a variety of other business arrangements, including spin-offs, strategic partnerships, joint ventures, Restructurings, divestitures, business combinations and other investments. Any such transaction may require us to incur non-recurring and other charges, increase our near and long-term expenditures, pose significant integration challenges, create additional tax, legal, accounting and operational complexities in our business, require additional expertise, result in dilution to our existing shareholders and disrupt our management and business, which could harm our operations and financial results. For example, in connection with our acquisition of the U.S. rights to VIMOVO, we assumed primary responsibility for the existing patent infringement litigation with respect to VIMOVO, and have also agreed to reimburse certain legal expenses of Pozen Inc., who subsequently entered into a business combination with Tribute Pharmaceuticals Canada Inc. to become known as Aralez Pharmaceuticals Inc., or Aralez, with respect to its continued involvement in such litigation. We also assumed responsibility for the existing patent infringement litigation with respect to RAVICTI upon the closing of the acquisition of Hyperion and have assumed responsibility for completing post-marketing clinical trials of RAVICTI that are required by the FDA and are ongoing. We expect that the RAVICTI litigation will result in substantial on-going expenses and potential distractions to our management team.

In connection with our acquisition of Raptor, we assumed Raptor’s post-marketing clinical study obligations in marketing authorization application, or the MAA, for QUINSAIR and contractual obligations under agreements with TripeX Pharmaceuticals, LLC, or TripeX, and PARI related to QUINSAIR. Under the agreement with TripeX, we are required to pursue commercially reasonable efforts to initiate, and subsequently to complete, an additional clinical trial of QUINSAIR in a non-cystic-fibrosis patient population within a specified period of time and an obligation to progress toward filing an NDA for approval of QUINSAIR in the United States in all or part of the cystic fibrosis patient population. These obligations are subject to certain exceptions due to, for example, manufacturing delays not under our control, or delays caused by the FDA. If we fail to properly exercise such efforts to initiate and complete an appropriate clinical trial, or fail to file an NDA for U.S. approval in the cystic fibrosis patient population, during the time periods specified in the asset purchase agreement, we may be subject to various claims by TripeX and parties affiliated with TripeX. In addition, if we do not spend a minimum amount on QUINSAIR development in each of the three years following our acquisition of Raptor, we may also be obligated to pre-pay a milestone payment related to initiating a clinical trial for QUINSAIR in a non-cystic-fibrosis indication. Under the license agreement with PARI, we are required to comply with diligence milestones related to development and commercialization of QUINSAIR in the United States, to spend a specified minimum amount per year on development activities in the United States until filing of the NDA for QUINSAIR in the United States. If we do not comply with these obligations, our licenses to certain intellectual property related to QUINSAIR may become non-exclusive in the United States or could be terminated. We are also now subject to contractual obligations under license agreements with the University of California, San Diego, or UCSD, with respect to PROCYSBI, including diligence obligations to develop PROCYSBI for the treatment of non-alcoholic steatohepatitis, or NASH, and Huntington’s disease, with which we currently are not in compliance. To the extent that we fail to perform the diligence obligations under the agreement, UCSD may, with respect to such indication, terminate the license or otherwise cause the license to become non-exclusive. If one or more of these licenses was terminated, we would have no further right to use or exploit the related intellectual property, which would limit our ability to develop PROCYSBI or QUINSAIR in other indications, and could impact our ability to continue commercializing PROCYSBI or QUINSAIR in their approved indications.
We face significant competition in seeking appropriate strategic transaction opportunities 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 may be insufficient and/or third parties may not view our commercial and development capabilities as being adequate. We may not be able to expand our business or realize our strategic goals if we do not have sufficient funding or cannot borrow or raise additional capital. There is no assurance that following any of our recent acquisition transactions or any other strategic transaction, we will achieve the anticipated revenues, net income, tax or other benefits that we believe justify such transactions. In addition, any failures or delays in entering into strategic transactions anticipated by analysts or the investment community could seriously harm our consolidated business, financial condition, results of operations or cash flow.

Our parent company may not be able to successfully maintain its current advantageous tax status and resulting tax rates, which could adversely affect our business and financial condition, results of operations and growth prospects.*

Our parent company is incorporated in Ireland and maintains subsidiaries in multiple jurisdictions, including Ireland, the U.K., the United States, Switzerland, Luxembourg, Germany, Canada and Bermuda. Prior to our merger transaction with Vidara, or the Vidara Merger, Vidara was able to achieve a favorable tax rate through the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions, including Ireland and Bermuda, together with intra-group service and transfer pricing arrangements, each on an arm’s length basis. We are continuing a substantially similar structure and arrangements. Taxing authorities, such as the U.S. Internal Revenue Service, or IRS, actively audit and otherwise challenge these types of arrangements, and have done so in the pharmaceutical industry. We expect that these challenges will continue as a result of the recent increase in scrutiny and political attention on corporate tax structures. The IRS may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management’s time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful in defending such a challenge, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our medicines or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations or cash flow.

The IRS may not agree with our conclusion that our parent company should be treated as a foreign corporation for U.S. federal income tax purposes following the combination of the businesses of Horizon Pharma, Inc. and Vidara Therapeutics International plc. *

Although our parent company is incorporated in Ireland, the IRS may assert that it should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal income tax purposes pursuant to Section 7874 of the Internal Revenue Code of 1986, as amended, or the Code. A corporation is generally considered a tax resident in the jurisdiction of its organization or incorporation for U.S. federal income tax purposes. Because our parent company is an Irish incorporated entity, it would generally be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 provides an exception pursuant to which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal income tax purposes.

Under Section 7874, a foreign corporation will be treated as a U.S. corporation for U.S. federal tax purposes if, due to an acquisition of a U.S. corporation, at least 80 percent of its stock (by vote or value) is held by former stockholders of the acquired U.S. corporation. We believe that we should be treated as a foreign corporation because the former stockholders of Horizon Pharma, Inc., or HPI, owned (within the meaning of Section 7874) less than 80 percent (by both vote and value) of the combined entity’s stock immediately after the Vidara Merger. However, there can be no assurance that there will not exist in the future a subsequent change in the facts or in law which might cause our parent company to be treated as a domestic corporation for U.S. federal income tax purposes, including with retroactive effect.

Further, there can be no assurance that the IRS will agree with the position that the ownership test was satisfied. There is limited guidance regarding the application of Section 7874 of the Code, including with respect to the provisions regarding the application of the ownership test. If our parent company were unable to be treated as a foreign corporation for U.S. federal income tax purposes, one of our significant strategic reasons for completing the Vidara Merger would be nullified and we may not be able to recoup the significant investment in completing the transaction.

Future changes to U.S. and non-U.S. tax laws could materially adversely affect our company. *

Under current law, we expect our parent company to be treated as a foreign corporation for U.S. federal income tax purposes. However, changes to the rules in Section 7874 of the Code or regulations promulgated thereunder or other guidance issued by the U.S. Department of the Treasury, or the U.S. Treasury, or the IRS could adversely affect our parent company’s status as a foreign corporation for U.S. federal income tax purposes, and any such changes could have prospective or retroactive application. If our parent company is treated as a domestic corporation, more of our income will be taxed by the United States which may substantially increase our effective tax rate.

83
On April 4, 2016, the U.S. Treasury and the IRS issued temporary regulations that expand the scope of transactions subject to the rules designed to eliminate the U.S. tax benefits of inversions. Under the temporary regulations, the former stockholders of U.S. corporations acquired by a foreign corporation within 36 months of the signing date of the last such acquisition are aggregated for the purpose of determining whether the foreign corporation will be treated as a domestic corporation for U.S. federal tax purposes because at least 80 percent of the stock of the foreign corporation is held by former stockholders of a U.S. corporation. The requirement to aggregate the stockholders in such acquisitions for the purpose of determining whether the 80 percent threshold is met may limit our ability to use our stock to acquire U.S. corporations or their assets in the future.

The U.S. Treasury and the IRS also issued proposed regulations on April 4, 2016 that address whether an interest in a related corporation is debt or equity. The proposed regulations would treat certain inter-company debt issued on or after that date as equity including, subject to certain exceptions, inter-company debt issued in certain distributions, acquisitions of related party stock and asset reorganizations. As drafted, the proposed regulations would limit the ability of our U.S. group to deduct interest on such new inter-company debt. The proposed regulations could also result in recharacterization of inter-company debt to equity for inter-company debt incurred to provide funding for an acquisition by the U.S. group if, and to the extent of, certain cash or property transfers by our U.S. group to the foreign affiliates within 36 months before or after these inter-company borrowings. These limitations could result in more of our future income being taxed by the United States and thereby increase our effective tax rate.

In July 2015, the International Tax Bipartisan Tax Working Group of the United States Senate Committee on Finance, or the Finance Committee, issued its report on international tax reform. The Finance Committee's co-chairs concluded that it will be necessary to limit earnings stripping by foreign multinationals through interest deductions on inter-company debt in order to eliminate a competitive advantage that foreign multinationals would otherwise have over domestic multinational companies. This and other international tax reforms proposed by the Finance Committee could result in more of our income being taxed by the United States and thereby increase our effective tax rate.

In addition, the Organization for Economic Co-operation and Development released its Base Erosion and Profit Shifting project final report on October 5, 2015. This report provides the basis for international standards for corporate taxation that are designed to prevent, among other things, the artificial shifting of income to tax havens and low-tax jurisdictions, the erosion of the tax base through interest deductions on inter-company debt and the artificial avoidance of permanent establishments (i.e., tax nexus with a jurisdiction). Legislation to adopt these standards has been enacted or is currently under consideration in a number of jurisdictions. As a result, our income may be taxed in jurisdictions where it is not currently taxed and at higher rates of tax than it is currently taxed, which may substantially increase our effective tax rate.

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 executive committee composed of our Chairman, President and Chief Executive Officer, Timothy P. Walbert; our Executive Vice President, Chief Business Officer, Robert F. Carey; our Executive Vice President, Chief Financial Officer, Paul W. Hoelscher; our Executive Vice President, Company Secretary and Managing Director, Ireland, David G. Kelly; our Executive Vice President, Chief Operating Officer, Barry J. Moze; our Executive Vice President, Research and Development and Chief Medical Officer, Jeffrey W. Sherman, M.D., FACP; our Executive Vice President, General Counsel, Brian K. Beeler; our Executive Vice President, Rheumatology and Primary Care Business Units, George Hampton; our Executive Vice President, Global Orphan Business Unit, Dave Happel; our Senior Vice President, Commercial Operations, Timothy J. Ackerman; and our Senior Vice President, Corporate Communications, Geoffrey M. Curtis. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide performance stock units, or PSUs, and stock options and restricted stock units that vest over time. The value to employees of PSUs, stock options and restricted stock units will be significantly affected by movements in our share 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 affairs, clinical development, 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 medicines and medicine candidates will be limited.

We are, with respect to our current medicines, and will be, with respect to any other medicine or medicine candidate for which we obtain FDA or EMA approval or which we acquire, subject to ongoing FDA or the EMA obligations and continued regulatory review, which may result in significant additional expense. Additionally, any other medicine candidate, if approved by the FDA or the EMA, 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 medicines.*

Any regulatory approvals that we obtain for our medicine candidates may also be subject to limitations on the approved indicated uses for which the medicine 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 medicine candidate. In addition, with respect to our current FDA-approved medicines (and with respect to our medicine candidates, if approved), the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the medicine are 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 cGMPs, GCPs, international conference on harmonization regulations, or ICH regulations, and GLPs, which are regulations and guidelines enforced by the FDA for all of our medicines in clinical development, for any clinical trials that we conduct post-approval. In connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we assumed responsibility for completing an ongoing Pediatric Research Equity Act post-marketing requirement study in children 12 years to 16 years and 11 months of age with juvenile rheumatoid arthritis. This report was submitted to the FDA in December 2015. With respect to RAVICTI, the FDA imposed several post-marketing requirements and a post-marketing commitment, which include remaining obligations to conduct studies in UCD patients during the first two months of life and from two months to two years of age, including a study of the pharmacokinetics in both age groups, and a randomized study to determine the safety and efficacy in UCD patients who are treatment naïve to phenylbutyrate treatment. 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. On June 29, 2016, we submitted an sNDA with the FDA for RAVICTI to expand the age range for chronic management of UCDs from two years of age and older to two months of age and older. Subject to positive data from on-going studies, we have targeted an sNDA submission in the first quarter of 2018 in relation to UCD patients during the first two months of life. In connection with our acquisition of Crealta Holdings LLC, or Crealta, in January 2016, we assumed responsibility for an observational study related to KRYSTEXXA. Thus far in this study there have been no new safety signals and the reported safety results parallel those in the KRYSTEXXA product label. We are continuing to screen and enroll patients in the near term. With respect to QUINSAIR, we are required to conduct post-marketing clinical studies in cystic fibrosis patients pursuant to obligations in the MAA for QUINSAIR and submit data to the EMA regularly regarding observed clinical product profile and safety assessment.

In addition, the FDA closely regulates the marketing and promotion of drugs and biologics. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturers’ promotional communications. A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of medicines for off-label uses and other sales practices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, false claims laws, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of medicines for unapproved uses, pricing and Medicare and/or Medicaid reimbursement.

Later discovery of previously unknown problems with a medicine, 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 medicine, withdrawal of the medicine from the market, or voluntary or mandatory medicine 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 medicine license approvals;
- medicine seizure or detention, or refusal to permit the import or export of medicines; and
- injunctions, the imposition of civil or criminal penalties, or exclusion, debarment or suspension from government healthcare programs.

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

**Coverage and reimbursement may not be available, or reimbursement may be available at only limited levels, for our medicines, which could make it difficult for us to sell our medicines profitably or to successfully execute planned medicine price increases.**

Market acceptance and sales of our medicines will depend in large part on global coverage and reimbursement policies and may be affected by future healthcare reform measures, both in the United States and other key international markets. Successful commercialization of our medicines will depend in part on the availability of governmental and third-party payer reimbursement for the cost of our medicines. Government health administration authorities, private health insurers and other organizations generally provide reimbursement for healthcare. In particular, in the United States, private health insurers and other third-party payers often provide reimbursement for medicines and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, the EU and other significant or potentially significant markets for our medicines and medicine candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medicines and services, particularly for new and innovative medicines and therapies, which has resulted in lower average selling prices. Further, the increased scrutiny of prescription drug pricing practices and emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on medicine pricing, reimbursement and usage, which may adversely affect our medicine 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 medicine price increases, or limit the amount by which we may be able to increase our medicine prices, which may adversely affect our medicine sales and results of operations.

Patients are unlikely to use our medicines unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our medicines. Third-party payers may limit coverage to specific medicines on an approved list, also known as a formulary, which might not include all of the FDA-approved medicines for a particular indication. Moreover, a third-party payer’s decision to provide coverage for a medicine does not imply that an adequate reimbursement rate will be approved. Additionally, one third-party payer’s decision to cover a particular medicine does not ensure that other payers will also provide coverage for the medicine, or will provide coverage at an adequate reimbursement rate. Even though we have contracts with some PBMs in the United States, that does not guarantee that they will perform in accordance with the contracts, nor does that preclude them from taking adverse actions against us, which could materially adversely affect our operating results. In addition, the existence of such PBM contracts does not guarantee coverage by such PBM’s contracted health plans or adequate reimbursement to their respective providers for our medicines. For example, two significant PBMs placed DUEXIS and VIMOVO on their exclusion lists beginning in 2015, which has resulted in a loss of coverage for patients whose healthcare plans have adopted these PBM lists. While DUEXIS and VIMOVO were removed from the CVS Caremark 2017 exclusion list, we cannot guarantee that CVS Caremark will not later add these medicines back to its exclusion list or that we will be able to otherwise expand formulary access for DUEXIS and VIMOVO under health plans that contract with CVS Caremark. Also, as noted above, we were recently in a contract and rebate dispute with Express Scripts involving DUEXIS, RAYOS and VIMOVO. In September 2016, we entered into a settlement agreement and mutual release with Express Scripts pursuant to which we and Express Scripts were released from any and all claims relating to the litigation without admitting any fault or wrongdoing and we agreed to pay Express Scripts $65.0 million. Additional healthcare plan formularies may also exclude our medicines from coverage due to the actions of certain PBMs, future price increases we may implement, our use of the HorizonCares program or any other co-pay programs, or other reasons. If our strategies to mitigate formulary exclusions are not effective, these events may reduce the likelihood that physicians prescribe our medicines and increase the likelihood that prescriptions for our medicines are not filled.
Outside of the United States, the success of our medicines, including BUPHENYL, LODOTRA, PROCYSBI, QUINSAIR, RAVICTI and, following the IMUKIN Acquisition, interferon gamma-1b (currently commercialized under the trade names IMUKIN, IMUKINE, IMMUKIN and IMMUKINE), 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, reimbursement for LODOTRA has been obtained in Germany, Italy, Sweden and Switzerland. Mundipharma is seeking coverage for LODOTRA in a number of countries and currently sells LODOTRA without coverage in a limited number of countries. BUPHENYL is marketed in select countries throughout Europe, the Middle East and the Asia-Pacific region. With respect to RAVICTI, we expect to begin commercializing the medicine in Europe in 2017. PROCYSBI is marketed in select countries in Europe and QUINSAIR was recently launched in certain countries in Europe, but we cannot be certain that existing reimbursement in EU countries will be maintained or that we will be able to secure reimbursement in additional 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 medicines 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 medicine or as volumes increase. Many countries in the EU have increased the amount of discounts required on medicines, 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. As a result of these pricing practices, it may become difficult to achieve or sustain 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 any of our medicines in any additional markets or for any other medicine candidates that we may develop. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our medicines. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize our medicines.

We expect to experience pricing pressures in connection with the sale of our medicines due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals relating to outcomes and quality. For example, in March 2016, the Centers for Medicare & Medicaid Services, or CMS, announced a Proposed Rule that would test new payment models for Medicare Part B prescription drugs, and provider services incident to, or otherwise related to, such drugs. Generally, the Proposed Rule includes payment models that are designed on quality and value propositions and include incentives to drive utilization of efficient therapies and make payments based on clinical outcomes. The Proposed Rule greatly differs from the current reimbursement methodology for Medicare Part B drugs. The comment period for the Proposed Rule closed on May 9, 2016. Since the closing of the comment period, the Proposed Rule has been subject to significant and ongoing discussion among stakeholders including industry, payers, healthcare providers and other interested organizations. The Proposed Rule would not take effect until CMS considers the comments received and issues a Final Rule.

There may be additional pressure by payers, healthcare providers, and members of Congress, to use generic drugs that contain the active ingredients found in our medicines or any other medicine candidates that we may develop or acquire. If we fail to successfully secure and maintain coverage and adequate reimbursement for our medicines or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our medicines 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 our HorizonCares program or any other co-pay or free medicine programs whereby we assist qualified patients with certain out-of-pocket expenditures for our medicine. If we are unsuccessful with our HorizonCares program or any other co-pay initiatives or free medicine programs, or we alternatively are unable to secure expanded formulary access through additional arrangements with PBMs or other payers, we would be at a competitive disadvantage in terms of pricing versus preferred branded and generic competitors. We may also experience financial pressure in the future which would make it difficult to support investment levels in areas such as managed care contract rebates, HorizonCares and other access tools.

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

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

87
If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to civil and/or criminal penalties, damages, fines, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management’s attention away from the operation of our business.

We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved medicine. An expansion in the government’s role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription medicines, lower reimbursements for providers using our medicines, reduce medicine utilization and adversely affect our business and results of operations. It is unclear whether and to what extent, if at all, other potential developments resulting from the ACA, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us with additional revenue to offset the annual excise tax (on certain medicine sales) enacted under the ACA, subject to limited exceptions. It is possible that the tax burden, if ours is not excepted, would adversely affect our financial performance, which in turn could cause the price of our ordinary shares to decline. The ACA, among other things, also established a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50 percent point-of-sale discounts off 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. Further, certain hospitals and other providers, or covered entities, may access the 340B Drug Pricing Program, administered by the Health Resources and Services Administration, or HRSA, to obtain discounted prices on “covered outpatient drugs” (prescription drugs and biologics other than vaccines) from drug manufacturers. Generally, manufacturers must offer 340B discounts to these covered entities as a prerequisite to Medicaid reimbursement for the drugs. The discount amount to “patients” (as defined by HRSA) of covered entities is significant. The number of covered entities that may access the 340B prices has been growing and includes certain free-standing cancer hospitals.

Moreover, certain politicians, including presidential candidates, have announced plans to regulate the prices of medicines. The majority of our medicines are purchased by private payers, and we do not believe that any such legislation, if enacted, would have a material effect on us or our business. However, we cannot know what form any such legislation may take or the market’s perception of how such legislation would affect us. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our current medicines and/or those for which we may receive regulatory approval in the future.

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

In the United States, we are subject directly, or indirectly through our customers, to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, civil monetary penalty statutes prohibiting beneficiary inducements, and similar state laws, federal and state privacy and security laws, sunshine laws, government price reporting laws, and other fraud laws. These laws may impact, among other things, our current and proposed sales, marketing and educational programs, as well as other possible relationships with customers, pharmacies, physicians, payers, and patients.

Compliance with these laws, including the development of a comprehensive compliance program, is difficult, costly and time consuming. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. These risks may be increased where there are evolving interpretations of applicable regulatory requirements, such as those applicable to manufacturer co-pay initiatives. Pharmaceutical manufacturer co-pay initiatives and free medicine programs are the subject of ongoing litigation (including other manufacturers and to which we are not a party) and evolving interpretations of applicable regulatory requirements and certain state laws, and any change in the regulatory or enforcement environment regarding such programs could impact our ability to offer such programs. If we are unsuccessful with our HorizonCares programs, any other co-pay initiatives or free medicine programs, we would be at a competitive disadvantage in terms of pricing versus preferred branded and generic competitors, or be subject to significant penalties. We are engaged in various business arrangements with current and potential customers, and we can give no assurance that such arrangements would not be subject to scrutiny under such laws, despite our efforts to properly structure such arrangements. Even if we structure our programs with the intent of compliance with such laws, there can be no certainty that we would not need to defend our business activities against enforcement or litigation. Further, we cannot give any assurances that prior business activities or arrangements of other companies that we acquire will not be scrutinized or subject to enforcement or litigation.
There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA, among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in significant civil monetary penalties.

We are unable to predict whether we could be subject to actions under any of these or other healthcare laws, or the impact of such actions. If we are found to be in violation of, or to encourage or assist the violation by third parties of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, withdrawal of regulatory approval, imprisonment, exclusion from government healthcare reimbursement programs, contractual damages, reputational harm, diminished profits and future earnings, injunctions and other associated remedies, or private “qui tam” actions brought by individual whistleblowers in the name of the government, and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business.

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

Undesirable side effects caused by any medicine candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, or cause us to evaluate the future of our development programs. In our two Phase 3 clinical trials with DUEXIS, the most commonly reported treatment-emergent adverse events were nausea, dyspepsia, diarrhea, constipation and upper respiratory tract infection. In Phase 3 endoscopic registration clinical trials with VIMOVO, the most commonly reported treatment-emergent adverse events were erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain, nausea and upper respiratory tract infection. The most common side effects observed in pivotal trials for ACTIMMUNE were “flu-like” or constitutional symptoms such as fever, headache, chills, myalgia and fatigue. The most commonly reported treatment-emergent adverse events in the Phase 3 clinical trials with RAYOS/LODOTRA included flare in rheumatoid arthritis related symptoms, abdominal pain, nasopharyngitis, headache, flushing, upper respiratory tract infection, back pain and weight gain. The most common adverse events reported in a Phase 2 clinical trial of PENNSAID 2% were application site reactions, such as dryness, exfoliation, erythema, pruritus, pain, induration, rash and scabbing. With respect to BUPHENYL, the most common side effects are change in the frequency of breathing, lack of or irregular menstruation, lower back, side, or stomach pain, mood or mental changes, muscle pain or twitching, nausea or vomiting, nervousness or restlessness, swelling of the feet or lower legs, unpleasant taste and unusual tiredness or weakness. With respect to RAVICTI, the most common side effects are diarrhea, nausea, decreased appetite, gas, vomiting, high blood levels of ammonia, headache, tiredness and dizziness. With respect to KRYSTEXXA, the most commonly reported serious adverse reactions in the pivotal trial were gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis, exacerbation of pre-existing congestive heart failure and vomiting. With respect to MIGERGOT, the most commonly reported adverse reactions are ischemia, cyanosis, absence of pulse, cold extremities, gangrene, precordial distress and pain, electrocardiogram change, muscle pain, nausea and vomiting, rectal or anal ulcer, parathesias, numbness weakness, vertigo, localized edemas and itching. With respect to PROCYSBI, the most common side effects include vomiting, nausea, abdominal pain, breath odor, diarrhea, skin odor, fatigue, rash and headache. With respect to QUINSAIR, the most common side effects include itching, wheezing, hives, rash, swelling, pale skin color, fast heartbeat, and faintness.

The FDA or other regulatory authorities may also require, or we may undertake, additional clinical trials to support the safety profile of our medicines or medicine candidates.

In addition, if we or others identify undesirable side effects caused by our medicines or any other medicine candidate that we may develop that receives marketing approval, or if there is a perception that the medicine 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 medicine or place restrictions on the way it is prescribed;
- we may be required to change the way the medicine is administered, conduct additional clinical trials or change the labeling of the medicine or implement a risk evaluation and mitigation strategy; and
- we may be subject to increased exposure to product liability and/or personal injury claims.

If any of these events occurred with respect to our medicines, our ability to generate significant revenues from the sale of these medicines 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 medicine 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, and we expect to continue to rely on CROs for the completion of on-going and planned clinical trials. We may also have the need to enter into other such agreements in the future if we were to develop other medicine candidates or conduct clinical trials in additional indications for our existing medicines. In connection with our on-going Phase 3 study to evaluate ACTIMMUNE for the treatment of FA, we are working with the Clinical Trials Coordination Center, an academic research organization, or ARO, that is part of the Center for Human Experimental Therapeutics at the University of Rochester as well as collaborating with the Friedreich’s Ataxia Research Alliance, or FARA, and select investigators of FARA’s Collaborative Clinical Research Network in FA. In connection with the investigator-initiated study to evaluate ACTIMMUNE in combination with PD-1/PD-L1 inhibitors in various forms of cancer including advanced urothelial carcinoma (bladder cancer) and renal cell carcinoma, we are collaborating with Fox Chase Cancer Center. In connection with our ongoing study to evaluate RAYOS/LODOTRA on the fatigue experienced by systemic lupus erythematosus patients, we are collaborating with the Alliance for Lupus Research. 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, our CROs and our ARO 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 or collaborators 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 may 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 or collaborators violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. We must also obtain certain third-party institutional review board, or IRB, and ethics committee approvals in order to conduct our clinical trials. Delays by IRBs and ethics committees in providing such approvals may delay our clinical trials.

If any of our relationships with these third-party CROs or collaborators terminate, we may not be able to enter into similar arrangements on commercially reasonable terms, or at all. If CROs or collaborators 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 medicines and medicine candidates. As a result, the results of our clinical trials may not be predictive of the results of later-stage clinical trials. Medicine 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. For example, Raptor announced on in September 2015, based on information then available, that it would not advance its program for the treatment of pediatric NASH with PROCYSBI after a Phase 2b trial failed achieve its primary endpoints.

Clinical development of drugs and biologics 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 medicine candidates may not be predictive of the results of later-stage clinical trials. Medicine 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. For example, Raptor announced on in September 2015, based on information then available, that it would not advance its program for the treatment of pediatric NASH with PROCYSBI after a Phase 2b trial failed achieve its primary endpoints.
With respect to our on-going Phase 3 clinical trial to evaluate ACTIMMUNE for the treatment of FA, and the investigator-initiated study to evaluate ACTIMMUNE in combination with OPDIVO® nivolumab in advanced solid tumors and to the extent that we are required to conduct additional clinical development of any of our existing or later acquired medicines or we conduct clinical development of earlier stage medicine candidates or for other additional indications for RAYOS/LODOTRA, we may experience delays in these clinical trials or investigator-initiated studies. We do not know whether any additional clinical trials will be initiated in the future, begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining IRB 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 medicine 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 medicine candidate being studied in relation to other available therapies, including any new drugs or biologics that may be approved for the indications we are investigating. Furthermore, we rely and expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our future clinical trials and while we have and 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 medicine 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 medicine candidate, 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 medicine candidates, the commercial prospects of our medicine candidates will be harmed, and our ability to generate medicine revenues from any of these medicine candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our medicine development and approval process and jeopardize our ability to commence medicine sales and generate revenues.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of one or more of our medicine candidates.

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 medicine 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. We conduct significant management operations at both our global headquarters located in Dublin, Ireland and our U.S. office located in Lake Forest, Illinois. If our Dublin or Lake Forest offices were affected by a natural or man-made disaster or other business interruption, our ability to manage our domestic and foreign operations could be impaired, which could materially and adversely affect our results of operations and financial condition. We currently rely, and intend to rely in the future, on third-party manufacturers and suppliers to produce our medicines and third-party logistics partners to ship our medicines. Our ability to obtain commercial supplies of our medicines could be disrupted and our results of operations and financial condition could be materially and adversely affected if the operations of these third-party suppliers or logistics partners 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.

We are dependent on information technology systems, infrastructure and data, which exposes us to data security risks.

We are dependent upon information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Our business partners face similar risks and any security breach of their systems could adversely affect our security posture. A security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, any of which could disrupt our business and/or result in increased costs or loss of revenue. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

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

We face an inherent risk of product liability claims as a result of the commercial sales of our medicines and the clinical testing of our medicine candidates. For example, we may be sued if any of our medicines or medicine candidates allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the medicine, 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 medicines and medicine 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 medicines or medicine 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 resources;
- substantial monetary awards to trial participants or patients;
- medicine recalls, withdrawals or labeling, marketing or promotional restrictions;

*
• loss of revenue;
• exhaustion of any available insurance and our capital resources; and
• the inability to commercialize our medicines or medicine candidates.

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 medicines we develop. We currently carry product liability insurance covering our clinical studies and commercial medicine sales in the amount of $75 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the on-going commercialization of our current medicines in the United States, and/or the potential commercial launches of any of our medicines in additional markets or for additional indications, 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 medicine 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, independent contractors, principal investigators, consultants, vendors, distributors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, distributors and CROs may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. 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. Misconduct by our employees and other third parties may also include 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 misconduct by our employees and other third parties, 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 civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment.
Risks Related to our Financial Position and Capital Requirements

In the past we have incurred significant operating losses, and we recently achieved operating profitability.*

We have a limited operating history and even less history operating as a combined organization following the acquisitions of Vidara, Hyperion, Crealta and Raptor. We have financed our operations primarily through equity and debt financings and have incurred significant operating losses in the past. We had an operating loss of $17.1 million for the nine months ended September 30, 2016, operating income of $55.4 million for the year ended December 31, 2015 and operating losses of $8.5 million and $42.9 million for the years ended December 31, 2014 and 2013, respectively. We had a net loss of $36.3 million and a net income of $39.5 million for the nine months ended September 30, 2016 and the year ended December 31, 2015, respectively, and net losses of $263.6 million and $149.0 million for the years ended December 31, 2014 and 2013, respectively. As of September 30, 2016, we had an accumulated deficit of $717.5 million. Our prior losses have resulted principally from costs incurred in our development activities for our medicines and medicine candidates, commercialization activities related to our medicines, costs associated with our acquisition transactions and costs associated with derivative liability accounting. Our prior losses, combined with possible future losses, have had and will continue to have an adverse effect on our shareholders’ deficit and working capital. While we anticipate that we will continue to generate operating profits in the future, whether we can sustain this will depend on the revenues we generate from the sale of our medicines being sufficient to cover our operating expenses.

We have limited sources of revenues and significant expenses. We cannot be certain that we will sustain profitability, which would depress the market price of our ordinary shares and could cause our investors to lose all or a part of their investment.*

Our ability to sustain profitability depends upon our ability to generate sales of our medicines. We have a limited history of commercializing our medicines as a company, and commercialization has been primarily in the United States. We may never be able to successfully commercialize our medicines or develop or commercialize other medicines in the United States or in the EU, which we believe represents our most significant commercial opportunity. Our ability to generate future revenues depends heavily on our success in:

• continued commercialization of our existing medicines and any other medicine candidates for which we obtain approval;
• obtaining FDA approvals for additional indications for ACTIMMUNE and RAVICTI;
• securing additional foreign regulatory approvals for our medicines in territories where we have commercial rights; and
• developing, acquiring and commercializing a portfolio of other medicines or medicine candidates in addition to our current medicines.

Even if we do generate additional medicine sales, we may not be able to sustain profitability on a quarterly or annual basis. Our failure to remain profitable would depress the market price of our ordinary shares and could impair our ability to raise capital, expand our business, diversify our medicine offerings or continue our operations.

We may need to obtain additional financing to fund additional acquisitions.*

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

• commercialize our existing medicines in the United States, including the substantial expansion of our sales force in recent years, and our planned commercial launch of RAVICTI in Europe in 2017;
• complete the regulatory approval process, and any future required clinical development related thereto, for our medicines and medicine candidates;
• potentially acquire other businesses or additional complementary medicines or medicines that augment our current medicine portfolio, including costs associated with refinancing debt of acquired companies; and
• conduct clinical trials with respect to potential additional indications, as well as conduct post-marketing requirements and commitments, with respect to our medicines and medicines we acquire.

While we believe that our existing cash and cash equivalents will be sufficient to fund our operations based on our current expectations of continued revenue growth, we may need to raise additional funds if we choose to expand our commercialization or development efforts more rapidly than presently anticipated, if we develop or acquire additional medicines or acquire companies, or if our revenue does 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 medicines or medicine candidates or one or more of our other research and development initiatives, or delay, cut back or abandon our plans to grow the business through acquisition. We also could be required to:

- seek collaborators for one or more of our current or future medicine 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 medicine candidates that we would otherwise seek to develop or commercialize ourselves.

In addition, if we are unable to secure financing to support future acquisitions, our ability to execute on a key aspect of our overall growth strategy would be impaired.

Any of the above events could significantly harm our business, financial condition and prospects.

We have incurred a substantial amount of debt, which could adversely affect our business, including by restricting our ability to engage in additional transactions or incur additional indebtedness, and prevent us from meeting our debt obligations.*

As of September 30, 2016, we had $1,147.2 million book value, or $1,270.0 million principal amount, of indebtedness, including $395.0 million in secured indebtedness. In connection with the acquisition of Hyperion, we issued $475.0 million aggregate principal amount of 6.625% Senior Notes due 2023, or the 2023 Senior Notes, in April 2015 and borrowed $400.0 million in principal amount of secured loans pursuant to a credit agreement we entered into in May 2015 with Citibank, N.A., as administrative and collateral agent, and the lenders from time to time party thereto providing for (i) the six-year $400.0 million term loan facility; (ii) an uncommitted accordion facility subject to the satisfaction of certain financial and other conditions; and (iii) one or more uncommitted refinancing loan facilities with respect to loans thereunder, or the 2015 Senior Secured Credit Facility. We repaid $1.0 million in principal amount from this facility quarterly from the third quarter of 2015 to the third quarter of 2016. In connection with the acquisition of Raptor, we issued $300.0 million aggregate principal amount of 8.75% Senior Notes due 2024, or the 2024 Senior Notes, in October 2016 and borrowed $375.0 million in principal amount of secured loans, or the 2016 Incremental Loan Facility, pursuant to an amendment to our credit agreement, or as amended, the credit agreement. Accordingly, we have a significant amount of debt outstanding on a consolidated basis.

This substantial level of debt could have important consequences to our business, including, but not limited to:

- reducing the benefits we expect to receive from our recent and any future acquisition transactions;
- making it more difficult for us to satisfy our obligations;
- requiring a substantial portion of our cash flows from operations to be dedicated to the payment of principal and interest on our indebtedness, therefore reducing our ability to use our cash flows to fund acquisitions, capital expenditures, and future business opportunities;
- exposing us to the risk of increased interest rates to the extent of any future borrowings, including borrowings under our credit agreement, at variable rates of interest;
- making it more difficult for us to satisfy our obligations with respect to our indebtedness, including our outstanding notes, our credit agreement, and any failure to comply with the obligations of any of our debt instruments, including restrictive covenants and borrowing conditions, could result in an event of default under the agreements governing such indebtedness;
- increasing our vulnerability to, and reducing our flexibility to respond to, changes in our business or general adverse economic and industry conditions;
- limiting our ability to obtain additional financing for working capital, capital expenditures, debt service requirements, acquisitions, and general corporate or other purposes and increasing the cost of any such financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; and placing us at a competitive disadvantage as compared to our competitors, to the extent they are not as highly leveraged and who, therefore, may be able to take advantage of opportunities that our leverage may prevent us from exploiting; and
- restricting us from pursuing certain business opportunities.
The credit agreement and the indentures governing the 2024 Senior Notes and the 2023 Senior Notes impose, and the terms of any future indebtedness may impose, various covenants that limit our ability and/or the ability of our restricted subsidiaries’ (as designated under such agreements) to, among other things, pay dividends or distributions, repurchase equity, prepay junior debt and make certain investments, incur additional debt and issue certain preferred stock, incur liens on assets, engage in certain asset sales, consolidate with or merge or sell all or substantially all of our assets, enter into transactions with affiliates, designate subsidiaries as unrestricted subsidiaries, and allow to exist certain restrictions on the ability of restricted subsidiaries to pay dividends or make other payments to us.

Our ability to obtain future financing and engage in other transactions may be restricted by these covenants. In addition, any credit ratings will impact the cost and availability of future borrowings and our cost of capital. Our ratings at any time will reflect each rating organization’s then opinion of our financial strength, operating performance and ability to meet our debt obligations. There can be no assurance that we will achieve a particular rating or maintain a particular rating in the future. A reduction in our credit ratings may limit our ability to borrow at acceptable interest rates. If our credit ratings were downgraded or put on watch for a potential downgrade, we may not be able to sell additional debt securities or borrow money in the amounts, at the times or interest rates or upon the more favorable terms and conditions that might otherwise be available. Any impairment of our ability to obtain future financing on favorable terms could have an adverse effect on our ability to refinance any of our then-existing debt and may severely restrict our ability to execute on our business strategy, which includes the continued acquisition of additional medicines or businesses.

*We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful.*

Our ability to make scheduled payments under or to refinance our debt obligations depends on our financial condition and operating performance, which is subject to prevailing economic, industry and competitive conditions and to certain financial, business and other factors beyond our control. Our ability to generate cash flow to meet our payment obligations under our debt may also depend on the successful implementation of our operating and growth strategies. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to pay the principal, premium, if any, and interest on our indebtedness.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or business operations, seek additional capital or restructure or refinance our indebtedness. We cannot ensure that we would be able to take any of these actions, that these actions would be successful and permit us to meet our scheduled debt service obligations or that these actions would be permitted under the terms of existing or future debt agreements, including the indentures that govern the 2024 Senior Notes and the 2023 Senior Notes and the credit agreement. In addition, any failure to make payments of interest and principal on our outstanding indebtedness on a timely basis would likely result in a reduction of our credit rating, which could harm our ability to refinance any of our then-existing debt and may severely restrict our ability to execute on our business strategy, which includes the continued acquisition of additional medicines or businesses.

If we cannot make scheduled payments on our debt, we will be in default and, as a result:

- our debt holders could declare all outstanding principal and interest to be due and payable;
- the administrative agent and/or the lenders under the credit agreement could foreclose against the assets securing the borrowings then outstanding; and
- we could be forced into bankruptcy or liquidation, which could result in you losing your investment.

*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 commercialization activities for our medicines, to potentially fund additional medicine or business acquisitions, to potentially fund additional regulatory approvals of certain of our medicines, to potentially fund development, life cycle management or manufacturing activities of our medicines for other indications, to potentially fund share repurchases, 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 shareholders. If we do not invest or apply our cash in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause the price of our ordinary shares to decline.
Our ability to use net operating loss carryforwards and certain other tax attributes may be limited.*

Under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percent change (by value) in its equity ownership over a three year period), the corporation’s ability to use pre-change net operating loss carryforwards and other pre-change tax attributes to offset post-change income may be limited. In September 2014, the Vidara Merger triggered an “ownership change” limitation and, as a result, we are subject to annual limits on our ability to use the net operating loss carryforwards of Horizon Pharma, Inc. and its subsidiaries. We estimate this will result in annual limits of approximately $90 million in the years from 2016 through to 2031. Furthermore, we continue to carry forward our annual limitation resulting from an ownership change date of August 2, 2012. The limitation on pre-change net operating losses incurred prior to the August 2, 2012 change date is approximately $20 million for 2016, $15 million for 2017 and $8 million in the years from 2018 through to 2028. During the second quarter of 2015, we also recognized additional net operating losses and federal and state tax credits as a result of our acquisition of Hyperion on May 7, 2015 in the amount of approximately $31 million of federal net operating losses, state operating losses of approximately $68 million (net of federal effect) and approximately $30 million of federal and state tax credits. During the three months ended September 30, 2016, we recognized an additional federal net operating loss of $19 million from Hyperion’s pre-acquisition tax return which is being carried forward into our U.S. consolidated tax group. We continue to carry forward the annual limitation related to Hyperion of $50 million resulting from the last ownership change date in 2014. Further, as a result of our acquisition of Crealta in the first quarter of 2016, we have recognized an additional estimated net operating loss carryforward of approximately $4 million. This estimate of the pre-acquisition net operating loss carryforward will be finalized once the pre-acquisition tax return has been filed, which is due on March 15, 2017. The net operating loss carryforward limitation is cumulative such that any use of the carryforwards below the limitations in one year will result in a corresponding increase in the limitations for the subsequent tax year.

Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code limits the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses to offset U.S. taxable income resulting from certain transactions. Based on the limited guidance available, we expect this limitation is applicable following the Vidara Merger. As a result, it is not currently expected that we or our other U.S. affiliates will be able to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain taxable transactions following the Vidara Merger. Notwithstanding this limitation, we expect that we will be able to fully use our U.S. net operating losses prior to their expiration. As a result of this limitation, however, it may take HPI longer to use its net operating losses. Moreover, contrary to these expectations, it is possible that the limitation under Section 7874 of the Code on the utilization of U.S. tax attributes could prevent us from fully utilizing our U.S. tax attributes prior to their expiration if we do not generate sufficient taxable income.

Any limitation on our ability to use our net operating loss and tax credit carryforwards, including the carryforwards of companies that we acquire, 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 share 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 share price and could require us to delay or abandon commercialization or development plans. 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. Additionally, the SEC has proposed new rules on U.S. domiciled money market funds due to come into effect in the fourth quarter of 2016, which may temporarily suspend redemptions or impose liquidity fees on investors withdrawing assets during volatile periods, and this may adversely affect our investment strategy and/or liquidity.

The U.K.’s referendum to leave the EU or “Brexit,” has and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the U.K.’s relationship with the EU. During this period of negotiation, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. Brexit may also have a detrimental effect on our customers, distributors and suppliers, which would, in turn, adversely affect our revenues and financial condition.
At September 30, 2016, we had $549.3 million of cash and cash equivalents consisting of cash and money market funds. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since September 30, 2016, 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 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.*

GAAP 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, our operation as an Irish company with multiple subsidiaries in different jurisdictions adds additional complexity to the application of GAAP and this complexity will be exacerbated further if we complete additional strategic transactions. 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.

Covenants under the indentures governing our 2024 Senior Notes and 2023 Senior Notes and the credit agreement may restrict our business and operations in many ways, and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.*

The indentures governing the 2024 Senior Notes and the 2023 Senior Notes and the credit agreement impose various covenants that limit our ability and/or our restricted subsidiaries’ ability to, among other things:

• pay dividends or distributions, repurchase equity, prepay, redeem or repurchase certain debt and make certain investments;
• incur additional debt and issue certain preferred stock;
• provide guarantees in respect of obligations of other persons;
• incur liens on assets;
• engage in certain asset sales;
• merge, consolidate with or sell all or substantially all of our assets to another person;
• enter into transactions with affiliates;
• sell assets and capital stock of our subsidiaries;
• enter into agreements that restrict distributions from our subsidiaries;
• designate subsidiaries as unrestricted subsidiaries; and
• allow to exist certain restrictions on the ability of restricted subsidiaries to pay dividends or make other payments to us.

These covenants may:

• limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
• limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;
• require us to use a substantial portion of our cash flow from operations to make debt service payments;
• limit our flexibility to plan for, or react to, changes in our business and industry;
• place us at a competitive disadvantage compared to less leveraged competitors; and
• increase our vulnerability to the impact of adverse economic and industry conditions.

If we are unable to successfully manage the limitations and decreased flexibility on our business due to our significant debt obligations, we may not be able to capitalize on strategic opportunities or grow our business to the extent we would be able to without these limitations.
Our failure to comply with any of the covenants could result in a default under the credit agreement or the indentures governing the 2024 Senior Notes or the 2023 Senior Notes, which could permit the administrative agent or the trustee, as applicable, or permit the lenders or the holders of the 2024 Senior Notes or the 2023 Senior Notes to cause the administrative agent or the trustee, as applicable, to declare all or part of any outstanding senior secured term loans, the 2023 Senior Notes or the 2024 Senior Notes to be immediately due and payable or to exercise any remedies provided to the administrative agent or the trustee, including, in the case of the credit agreement proceeding against the collateral granted to secure our obligations under the credit agreement. An event of default under the credit agreement or the indentures governing the 2024 Senior Notes or the 2023 Senior Notes could also lead to an event of default under the terms of the other agreements and the indenture governing our 2.50% Exchangeable Senior Notes due 2022, or the Exchangeable Senior Notes. Any such event of default or any exercise of rights and remedies by our creditors could seriously harm our business.

If intangible assets that we have recorded in connection with our acquisition transactions become impaired, we could have to take significant charges against earnings.

In connection with the accounting for our various acquisition transactions, we have recorded significant amounts of intangible assets. Under GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite-lived intangible assets has been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders’ equity in future periods.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our medicines and medicine 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 may fail to result in issued patents with claims that cover our medicines in the United States or in other foreign countries. If this were to occur, early generic competition could be expected against our current medicines and other medicine candidates in development. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which prior art can invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the APIs in DUEXIS, VIMOVO and RAYOS/LODOTRA have been on the market as separate medicines for many years, it is possible that these medicines 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. In addition, claims directed to dosing and dose adjustment may be substantially less likely to issue in light of the Supreme Court decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc., where the court held that claims directed to methods of determining whether to adjust drug dosing levels based on drug metabolite levels in the red blood cells were not patent eligible because they were directed to a law of nature. This decision may have wide-ranging implications on the validity and scope of pharmaceutical method claims.

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.

Patent litigation is currently pending in the United States District Court for the District of New Jersey against several companies intending to market a generic version of VIMOVO before the expiration of certain of our patents listed in the Orange Book. These cases are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy’s; (ii) Lupin; (iii) Mylan; and (iv) Actavis Pharma. The cases arise from Paragraph IV Patent Certification notice letters from each of Dr. Reddy’s, Lupin, Mylan and Actavis Pharma advising each had filed an ANDA with the FDA seeking approval to market generic versions of VIMOVO before the expiration of the patents-in-suit.

On February 24, 2015, Dr. Reddy’s Laboratories, Inc. filed a Petition for inter partes review, or IPR, of U.S. Patent No. 8,557,285, one of the patents in litigation in the above referenced VIMOVO cases. On October 9, 2015, the United States Patent and Trademark Office, or the U.S. PTO, denied such Petition for IPR.

On May 21, 2015, the Coalition for Affordable Drugs VII LLC, or the Coalition for Affordable Drugs, filed a Petition for IPR of U.S. Patent No. 6,926,907, one of the patents in litigation in the above referenced VIMOVO cases. On December 8, 2015, the U.S. PTO denied such Petition for IPR.

On June 5, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of U.S. Patent No. 8,858,996, or the ‘996 patent, one of the patents in litigation in the above referenced VIMOVO cases. On December 17, 2015, the U.S. PTO denied such Petition for IPR.
On August 7, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of U.S. Patent No. 8,852,636, one of the patents in litigation in the above referenced VIMOVO cases. On February 11, 2016, the U.S. PTO denied such Petition for IPR.

On August 12, 2015, the Coalition for Affordable Drugs filed another Petition for IPR of U.S. Patent No. 8,945,621, or the ’621 patent, one of the patents in litigation in the above referenced VIMOVO cases. On February 22, 2016, the PTAB issued a decision to institute the IPR. The PTAB hearing for the ’621 patent is set for November 16, 2016. The PTAB must issue a final written decision on the IPR of the ’621 patent no later than February 22, 2017.

On August 19, 2015, the Coalition for Affordable Drugs filed Petitions for IPR of the ’996 patent and U.S. Patent Nos. 8,852,636 and 8,865,190, or the ’190 patent, all patents in litigation in the above referenced VIMOVO cases. On March 1, 2016, the PTAB issued decisions to institute the IPRs for the ’996 patent and the ’190 patent. The PTAB issued a final written decision on the IPR of the ’996 patent and the ’190 patent no later than March 1, 2017. Also on March 1, 2016, the PTAB denied the Petition for IPR for U.S. Patent No. 8,852,636. The PTAB hearings for the ’996 and ’190 patents are both set for November 29, 2016.

Patent litigation is currently pending in the United States District Court for the District of New Jersey against several companies intending to market a generic version of PENNSAID 2% prior to the expiration of certain of our patents listed in the Orange Book. These cases are collectively known as the PENNSAID 2% cases, and involve the following sets of defendants: (i) Actavis; and (ii) Lupin. These cases arise from Paragraph IV Patent Certification notice letters from each of Actavis and Lupin advising each had filed an ANDA with the FDA seeking approval to market a generic version of PENNSAID 2% before the expiration of the patents-in-suit. The status of these cases is as set forth above.

We received from Actavis a Paragraph IV Patent Certification Notice Letter dated September 27, 2016, against Orange Book listed U.S. Patent No. 9,415,029, advising that Actavis had filed an ANDA with the FDA for a generic version of PENNSAID 2%.

We have received from Apotex three Paragraph IV Patent Certification Notice Letters dated April 1, 2016, June 30, 2016, and September 21, 2016 against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, 8,871,809, 9,066,913, 9,101,591, 9,132,110, 9,168,304, 9,168,305, 9,220,784, 9,339,551, 9,339,552 and 9,415,029, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%.

Patent litigation is currently pending in the United States District Court for the Eastern District of Texas against Par Pharmaceutical and in the United States District Court for the District of New Jersey against Lupin and against Par Pharmaceutical, who are each intending to market generic versions of RAVICTI prior to the expiration of certain of our patents listed in the Orange Book. These cases are collectively known as the RAVICTI cases, and arise from Paragraph IV Patent Certification notice letters from each of Par Pharmaceutical and Lupin advising each had filed an ANDA with the FDA seeking approval to market a generic version of RAVICTI before the expiration of the patents-in-suit.

We intend to vigorously defend our intellectual property rights relating to our medicines, but we cannot predict the outcome of the VIMOVO cases, the PENNSAID 2% cases, the RAVICTI cases or the IPRs. Any adverse outcome in these matters or any new generic challenges that may arise could result in one or more generic versions of our medicines 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 our medicines, 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 our medicines 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 medicines. 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. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our medicines or any other medicine candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third-party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

With respect to RAVICTI, the composition of matter patent we hold would have expired in the United States in February 2015 without term extension. However, Hyperion applied for a term extension of approximately four years for this patent under the Drug Price Competition and Patent Term Restoration Act. Hyperion recently received notice that the U.S. PTO has determined that the length of the extension is 1,267 days. We cannot guarantee that pending patent applications related to RAVICTI will result in additional patents or that other existing and future patents related to RAVICTI will be held valid and enforceable or will be sufficient to deter generic competition in the United States. Therefore, it is possible that upon expiration of the RAVICTI composition of matter patent, we would need to rely on forms of regulatory exclusivity, to the extent available, to protect against generic competition.

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

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The 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. In addition, the ACA allows applicants seeking approval of biosimilar or interchangeable versions of biological products such as ACTIMMUNE to initiate a process for challenging some or all of the patents covering the innovator biological product used as the reference product. This process is complicated and could result in the limitation or loss of certain patent rights. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

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

Our commercial success depends in part on us avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the U.S. PTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which our collaborators are developing medicine candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our medicine 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 our medicines and/or any other medicine 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 medicine 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 medicine candidates, any molecules formed during the manufacturing process or any final medicine itself, the holders of any such patents may be able to block our ability to commercialize such medicine 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 medicine 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 medicine 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 medicines, 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 medicine 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 medicine 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 medicines, 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 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 Vectura Group plc’s, or Vectura, 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 Vectura or our other license agreements, or if 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 medicines covered by the license, including RAYOS/LODOTRA.

In connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we (i) received the benefit of a covenant not to sue under AstraZeneca’s patent portfolio with respect to Nexium (which shall automatically become a license under such patent portfolio if and when AstraZeneca reacquires control of such patent portfolio from Merck Sharp & Dohme Corp. and certain of its affiliates), (ii) were assigned AstraZeneca’s amended and restated collaboration and license agreement for the United States with Aralez, under which AstraZeneca has in-licensed exclusive rights under certain of Aralez’s patents with respect to VIMOVO, and (iii) acquired AstraZeneca’s co-ownership rights with Aralez with respect to certain joint patents covering VIMOVO, all for the commercialization of VIMOVO in the United States. If we fail to comply with our obligations under our agreements with AstraZeneca or if we fail to comply with our obligations under our agreements with Aralez, our rights to commercialize VIMOVO in the United States may be adversely affected or terminated by AstraZeneca or Aralez.
We also license rights to patents, know-how and trademarks for ACTIMMUNE from Genentech Inc., or Genentech, under an agreement that remains in effect for so long as we continue to commercialize and sell ACTIMMUNE. However, Genentech may terminate the agreement upon our material default, if not cured within a specified period of time. Genentech may also terminate the agreement in the event of our bankruptcy or insolvency. Upon such a termination of the agreement, all intellectual property rights conveyed to us under the agreement, including the rights to the ACTIMMUNE trademark, revert to Genentech. If we fail to comply with our obligations under this agreement, we could lose the ability to market and distribute ACTIMMUNE, which would have a material adverse effect on our business, financial condition and results of operations.

We rely on a license from Ucyclyd with respect to technology developed by Ucyclyd in connection with the manufacturing of RAVICTI. The purchase agreement under which Hyperion purchased the worldwide rights to RAVICTI contains obligations to pay Ucyclyd regulatory and sales milestone payments relating to RAVICTI as well as royalties on the net sales of RAVICTI. On May 31, 2013, when Hyperion acquired BUPHENYL under a restated collaboration agreement with Ucyclyd, Hyperion received a license to use some of the manufacturing technology developed by Ucyclyd in connection with the manufacturing of BUPHENYL. The restated collaboration agreement also contains obligations to pay Ucyclyd regulatory and sales milestone payments, as well as royalties on net sales of BUPHENYL. If we fail to make a required payment to Ucyclyd and do not cure the failure within the required time period, Ucyclyd may be able to terminate the license to use its manufacturing technology for RAVICTI and BUPHENYL. If we lose access to the Ucyclyd manufacturing technology, we cannot guarantee that an acceptable alternative method of manufacture could be developed or acquired. Even if alternative technology could be developed or acquired, the loss of the Ucyclyd technology could still result in substantial costs and potential periods where we would not be able to market and sell RAVICTI and/or BUPHENYL. We also license intellectual property necessary for commercialization of RAVICTI from an external party. This party may be entitled to terminate the license if we breach the agreement, including failure to pay required royalties on net sales of RAVICTI, or we do not meet specified diligence obligations in our development and commercialization of RAVICTI, and we do not cure the failure within the required time period. If the license is terminated, it may be difficult or impossible for us to continue to commercialize RAVICTI, which would have a material adverse effect on our business, financial condition and results of operations.

We also hold an exclusive license to patents and technology from Duke University, or Duke, and Mountain View Pharmaceuticals, Inc., or MVP, covering KRYSTEXXA. Duke and MVP may terminate the license if we commit fraud or for our willful misconduct or illegal conduct. Duke and MVP may also terminate the license upon our material breach of the agreement, if not cured within a specified period of time, or upon written notice if we have committed two or more material breaches under the agreement. Duke and MVP may also terminate the license in the event of our bankruptcy or insolvency. If the license is terminated, it may be impossible for us to continue to commercialize KRYSTEXXA, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, we are subject to contractual obligations under our agreements with Triplex and PARI related to QUINSAIR. Under the agreement with Triplex, we are required to pursue commercially reasonable efforts to initiate, and subsequently to complete, an additional clinical trial of QUINSAIR in a non-cystic-fibrosis patient population within a specified period of time and an obligation to progress toward filing an NDA for approval of QUINSAIR in the United States in all or part of the cystic fibrosis patient population. These obligations are subject to certain exceptions due to, for example, manufacturing delays not under our control, or delays caused by the FDA. If we fail to properly exercise such efforts to initiate and complete an appropriate clinical trial, or fail to file an NDA for U.S. approval in the cystic fibrosis patient population, during the time periods specified in the asset purchase agreement, we may be subject to various claims by Triplex and parties affiliated with Triplex. In addition, if we do not spend a minimum amount on QUINSAIR development in each of the three years following our acquisition of Raptor, we may also be obligated to pre-pay a milestone payment related to initiating a clinical trial for QUINSAIR in a non-cystic-fibrosis indication. Under the license agreement with PARI, we are required to comply with diligence milestones related to development and commercialization of QUINSAIR in the United States, to spend a specified minimum amount per year on development activities in the United States until filing of the NDA for QUINSAIR in the United States. If we do not comply with these obligations, our licenses to certain intellectual property related to QUINSAIR may become non-exclusive in the United States or could be terminated. We are also subject to contractual obligations under our license agreements with the UCSD with respect to PROCYSBI, including diligence obligations to develop PROCYSBI for the treatment of NASH and Huntington’s disease, with which we currently are not in compliance. To the extent that we fail to perform the diligence obligations under the agreement, UCSD may, with respect to such indication, terminate the license or otherwise cause the license to become non-exclusive. If one or more of these licenses was terminated, we would have no further right to use of exploit the related intellectual property, which would limit our ability to develop PROCYSBI or QUINSAIR in other indications, and could impact our ability to continue commercializing PROCYSBI or QUINSAIR in their approved indications.
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 one of our patents, or a patent of one of 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.

There are numerous post grant review proceedings available at the U.S. PTO (including IPR, post-grant review and ex-parte reexamination) and similar proceedings in other countries of the world that could be initiated by a third-party that could potentially negatively impact our issued patents.

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

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

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 licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our medicine 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 even 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 Ordinary Shares

The market price of our ordinary shares historically has been volatile and is likely to continue to be volatile, and you could lose all or part of any investment in our ordinary shares.

The trading price of our ordinary shares has been volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this report, these factors include:

• our failure to successfully execute our commercialization strategy with respect to our approved medicines, particularly our commercialization of our medicines in the United States;

• actions or announcements by third-party or government payers with respect to coverage and reimbursement of our medicines;
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 medicines and medicine candidates;
unanticipated serious safety concerns related to the use of our medicines;
adverse regulatory decisions;
changes in laws or regulations applicable to our business, medicines or medicine candidates, including but not limited to clinical trial requirements for approvals or tax laws;
inability to comply with our debt covenants and to make payments as they become due;
inability to obtain adequate commercial supply for any approved medicine 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 and/or acquire additional medicine candidates or obtain approvals for additional indications for our existing medicine candidates;
introduction of new medicines or services offered by us or our competitors;
overall performance of the equity markets, including the pharmaceutical sector, and general political and economic conditions;
failure to meet or exceed revenue and financial projections that 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;
inaccurate or significant adverse media coverage;
publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
our inability to successfully enter new markets;
the termination of a collaboration or the inability to establish additional collaborations;
announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
our inability to maintain an adequate rate of growth;
ineffectiveness of our internal controls or our inability to otherwise comply with financial reporting requirements;
adverse U.S. and foreign tax exposure;
aditions or departures of key management, commercial or regulatory personnel;
issuances of debt or equity securities;
significant lawsuits, including patent or shareholder litigation;
changes in the market valuations of similar companies to us;
sales of our ordinary shares by us or our shareholders in the future;
trading volume of our ordinary shares;
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 Select Market and the stock 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 ordinary shares, regardless of our actual operating performance.
We have never declared or paid dividends on our share capital and we do not anticipate paying dividends in the foreseeable future.*

We have never declared or paid any cash dividends on our ordinary shares. 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, including due to limitations that are currently imposed by the 2015 Senior Secured Credit Facility, the 2016 Incremental Loan Facility, the 2024 Senior Notes and the 2023 Senior Notes. Any return to shareholders will therefore be limited to the increase, if any, of our ordinary share price.

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 2000, 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. These effects are exacerbated by our transition to an Irish company and the integration of numerous acquired businesses and operations into our historical business and operating structure. 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 medicines 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 that 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 ordinary shares could be delisted from The NASDAQ Global Select Market, which would adversely affect the liquidity of our ordinary shares 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 expense and expend significant management efforts, particularly because of our Irish parent company structure and international operations. In particular, prior to the acquisition of Crealta, Crealta and its affiliated entities were not subject to the requirements of the Sarbanes-Oxley Act. We are taking measures to establish or implement an internal control environment at these entities aimed at successfully adopting the requirements of Section 404. However, it is possible that we may experience delays in implementing or be unable to implement the required internal controls over financial reporting and other disclosure controls and procedures. If we are not able to comply with the requirements of Section 404 or if we or our independent registered public accounting firm identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our ordinary shares 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 as we respond to their requirements.

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

If our existing shareholders sell, or indicate an intention to sell, substantial amounts of our ordinary shares in the public market, the trading price of such ordinary shares could decline. In addition, our ordinary shares 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 Rules 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares could decline.
Certain holders of our ordinary shares 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 our affiliates. For example, we are subject to a registration rights agreement with certain former Vidara shareholders that acquired our ordinary shares in connection with our acquisition of Vidara. Pursuant to this agreement, we filed and are required to maintain a registration statement covering the resale of ordinary shares held by these shareholders and in certain circumstances, these holders can require us to participate in an underwritten public offering of their ordinary shares. Any sales of securities by these shareholders or a public announcement of such sales could have a material adverse effect on the trading price of our ordinary shares.

In addition, any conversion or exchange of our Exchangeable Senior Notes, whether pursuant to their terms or pursuant to privately negotiated transactions between the issuer and/or us and a holder of such securities, could depress the market price for our ordinary shares.

**Future sales and issuances of our ordinary shares, securities convertible into our ordinary shares or rights to purchase ordinary shares or convertible securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to decline.***

Additional capital may be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities or securities convertible into or exchangeable for ordinary shares, our shareholders may experience substantial dilution. We may sell ordinary shares, and we may sell convertible or exchangeable 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 such ordinary shares, convertible or exchangeable securities or other equity securities in subsequent transactions, existing shareholders may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of ordinary shares. We also maintain equity incentive plans, including our Amended and Restated 2014 Equity Incentive Plan, 2014 Non-Employee Equity Plan and 2014 Employee Share Purchase Plan, and intend to grant additional ordinary share awards under these and future plans, which will result in additional dilution to our existing shareholders.

**Irish law differs from the laws in effect in the United States and may afford less protection to holders of our securities.**

It may not be possible to enforce court judgments obtained in the United States against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised that the U.S. currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

As an Irish company, we are governed by the Irish Companies Acts, which differ in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the United States.

**Provisions of our articles of association could delay or prevent a takeover of us by a third-party.**

Our articles of association could delay, defer or prevent a third-party from acquiring us, despite the possible benefit to our shareholders, or otherwise adversely affect the price of our ordinary shares. For example, our articles of association:

- permit our board of directors to issue one or more series of preferred shares with rights and preferences designated by our board of directors;
- impose advance notice requirements for shareholder proposals and nominations of directors to be considered at shareholder meetings;
- stagger the terms of our board of directors into three classes; and
- require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally at a meeting of shareholders to amend or repeal our articles of association.
In addition, several mandatory provisions of Irish law could prevent or delay an acquisition of us. For example, Irish law does not permit shareholders of an Irish public limited company to take action by written consent with less than unanimous consent. We are also subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in our ordinary shares in certain circumstances.

These provisions may discourage potential takeover attempts, discourage bids for our ordinary shares at a premium over the market price or adversely affect the market price of, and the voting and other rights of the holders of, our ordinary shares. These provisions could also discourage proxy contests and make it more difficult for you and our other shareholders to elect directors other than the candidates nominated by our board of directors, and could depress the market price of our ordinary shares.

A transfer of our ordinary shares may be subject to Irish stamp duty.

In certain circumstances, the transfer of shares in an Irish incorporated company will be subject to Irish stamp duty, which is a legal obligation of the buyer. This duty is currently charged at the rate of 1.0 percent of the price paid or the market value of the shares acquired, if higher. Because our ordinary shares are traded on a recognized stock exchange in the United States, an exemption from this stamp duty is available to transfers by shareholders who hold ordinary shares beneficially through brokers which in turn hold those shares through the Depositary Trust Company, or DTC, to holders who also hold through DTC. However, a transfer by or to a record holder who holds ordinary shares directly in his, her or its own name could be subject to this stamp duty.

We, in our absolute discretion and insofar as the Companies Acts or any other applicable law permit, may, or may provide that one of our subsidiaries will pay Irish stamp duty arising on a transfer of our ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of ordinary shares which would otherwise be payable by the transferee is paid by us or any of our subsidiaries on behalf of the transferee, then in those circumstances, we will, on our behalf or on behalf of such subsidiary (as the case may be), be entitled to (i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those ordinary shares and (iii) claim a first and permanent lien on the ordinary shares on which stamp duty has been paid by us or such subsidiary for the amount of stamp duty paid. Our lien shall extend to all dividends paid on those ordinary shares.

Dividends paid by us may be subject to Irish dividend withholding tax.

In certain circumstances, as an Irish tax resident company, we will be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to our shareholders. Shareholders that are resident in the United States, EU countries (other than Ireland) or other countries with which Ireland has signed a tax treaty (whether the treaty has been ratified or not) generally should not be subject to Irish withholding tax so long as the shareholder has provided its broker, for onward transmission to our qualifying intermediary or other designated agent (in the case of shares held beneficially), or our or its transfer agent (in the case of shares held directly), with all the necessary documentation by the appropriate due date prior to payment of the dividend.

However, some shareholders may be subject to withholding tax, which could adversely affect the price of our ordinary shares.

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

The trading market for our ordinary shares 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 rating or publish inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts cease coverage of our company or fail to publish reports on our company regularly, demand for our ordinary shares could decrease, which might cause our share price and trading volume to decline.

Securities class action litigation could divert our 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 equity securities of pharmaceutical companies. These broad market fluctuations may cause the market price of our ordinary shares 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. For example, following declines in our stock price, two federal securities class action lawsuits were filed in March 2016 against us and certain of our current and former officers alleging violations of the Securities Exchange Act of 1934, as amended. Subsequently, the two actions were consolidated, and plaintiff added claims under the Securities Act and named additional defendants. This consolidated class action (captioned Schaffer v. Horizon Pharma plc, et al., Case No. 1:16-cv-01763) is currently pending in the United States District Court for the Southern District of New York. Even if we are successful in defending against this or any similar claims that may be brought in the future, litigation could result in substantial costs and may be a distraction to our management, and may lead to an unfavorable outcome 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, 2016:

- In August 2016, we issued an aggregate of 153,743 ordinary shares to Atlas Venture Fund VI, L.P. upon the cashless exercise of a warrant to purchase an aggregate of 197,457 ordinary shares.
- In August 2016, we issued an aggregate of 4,701 ordinary shares to Atlas Venture Entrepreneurs' Fund VI, L.P. upon the cashless exercise of a warrant to purchase an aggregate of 6,038 ordinary shares.
- In August 2016, we issued an aggregate of 2,815 ordinary shares to Atlas Venture Fund VI GmbH &Co. KG upon the cashless exercise of a warrant to purchase an aggregate of 3,615 ordinary shares.
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 PLC

Date: November 7, 2016

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

Date: November 7, 2016

By: /s/ Paul W. Hoelscher
   Paul W. Hoelscher
   Executive Vice President, Chief Financial Officer
   (Principal Financial Officer)
<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1(1)</td>
<td>Transaction Agreement and Plan of Merger, dated March 18, 2014, by and among Horizon Pharma, Inc., Vidara Therapeutics Holdings LLC, Vidara Therapeutics International Ltd. (now known as Horizon Pharma Public Limited Company), Hamilton Holdings (USA), Inc. and Hamilton Merger Sub, Inc.†</td>
</tr>
<tr>
<td>2.2(2)</td>
<td>First Amendment to Transaction Agreement and Plan of Merger, dated June 12, 2014, by and between Horizon Pharma, Inc. and Vidara Therapeutics Holdings LLC.</td>
</tr>
<tr>
<td>2.3(3)</td>
<td>Agreement and Plan of Merger, dated March 29, 2015, by and among Horizon Pharma, Inc., Ghrian Acquisition Inc. and Hyperion Therapeutics, Inc.†</td>
</tr>
<tr>
<td>2.4(4)*</td>
<td>Agreement and Plan of Merger, dated December 10, 2015, by and among Horizon Pharma USA, Inc., HZNP Limited, Criostail LLC, Crealta Holdings LLC and the other parties thereto.‡</td>
</tr>
<tr>
<td>2.5(5)</td>
<td>Agreement and Plan of Merger, dated September 12, 2016, by and among Horizon Pharma Public Limited Company, Misneach Corporation and Raptor Pharmaceutical Corp.†</td>
</tr>
<tr>
<td>3.1(6)</td>
<td>Memorandum and Articles of Association of Horizon Pharma Public Limited Company, as amended.</td>
</tr>
<tr>
<td>4.1(7)**</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>4.2(8)**</td>
<td>Form of Warrant issued by Horizon Pharma, Inc. in Public Offering of Units.</td>
</tr>
<tr>
<td>4.4(9)</td>
<td>Form of 2.50% Exchangeable Senior Note due 2022 (included in Exhibit 4.3).</td>
</tr>
<tr>
<td>4.6(10)</td>
<td>Form of 6.625% Senior Note due 2023 (included in Exhibit 4.5).</td>
</tr>
<tr>
<td>4.8(12)</td>
<td>Indenture, dated October 25, 2016, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and U.S. Bank National Association, as trustee.</td>
</tr>
<tr>
<td>4.9(12)</td>
<td>Form of 8.75% Senior Note due 2024 (included in Exhibit 4.8).</td>
</tr>
<tr>
<td>10.1*</td>
<td>Fifth Amendment to Commercial Supply Agreement, effective as of August 31, 2016, by and between Horizon Pharma Ireland Limited and Bio-Technology General (Israel) Ltd.</td>
</tr>
<tr>
<td>10.2(12)</td>
<td>Amendment No. 1, dated October 25, 2016, to Credit Agreement, dated May 7, 2015, by and among Horizon Pharma, Inc., as borrower, Horizon Pharma Public Limited Company, as Irish Holdco and a guarantor, the subsidiary guarantors party thereto, as subsidiary guarantors, the lenders party thereto and Citibank, N.A., as administrative agent and collateral agent.</td>
</tr>
<tr>
<td>10.3*</td>
<td>Amended and Restated License Agreement, effective October 30, 2012, by and between The Regents of the University of California and Horizon Orphan LLC (as successor in interest to Raptor Therapeutics Inc.), as amended March 1, 2013 and December 16, 2013.</td>
</tr>
<tr>
<td>10.4*</td>
<td>API Supply Agreement, dated November 3, 2010, by and among Cambrex Profarmaco Milano, Horizon Orphan LLC (as successor in interest to Raptor Therapeutics Inc.) and Horizon Pharma Europe B.V. (as successor in interest to Raptor Pharmaceuticals Europe B.V.), as amended April 9, 2013.</td>
</tr>
<tr>
<td>10.5*</td>
<td>Manufacturing Services Agreement, dated November 15, 2010, by and among Patheon Pharmaceuticals Inc., Horizon Orphan LLC (as successor in interest to Raptor Therapeutics Inc.) and Horizon Pharma Europe B.V. (as successor in interest to Raptor Pharmaceuticals Europe B.V.), as amended April 5, 2012 and June 21, 2013.</td>
</tr>
<tr>
<td>10.6*</td>
<td>Confidential Settlement Agreement and Mutual Release, dated September 26, 2016, by and between Horizon Pharma USA, Inc. and Express Scripts, Inc.</td>
</tr>
<tr>
<td>10.7(+)</td>
<td>Executive Employment Agreement, effective as of October 25, 2016, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and David A. Happel.</td>
</tr>
</tbody>
</table>
31.1 Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.

31.2 Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.

32.1 Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.

32.2 Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.

101.INS XBRL Instance Document
101.SCH XBRL Taxonomy Extension Schema Document
101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF XBRL Taxonomy Extension Definition Linkbase Document
101.LAB XBRL Taxonomy Extension Label Linkbase Document
101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

† Indicates management contract or compensatory plan.
†† Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Horizon Pharma Public Limited Company undertakes to furnish supplemental copies of any of the omitted schedules upon request by the Securities and Exchange Commission.
††† Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Horizon Pharma Public Limited Company undertakes to furnish supplemental copies of any of the omitted schedules upon request by the Securities and Exchange Commission; provided, however, that Horizon Pharma Public Limited Company may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedule so furnished.

* 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.

** Indicates an instrument, agreement or compensatory arrangement or plan assumed by Horizon Pharma Public Limited Company in the merger transaction with Vidara Therapeutics International Public Limited Company and no longer binding on Horizon Pharma, Inc.

(2) Incorporated by reference to Horizon Pharma, Inc.’s Current Report on Form 8-K, filed on June 18, 2014.
(3) Incorporated by reference to Horizon Pharma Public Limited Company’s Amendment No. 1 to Current Report on Form 8-K, filed on April 9, 2015.
(6) Incorporated by reference to Horizon Pharma Public Limited Company’s Registration Statement on Form S-8, filed on May 4, 2016.
(7) Incorporated by reference to Horizon Pharma, Inc.’s Current Report on Form 8-K, filed on March 1, 2012.
FIFTH AMENDMENT TO COMMERCIAL SUPPLY AGREEMENT

THIS FIFTH AMENDMENT TO THE AGREEMENT ("Fifth Amendment") is entered into effective as of this 31st day of August 2016 ("Fifth Amendment Effective Date") by and between Horizon Pharma Ireland Limited ("HPIL"), an Irish company, and Bio-Technology General (Israel) Ltd., an Israeli company ("BTG" and together collectively with HPIL, "Parties", and each individually a "Party").


WHEREAS, on December 14, 2015, BTG sent a notice of termination of the Agreement to Crealta Pharmaceuticals LLC ("Termination Notice").

WHEREAS, on January 13, 2016, affiliates of HPIL completed the acquisition of Crealta Pharmaceuticals LLC and, immediately thereafter, the Agreement was assigned from Crealta Pharmaceuticals LLC to HPIL.

WHEREAS, BTG desires to rescind its Termination Notice and continue to manufacture the Product for HPIL.

NOW, THEREFORE, in consideration of the mutual agreements, covenants and conditions hereinafter set forth and in accordance with Section 14.08 of the Agreement, the Parties hereby mutually agree to modify the terms of the Agreement as follows:

1. Definitions. All of the Definitions contained in Article 1 of the Agreement shall have the same meanings herein unless specifically stated otherwise. Any capitalized terms not specifically defined herein, shall have the same meaning ascribed to them as set forth in the Agreement.

2. Termination Letter. BTG hereby withdraws the Termination Notice and HPIL hereby accepts such withdrawal of the Termination Notice.

3. Term. Section 11.01 of the Agreement is deleted and replaced in its entirety with the following:
   "This Agreement shall be in effect from the Effective Date and shall continue in effect until December 31, 2030, unless earlier terminated pursuant to a Notice served by either Party in accordance with Section 11.02 ("Initial Term"), subject to extension pursuant to the following sentence. This Agreement shall renew automatically following the initial Term for successive three (3) year periods, unless earlier terminated pursuant to a Notice served by either Party in accordance with Section 11.02 (each, a "Renewal Term"). The "Term" shall mean the initial Term and any and all Renewal Terms.

4. Elective Termination. Section 11.02(i) is deleted in its entirety and replaced with the following:
   "(i) After January 1, 2024, either Party may terminate this Agreement at any time during the Term by giving at least three (3) years’ advance Notice to the other Party."

5. Batches, Orders, Capacity. With respect to the Agreement, the Parties agree as follows:
   a. Section 5.01 is deleted in its entirety.
   b. Annually, HPIL is obligated to order and pay for at least [***] batches of approximately [***] grams of Product per batch per year from BTG.
   c. HPIL shall order batches in multiples of [***], and BTG shall manufacture each such batch to have approximately [***] grams of Product.

***Confidential Treatment Requested
d. Annually, BTG shall reserve sufficient capacity to manufacture at the Facility at least [...***...] batches of Product and each such batch shall have approximately [...***...] grams of Product.

6. **Price**: Exhibit E to the Agreement is amended by adding the following provision immediately after (iii):
   
   As and from [...***...], for each calendar year and excluding costs charged separately by BTG as set forth in the Agreement or otherwise mutually agreed by the Parties in writing, the Price of the Product shall be as follows (assuming that each such batch has approximately [...***...] grams of Product):
   
   • If Horizon orders a total of [...***...] batches during an applicable calendar year then the price per gram for Product shall be USD [...***...].
   • If Horizon orders at total of [...***...]. or [...***...] batches during an applicable calendar year, then the price per gram for Product shall be USD [...***...].
   • If Horizon orders a total of [...***...] or more batches during an applicable calendar year, then the price per gram for Product shall be USD [...***...].

7. **No Modification**: Except as expressly provided for herein, the Agreement shall remain in full force and effect without amendment. If there is any conflict or inconsistency between this Fifth Amendment and the Agreement, this Fifth Amendment shall prevail, The Agreement, as modified by this Amendment, contains the entire agreement between the Parties hereto with respect to the subject matter contemplated herein and shall not be modified or amended except by a written instrument signed by both Parties hereto.

***SIGNATURE PAGE Follows***

***Confidential Treatment Requested***
IN WITNESS WHEREOF, each Party has caused this Fifth Amendment to be executed on its behalf by a duly authorized representative effective as of the Fifth Amendment Effective Date.

Horizon Pharma Ireland Limited

By: /s/ David G. Kelly
Name: David G. Kelly
Title: Director

Bio-Technology General (Israel) Ltd.

By: /s/ Michel Pettigrew
Name: Michel Pettigrew
Title: Board Member

Bio-Technology General (Israel) Ltd.

By: /s/ Tal Levi
Name: Tal Levi
Title: General Manager
SECOND AMENDMENT

[Drafted as AMENDED AND RESTATED]

LICENSE AGREEMENT

BETWEEN

RAPTOR THERAPEUTICS, INC.

AND

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

FOR

CASE NO. SD2006-092
# Table of Contents

<table>
<thead>
<tr>
<th>Recitals</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 1.   Definitions</td>
<td>2</td>
</tr>
<tr>
<td>Article 2.   Grants</td>
<td>4</td>
</tr>
<tr>
<td>Article 3.   Consideration</td>
<td>5</td>
</tr>
<tr>
<td>Article 4.   Reports, Records and Payments</td>
<td>11</td>
</tr>
<tr>
<td>Article 5.   Patent Matters</td>
<td>13</td>
</tr>
<tr>
<td>Article 6.   Governmental Matters</td>
<td>16</td>
</tr>
<tr>
<td>Article 7.   Termination or Expiration of the Agreement</td>
<td>16</td>
</tr>
<tr>
<td>Article 8.   Limited Warranty and Indemnification</td>
<td>17</td>
</tr>
<tr>
<td>Article 9.   Use of Names and Trademarks</td>
<td>19</td>
</tr>
<tr>
<td>Article 10.  Miscellaneous Provisions</td>
<td>20</td>
</tr>
</tbody>
</table>

| Exhibit A:   Patent Rights as of Execution Date | Appendix |
| Exhibit B:   Transactions Occurring Between Effective Date and Execution Date | Appendix |
| Exhibit C:   Certificate of Merger of Encode Therapeutics, Inc., with and into Bennu Pharmaceutical, Inc. | Appendix |
| Exhibit D:   Certificate of Amendment of Certificate of Incorporation of Bennu Pharmaceuticals, Inc. | Appendix |
LICENSE AGREEMENT

This agreement ("Agreement") is made by and between Raptor Therapeutics, Inc. (f/k/a Encode Pharmaceuticals, Inc.), a Delaware corporation having an address at 9 Commercial Blvd., Suite 200, Novato, CA, 94949 ("LICENSEE") and The Regents of the University of California, a California corporation having its statewide administrative offices at 1111 Franklin Street, Oakland, California 94607-5200 ("UNIVERSITY"), represented by its San Diego campus having an address at University of California, San Diego, Technology Transfer Office, Mail Code 0910, 9500 Gilman Drive, La Jolla, California 92093-0910 ("UCSD").

This Agreement is effective on October 31, 2007 ("Effective Date") with Raptor Therapeutics, which became LICENSEE upon a merger of Encode Pharmaceuticals, Inc. with and into Bennu Pharmaceuticals, Inc., effective December 17, 2007 (Exhibit C), which changed its name from Bennu Pharmaceuticals, Inc. to Raptor Therapeutics, Inc., effective November 5, 2008 (Exhibit D), was amended ("First Amendment") effective November 11, 2008 ("First Amendment Date") and is amended and restated, herein, as an Amended and Restated License ("Second Amendment") as of 30 October 2012 ("Execution Date").

RECITALS

WHEREAS, the inventions disclosed in UCSD Disclosure Docket No. SD SD2006-092 and titled “Enterically Coated Cysteamine” ("Invention"), were made in the course of research at UCSD by Drs. Ranjan Dohil and Jerry Schneider (hereinafter and collectively, the “Inventors”) and are covered by Patent Rights as defined below;

WHEREAS, the Inventors are employees of UCSD, and they are obligated to assign all of their right, title and interest in the Invention to UNIVERSITY;

WHEREAS, LICENSEE entered into a secrecy agreement (UC Control No. 2007-20-0348) with UNIVERSITY, effective January 31, 2007, for the purpose of evaluating the Invention;

WHEREAS, LICENSEE entered into a secrecy agreement (UC Control No. 2008-03-0236) with UNIVERSITY, effective November 11, 2008, for the purpose of evaluating the Invention;

WHEREAS, UNIVERSITY is desirous that the Invention be developed and utilized to the fullest possible extent so that its benefits can be enjoyed by the general public;

WHEREAS, LICENSEE is desirous of obtaining certain rights from UNIVERSITY for commercial development, use, and sale of the Invention, and the UNIVERSITY is willing to grant such rights;

WHEREAS, LICENSEE understands that UNIVERSITY may publish or otherwise disseminate information concerning the Invention and Technology (as defined below) at any time and that LICENSEE is paying consideration thereunder for its early access to the Invention and Technology, not continued secrecy therein;
WHEREAS, LICENSEE and UNIVERSITY wish to update terminology of the Agreement to current UNIVERSITY practice and harmonize terms of this Agreement with a separate license agreement, between LICENSEE and UNIVERSITY with respect to certain rights under the invention entitled “Intravenous cysteamine for rapid elevation of adiponectin levels during myocardial infarction and other situations of oxidative stress/ischemia,” (“CV License Agreement”), which is to be effective concurrently herewith;

WHEREAS, LICENSEE and UNIVERSITY wish to simultaneously update diligence timelines to reflect the commercial priorities of LICENSEE and to accommodate developmental delays; and

WHEREAS, transactions that have occurred between the Effective Date and the Execution Date, are listed in Exhibit B.

NOW, THEREFORE, the parties agree:

ARTICLE 1 DEFINITIONS

The terms, as defined herein, shall have the same meanings in both their singular and plural forms.

1.1 “Affiliate” means any corporation or other business entity which is bound in writing by LICENSEE to the terms set forth in this Agreement and in which LICENSEE owns or controls, directly or indirectly, at least fifty percent (50%) of the outstanding stock or other voting rights entitled to elect directors, or in which LICENSEE is owned or controlled directly or indirectly by at least fifty percent (50%) of the outstanding stock or other voting rights entitled to elect directors; but in any country where the local law does not permit foreign equity participation of at least fifty percent (50%), then an “Affiliate” includes any company in which LICENSEE owns or controls or is owned or controlled by, directly or indirectly, the maximum percentage of outstanding stock or voting rights permitted by local law.

1.2 “Field” means human therapeutics, subject to diligence specified in Section 3.4.

1.3 “Licensed Method” means any method that uses Technology, or that is claimed in Patent Rights (as defined below), the use of which would constitute, but for the license granted to LICENSEE under this Agreement, an infringement, an inducement to infringe or contributory infringement, of any pending or issued claim within Patent Rights.

1.4 “Licensed Product” means any service, composition or product that uses Technology, or that is claimed in Patent Rights, or that is produced by the Licensed Method, or the manufacture, use, sale, offer for sale, or importation of which would constitute, for the license granted to LICENSEE under this Agreement, an infringement, an inducement to infringe or contributory infringement, of any pending or issued claim within the Patent Rights.

1.5 “Net Sales” means […]***…]

***Confidential Treatment Requested

-2-
1.6 “Patent Costs” means [...***...].

1.7 “Patent Rights” means [...***...].

The “Patent Rights” in which UNIVERSITY has rights as of the Execution Date are set forth in Exhibit A, which are all such patent applications or patents described in this Section 1.7 as of the Execution Date.

1.8 “Sublicense” means an agreement into which LICENSEE enters with a third party that is not an Affiliate for the purpose of (i) granting rights under the Patent Rights to make, have made, use, sell or import Licensed Products; (ii) granting an option under the Patent Rights to make, have made, use, sell or import Licensed Products; or (iii) forbearing the enforcement of any Patent Rights granted to LICENSEE under this Agreement. “Sublicensee” means a third party with whom LICENSEE enters into a Sublicense.

1.9 “Sublicense Fees” means all upfront fees, milestone payments and similar license fees received by LICENSEE from its Sublicensees in consideration for the grant of a Sublicense, but excluding:

(i) any royalty payments;
(ii) payments for equity or debt securities of LICENSEE (except to the extent such payments exceed the fair market value of such securities upon date of receipt, in which case such premiums over fair market value shall be deemed to be “Sublicense Fees”);

(iii) research or development funding to be applied directly to the future research and/or development of Licensed Products; and

(iv) payments and reimbursement of Patent Costs paid to UNIVERSITY by LICENSEE with respect to the filing, preparation, prosecution or maintenance of the Patent Rights.

1.10 “Technology” means the written technical information and know-how relating to the Invention, which the UNIVERSITY provides to LICENSEE prior to and during the Term of this Agreement.

1.11 “Term” means the period of time beginning on the Effective Date and ending on the later of (i) the expiration date of the longest-lived Patent Rights on a country-by-country basis or (ii) ten (10) years after the first commercial sale of a Licensed Product.

1.12 “Territory” means world-wide.

**ARTICLE 2 GRANTS**

2.1 **License.** Subject to the limitations set forth in this Agreement, UNIVERSITY hereby grants to LICENSEE, and LICENSEE hereby accepts, a license under Patent Rights to make and have made, to use and have used, to sell and have sold, to offer for sale, and to import and have imported Licensed Products and to practice Licensed Methods and to use Technology, in the Field within the Territory and during the Term.

The license granted herein is exclusive for Patent Rights and non-exclusive for Technology.

2.2 **Sublicense.**

(a) The license granted in Paragraph 2.1 includes the right of LICENSEE to grant Sublicenses to third parties during the Term but only for as long the license is exclusive.

(b) With respect to Sublicense granted pursuant to Paragraph 2.2(a), LICENSEE shall:

(i) not receive, or agree to receive, any non-cash consideration in lieu of cash as consideration from a third party under a Sublicense granted pursuant to Paragraph 2.2(a) without the express written consent of UNIVERSITY;

(ii) to the extent applicable, include all of the rights of and obligations due to UNIVERSITY and contained in this Agreement;
within thirty (30) days of the execution of the Sublicense agreement, provide UNIVERSITY with a copy of each Sublicense issued; and

(iv) collect and guarantee payment of all payments due, directly or indirectly, to UNIVERSITY from Sublicensees and summarize and deliver all reports due, directly or indirectly, to UNIVERSITY from Sublicensees.

(c) Upon termination of this Agreement for any reason, UNIVERSITY, at its sole discretion, shall determine whether LICENSEE shall cancel or assign to UNIVERSITY any and all Sublicenses.

2.3 Reservation of Rights. UNIVERSITY reserves the right to:

(a) use the Invention, Technology and Patent Rights for educational and research purposes;

(b) publish or otherwise disseminate any information about the Invention and Technology at any time; and

(c) allow other nonprofit institutions to use and publish or otherwise disseminate any information about Invention, Technology and Patent Rights for educational and research purposes.

ARTICLE 3 CONSIDERATION

3.1 Fees and Royalties. The parties hereto understand that the fees and royalties payable by LICENSEE to UNIVERSITY under this Agreement are partial consideration for the license granted herein to LICENSEE under Technology, and Patent Rights. LICENSEE shall pay UNIVERSITY:

(a) a license issue fee of fifty thousand dollars (US$50,000), within thirty (30) days after the Effective Date;

(b) license maintenance fees of fifteen thousand dollars (US$15,000) per year and payable on the first anniversary of the Effective Date and annually thereafter on each anniversary; provided however, that LICENSEE's obligation to pay this fee shall end on the date when LICENSEE is commercially selling a Licensed Product;

(c) milestone payments in the amounts payable according to the following schedule or events:

<table>
<thead>
<tr>
<th>Amount</th>
<th>Date or Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i)</td>
<td>For each orphan indication, the following amounts will be paid:</td>
</tr>
<tr>
<td>[...***...]</td>
<td></td>
</tr>
</tbody>
</table>

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-5-
(ii) For each non-orphan indication, the following amounts will be paid:

[...***...]

(d) an earned royalty of [...***...].

(e) a percentage of all Sublicense Fees received by LICENSEE from its Sublicensees [...***...]

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(f) on each and every **Sublicense royalty** payment received by LICENSEE from its Sublicensees on Net Sales of Licensed Product by Sublicensee, the higher of (i) the percentage of royalties received by LICENSEE according to the schedule in 3.1(e); or (ii) royalties based on the royalty rate in Paragraph 3.1(d) as applied to Net Sales of Sublicensee. For the sake of clarity, royalties due for Net Sales by Licensee and/or Affiliate(s), Section 3.1(d) will apply and for Net Sales by Sublicensee, this Section 3.1(f), will apply;

(g) beginning the calendar year of commercial sales of the first Licensed Product by LICENSEE, its Sublicensee, or an Affiliate and if the total earned royalties paid by LICENSEE under Paragraphs 3.1(d) and (f) to UNIVERSITY in any such year cumulatively amounts to less than:

a. 

b. 

(“minimum annual royalty”), LICENSEE shall pay to UNIVERSITY on or before February 28 following the last quarter of such year the difference between the applicable minimum annual royalty above and the total earned royalty paid by LICENSEE for such year under Paragraphs 3.1(d) and (f); provided, however, that for the year of commercial sales of the first Licensed Product, the amount of minimum annual royalty payable shall be pro-rated for the number of months remaining in that calendar year.

3.2 Payment. All fees and royalty payments specified in Paragraphs 3.1(a) through 3.1(g) above shall be paid by LICENSEE pursuant to Paragraph 4.3 and shall be delivered by LICENSEE to UNIVERSITY as noted in Paragraph 10.1.

Notwithstanding anything to the contrary, in the event that LICENSEE would owe amounts (specifically not including annual license maintenance fees) to UNIVERSITY under this Agreement and also under the CV License Agreement with respect to a specific Licensed Product, only the higher amount shall be due. By way of example, in the event LICENSEE owes [...***…]
3.3 **Patent Costs.** LICENSEE shall reimburse UNIVERSITY all past (prior to the Effective Date) and future (on or after the Effective Date) Patent Costs within thirty (30) days following the date an itemized invoice is sent from UNIVERSITY to LICENSEE. In UNIVERSITY’s discretion, for Patent Costs anticipated to exceed [...***...](“Anticipated Costs”), UNIVERSITY will inform LICENSEE no less than thirty (30) days prior to the date when Anticipated Costs are incurred. UNIVERSITY may, at its discretion and in accordance with Paragraph 5.1(c), require full advance payment of Anticipated Costs at least fifteen (15) business days before required filing dates (“Advance Payment Deadline”). [...***...]. In the event that the Anticipated Costs paid by LICENSEE are greater than the actual cost, the excess amount is creditable against future Patent Costs. In the event that the actual costs exceed the Anticipated Costs paid in advance by LICENSEE, LICENSEE shall pay such excess costs within thirty (30) days following the date an itemized invoice is sent as set forth in Paragraph 4.3.

3.4 **Due Diligence.**

(a) LICENSEE shall, either directly or through its Affiliate(s) or Sublicensee(s):

(i) secure one million dollars (US$1,000,000) of funding on or before December 15 2008 (“First Financing Milestone”);

(ii) [...***...];

(iii) [...***...] spend not less than [...***...] for the development of Licensed Products during [...***... of this Agreement. LICENSEE may, at its sole option, fund the research of any one of the Inventors and credit the amount of such funding actually paid to UCSD against its obligation under this paragraph;

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-8-
For the indications of Cystinosis, Huntington's Disease, and Non-alcoholic Steatohepatitis ("NASH") perform the following activities [...***...]:

<table>
<thead>
<tr>
<th>Years from Effective Date</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cystinosis</td>
<td>[...<em><strong>...] [...</strong></em>...]</td>
</tr>
<tr>
<td>NASH</td>
<td>[...<em><strong>...] [...</strong></em>...]</td>
</tr>
</tbody>
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-9-
(v) market Licensed Products in the United States [...***...] of receiving regulatory approval to market such Licensed Products;

(vi) fill the market demand for Licensed Products following commencement of marketing at any time during the term of this Agreement; and

(vii) obtain all necessary governmental approvals for the manufacture, use and sale of Licensed Products.

(b) If LICENSEE fails to perform any of its obligations specified in Paragraphs 3.4(a)(i)-(vii), then UNIVERSITY shall have the right and option to either terminate this Agreement or change LICENSEE’s exclusive license to a nonexclusive license. This right, if exercised by UNIVERSITY, supersedes the rights granted in Article 2.

(c) If, [...***...] the Effective Date, LICENSEE fails to show it has initiated and is maintaining an active development program for a clinical indication in the Field, and UNIVERSITY receives a bona fide inquiry from a third party with a bona fide financial plan that would enable the licensure and development of a therapy for such clinical indication, UNIVERSITY shall give notice to LICENSEE. LICENSEE shall, [...***...], either (i) complete a Sublicense grant to the third party, or (ii) shall provide UNIVERSITY a detailed plan for the development of a product to treat said clinical indication and shall begin actual implementation of, and maintain such plan immediately. If LICENSEE does not either (i) complete a Sublicense grant or (ii) demonstrate implementation of said development plan within [...***...] days of receipt of such notice from UNIVERSITY, then UNIVERSITY shall have the right to exclude such clinical indication from the Field.
ARTICLE 4 REPORTS, RECORDS AND PAYMENTS

4.1 Reports.

(a) Progress Reports. Beginning six months after Effective Date and ending after first commercial sale of the last Licensed Product to be introduced, LICENSEE shall report to UNIVERSITY progress covering LICENSEE's (and Affiliate's and Sublicensee's) activities for the preceding six (6) months to develop and test all Licensed Products and obtain governmental approvals necessary for marketing the same. Such semi-annual reports shall be due within sixty (60) days of the reporting period and include a summary of work completed, summary of work in progress, current schedule of anticipated events or milestones, market plans for introduction of Licensed Products, and summary of resources (dollar value) spent in the reporting period.

(b) Royalty Reports. After the first commercial sale of a Licensed Product anywhere in the world, LICENSEE shall submit to UNIVERSITY quarterly royalty reports on or before each February 28, May 31, August 31 and November 30 of each year. Each royalty report shall cover LICENSEE's (and each Affiliate's and Sublicensee's) most recently completed calendar quarter and shall show:

(i) the date of first commercial sale of a Licensed Product in each country;

(ii) the gross sales, deductions as provided in Paragraph 1.5 and Net Sales during the most recently completed calendar quarter and the royalties, in US dollars, payable with respect thereto;

(iii) the number of each type of Licensed Product sold;

(iv) Sublicense Fees and royalties received during the most recently completed calendar quarter in US dollars, payable with respect thereto;

(v) the method used to calculate the royalties; and

(vi) the exchange rates used.

If no sales of Licensed Products have been made and no Sublicense revenue has been received by LICENSEE during any reporting period, LICENSEE shall so report.

(c) Timely Reports. LICENSEE acknowledges the important value that timely reporting provides in UNIVERSITY's effective management of its rights under this Agreement. LICENSEE further acknowledges that failure to render the reports required under this Paragraph 4.1 may harm UNIVERSITY's ability to manage its rights under this Agreement. As such, reports not submitted by the required due date under this Paragraph 4.1 will cause to be due by LICENSEE to UNIVERSITY a late reporting fee of [...] per month until such report, compliant with the requirements of this Paragraph 4.1, is received by UNIVERSITY. Payment of this fee is subject to Paragraph 4.3, Paragraph 7.1 and Paragraph 10.1 herein.

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-11-
4.2 Records & Audits.

(a) LICENSEE shall keep, and shall require its Affiliates and Sublicensees to keep, accurate and correct records of all Licensed Products manufactured, used, and sold, and Sublicense fees received under this Agreement. Such records shall be retained by LICENSEE for at least five (5) years following a given reporting period.

(b) All records shall be available during normal business hours for inspection at the expense of UNIVERSITY by UNIVERSITY's Internal Audit Department or by a Certified Public Accountant selected by UNIVERSITY and in compliance with the other terms of this Agreement for the sole purpose of verifying reports and payments or other compliance issues. Such inspector shall not disclose to UNIVERSITY any information other than information relating to the accuracy of reports and payments made under this Agreement or other compliance issues. In the event that any such inspection shows an under reporting and underpayment in excess of […***…] for any […***…], then LICENSEE shall pay the cost of the audit as well as any additional sum that would have been payable to UNIVERSITY had the LICENSEE reported correctly, plus an interest charge at a rate of […***…] per year. Such interest shall be calculated from the date the correct payment was due to UNIVERSITY up to the date when such payment is actually made by LICENSEE. For underpayment not in excess of […***…] for any […***…] period, LICENSEE shall pay the difference within […***…] without interest charge or inspection cost.

4.3 Payments.

(a) All fees reimbursements and royalties due UNIVERSITY shall be paid in United States dollars and all checks shall be made payable to “The Regents of the University of California”, referencing UNIVERSITY’s taxpayer identification number, 95-6006144, and sent to UNIVERSITY according to Paragraph 10.1 (Correspondence). When Licensed Products are sold in currencies other than United States dollars, LICENSEE shall first determine the earned royalty in the currency of the country in which Licensed Products were sold and then convert the amount into equivalent United States funds, using the exchange rate quoted in the Wall Street Journal on the last business day of the applicable reporting period.

(b) Royalty Payments.

(i) Royalties shall accrue when Licensed Products are invoiced, or if not invoiced, when delivered to a third party or Affiliate.

(ii) LICENSEE shall pay earned royalties […***…] on or before […***…] of each calendar year. Each such payment shall be for earned royalties accrued within LICENSEE’s most recently completed calendar quarter.

(iii) Royalties earned on sales occurring or under Sublicense granted pursuant to this Agreement in any country outside the United States shall not be reduced by LICENSEE for any taxes, fees, or other charges imposed by the government of such country on the payment of royalty income, except that all payments made by LICENSEE in fulfillment of

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UNIVERSITY’s tax liability in any particular country may be credited against earned royalties or fees due UNIVERSITY for that country. LICENSEE shall pay all bank charges resulting from the transfer of such royalty payments.

(iv) If at any time legal restrictions prevent the prompt remittance of part or all royalties by LICENSEE with respect to any country where a Licensed Product is sold or a Sublicense is granted pursuant to this Agreement, LICENSEE shall convert the amount owed to UNIVERSITY into US currency and shall pay UNIVERSITY directly from its US sources of fund for as long as the legal restrictions apply.

(v) In the event that any patent or patent claim within Patent Rights is held invalid in a final decision by a patent office from which no appeal or additional patent prosecution has been or can be taken, or by a court of competent jurisdiction and last resort and from which no appeal has or can be taken, all obligation to pay royalties based solely on that patent or claim or any claim patently indistinct therefrom shall cease as of the date of such final decision. LICENSEE shall not, however, be relieved from paying any royalties that accrued before the date of such final decision, that are based on another patent or claim not involved in such final decision, or that are based on the use of Technology.

(vi) Royalty payments under Article 3, recoveries and settlements under Article 5, and royalty reports under 4.1(b) shall be rendered for any and all Licensed Products even if due after expiration of the Agreement.

(c) Late Payments. In the event royalty, reimbursement and/or fee payments are not received by UNIVERSITY when due, LICENSEE shall pay to UNIVERSITY interest charges at a rate of […***…] per year. Such interest shall be calculated from the date payment was due until actually received by UNIVERSITY.

ARTICLE 5 PATENT MATTERS

5.1 Patent Prosecution and Maintenance.

(a) Provided that LICENSEE has reimbursed UNIVERSITY for Patent Costs pursuant to Paragraph 3.3, UNIVERSITY shall diligently prosecute and maintain the United States and, if available, foreign patents, and applications in Patent Rights using counsel of its choice. […] UNIVERSITY shall provide LICENSEE with copies of all relevant documentation relating to such prosecution and LICENSEE shall keep this documentation confidential. The counsel shall take instructions only from UNIVERSITY, and all patents and patent applications in Patent Rights shall be assigned solely to UNIVERSITY. UNIVERSITY shall in any event control all patent filings and all patent prosecution decisions and related filings (e.g. responses to office actions) shall be at UNIVERSITY’s final discretion (prosecution includes, but is not limited to, interferences, oppositions and any other inter partes matters originating in a patent office).

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-13-
(b) UNIVERSITY shall consider amending any patent application in Patent Rights to include claims reasonably requested by LICENSEE to protect the products contemplated to be sold by LICENSEE under this Agreement.

(c) LICENSEE may elect to terminate its reimbursement obligations with respect to any patent application or patent in Patent Rights upon three (3) months’ written notice to UNIVERSITY. UNIVERSITY shall use reasonable efforts to curtail further Patent Costs for such application or patent when such notice of termination is received from LICENSEE. UNIVERSITY, in its sole discretion and at its sole expense, may continue prosecution and maintenance of said application or patent, and LICENSEE shall have no further license with respect thereto. Non-payment of any portion of Patent Costs or Anticipated Costs with respect to any application or patent may be deemed by UNIVERSITY as an election by LICENSEE to terminate its reimbursement obligations with respect to such application or patent. UNIVERSITY is not obligated to file, prosecute, or maintain Patent Rights in any country where LICENSEE is not paying Patent Costs at any time or to file, prosecute, or maintain Patent Rights to which LICENSEE has terminated its license hereunder.

(d) LICENSEE shall apply for an extension of the term of any patent in Patent Rights if appropriate under the Drug Price Competition and Patent Term Restoration Act of 1984 and/or European, Japanese and other foreign counterparts of this law. LICENSEE shall prepare all documents for such application, and UNIVERSITY shall execute such documents and take any other additional action as LICENSEE reasonably requests in connection therewith.

5.2 Patent Infringement.

(a) In the event that UNIVERSITY (to the extent of the actual knowledge of the licensing professional responsible for the administration of this Agreement) or LICENSEE learns of infringement of potential commercial significance of any patent licensed under this Agreement, the knowledgeable party will provide the other (i) with written notice of such infringement and (ii) with any evidence of such infringement available to it (the “Infringement Notice”). During the period in which, and in the jurisdiction where, LICENSEE has exclusive rights under this Agreement, neither UNIVERSITY nor LICENSEE will notify a third party (including the infringer) of infringement or put such third party on notice of the existence of any Patent Rights without first obtaining consent of the other. UNIVERSITY shall have the right to terminate this Agreement immediately without the obligation to provide sixty (60) days' notice as set forth in Paragraph 7.1 if LICENSEE notifies a third party of infringement or puts such third party on notice of the existence of any Patent Rights with respect to such infringement without first obtaining the written consent of UNIVERSITY. Both UNIVERSITY and LICENSEE will use their diligent efforts to cooperate with each other to terminate such infringement without litigation.

(b) If infringing activity of potential commercial significance by the infringer has not abated within ninety (90) days following the date the Infringement Notice takes effect, LICENSEE may institute suit for patent infringement against the infringer. UNIVERSITY may voluntarily join such suit at its own expense, but may not thereafter commence suit against the infringer for the acts of infringement that are the subject of LICENSEE's suit or any judgment rendered in that suit. LICENSEE may not join UNIVERSITY in a suit initiated by LICENSEE.
without UNIVERSITY'S prior written consent. If, in a suit initiated by LICENSEE, UNIVERSITY is involuntarily joined other than by LICENSEE, LICENSEE will pay any costs incurred by UNIVERSITY arising out of such suit, including but not limited to, any legal fees of counsel that UNIVERSITY selects and retains to represent it in the suit.

(c) If, within a hundred and twenty (120) days following the date the Infringement Notice takes effect, infringing activity of potential commercial significance by the infringer has not been abated and if LICENSEE has not brought suit against the infringer, UNIVERSITY may institute suit for patent infringement against the infringer. If UNIVERSITY institutes such suit, LICENSEE may not join such suit without UNIVERSITY’S consent and may not thereafter commence suit against the infringer for the acts of infringement that are the subject of UNIVERSITY’S suit or any judgment rendered in that suit.

(d) Any recovery or settlement received in connection with any suit will first be shared by UNIVERSITY and LICENSEE equally to cover the litigation costs each incurred, and next shall be paid to UNIVERSITY or LICENSEE to cover any litigation costs it incurred in excess of the litigation costs of the other. In any suit initiated by LICENSEE, any recovery in excess of litigation costs will be shared between LICENSEE and UNIVERSITY as follows: (i) for any recovery other than amounts paid for willful infringement: (A) UNIVERSITY will receive […] of the recovery if UNIVERSITY was not a party in the litigation and did not incur any litigation costs; (B) UNIVERSITY will receive […] of the recovery if UNIVERSITY was a party in the litigation, but did not incur any litigation costs, including the provisions of Paragraph 5.2(b) above, or (C) UNIVERSITY will receive […] of the recovery if UNIVERSITY incurred any litigation costs in connection with the litigation; and (ii) for any recovery for willful infringement, UNIVERSITY will receive […] of the recovery. In any suit initiated by UNIVERSITY, […].

UNIVERSITY and LICENSEE agree to be bound by all determinations of patent infringement, validity, and enforceability (but no other issue) resolved by any adjudicated judgment in a suit brought in compliance with this Paragraph 5.2.

(e) Any agreement made by LICENSEE for purposes of settling litigation or other dispute shall comply with the requirements of Paragraph 2.2 (Sublicenses) of this Agreement.

(f) Each party will cooperate with the other in litigation proceedings instituted hereunder but at the expense of the party who initiated the suit (unless such suit is being jointly prosecuted by the parties).

(g) Any litigation proceedings will be controlled by the party bringing the suit, except that UNIVERSITY may be represented by counsel of its choice in any suit brought by LICENSEE.

5.3 Patent Marking. LICENSEE shall mark all Licensed Products made, used or sold under the terms of this Agreement, or their containers, in accordance with the applicable patent marking laws. LICENSEE shall be responsible for all monetary and legal liabilities arising
from or caused by (i) failure to abide by applicable patent marking laws and (ii) any type of incorrect or improper patent marking.

ARTICLE 6 GOVERNMENTAL MATTERS

6.1 Governmental Approval or Registration. If this Agreement or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, LICENSEE shall assume all legal obligations to do so. LICENSEE shall notify UNIVERSITY if it becomes aware that this Agreement is subject to a United States or foreign government reporting or approval requirement. LICENSEE shall make all necessary filings and pay all costs including fees, penalties, and all other out-of-pocket costs associated with such reporting or approval process.

6.2 Export Control Laws. LICENSEE shall observe all applicable United States and foreign laws with respect to the transfer of Licensed Products and related technical data to foreign countries, including, without limitation, the International Traffic in Arms Regulations and the Export Administration Regulations.

ARTICLE 7 TERMINATION OR EXPIRATION OF THE AGREEMENT

7.1 Termination by UNIVERSITY.

(a) If LICENSEE fails to perform or violates any term of this Agreement, then UNIVERSITY may give written notice of default (“Notice of Default”) to LICENSEE. If LICENSEE fails to cure the default within […***…] of the Notice of Default, UNIVERSITY may terminate this Agreement and the license granted herein by a second written notice (“Notice of Termination”) to LICENSEE. If a Notice of Termination is sent to LICENSEE, this Agreement shall automatically terminate on the effective date of that notice. Termination shall not relieve LICENSEE of its obligation to pay any fees owed at the time of termination and shall not impair any accrued right of UNIVERSITY. During the term of any such Notice of Default or period to cure, to the extent the default at issue is a failure to pay past or ongoing Patent Costs as provided for under this Agreement, UNIVERSITY shall have no obligation to incur any new Patent Costs under this Agreement and shall have no obligation to further prosecute Patent Rights or file any new patents under Patent Rights.

(b) This Agreement will terminate immediately, without the obligation to provide […***…] notice as set forth in Paragraph 7.1(a), if LICENSEE files a claim including in any way the assertion that any portion of UNIVERSITY’s Patent Rights is invalid or unenforceable where the filing is by the LICENSEE, a third party on behalf of the LICENSEE, or a third party at the written urging of the LICENSEE.

7.2 Termination by LICENSEE.

(a) LICENSEE shall have the right at any time and for any reason to terminate this Agreement upon a […***…] written notice to UNIVERSITY. Said notice shall state LICENSEE’s reason for terminating this Agreement.
Any termination under Paragraph 7.2(a) shall not relieve LICENSEE of any obligation or liability accrued under this Agreement prior to termination or rescind any payment made to UNIVERSITY or action by LICENSEE prior to the time termination becomes effective. Termination shall not affect in any manner any rights of UNIVERSITY arising under this Agreement prior to termination.

7.3 Survival on Termination or Expiration. The following Paragraphs and Articles shall survive the termination or expiration of this Agreement:

(a) Article 4 (Reports, Records and Payments);
(b) Paragraph 7.3 (Survival on Termination or Expiration);
(c) Paragraph 7.4 (Disposition of Licensed Products on Hand);
(d) Article 8 (Limited Warranty and Indemnification);
(e) Article 9 (Use Of Names and Trademarks);
(f) Paragraph 10.2 hereof (Secrecy);
(g) Paragraph 10.5 (Failure to Perform); and
(h) Paragraph 10.6 (Governing Law).

7.4 Disposition of Licensed Products on Hand. Upon termination of this Agreement, LICENSEE may dispose of all previously made or partially made Licensed Product within a period of one hundred and twenty (120) days of the effective date of such termination provided that the sale of such Licensed Product by LICENSEE, its Sublicensees, or Affiliates shall be subject to the terms of this Agreement, including but not limited to the rendering of reports and payment of royalties required under this Agreement.

ARTICLE 8 LIMITED WARRANTY AND INDEMNIFICATION

8.1 Limited Warranty.

(a) UNIVERSITY warrants that it has the lawful right to grant this license. This warranty does not include Patent Rights to the extent assigned, or otherwise licensed, by UNIVERSITY’ s inventors to third parties prior to the Effective Date.

(b) The license granted herein and the associated Technology are provided “AS IS” and without WARRANTY OF MERCHANTABILITY or WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE or any other warranty, express or implied. UNIVERSITY makes no representation or warranty that the Licensed Product, Licensed Method or the use of Patent Rights or Technology will not infringe any other patent or other proprietary rights.

(c) EXCEPT WITH RESPECT TO A BREACH OF PARAGRAPH 8.1(a) ABOVE, UNIVERSITY WILL NOT BE LIABLE FOR ANY LOST PROFITS, COSTS OF
PROCURING SUBSTITUTE GOODS OR SERVICES, LOST BUSINESS, ENHANCED DAMAGES FOR INTELLECTUAL PROPERTY INFRINGEMENT, OR FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, OR OTHER SPECIAL DAMAGES SUFFERED BY LICENSEE, SUBLICENSEES, JOINT VENTURES, OR AFFILIATES ARISING OUT OF OR RELATED TO THIS AGREEMENT FOR ALL CAUSES OF ACTION OF ANY KIND (INCLUDING TORT, CONTRACT, NEGLIGENCE, STRICT LIABILITY AND BREACH OF WARRANTY) EVEN IF UNIVERSITY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

(d) Nothing in this Agreement shall be construed as:

(i) a warranty or representation by UNIVERSITY as to the validity or scope of any Patent Rights;

(ii) a warranty or representation that anything made, used, sold or otherwise disposed of under any license granted in this Agreement is or shall be free from infringement of patents of third parties;

(iii) an obligation to bring or prosecute actions or suits against third parties for patent infringement except as provided in Paragraph 5.2 hereof;

(iv) conferring by implication, estoppel or otherwise any license or rights under any patents of UNIVERSITY other than Patent Rights as defined in this Agreement, regardless of whether those patents are dominant or subordinate to Patent Rights; or

(v) an obligation to furnish any know-how not provided in Patent Rights and Technology; or

(vi) an obligation to update Technology.

8.2 **Indemnification.**

(a) LICENSEE will, and will require Sublicensees to, indemnify, hold harmless, and defend UNIVERSITY and its officers, employees, and agents; the sponsors of the research that led to the Invention; and the inventors of patents or patent applications under Patent Rights, and their employers; against any and all claims, suits, losses, damages, costs, fees, and expenses resulting from, or arising out of, the exercise of this license or any Sublicense, except to the extent arising out of or related to Patent Rights to the extent assigned, or otherwise licensed, by UNIVERSITY’ s inventors to third parties. This indemnification will include, but will not be limited to, any product liability.

(b) LICENSEE, at its sole cost and expense, shall insure its activities in connection with the work under this Agreement and obtain, keep in force and maintain insurance or an equivalent program of self-insurance as follows:

(i) Prior to [...***...]:

***Confidential Treatment Requested

-18-
Prior to initiation of human clinical trials, comprehensive or commercial general liability insurance (contractual liability included) with limits of at least: (A) each occurrence, [...***...]; (B) products/completed operations aggregate, [...***...]; (C) personal and advertising injury, [...***...]; and (D) general aggregate (commercial form only), [...***...]; and

Upon initiation of human clinical trials, comprehensive or commercial general liability insurance (contractual liability included) with limits of at least: (A) each occurrence, [...***...]; (B) products/completed operations aggregate, [...***...]; (C) personal and advertising injury, [...***...]; and (D) general aggregate (commercial form only), [...***...]; Worker's Compensation as legally required in the jurisdiction in which the LICENSEE is doing business;

(ii) On and after [...***...], comprehensive or commercial general liability insurance (contractual liability included) with limits of at least: (A) each occurrence, [...***...]; (B) products/completed operations aggregate, [...***...]; (C) personal and advertising injury, [...***...]; and (D) general aggregate (commercial form only), [...***...]; Worker's Compensation as legally required in the jurisdiction in which the LICENSEE is doing business;

(iii) the coverage and limits referred to above shall not in any way limit the liability of LICENSEE; and

(iv) If the above insurance is written on a claims-made form, it shall continue for three (3) years following termination or expiration of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the Effective Date.

Upon request, LICENSEE shall furnish UNIVERSITY with certificates of insurance showing compliance with all requirements. Such certificates shall: (i) provide for thirty (30) day advance written notice to UNIVERSITY of any modification; (ii) indicate that UNIVERSITY has been endorsed as an additional insured party under the coverage referred to above; and (iii) include a provision that the coverage shall be primary and shall not participate with nor shall be excess over any valid and collectable insurance or program of self-insurance carried or maintained by UNIVERSITY.

UNIVERSITY shall notify LICENSEE in writing of any claim or suit brought against UNIVERSITY in respect of which UNIVERSITY intends to invoke the provisions of this Article. LICENSEE shall keep UNIVERSITY informed on a current basis of its defense of any claims under this Article.

ARTICLE 9 USE OF NAMES AND TRADEMARKS

9.1 Nothing contained in this Agreement confers any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of either party hereto (including contraction, abbreviation or simulation of any of the foregoing).
Unless required by law, the use by LICENSEE of the name, “The Regents of the University of California” or the name of any campus of the University Of California is prohibited, without the express written consent of UNIVERSITY.

9.2 UNIVERSITY may disclose to the Inventors the terms and conditions of this Agreement upon their request. If such disclosure is made, UNIVERSITY shall request the Inventors not disclose such terms and conditions to others.

9.3 UNIVERSITY may acknowledge the existence of this Agreement and the extent of the grant in Article 2 to third parties, but UNIVERSITY shall not disclose the financial terms of this Agreement to third parties, except where UNIVERSITY is required by law to do so, such as under the California Public Records Act. LICENSEE hereby grants permission for UNIVERSITY (including UCSD) to include LICENSEE's name and a link to LICENSEE's website in UNIVERSITY's and UCSD's annual reports and on UNIVERSITY's (including UCSD's) websites that showcase technology transfer-related stories.

ARTICLE 10 MISCELLANEOUS PROVISIONS

10.1 Correspondence. Any notice or payment required to be given to either party under this Agreement shall be deemed to have been properly given and effective:

(a) on the date of delivery if delivered in person, or

(b) five (5) days after mailing if mailed by first-class or certified mail, postage paid, to the respective addresses given below, or to such other address as is designated by written notice given to the other party.

If sent to LICENSEE:

Raptor Therapeutics, Corp.
9 Commercial Blvd., Suite 200
Novato, CA 94949
Attention: Ted Daley, President
Phone: 415-382-8111 x227
Fax: 415-382-1368

If sent to UNIVERSITY by mail:

University of California, San Diego
Technology Transfer Office
9500 Gilman Drive
Mail Code 0910
La Jolla, CA 92093-0910
Attention: Assistant Vice Chancellor

-20-
10.2 **Secrecy.**

(a) “Confidential Information” shall mean information, including Technology, relating to the Invention and disclosed by UNIVERSITY to LICENSEE during the term of this Agreement, which if disclosed in writing shall be marked “Confidential”, or if first disclosed otherwise, shall within thirty (30) days of such disclosure be reduced to writing by UNIVERSITY and sent to LICENSEE:

(b) LICENSEE shall:

(i) use the Confidential Information for the sole purpose of performing under the terms of this Agreement;

(ii) safeguard Confidential Information against disclosure to others with the same degree of care as it exercises with its own data of a similar nature;

(iii) not disclose Confidential Information to others (except to its employees, agents or consultants or Sublicensees who are bound to LICENSEE by a like obligation of confidentiality) without the express written permission of UNIVERSITY, except that LICENSEE shall not be prevented from using or disclosing any of the Confidential Information that:

(A) LICENSEE can demonstrate by written records was previously known to it;

(B) is now, or becomes in the future, public knowledge other than through acts or omissions of LICENSEE;

(C) is lawfully obtained by LICENSEE from sources independent of UNIVERSITY;

(D) is required to be disclosed by law or a court of competent jurisdiction; and
The secrecy obligations of LICENSEE with respect to Confidential Information shall continue for a period ending five (5) years from the termination date of this Agreement.

10.3 Assignability. This Agreement is binding upon and inures to the benefit of UNIVERSITY, its successors and assigns. But it is personal to Licensee and assignable by Licensee only with the written consent of UNIVERSITY. Notwithstanding the foregoing, the consent of UNIVERSITY will not be required if the assignment is in conjunction with the transfer of all or substantially all of the business of LICENSEE to which this Agreement relates.

10.4 No Waiver. No waiver by either party of any breach or default of any covenant or agreement set forth in this Agreement shall be deemed a waiver as to any subsequent and/or similar breach or default.

10.5 Failure to Perform. In the event of a failure of performance due under this Agreement and if it becomes necessary for either party to undertake legal action against the other on account thereof, then the prevailing party shall be entitled to reasonable attorney's fees in addition to costs and necessary disbursements.

10.6 Governing Laws. THIS AGREEMENT SHALL BE INTERPRETED AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CALIFORNIA, but the scope and validity of any patent or patent application shall be governed by the applicable laws of the country of the patent or patent application.

10.7 Force Majeure. A party to this Agreement may be excused from any performance required herein if such performance is rendered impossible or unfeasible due to any catastrophe or other major event beyond its reasonable control, including, without limitation, war, riot, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and floods, fires, explosions, or other natural disasters. When such events have abated, the non-performing party's obligations herein shall resume.

10.8 Headings. The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

10.9 Entire Agreement. This Agreement embodies the entire understanding of the parties and supersedes all previous communications, representations or understandings, either oral or written, between the parties relating to the subject matter hereof.

10.10 Amendments. No amendment or modification of this Agreement shall be valid or binding on the parties unless made in writing and signed on behalf of each party.

10.11 Severability. In the event that any of the provisions contained in this Agreement is held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if the invalid, illegal, or unenforceable provisions had never been contained in it.
IN WITNESS WHEREOF, both UNIVERSITY and LICENSEE have executed this Agreement, in duplicate originals, by their respective and duly authorized officers on the day and year written.

RAPTOR THERAPEUTICS, INC.:

By: /s/Thomas E. Daley
Name: Thomas E. Daley
Title: President
Date: December 12, 2012

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA:

By: /s/Jane Moores, Ph.D
Name: Jane Moores, Ph.D.
Title: Assistant Vice-Chancellor – Technology Transfer
Date: 12/13/12
Exhibit A: Patent Rights as of Execution Date

<table>
<thead>
<tr>
<th>UC Case No.</th>
<th>Jurisdiction</th>
<th>Filing Date</th>
<th>Serial / Patent No.</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested

-1-
<table>
<thead>
<tr>
<th>Date</th>
<th>Relevant Section of Agreement</th>
<th>Transaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>[…]***</td>
<td>[…]***</td>
<td>[…]***</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested
***Confidential Treatment Requested

-2-
Exhibit C: Certificate of Merger of Encode Therapeutics, Inc., with and into Bennu Pharmaceutical, Inc.
CERTIFICATE OF MERGER
OF ENCODE PHARMACEUTICALS, INC.
WITH AND INTO BENNU PHARMACEUTICALS INC.

Pursuant to Title 8, Section 251 of the Delaware General Corporation Law, the undersigned corporation, organized and existing under the Delaware General Corporation Law, does HEREBY CERTIFY AS FOLLOWS:

FIRST: That the name and state of incorporation of each of the constituent corporations to the merger (each a “Constituent Corporation”) is as follows:

<table>
<thead>
<tr>
<th>Name</th>
<th>State of Incorporation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bennu Pharmaceuticals Inc. (&quot;Bennu&quot;)</td>
<td>Delaware</td>
</tr>
<tr>
<td>Encode Pharmaceuticals, Inc.</td>
<td>Delaware</td>
</tr>
</tbody>
</table>

SECOND: That Merger Agreement (the “Merger Agreement”) entered into as of November 29, 2007, by and among the Constituent Corporations, Raptor Pharmaceuticals Corp., a Delaware corporation (“Raptor”), and Nicholas Stergis has been approved, adopted, certified, executed and acknowledged by each of the Constituent Corporations and Raptor pursuant to Section 251 of the Delaware General Corporation Law.

THIRD: That the name of the surviving corporation of the merger shall be Bennu Pharmaceuticals Inc. (the “Surviving Corporation”) and that the Surviving Corporation shall be wholly owned by Raptor, immediately subsequent to the effective time of the merger.

FOURTH: The Certificate of Incorporation of the Surviving Corporation shall be the Certificate of Incorporation of Benner immediately prior to the effective time of the merger and was filed with the Secretary of State of Delaware on August 1, 2007 as amended on August 30, 2007.

FOURTH: That executed copies of the Merger Agreement are on file at the principal place of business of the Surviving Corporation at 9 Commercial Boulevard, Suite 200, Novato, CA 94949.

FIFTH: That this Certificate of Merger shall be effective at 11:59 P.M., Delaware time, on December 14, 2007.

SIXTH: That a copy of the Merger Agreement will be furnished by the Surviving Corporation, upon request and without cost to any stockholder of either constituent corporation.

[REMAINDER OF PAGE INTENTIONALLY BLANK]
IN WITNESS WHEREOF, Beam Pharmaceuticals Inc. has caused this Certificate of Merger to be executed by its duly authorized officer this 14th day of December, 2007.

BENNU PHARMACEUTICALS INC.

By /s/ Kim R. Tsuchimoto
Name: Kim R. Tsuchimoto
Title: Chief Financial Officer

[Signature Page to Certificate of Merger]
CERTIFICATE OF AMENDMENT
OF
CERTIFICATE OF INCORPORATION
OF
BENNU PHARMACEUTICALS INC.

The undersigned hereby certifies as follows:

1. She is the duly elected, qualified and acting Secretary of Bennu Pharmaceuticals Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware (the “Corporation”).

2. Article I of the Corporation's Certificate of Incorporation is hereby amended and restated in its entirety to read as follows:

   “The name of the corporation (hereinafter called the 'Corporation') is Raptor Therapeutics Inc.”

3. The amendment set forth herein has been duly approved and adopted by the Board of Directors of the Corporation.

4. The necessary number of Issued and outstanding shares of capital stock of the Corporation required by statute were voted in favor of the amendment.

5. Such amendment was duly adopted in accordance with the provisions of Sections 228 and 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, Bennu Pharmaceuticals Inc. has caused this Certificate of Amendment to be signed by its Secretary this 4th day of November, 2008.

/s/ Kim. R. Tsuchimoto
Kim R. Tsuchimoto, Secretary
CERTIFICATE OF INCORPORATION
OF
PROMETHEUS PHARMACEUTICALS INC.

I.

The name of the Corporation is Prometheus Pharmaceuticals Inc.

II.

The address of the registered office of the Corporation in the State of Delaware is 2711 Centerville Road, Suite 400, in the City of Wilmington, County of New Castle, and the name of its registered agent at that address is Corporation Service Company.

III.

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

IV.

The total number of shares of stock which the Corporation shall have authority to issue is Three Thousand (3,000). The par value of each of such shares is $0.001. An such shares are of one class and are shares of Common Stock.

V.

The number of directors which shall constitute the whole Board of Directors shall be fixed by, or in the manner provided in, the Bylaws of the Corporation.

VI.

In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter, amend and rescind the Bylaws of the Corporation.

VII.

Election of directors at an annual or special meeting of stockholders need not be by written ballot unless the Bylaws of the Corporation shall so provide.

VIII.

No director shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director; provided that this Article VIII shall not eliminate or limit the liability of a director (i) for any breach of such director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of the law, (iii) under Section 174 of the General Corporation Law of the State of Delaware, or (iv) for any transaction from which such director
derives an improper personal benefit. If the General Corporation Law of the State of Delaware is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware as so amended.

IX.

The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred on stockholders herein are granted subject to this reservation.

X.

The name and mailing address of the incorporator of the Corporation are:

<table>
<thead>
<tr>
<th>Name</th>
<th>Mailing Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claudia Immerzeel</td>
<td>c/o Paul Hastings Janofsky &amp; Walker LLP</td>
</tr>
<tr>
<td></td>
<td>515 S. Figueroa Street, 25th Floor</td>
</tr>
<tr>
<td></td>
<td>Los Angeles, CA 90071</td>
</tr>
</tbody>
</table>
IN WITNESS WHEREOF, this Certificate of Incorporation has been signed on the 1st day of August, 2007.

/s/ Claudia Immerzeel
Claudia Immerzeel, Incorporator
CERTIFICATE OF AMENDMENT OF CERTIFICATE
OF INCORPORATION BEFORE PAYMENT OF
ANY PART OF THE CAPITAL
OF
PROMETHEUS PHARMACEUTICALS INC.

It is hereby certified that

1. The name of the corporation (hereinafter called the “Corporation”) is Prometheus Pharmaceuticals Inc.

2. The Corporation has not received any payment for any of its stock.

3. The Certificate of Incorporation of the Corporation is hereby amended by striking out Article 1 thereof and by substituting in lieu of said Article the following new Article:

   “I.

   “The name of the Corporation is Bennu Pharmaceuticals Inc.”

4. The amendment of the Certificate of Incorporation of the corporation herein certified was duly adopted, pursuant to the provisions of Section 241 of the General Corporation Law of the State of Delaware, by the sole incorporator, no directors having been named in the Certificate of Incorporation and no directors having been elected.


/s/ Claudia Immerzeel
Claudia Immerzeel, Sole Incorporator
THIRD AMENDMENT to LICENSE AGREEMENT

UC CONTROL NUMBER 2008-03-0236, EFFECTIVE OCTOBER 31, 2007

between

RAPTOR THERAPEUTICS, INC.

and

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

for:

CASE NO. SD2006-092: “Enterically Coated Cysteamine”

This third amendment (“Third Amendment”) to the License Agreement, UC Control No. 2008-03-0236, for Case No. SD2006-092 “Enterically Coated Cysteamine” effective October 31, 2007, as amended and restated as of October 30, 2012, (“Agreement”) is made as of 1 March, 2013 (the “Amendment Date”) by and between Raptor Pharmaceuticals, Inc. (f/k/a Raptor Therapeutics, Inc.), a Delaware corporation having an address at 9 Commercial Blvd., Suite 200, Novato, CA, 94949 (“LICENSEE”) and The Regents of the University of California, a California corporation having its statewide administrative offices at 1111 Franklin Street, Oakland, California 94607-5200 (“UNIVERSITY”), represented by its San Diego campus having an address at University of California, San Diego, Technology Transfer Office, Mail Code 0910, 9500 Gilman Drive, La Jolla, California 92093-0910 (“UCSD”).

Whereas, on December 28, 2012, Raptor Therapeutics, Inc. was merged with Raptor Discoveries, Inc. and as part of such reorganization was renamed Raptor Pharmaceuticals, Inc.

Whereas, LICENSEE and UNIVERSITY wish to amend the Agreement to clarify certain of LICENSEE’s obligations with respect to the development of Licensed Products under such Agreement.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the parties amend the Agreement and otherwise agree as follows:

1. Each reference to “Raptor Therapeutics, Inc.” in the Agreement is hereby replaced with “Raptor Pharmaceuticals, Inc.”.

2. The following Section 1.13 is hereby added to the Agreement:

   “1.13 “Regulatory Authority” means (a) the FDA in the United States or (b) any equivalent agency or governmental authority in any country or other jurisdiction outside the United States that has responsibility for granting any licenses or approvals necessary for the marketing and/or sale of a Licensed Product in such country or other jurisdiction (including, without limitation, any supra-national agency such as the “European Medicines Agency” (EMA)).”
Section 3.4(b) of the Agreement is hereby deleted and restated in its entirety as follows:

(b) If LICENSEE fails to perform any of its obligations specified in Paragraphs 3.4(a)(i)-(vii), then:

(i) UNIVERSITY shall have the right and option to either terminate this Agreement or change LICENSEE’s exclusive license to a nonexclusive license;

(ii) Notwithstanding Paragraph 3.4(b)(i), in the event that LICENSEE believes in good faith that there exists a significant issue related to the safety and/or efficacy of a Licensed Product for treatment of any indication, or that further development of a Licensed Product is not commercially viable in such indication, then LICENSEE shall so notify UNIVERSITY in writing, and upon University’s written agreement, LICENSEE shall have the right to delay or discontinue development of such Licensed Product for the treatment of such indication for up to six (6) months. In the event that LICENSEE does not receive a response from UNIVERSITY within thirty (30) days of LICENSEE’s written notice, UNIVERSITY shall be deemed to have provided its written agreement upon the end of such thirty (30) day period. If, after six (6) months, LICENSEE does not resume development of such Licensed Product for the treatment of such indication, UNIVERSITY shall have the right and option, from and after the date of written notice from UNIVERSITY: (A) to terminate this Agreement solely with respect to such indication, in which event, such indication shall be deemed to be excluded from the definition of “Field”; or (B) to change LICENSEE’s exclusive license to a non-exclusive license solely with respect to such indication; and

(iii) Notwithstanding Paragraph 3.4(b)(i), from and after the date on which LICENSEE first obtains regulatory approval from a Regulatory Authority for any indication (e.g., cystinosis), UNIVERSITY would not exercise its rights under Paragraph 3.4(b)(i) with respect to such indication, or to change LICENSEE’s exclusive license to a non-exclusive license for such indication, as a result of LICENSEE’s failure to satisfy its obligations under Paragraph 3.4(a) with respect to a different indication, which is not yet approved for sale.”

These rights, if exercised by UNIVERSITY, supersede the rights granted in Article 2.

4. MISCELLANEOUS.

4.1 Defined Terms. All terms used, but not defined, herein shall have the respective meanings set forth in the Agreement.

4.2 Continuing Effect. This Third Amendment shall be effective for all purposes from and after the Amendment Date. Except as otherwise expressly modified by this Third Amendment, the Agreement shall remain in full force and effect in accordance with its terms.

4.3 Governing Laws. This Third Amendment shall be governed by, interpreted and construed in accordance with the laws of the State of California, without regard to conflicts of law principles.
4.4 **Counterparts.** The parties agree that this Third Amendment may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute but one and the same instrument. Signatures to this Third Amendment delivered by facsimile or other form of electronic transmission will be deemed to be binding as originals.

[Signature Page Follows]
IN WITNESS WHEREOF, both UNIVERSITY and LICENSEE have executed this Third Amendment, in duplicate originals, by their respective and duly authorized officers on the day and year written below.

RAPTOR PHARMACEUTICALS, INC.:

By: /s/ Thomas E. Daley
Name: Thomas E. Daley
Title: Chief Business Officer
Date: 3/11/13

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA:

By: /s/ Jane Moores, Ph.D.
Name: Jane Moores, Ph.D.
Title: Assistant Vice-Chancellor, Intellectual Property
Date: 3/6/13
FOURTH AMENDMENT to LICENSE AGREEMENT
UC CONTROL NUMBER 2008-03-0236, EFFECTIVE OCTOBER 31, 2007
between
RAPTOR PHARMACEUTICALS, INC.
and
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA
for:
CASE NO. SD2006-092: “Enterically Coated Cysteamine”

This fourth amendment (“Fourth Amendment”) to the License Agreement, UC Control No. 2008-03-0236, for Case No. SD2006-092 “Enterically Coated Cysteamine” effective October 31, 2007, as amended as of November 11, 2008, amended and restated as of October 30, 2012 and amended as of March 1, 2013 (“Agreement”) is made as of December 16, 2013 (the “4th Amendment Date”) by and between Raptor Pharmaceuticals, Inc. (f/k/a Raptor Therapeutics, Inc.), a Delaware corporation having an address at 5 Hamilton Landing, Suite 160, Novato, CA, 94949 (“LICENSEE”) and The Regents of the University of California, a California corporation having its statewide administrative offices at 1111 Franklin Street, Oakland, California 94607-5200 (“UNIVERSITY”), represented by its San Diego campus having an address at University of California, San Diego, Technology Transfer Office, Mail Code 0910, 9500 Gilman Drive, La Jolla, California 92093-0910 (“UCSD”).

Whereas, LICENSEE has moved its physical address and the address for correspondence will be updated to reflect this new situation;

Whereas, LICENSEE has changed its fiscal calendar such that it is now on a calendar year fiscal calendar; and

Whereas, LICENSEE and UNIVERSITY wish to amend the Agreement to clarify certain of LICENSEE’s obligations with respect to the timing of reports and payments for royalties.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the parties amend the Agreement and otherwise agree as follows:

1. Section 4.1(b) of the Agreement is hereby deleted and restated in its entirety as follows:

   (b) Royalty Reports. After the first commercial sale of a Licensed Product anywhere in the world, LICENSEE shall submit to UNIVERSITY quarterly royalty reports on or before each March 31, June 30, September 30 and December 31 of each year. Each royalty report shall cover LICENSEE’s (and each Affiliate’s and Sublicensee’s) most recently completed calendar quarter (until the expiration or termination of such period or the earlier expiration or termination of this Agreement) and shall show:
the date of first commercial sale of a Licensed Product in each country;

(ii) the gross sales, deductions as provided in Paragraph 1.5 and Net Sales during the most recently completed calendar quarter and the royalties, in US dollars, payable with respect thereto;

(iii) the applicable Indication for each type of Licensed Product sold;

(iv) the number of each type of Licensed Product sold;

(v) Sublicense Fees and royalties received during the most recently completed calendar quarter in US dollars, payable with respect thereto;

(vi) the method used to calculate the royalties; and

(vii) the exchange rates used.

If no sales of Licensed Products have been made and no Sublicense revenue has been received by LICENSEE during any reporting period, LICENSEE shall so report.

2. Section 4.3(b)(ii) of the Agreement is hereby deleted and restated in its entirety as follows:

“(ii) LICENSEE shall pay to UNIVERSITY earned royalties within forty-five (45) days after the end of each previously stated quarter [noted in section 4.1(b)]. Each such payment shall be for earned royalties accrued within such preceding quarter.”

3. Section 10.1 of the Agreement is hereby deleted and restated in its entirety as follows:

10.1 Correspondence. Any notice or payment required to be given to either party under this Agreement shall be deemed to have been properly given and effective:

(b) on the date of delivery if delivered in person, or

(c) five (5) days after mailing if mailed by first-class or certified mail, postage paid, to the respective addresses given below, or to such other address as is designated by written notice given to the other party.

If sent to LICENSEE:
Raptor Pharmaceuticals, Inc.
5 Hamilton Landing, Suite 160
Novato, CA 94949
Attention: Ted Daley, Chief Business Officer
Phone: 415-408-6207 (direct)
Fax: 415-382-8002
If sent to UNIVERSITY by mail:
University of California, San Diego
Technology Transfer Office 9500 Gilman Drive
Mail Code 0910
La Jolla, CA 92093-0910
Attention: Assistant Vice Chancellor

If sent to UNIVERSITY by courier:
University of California, San Diego
Technology Transfer Office
10300 North Torrey Pines Road
Torrey Pines Center North, Third Floor
La Jolla, CA 92037
Attention: Assistant Vice Chancellor

4. MISCELLANEOUS.

4.1 Defined Terms. All terms used, but not defined, herein shall have the respective meanings set forth in the Agreement.

4.2 Continuing Effect. This Fourth Amendment shall be effective for all purposes from and after the 4th Amendment Date. Except as otherwise expressly modified by this Fourth Amendment, the Agreement shall remain in full force and effect in accordance with its terms.

4.3 Governing Laws. This Fourth Amendment shall be governed by, interpreted and construed in accordance with the laws of the State of California, without regard to conflicts of law principles.

4.4 Counterparts. The parties agree that this Fourth Amendment may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute but one and the same instrument. Signatures to this Fourth Amendment delivered by facsimile or other form of electronic transmission will be deemed to be binding as originals.
IN WITNESS WHEREOF, both UNIVERSITY and LICENSEE have executed this Fourth Amendment, in duplicate originals, by their respective and duly authorized officers on the day and year written below.

RAPTOR PHARMACEUTICALS, INC.:

By: /s/ Thomas E. Daley
Name: Thomas E. Daley
Title: Chief Business Officer
Date: 12/16/13

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA:

By: /s/ Jane Moores, Ph.D.
Name: Jane Moores, Ph.D.
Title: Assistant Vice-Chancellor, Intellectual Property
Date: 1/6/14
This API Supply Agreement (“Agreement”) is made as of the 3rd day of November, 2010 (“Effective Date”), by and between Raptor Therapeutics, Inc., a Delaware Corporation, with a place of business at 9 Commercial Boulevard, Suite 200, Novato, California 94949, U.S.A. (“RAPTOR”), and Cambrex Profarmaco Milano, Via Cucchiari 17, 20155 Milan, Italy (“CAMBREX”). RAPTOR and CAMBREX may be referred to individually as a “Party” or collectively as the “Parties.”

**Background**

RAPTOR is engaged in the business of developing and commercializing therapeutic products through the application of specialized drug targeting platforms and formulation expertise for under-served patient populations;

CAMBREX is engaged in the manufacture and supply of active pharmaceutical ingredients for research and development purposes and/or commercial use;

RAPTOR desires to purchase from CAMBREX, and CAMBREX desires to supply to RAPTOR, the active pharmaceutical ingredient known as cysteamine bitartrate (as further defined below, the “API”) for use by RAPTOR in manufacturing finished products incorporating such active pharmaceutical ingredient, all in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the Parties hereto agree as follows:

**ARTICLE 1**

**DEFINITIONS**

1.1 “Affiliate” or “Affiliates” shall mean, with respect to a Party, any corporation, limited liability company or other business entity controlling, controlled by or under common control with such Party, for so long as such relationship exists. For the purposes of this definition, control means: (a) to possess, directly or indirectly, the power to direct affirmatively the management and policies of such corporation, limited liability company or other business entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) ownership of more than fifty percent (50%) of the voting stock in such corporation, limited liability company or other business entity (or such lesser percent as may be the maximum that may be owned pursuant to Applicable Laws of the country of incorporation or domicile, as applicable).

1.2 “API” shall mean cysteamine bitartrate, with the chemical structure set forth in Exhibit 1.2 attached hereto.
1.3 “Applicable Laws” shall mean: (a) all relevant federal, state and local laws, statutes, rules, regulations, and ordinances in the United States, Europe and/or any other jurisdiction, as well as industry standards and guidelines applicable to the manufacture and supply of API, including, the United States Federal Food, Drug and Cosmetic Act; (b) cGMPs; and (c) all applicable regulations and guidelines of any Regulatory Authority; in each case, together, with any and all amendments thereto.

1.4 “cGMPs” shall mean current good manufacturing practices, as provided for (and as amended from time to time) in the Current Good Manufacturing Practice regulations promulgated by the FDA under the United States Food, Drug and Cosmetic Act and in the European Community Directive 91/356/EEC (Principles and guidelines of good manufacturing practice for medicinal products), as well as applicable documents developed by the International Conference on Harmonization (ICH), and similar requirements of other Regulatory Authorities, and subject to any arrangements, additions or clarifications, and the respective roles and responsibilities, agreed from time to time between the Parties.

1.5 “Drug Master File” or “DMF” shall mean a drug master file filed with the FDA or the EMEA which includes information relating to the facilities, processes, or articles used in manufacturing, processing, packaging, and storing of the API, or any equivalent filing in any jurisdiction outside the United States or Europe.

1.6 “EMEA” shall mean the European Medicines Evaluation Agency, or any successor entity thereto performing substantially similar functions.

1.7 “Facility” shall mean CAMBREX’s cGMP-compliant facilities located at Via Cucchiari 17, 20155 Milan, Italy.

1.8 “FDA” shall mean the United States Food and Drug Administration, or any successor entity thereto performing substantially similar functions.

1.9 “Inflation Index” shall mean the annual average rate of change in the Harmonized Indices of Consumer Prices for the European Union, as published by Eurostat (or, to the extent that such index ceases to exist, any alternative inflation index mutually agreed by the Parties).

1.10 “Price” shall mean the price for the API set forth in Exhibit 3.1.

1.11 “Product” shall mean a finished pharmaceutical product incorporating the API.

1.12 “Regulatory Authority” shall mean the FDA, EMEA or a regulatory body with similar regulatory authority in a jurisdiction other than the United States or Europe.

1.13 “Specifications” shall mean those specifications and release requirements and/or procedures and/or other similar requirements for the manufacture of API, as the same are set forth in Exhibit 1.13.
1.14 Additional Defined Terms. Each of the following terms shall have the meaning described in the corresponding section of this Agreement indicated below:

<table>
<thead>
<tr>
<th>Term</th>
<th>Section Defined</th>
<th>Term</th>
<th>Section Defined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agreement</td>
<td>Introduction</td>
<td>[...****...]</td>
<td>2.1</td>
</tr>
<tr>
<td>CAMBREX</td>
<td>Introduction</td>
<td>Party / Parties</td>
<td>Introductions</td>
</tr>
<tr>
<td>Confidential Information</td>
<td>8.1</td>
<td>Purchase Order</td>
<td>2.3.2</td>
</tr>
<tr>
<td>Effective Date</td>
<td>Introduction</td>
<td>Q1, Q2, Q3, Q4</td>
<td>2.2</td>
</tr>
<tr>
<td>Force Majeure Event</td>
<td>11.6</td>
<td>Quality Agreement</td>
<td>4.2</td>
</tr>
<tr>
<td>Indemnitee</td>
<td>10.3</td>
<td>RAPTOR</td>
<td>Introduction</td>
</tr>
<tr>
<td>Indemnitor</td>
<td>10.3</td>
<td>Renewal Term</td>
<td>7.1</td>
</tr>
<tr>
<td>Initial Term</td>
<td>7.1</td>
<td>Required Changes</td>
<td>4.4</td>
</tr>
<tr>
<td>JAMS</td>
<td>11.4</td>
<td>Rolling Forecast</td>
<td>2.2</td>
</tr>
<tr>
<td>Laboratory</td>
<td>4.3.2</td>
<td>Shortage of Supply</td>
<td>2.5</td>
</tr>
<tr>
<td>Late Shipment</td>
<td>7.3</td>
<td>Term</td>
<td>7.1</td>
</tr>
</tbody>
</table>

ARTICLE 2
SUPPLY

2.1 API Supply. Subject to the terms and conditions of this Agreement, CAMBREX shall supply to RAPTOR, such quantities of the API as may be specified in purchase orders submitted by RAPTOR pursuant to Section 2.3 below from time to time during the Term. All API to be supplied under this Agreement shall be manufactured by CAMBREX at the Facility, in conformance with Applicable Laws, the Specifications and the Quality Agreement. Subject to Section 2.5, RAPTOR agrees that during the Term, RAPTOR will purchase: [...****...].

2.2 Forecasts. Beginning no later than [...****...], RAPTOR shall provide CAMBREX with an initial forecast of the quantities of the API estimated to be required during [...****...] (each, a “Rolling Forecast”). Subject to Section 2.3 below, such Rolling Forecasts are non-binding and serve only to facilitate CAMBREX’s production scheduling.

2.3 Orders.

2.3.1 Orders. Together with each Rolling Forecast provided under Section 2.2 above, RAPTOR shall place a firm order with CAMBREX for supplies of API for delivery in [...****...]. The total quantity of API ordered by RAPTOR for delivery in [...****...] shall equal at least the...
quantity of API forecasted for […] in such Rolling Forecast. For the avoidance of doubt, RAPTOR may order quantities of API in addition to those specified in the then-current Rolling Forecast for delivery hereunder in accordance with the lead times therefor and subject to CAMBREX's total capacity constraints; provided that CAMBREX shall use commercially reasonable efforts to accept and fulfill all orders for API provided by RAPTOR under this Agreement.

2.3.2 Form of Orders. RAPTOR’s orders shall be made pursuant to a written purchase order (each, a “Purchase Order”) that specifies […] unless otherwise mutually agreed and CAMBREX shall use commercially reasonable efforts to achieve a maximum lead time of no more than […] RAPTOR is informed and understands that production of the API is scheduled based upon demand, and no campaign for production of the API will be scheduled until a firm Purchase Order is placed. To the extent a particular Purchase Order issued by RAPTOR pursuant to this Section 2.3.2 is for less than a full lot of API (or a multiple thereof), upon CAMBREX’s reasonable written request, RAPTOR will confirm its acceptance to increase the applicable Purchase Order to a full lot of API (or the nearest whole multiple thereof). Subject to the preceding sentence, CAMBREX shall accept all orders RAPTOR submits to CAMBREX in accordance with this Article 2. CAMBREX shall provide to RAPTOR written notice of CAMBREX’s acceptance (each, an “Acceptance Notice”) of each Purchase Order within […] of CAMBREX’s receipt of such Purchase Order and each such notice shall include confirmation of the delivery date of the applicable quantity of API; provided that to the extent no delivery date is included in an Acceptance Notice issued by CAMBREX or CAMBREX fails to issue an Acceptance Notice within the applicable time period, the applicable delivery date shall be deemed to be the delivery date specified by RAPTOR in the corresponding Purchase Order. Except as to the quantity of API, delivery date and delivery location specified in a Purchase Order which shall be binding on the Parties, NO TERMS OR CONDITIONS CONTAINED IN ANY PURCHASE ORDER, ORDER ACKNOWLEDGMENT OR SIMILAR STANDARDIZED FORM SHALL BE CONSTRUED TO AMEND OR MODIFY THE TERMS OF THIS AGREEMENT, AND ALL SUCH TERMS AND CONDITIONS ARE HEREBY EXCLUDED.

2.4 Shipping. CAMBREX shall deliver quantities of API ordered by RAPTOR in accordance with Section 2.3 above, to the location specified in the applicable Purchase Order. All shipments shall be […] CAMBREX shall ship API, together with all relevant documentation relating to the API, in accordance with any agreed-upon shipment specifications or as otherwise reasonably directed by RAPTOR in writing and in accordance with this Agreement. RAPTOR shall only be obligated to pay for quantities of API actually delivered in compliance with the applicable Purchase Order and the terms of this Agreement.

2.5 Shortage of Supply. If CAMBREX is unable, or anticipates that it will not be able, to supply RAPTOR’s requirements for the API in accordance with Section 2.3 above a “Shortage
of Supply”), CAMBREX shall immediately notify RAPTOR in writing of the same, and shall include in such notice its best estimate of the duration of the delay. CAMBREX shall, at its own cost, use commercially reasonable efforts to remedy any Shortage of Supply and resume supplying API meeting the requirements of this Agreement to RAPTOR as soon as possible. In addition to the foregoing measures, if CAMBREX is unable to supply RAPTOR’s requirements of API, CAMBREX shall allocate the quantities of the API that CAMBREX has in inventory, and that CAMBREX is able to produce, on a reasonable worldwide basis (based upon sales history and realistic forecasted demand). […] In the event of a Shortage of Supply exceeding […***…], in addition to any other rights or remedies that RAPTOR may have under this Agreement, or at law or in equity, RAPTOR shall be relieved from its obligations to purchase any quantities of API identified in any outstanding Purchase Order.

ARTICLE 3
PAYMENTS

3.1 Price. Except as otherwise provided herein, the Price for the API subject to this Agreement shall be listed on Exhibit 3.1. […]

3.2 Invoicing; Payment. CAMBREX (or CAMBREX’s agent, GYMA Laboratories) shall submit an invoice to RAPTOR upon shipment of API ordered by RAPTOR hereunder. All invoices shall be sent to the address specified in the Purchase Order therefor, and each invoice shall state the Price for the API in a given shipment, plus any taxes and other costs incident to the purchase or shipment initially paid by CAMBREX but to be borne by RAPTOR hereunder. All payments shall be made by direct bank transfer to an account designated in CAMBREX’s invoice. Payment terms shall be […] from invoice date. Payment by RAPTOR shall

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not constitute acceptance of any shipment of API or impair RAPTOR’s right of inspection and rejection under Article 4 below.

**ARTICLE 4**

**QUALITY**

4.1 Quality Assurance. All API supplied by CAMBREX shall meet the current Specifications and shall be manufactured in accordance with all Applicable Laws and the Quality Agreement at the Facility. CAMBREX agrees that, prior to each shipment of API hereunder, it shall perform quality control procedures reasonably necessary to ensure that the API to be shipped conforms fully with the Specifications. Each shipment of API shall be accompanied by a certificate of analysis […] and such additional documents as may be specified in the Quality Agreement or as otherwise reasonably required by RAPTOR from time to time.

4.2 Quality Agreement. Prior to RAPTOR issuing its first Purchase Order to CAMBREX pursuant to this Agreement (and in any event, […] after the Effective Date), the Parties shall enter into an agreement specifying the Parties’ respective responsibilities for storage, release, quality control and quality assurance with respect to the API (the “Quality Agreement”). The Quality Agreement is not intended and shall not be construed to limit any of the rights and obligations of the Parties set forth in the body of this Agreement. Subject to the foregoing, to the extent possible, the Quality Agreement will be interpreted with the terms set forth in the body of this Agreement. If there is any conflict or inconsistency between the terms of the Quality Agreement and the terms set forth in the body of this Agreement, however, the terms set forth in the body of this Agreement shall control.

4.3 Rejection and Replacement of API.

4.3.1 Inspection by RAPTOR. RAPTOR and/or its designee shall have […] following its receipt of a shipment of API to reject such API on the grounds that all or part of the shipment fails to conform to the applicable Specifications or otherwise fails to conform to the warranties given by CAMBREX in Section 9.2, which rejection shall be accomplished by giving written notice to CAMBREX summarizing the manner in which all or part of such shipment fails to meet the foregoing requirements.

4.3.2 Resolution of Disputes. CAMBREX shall respond in writing to a rejection notice from RAPTOR within […] from the date of receipt of such rejection notice in accordance with Section 4.3.1 above. If CAMBREX does not agree with RAPTOR’s determination that such API fails to conform to the Specifications or the warranties provided by CAMBREX in Section 9.2, then CAMBREX and RAPTOR shall use reasonable efforts to resolve such disagreement as promptly as possible. Without limiting the foregoing, […]
4.3.3 **Replacement of API.** API accepted by CAMBREX as not meeting the applicable requirements and/or the Specifications, or which is determined by the Laboratory not to meet such requirements and/or the Specifications, shall be returned by RAPTOR to CAMBREX, or disposed of, as directed by CAMBREX and at CAMBREX’s expense. CAMBREX shall replace all such rejected API within the shortest possible time, but in any event, within […] days after its receipt of notice of such rejection (or, if applicable, the Laboratory’s determination that such API was non-conforming), […] days. Without limiting any other provision in this Agreement, RAPTOR may withhold payment for such shipment or the portion thereof that has been rejected by RAPTOR pursuant to this Section 4.3. The warranties given by CAMBREX in Section 9.2 below shall survive any failure to reject by RAPTOR under this Section 4.3.

4.4 **Changes.**

4.4.1 CAMBREX shall maintain change control systems that ensure that all major changes are appropriately notified in a timely manner and in certain cases, as provided in Section 4.4.2 below or otherwise agreed by the Parties in the Quality Agreement, are agreed with RAPTOR.

4.4.2 CAMBREX shall promptly inform RAPTOR in writing of any proposal of major change to the manufacturing process, equipment, packaging, testing, specifications, or any item specially mentioned in the DMF. […] Notwithstanding the foregoing, in no event will CAMBREX implement any major changes with respect to quantities of API to be supplied to RAPTOR, before obtaining RAPTOR’s approval (if applicable) and prior to all necessary filings with and approvals by applicable Regulatory Authorities have been made or obtained by CAMBREX and/or RAPTOR, as applicable.
ARTICLE 5
RECORDS; INSPECTIONS

5.1 Record Keeping. CAMBREX shall generate and maintain complete and accurate records and samples as necessary to evidence compliance with this Agreement and all Applicable Laws and other requirements of applicable governmental authorities relating to the manufacture of API. All such records and samples shall be maintained by CAMBREX in accordance with the procedures set out in the Quality Agreement for the applicable time period specified therein.

5.2 Inspection. During the term of this Agreement, and for [...***...] thereafter, or as otherwise required by Applicable Laws, RAPTOR (and/or its designee) shall have the right to inspect and audit, during regular business hours: (a) any facility at which any of the manufacturing or processing activities relating to the API are performed, including the Facility; (b) any of CAMBREX’s manufacturing and quality control records and all other documentation relating to the manufacturing and processing activities with respect to the API (including any internal quality control audits or reviews conducted by CAMBREX); and (c) accounts and records for the purpose of determining the amounts payable or owed under this Agreement. Such inspections and audits shall be conducted [...***...] and in accordance with any procedures for audits specified in the Quality Agreement; provided however that RAPTOR shall have the right to conduct additional inspections and audits under this Section 5.2 [...***...].

ARTICLE 6
REGULATORY MATTERS

6.1 Regulatory Actions. CAMBREX shall permit the FDA and other Regulatory Authorities, as applicable, to conduct such inspections of the Facility, and/or any other facility at which any of the manufacturing or processing activities relating to the API are performed, as such Regulatory Authorities may request, including pre-approval inspections, and shall cooperate with such Regulatory Authorities with respect to such inspections and any related matters, in each case that is related to the manufacture and supply of APL. CAMBREX shall (a) give RAPTOR prior written notice of any such inspections related to the API; and (b) keep RAPTOR informed about the results and conclusions of each such regulatory inspection, including any actions taken by CAMBREX to remedy any conditions cited in such inspections related to the API; all as further described, and in accordance with the procedures specified, in the Quality Agreement.

6.2 Regulatory Cooperation. CAMBREX agrees to provide to RAPTOR, as requested, with all information and data in CAMBREX’s possession or control necessary or reasonably useful for RAPTOR (and/or its designees) to apply for, obtain and maintain regulatory approvals for any Product in any country, including information relating to the Facility, or the methodology, raw materials and intermediates used in the manufacture, processing or packaging of API, or any other matters required or requested to be provided to the FDA or any other Regulatory Authority. In addition, CAMBREX agrees to cooperate with RAPTOR (and/or its designees) with respect to
6.3 **Drug Master Files.** CAMBREX shall provide, or cooperate with RAPTOR to provide, the appropriate authorizations to each applicable Regulatory Authority allowing RAPTOR (and/or its designee) the right to reference all Drug Master Files to support any regulatory filing for any Product developed, manufactured and/or commercialized by RAPTOR, its Affiliates and/or licensees. If the [...] filed with the FDA as of the Effective Date is not sufficient to support the applicable regulatory filing for a Product, CAMBREX shall supplement such Drug Master File or file a separate Drug Master File(s) with the applicable Regulatory Authority(ies) (including, if applicable, the EMEA,) as necessary to support such regulatory filing(s); provided that [...***…]. Any such new DMF filing will also require process validation and pilot work, and [...***…]. In addition, RAPTOR agrees to purchase [...***…] of API manufactured for the purposes of performing such validation/pilot work. CAMBREX shall use commercially reasonable efforts to correct any deficiencies of such Drug Master File(s) identified by any Regulatory Authority in a prompt and efficient manner so as to prevent any delay in RAPTOR (or any of its Affiliates or licensees) obtaining regulatory approval for a Product based on such Drug Master File(s). In addition, CAMBREX shall be responsible for maintaining such Drug Master File(s) in accordance with Applicable Laws and ensuring that all data and information incorporated therein is accurate and current as necessary to support obtaining and maintaining the applicable regulatory filing(s) and regulatory approval(s) by RAPTOR (and/or its designees) provided that [...***…].

6.4 **Recall.** Any recalling any of RAPTOR’s Products shall, as between the Parties, be controlled solely by RAPTOR; provided, however, that if CAMBREX reasonably believes a recall may be necessary with respect to any API provided under this Agreement, CAMBREX shall immediately notify RAPTOR in writing. CAMBREX shall provide assistance to RAPTOR (and/or its designee), as reasonably requested, in conducting such recall, including providing all pertinent records that may assist RAPTOR in effecting such recall.

**ARTICLE 7**

**TERM AND TERMINATION**

7.1 **Term.** The term of this Agreement shall commence on the Effective Date and shall continue for an initial term of ten (10) years (“Initial Term”). Thereafter, this Agreement shall automatically be renewed for successive two (2) year periods (each, a “Renewal Term;” and all such Renewal Terms together with the Initial Term, collectively, the “Term”), unless either Party notifies the other Party in writing at least one (1) year prior to the expiration of the then-current Term that such Party does not wish to renew this Agreement for an additional term.
7.2 **Termination for Material Breach.** If either Party materially breaches this Agreement or the Quality Agreement at any time, the non-breaching Party shall have the right to terminate this Agreement by written notice to the breaching Party, if such breach is not cured […] after written notice is given by the non-breaching Party to the breaching Party specifying the breach.

7.3 **Termination for Failure to Supply.** Without limiting any other provision of this Agreement, including Sections 2.5 and 7.2 above, if […] Late Shipments of API occur in any […] then RAPTOR shall have the right to terminate this Agreement immediately by written notice to CAMBREX. For purposes of this Section 7.3, a “Late Shipment” shall mean […]..

7.4 **Termination by RAPTOR.** RAPTOR may terminate this Agreement immediately upon written notice to CAMBREX if: (a) RAPTOR, in its sole discretion, determines that Products will not be marketed by RAPTOR (or its designee); or (b) the FDA or EMEA withdraws approval of, or fails to approve, the manufacturing or marketing by RAPTOR (or its designee) of all Products then in development.

7.5 **Effects of Termination.** It is understood that termination or expiration of this Agreement shall not relieve a Party from any liability that, at the time of such termination or expiration, has already accrued to the other Party, except as specified in this Section 7.5. Upon expiration or termination of this Agreement for any reason (other than by RAPTOR pursuant to Section 7.2 above), to the extent CAMBREX so notifies RAPTOR, RAPTOR shall have the obligation to purchase all API ordered under any outstanding Purchase Orders. […]..

7.6 **Survival.** The provisions of Sections 4.1, 5.1, 5.2, 7.5, 11.2, 11.3 and 11.4 and Articles 6, 8, 9 and 10 shall survive the expiration or termination of this Agreement for any reason. In addition, the provisions of the Quality Agreement shall survive expiration or termination of this Agreement until the date of expiration of the last-to-expire batch of API delivered by CAMBREX to RAPTOR hereunder. All other rights and obligations of the Parties shall cease upon termination of this Agreement. Except as otherwise expressly provided in this Section 7.6, all other rights and obligations of the Parties shall terminate.

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-10-
ARTICLE 8
CONFIDENTIALITY

8.1 Confidential Information. Except as otherwise provided in this Article 8, during the Term and for a period of […] thereafter, each Party shall maintain in confidence and only use for the purposes of this Agreement any confidential information, data and/or materials supplied to such Party by the other Party (“Confidential Information”). A receiving Party’s obligations under this Article 8 shall not apply to any information, data or material that, in each case as demonstrated by written documentation: (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; (d) was subsequently lawfully disclosed to the receiving Party by a person other than the disclosing Party; or (e) was independently developed by the receiving Party without reference to any Confidential Information of the disclosing Party.

8.2 Confidentiality; Non-Disclosure. Each Party agrees not to disclose any Confidential Information of the other Party except to those employees and consultants who have a need to know and provided that each person to whom Confidential Information is disclosed agrees to be bound by the same terms regarding the disclosure and use of Confidential Information as set forth in this Article 8. Each Party further agrees not to use or disclose the Confidential Information of the other Party except as otherwise permitted by this Agreement, or as may be necessary to exercise its rights or perform its obligations under this Agreement. Nothing contained in this Article 8 shall prevent either Party from disclosing any Confidential Information of the other Party to: (a) regulatory agencies for the purpose of obtaining approval to distribute and market Products; provided, however, that all reasonable steps are taken to maintain the confidentiality of such Confidential Information to be disclosed; (b) to accountants, lawyers or other professional advisors or in connection with a merger, acquisition, securities offering or other strategic transaction, subject in each case, to the recipient entering into an agreement to protect such Confidential Information from disclosure; or (c) is required by law or regulation to be disclosed; provided, however, that the Party subject to such disclosure requirement has provided written notice to the other Party promptly upon receiving notice of such requirement in order to enable the other Party to seek a protective order or otherwise prevent disclosure of such Confidential Information.

ARTICLE 9
REPRESENTATIONS AND WARRANTIES

9.1 Mutual Warranties. Each Party represents and warrants to the other Party that: (a) it has the power and authority to enter into this Agreement and to perform its obligations hereunder and to grant to the other Party the rights granted to such other Party under this Agreement; (b) it has obtained all necessary corporate approvals to enter into and execute this Agreement and to perform its obligations hereunder; and (c) the execution, delivery and

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performance of this Agreement 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 will it enter into or assume during the Term, any contract or other obligation with a third party that would in any way limit the performance of its obligations under this Agreement.

9.2 CAMBREX Warranties. CAMBREX represents and warrants that:

9.2.1.1 API. All API supplied hereunder shall comply with all Applicable Laws and the Quality Agreement and meet all Specifications, and CAMBREX shall perform and document all manufacturing and supply activities contemplated herein in compliance with all Applicable Laws.

9.2.1.2 Shelf Life. The API has a shelf life of […***…]. All API supplied by CAMBREX under this Agreement shall have a shelf life of no less than […***…] at the time of delivery of such API to RAPTOR (or its designee).

9.2.1.3 Facilities and Equipment. The Facility, all equipment used for the manufacture of API within the Facility and the activities contemplated herein will comply with all Applicable Laws and CAMBREX shall obtain and maintain all governmental registrations, permits, licenses and approvals necessary for CAMBREX to manufacture and supply API to RAPTOR, and otherwise to perform its obligations, under this Agreement.

9.2.1.4 No Encumbrance. Title to all API provided to RAPTOR under this Agreement shall pass as provided in this Agreement, free and clear of any security interest, lien, or other encumbrance.

9.2.1.5 Personnel. Neither CAMBREX, nor any of its Affiliates, nor, to the best of CAMBREX’s knowledge, any of their respective employees have been “debarred” by the FDA, or subject to a similar sanction from any Regulatory Authority in any jurisdiction outside the United States, nor have debarment proceedings against CAMBREX, any of its Affiliates, or any of their respective employees been commenced. CAMBREX will promptly notify RAPTOR in writing if any such proceedings have commenced or if CAMBREX, any of its Affiliates, or any of their respective employees are debarred by the FDA or any other Regulatory Authority.

9.3 RAPTOR Warranties. RAPTOR represents and warrants that it shall comply in all materials respects with all Applicable Laws pertaining to the distribution, sale, and/or marketing of Product.

9.4 DISCLAIMER. EXCEPT AS PROVIDED IN THIS ARTICLE 9, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES (EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER HEREOF AND EACH PARTY EXPRESSLY DISCLAIMS ANY SUCH ADDITIONAL REPRESENTATIONS AND WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES.

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-12-
OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 10
INDEMNIFICATION AND LIMITATION OF LIABILITY

10.1 RAPTOR. It is understood that CAMBREX has no control over the ultimate use of the API or Products. RAPTOR shall indemnify, defend and hold harmless CAMBREX, its directors, officers, employees, agents, successors and assigns from and against any liabilities, expenses or costs (including reasonable attorneys’ fees and court costs) arising out of […***…].

10.2 CAMBREX. CAMBREX shall indemnify, defend and hold harmless RAPTOR, its directors, officers, employees, agents, successors and assigns from and against all liabilities, expenses, and costs (including reasonable attorneys’ fees and court costs) arising out of any […***…].

10.3 Indemnification Procedure. Any Party seeking indemnification under this Article 10 (the “Indemnitee”) shall: (a) promptly notify the indemnifying Party (the “Indemnitor”) of such claim; (b) provide the Indemnitor sole control over the defense and/or settlement thereof; and (c) at the Indemnitor’s request and expense, provide full information and reasonable assistance to Indemnitor with respect to such claims. Without limiting the foregoing, with respect to claims brought under Section 10.1 or 10.2 above, the Indemnitee, at its own expense, shall have the right to participate with counsel of its own choosing in the defense and/or settlement of any such claim. The indemnification under this Article 10 shall not apply to amounts paid in settlement of any claim if such settlement is effected without the consent of the Indemnitor.

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-13-
10.4 **Insurance.** During the Term and for a period of [...***...] thereafter, CAMBREX shall maintain, with financially sound and reputable insurers, insurance reasonably sufficient to cover CAMBREX’s activities and obligations under this Agreement. Without limiting the foregoing, CAMBREX shall maintain: [...***...]. At the reasonable request of RAPTOR, CAMBREX shall provide to RAPTOR copies of certificates of insurance evidencing coverage in accordance with this Section 10.4.

10.5 **LIMITATION OF LIABILITY.** EACH PARTY’S LIABILITY SHALL BE LIMITED AS SET FORTH HEREIN AND IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE, CONSEQUENTIAL OR EXEMPLARY OR PUNITIVE DAMAGES; INCLUDING LOST PROFITS, OR OPPORTUNITY OR GOODWILL, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY AND EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED HOWEVER THAT THE FOREGOING SHALL NOT BE DEEMED TO LIMIT THE INDEMNIFICATION OBLIGATIONS OF EITHER PARTY UNDER THIS ARTICLE 10 TO THE EXTENT A THIRD PARTY RECOVERS ANY PUNITIVE, EXEMPLARY, SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES. CAMBREX’S MAXIMUM LIABILITY TO RAPTOR FOR EACH EVENT GIVING RISE TO ANY INJURIES, CLAIMS, LOSSES, EXPENSES, OR DAMAGES, INCLUDING, BUT NOT LIMITED TO EVENTS RESULTING FROM NEGLIGENCE, ERRORS, OMISSIONS OR STRICT LIABILITY, SHALL NOT EXCEED [...***...]. To the extent that this clause conflicts with any other clause of this Agreement, this clause shall take precedence over such conflicting clause. If applicable law prevents enforcement of this Section 10.5, then this Section shall be deemed modified to provide the maximum protection to each Party as is allowable under applicable law.

**ARTICLE 11**

**GENERAL PROVISIONS**

11.1 **Assignment.** The Parties agree that their rights and obligations under this Agreement may not be assigned or otherwise transferred to a third party without the prior written consent of the other Party hereto. Notwithstanding the foregoing, either Party may transfer or assign its rights and obligations under this Agreement to a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise; provided that such assignee or transferee has agreed to be bound by the terms and

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conditions of this Agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties hereto, their successors and assigns.

11.2 Governing Law. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of New York, as if entered into by New York residents and executed and wholly performed within the State of New York.

11.3 Disputes. Except for any disputes with respect to non-conforming API, which shall be resolved in accordance with Section 4.3 above, if CAMBREX and RAPTOR are unable to resolve any dispute between them, either CAMBREX or RAPTOR may, by written notice to the other, have such dispute referred to the senior management of CAMBREX and RAPTOR for attempted resolution by good faith negotiations within […]***[…] after such notice is received. If the Parties are unable to resolve such dispute in accordance with the aforementioned procedure or within such […]***[…] period, subject to Section 11.4 below, either Party shall have the right to pursue any and all other remedies available to such Party.

11.4 Arbitration. Except for any disputes with respect to non-conforming API, which shall be resolved in accordance with Section 4.3 above, any dispute or claim arising out of or in connection with this Agreement or the performance, breach or termination thereof which is unable to be resolved pursuant to discussions between the Parties in accordance with Section 11.3 above, shall, upon notice by either Party to the other, be submitted to binding arbitration in New York City, New York under the Rules of the Judicial Arbitration and Mediation Services, Inc. (or any successor entity thereto, collectively, “JAMS”) by one (1) arbitrator appointed in accordance with said rules. The arbitrator may engage an independent expert with experience in the subject matter of the dispute to advise the arbitrator. The decision and/or award rendered by the arbitrator shall be written, final and non-appealable and may be entered in any court of competent jurisdiction. The Parties agree that, any provision of applicable law notwithstanding, they will not request, and the arbitrator shall have no authority to award, punitive or exemplary damages against any Party. The costs of any arbitration, including administrative fees and fees of the arbitrator, shall be shared equally by the Parties, unless otherwise determined by the arbitrator. Each Party shall bear the cost of its own attorneys’ and expert fees. Notwithstanding the foregoing, either Party may apply to any court of competent jurisdiction for injunctive relief without breach of this arbitration provision.

11.5 Notices. Any notice or report required or permitted to be given or made under this Agreement by either Party shall be in writing and in English and delivered to the other Party at its address indicated below (or to such other address as a Party may specify by like notice) by courier or by registered or certified airmail, postage prepaid, or by facsimile; provided, however, that all facsimile notices shall be promptly confirmed, in writing, by courier or by registered or certified airmail, postage prepaid. All notices shall be effective as of the date received by the addressee.

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-15-
11.6 **Force Majeure.** Neither Party will be liable for its failure to perform any of its obligations hereunder during any period in which such performance is delayed by acts of God, fire, war, embargo, riots, or other similar cause outside the reasonable control of such Party ("Force Majeure Event"). A Party affected by a Force Majeure Event will promptly notify the other Party, explaining the nature and expected duration thereof and such Party shall use all reasonable efforts to remedy or mitigate such Force Majeure Event and the effects thereof. Notwithstanding the foregoing, if a Party is unable to perform any of its obligations under this Agreement for a period of more than [...] as a result of a Force Majeure Event, the other Party may terminate this Agreement upon written notice to the affected Party.

11.7 **Interpretation.** The headings to the several Articles and Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference only and shall not affect its meaning or interpretation. In this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable.

11.8 **Waiver.** Any waiver of the terms and conditions hereof must be explicitly in writing and executed by a duly authorized officer of the Party waiving compliance. The waiver by either of the Parties of any breach of any provision hereof by the other shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself. The delay or failure of any Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party’s rights at a later time to enforce the same.

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11.9 **Severability.** Should any section, or portion thereof, of this Agreement be held invalid or unenforceable in any jurisdiction by any court of competent authority or by a legally enforceable directive of any governmental body, such section or portion thereof shall be validly reformed so as to approximate the intent of the Parties as nearly as possible and, if unreformable, shall be deemed divisible and deleted with respect to such jurisdiction, but the Agreement shall not otherwise be affected.

11.10 **Independent Contractors.** The relationship of RAPTOR and CAMBREX established by this Agreement is that of independent contractors. Nothing in this Agreement shall be construed to create a partnership, joint venture, agency or other fiduciary relationship between RAPTOR and CAMBREX. Neither Party shall have any right, power or authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other.

11.11 **Entire Agreement; Amendment.** The terms and provisions contained in the Agreement (including the Exhibits hereto and any Purchase Orders issued pursuant hereto) and the Quality Agreement constitute the entire agreement between the Parties and shall supersede all previous communications, representations, agreements or understandings, either oral or written, between the Parties with respect to the subject matter hereof. No agreement or understanding varying or extending this Agreement shall be binding upon either Party hereto, unless set forth in a writing which specifically refers to the Agreement signed by duly authorized officers or representatives of the respective Parties, and the provisions hereof not specifically amended thereby shall remain in full force and effect.

11.12 **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original, but which together shall constitute one and the same instrument.

[Remainder of page intentionally left blank; signature page follows]
IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this API Supply Agreement as of the Effective Date.

RAPTOR THERAPEUTICS, INC.

By: /s/ Thomas E. Daley
Name: Thomas E. Daley
Title: President

CAMBREX PROFARMACO MILANO

By: /s/ Paolo Russolo
Name: Paolo Russolo
Title: President
Exhibit 1.2

[...***...]
Exhibit 1.13

Specifications
Exhibit 3.1

Price

[***]

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Amendment to API Supply Agreement
between Cambrex Profarmaco Milano, and Raptor Pharmaceuticals Inc.

Background: This Amendment is made by and between Cambrex Profarmaco Milano, ("Cambrex") and Raptor Pharmaceuticals Inc. (formerly named Raptor Therapeutics, Inc.) ("Raptor") pursuant to Section 11.11 of that certain API Supply Agreement dated November 3, 2010 by and between the parties (the "Agreement"). Cambrex and Raptor wish to amend the Agreement to add Raptor’s wholly owned subsidiary, Raptor Pharmaceuticals Europe B.V., as an additional party to the Agreement.

NOW THEREFORE in consideration of the premises hereof and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the parties, the parties agree to amend the Agreement as follows:

1. Amendment to Agreement:
   
   Raptor Pharmaceuticals Europe B.V. ("Raptor BV"), a wholly owned subsidiary of Raptor, located at Naritaweg 165, Telestone-Teleport, 1043 BW Amsterdam, the Netherlands, is hereby added as a party to the Agreement and will thereupon have all the rights and obligations of "RAPTOR" thereunder. All references to "RAPTOR" in the Agreement shall refer to Raptor and/or Raptor BV, as applicable. Raptor BV may procure its API supply from Cambrex separately from Raptor.

2. API Supply. For the avoidance of doubt, the purchases made by both Raptor and Raptor BV in [...] shall be included in determining whether RAPTOR has satisfied the [...] requirement set forth in Section 2.1 of the Agreement.

3. Forecasts. For the further avoidance of doubt, the Rolling Forecasts set forth in Section 2.2 of the Agreement may be provided by either Raptor or Raptor BV.

4. No Other Modifications. The "Background" section of this document is incorporated into the Amendment. Except as expressly amended by this Amendment, the terms and conditions of the Agreement shall remain in full force and effect.

5. Counterparts. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original and all or which together shall constitute one instrument.

6. Entire Agreement. The Agreement, as amended hereby, together with this Amendment, constitute the full, complete, final and integrated agreement between the parties related to the subject matter hereof and thereof and supersede all previous written or oral negotiations, commitments, agreements, transactions or understandings concerning the subject matter hereof.

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IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed by their authorized representatives, effective as of April 9, 2013.

RAPTOR PHARMACEUTICALS INC.  
By: /s/ Georgia Erbez  
Name: Georgia Erbez  
Title: CFO

CAMBREX PROFARMACO MILANO  
By: /s/ Paolo Russolo  
Name: Paolo Russolo  
Title: President

RAPTOR PHARMACEUTICALS EUROPE B.V.  
By: /s/ Henk Doude von Troostwijk  
Name: Henk Doude von Troostwijk  
Title: Director B

By: /s/ Kim R. Tsuchimoto  
Name: Kim R. Tsuchimoto  
Title: Director A
Manufacturing Services Agreement

November 15, 2010
ARTICLE 1

INTERPRETATION

1.1 Definitions  
1.2 Currency  
1.3 Sections And Headings  
1.4 Singular Terms  
1.5 Schedules

ARTICLE 2

PATHEON’S MANUFACTURING SERVICES

2.1 Manufacturing Services  
2.2 Active Material Yield

ARTICLE 3

CLIENT’S OBLIGATIONS

3.1 Payment  
3.2 Active Materials

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing  
4.2 Price Adjustments — Subsequent Years’ Pricing  
4.3 Price Adjustments Current Year Pricing  
4.4 Adjustments Due To Technical Changes  
4.5 Multi-Country Packaging Requirements.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders And Forecasts.  
5.2 Reliance By Patheon  
5.3 Minimum Orders  
5.4 Shipments  
5.5 On Time Delivery..  
5.6 Invoices And Payment

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.  
6.2 Product Recalls And Returns  
6.3 Patheon’s Responsibility For Defective And Recalled Products.
ARTICLE 7

CO-OPERATION

7.1 [...] Review
7.2 Governmental Agencies.
7.3 Records And Accounting By Patheon.
7.4 Inspection
7.5 Access.
7.6 Notification Of Regulatory Inspections.
7.7 Reports
7.8 FDA Filings

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term.
8.2 Termination For Cause
8.3 Product Discontinuation.
8.4 Obligations On Termination.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority
9.2 Client Warranties
9.3 Patheon Warranties
9.4 Debarred Persons.
9.5 Permits
9.6 No Warranty.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages.
10.2 Limitation Of Liability.
10.3 Patheon
10.4 Client
10.5 Reasonable Allocation Of Risk.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidentiality.

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## ARTICLE 12

### DISPUTE RESOLUTION

12.1 Commercial Disputes.  
12.2 Technical Dispute Resolution

## ARTICLE 13

### MISCELLANEOUS

13.1 Inventions.  
13.2 Intellectual Property  
13.3 Insurance  
13.4 Independent Contractors  
13.5 No Waiver.  
13.6 Assignment  
13.7 Force Majeure.  
13.8 Additional Product.  
13.9 Notices.  
13.10 Severability  
13.11 Entire Agreement  
13.12 Other Terms.  
13.13 No Third Party Benefit Or Right.  
13.14 Execution In Counterparts  
13.15 Use Of Client Name  
13.16 Governing Law.
MANUFACTURING SERVICES AGREEMENT

THIS MANUFACTURING SERVICES AGREEMENT (the “Agreement”) is made as of November 15, 2010 (the “Effective Date”)

BETWEEN:

PATHEON PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware

(“Patheon”),

and -

RAPTOR THERAPEUTICS, INC.,
a corporation existing under the laws of the State of Delaware

(“Client”)

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

INTERPRETATION

1.1 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

“Active Materials”, “Active Pharmaceutical Ingredients” or “API” means the materials listed on Schedule D;

“Active Materials Credit Value” means the value of the Active Materials for certain purposes of this Agreement, as set forth on Schedule D;

“Actual Annual Yield” or “AAY” has the meaning specified in Section 2.2(a);

“Affiliate” means

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement;
For this definition, “control” means the ownership of shares carrying at least a majority of the votes for the election of the directors of a corporation.

“Annual Product Review Report” means the annual product review report prepared by Patheon as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

“Annual Report” means the annual report to the FDA prepared by Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

“Annual Volume” means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B;

“Applicable Laws” means (i) for Patheon, all the Laws of State of Ohio and all other state and federal laws applicable to the manufacture of the Products; and (ii) for Client and the Products, the Laws of all jurisdictions where the Products are manufactured, distributed, and marketed as these are agreed and understood by the parties in this Agreement;

“Authority” means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

“Breach Notice” will have the meaning specified in Section 8.2(a);

“Business Day” means a day other than a Saturday, Sunday or a day that is a statutory holiday in the State of Ohio or the State of California;

“cGMPs” means current good manufacturing practices as described in Parts 210 and 211 of Title 21 of the United States’ Code of Federal Regulations together with the latest FDA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

“Client Intellectual Property” means Intellectual Property generated or derived by Client before entering into this Agreement, or by Patheon while performing any Manufacturing Services or otherwise generated or derived by Patheon in its business which Intellectual Property is specific to, or dependent upon, Client’s Active Material or Product;

“Client Property” will have the meaning specified in Section 8.4(f);

“CMC” has the meaning specified in Section 7.8(c);

“Components” means, collectively, all packaging components, raw materials, and ingredients (including labels, product inserts and other labelling for the Products),

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required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

“Confidentiality Agreement” means the agreement about the non-disclosure of confidential information between Patheon and Client (formerly know as Bennu Pharmaceuticals, Inc.) [...***...];

“Deficiency” has the meaning specified in Section 7.8(d);

“Deficiency Notice” has the meaning specified in Section 6.1(a);

“Delivery Date” means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(e);

“Deficiency” has the meaning specified in Section 7.8(d);

“Equipment” will have the meaning ascribed to it in {the Capital Equipment Agreement related to this MSA if any}]

“FDA” means the United States Food and Drug Administration;

“Firm Orders” has the meaning specified in Section 5.1(c);

“First Firm Order” has the meaning specified in Section 5.1(b);

“Force Majeure” will have the meaning specified in Section 13.7;

“Initial Manufacturing Month” has the meaning specified in Section 5.1(b);

“Initial Manufacturing Period” has the meaning specified in Section 5.1(b);

“Initial Term” has the meaning specified in Section 8.1;

“Intellectual Property” includes, without limitation, rights in patents, patent applications, formulae: trade-marks, trade-
mark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

“Invention” means information about any innovation, improvement, development, discovery, computer program, device.
trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or
medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

“Inventory” means all inventories of Components and work-in-process produced or held by Patheon for the manufacture
of the Products but, for greater certainty, does not include the Active Materials;

“Late Delivery” has the meaning specified in Section 5.5:

“Laws” means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

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"Manufacturing Services" means the manufacturing, quality control, quality assurance, stability testing, packaging, and related services, set forth in this Agreement, required to manufacture Product or Products from Active Materials and Components;

"Manufacturing Site" means the facility owned and operated by Patheon that is located at 2110 East Galbraith Road, Cincinnati, OH 45237-1625;

"Materials" means all Components, […***…], and other materials used to manufacture the Product other than Active Materials;

"Minimum Run Quantity" means the minimum number of batches of a Product to be produced during the same cycle of manufacturing as set forth in Schedule B;

"Patheon Intellectual Property" means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, Intellectual Property developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business which Intellectual Property is not specific to, or dependent upon, Client’s Active Material or Product including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products, drug product dosage forms or drug delivery systems unrelated to the specific requirements of the Product(s);

"Price" means the price measured in US Dollars to be charged by Patheon for performing the Manufacturing Services, and includes the cost of Components, certain cost items as set forth in Schedule B, and annual stability testing costs as set forth in Schedule C.

"Product(s)" means the product(s) listed on Schedule A;

"Quality Agreement" means the agreement (the form of which is set forth in Schedule F) between the parties setting out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client;

"Recall" has the meaning specified in Section 6.2(a);

"Regulatory Authority" means the FDA and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products including the Products in the Territory;

"RFID" means Radio Frequency Identification Devices which (at present or in the future) may be affixed to Products or Materials to assist in inventory control, tracking, and identification;

"Remediation Period" has the meaning specified in Section 8.2(a);

"Shortfall" has the meaning specified in Section 2.2(b);

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“Specifications” means the file, for each Product, which is given by Client to Patheon in accordance with the procedures listed in Schedule A and which contains documents relating to each Product, including, without limitation:

(a) specifications for Active Materials and Components;
(b) manufacturing specifications, directions, and processes;
(c) storage requirements;
(d) all environmental, health and safety information for each the Product including material safety data sheets; and
(e) the finished Product specifications, packaging specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

“Target Yield” has the meaning specified in Section 2.2(a);

“Target Yield Determination Batches” has the meaning specified in Section 2.2(a);

“Technical Dispute” has the meaning specified in Section 12.2;

“Territory” means […***…];

“Third Party Rights” means the Intellectual Property of any third party;

“Year” means in the first year of this Agreement the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year.

1.2 **Currency.**

Unless otherwise indicated, all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.

1.3 **Sections and Headings.**

The division of this Agreement into Articles, Sections, Subsections, and Schedules and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section or Schedule refers to the specified Section or Schedule to this Agreement. In this Agreement, the terms "this Agreement", “hereof”, “herein”, “hereunder” and similar expressions refer to this Agreement and not to any particular part, Section or Schedule of this Agreement.

1.4 **Singular Terms.**

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.
1.5 Schedules.

The following Schedules are attached to, incorporated in, and form part of this Agreement:

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Product List and Specifications</td>
</tr>
<tr>
<td>B</td>
<td>Minimum Run Quantity, Annual Volume, and Price</td>
</tr>
<tr>
<td>C</td>
<td>Annual Stability Testing</td>
</tr>
<tr>
<td>D</td>
<td>Active Materials, Active Materials Credit Value, and […]***…]</td>
</tr>
<tr>
<td>E</td>
<td>Technical Dispute Resolution</td>
</tr>
<tr>
<td>F</td>
<td>Commercial Quality Agreement</td>
</tr>
<tr>
<td>G</td>
<td>(Reserved)</td>
</tr>
<tr>
<td>H</td>
<td>Quarterly Active Materials Inventory Report</td>
</tr>
<tr>
<td>I</td>
<td>Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield</td>
</tr>
<tr>
<td>J</td>
<td>(Reserved)</td>
</tr>
<tr>
<td>[K</td>
<td>Capital Equipment Agreement]</td>
</tr>
</tbody>
</table>

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ARTICLE 2
PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services for the Territory for the fees specified in Schedules B and C to manufacture Products for Client in accordance with Specifications and requirements in the Quality Agreement agreed to by the parties. Unless specifically agreed to by Client, Price for Products will include costs items. Schedule B sets forth a list of cost items that are included in the Price for Products. If any cost items are to be excluded from the Price, Patheon will provide a list of the excluded items to Client in advance for approval. Client agrees to pay additional fees for the excluded items approved in advance by Client. Patheon may change the Manufacturing Site for the Products only with the prior written consent of Client, this consent not to be unreasonably withheld. If Manufacturing Services have not started within [...***...] of the date of execution of this Agreement, Patheon may amend the fees set out in Schedules B and C. As long as Patheon is in compliance with the terms and conditions of this Agreement, Client will utilize Patheon to manufacture [...***...].

(a) Conversion of Active Materials and Components. Patheon will convert Active Materials and Components into Products.

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon's quality assurance group. Patheon will perform its batch review and release responsibilities in accordance with Patheon's standard operating procedures. Each time Patheon ships Products to Client, it will give Client a certificate of analysis and certificate of compliance including a statement that the batch has been manufactured and tested in accordance with Specifications and cGMPs. Client will have sole responsibility for the release of Products to the market. The form and style of batch documents, including, but not limited to, batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of Patheon. Specific Product related information contained in those batch documents is Client property.

(c) Components. Patheon will purchase and test all Components (with the exception of those that are supplied by Client) at Patheon's expense and as required by the Specifications.

(d) Stability Testing. Patheon will conduct stability testing on the Products in accordance with the protocols set out in the Specifications for the separate fees and during the time periods set out in Schedule C. Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs. Patheon will notify Client within one Business Day, after which Patheon and Client will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure, including which party will bear the cost of the investigation. Patheon will not be liable for these costs unless it has failed to perform the Manufacturing

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- 7 -
Services in accordance with the Specifications, cGMPs, and Applicable Laws. Patheon will give Client all stability test data and results at Client's request.

(e) **Packaging.** Patheon will package the Products as set out in the Specifications. Client will be responsible for the cost of artwork development. Patheon will determine and imprint the batch numbers and expiration dates for each Product shipped. The batch numbers and expiration dates will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon’s name will not appear on the label or anywhere else on the Products unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name.

(f) **Active Materials and Client Supplied Components Importing.** At least \[***\] before the scheduled production date, Client will deliver the Active Materials to the Manufacturing Site \[***\] sufficient for Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If the Active Materials are not received \[***\] before the scheduled production date, the Firm Order may not be cancelled but Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials. There will be no penalty to Client under these circumstances. But if Patheon is unable to manufacture Product to meet this new shipment date due to prior third party production commitments, Patheon may delay the shipment until a later date as agreed to by the parties. All shipments of Active Material will be accompanied by certificate(s) of analysis from the Active Material manufacturer and the Client, confirming the identity and purity of the Active Materials and its compliance with the Active Material specifications.

(g) \[***\]

(h) **Product Rejection for Finished Product Specification Failure.** Internal process specifications will be defined and mutually agreed upon. If Patheon manufactures Product in accordance with the agreed upon process specifications and a batch or portion of batch of Product does not meet a Finished Product Specification, \[***\]. If Client previously paid for the non-conforming Product, Patheon will promptly, at Client's election, either: (i) refund the labor and overhead costs associated with such non-conforming Product; or (ii) offset such costs against other amounts due to Patheon hereunder.

2.2 **Active Material Yield.**

(a) **Reporting.** Patheon will give Client a \[***\] inventory report of the Active Materials held by Patheon using the inventory report form set out in Schedule H, which will contain the following information for the quarter:

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- 8 -
**Quantity Received:** The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

**Quantity Dispensed:** The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications held at the beginning of the applicable period, less the inventory of Active Materials that complies with the Specifications held at the end of the period. The Quantity Dispensed will only include Active Materials received and dispensed in commercial manufacturing of Products and, for certainty, will not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or dispensed in technical transfer activities or development activities during the applicable period, including without limitation, any regulatory, stability, validation or test batches manufactured during the applicable period.

**Quantity Converted:** The total amount of Active Materials contained in the Products manufactured with the Quantity Dispensed (including any additional Products produced in accordance with Section 6.1 or 6.2), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 because of Patheon's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Within [...] after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials on the reconciliation report form set forth in Schedule I including the calculation of the "Actual Annual Yield" or "AAY" for the Product at the Manufacturing Site during the Year AAY is the percentage of the Quantity Dispensed that was converted to Products and is calculated as follows:

\[
\frac{\text{Quantity Converted during the Year}}{\text{Quantity Dispensed during the Year}} \times 100\%
\]

After Patheon has produced a minimum of [...] successful commercial production batches of Product or has produced commercial production batches for at least [...] at the Manufacturing Site (collectively, the "Target Yield Determination Batches"), the Parties will mutually agree on the target yield for the Product at the Manufacturing Site (each, a "Target Yield"); The Target Yield will be revised [...] to reflect the actual manufacturing experience as agreed to by the parties.

(b) **Shortfall Calculation.** If the Actual Annual Yield falls more than [...] below the respective Target Yield in a [...] (the "Shortfall") will be calculated as follows.

[...****...]

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(c) **Credit for Shortfall.** If there is a Shortfall for a Product in a Year, then Patheon will credit Client's account for the amount of the Shortfall not later than [...] after the end of the Year.

Each credit under this Section 2.2(c) will be summarized on the reconciliation report form set forth in Schedule I. Upon expiration or termination of this Agreement, any remaining credit owing under this Section 2.2 will be paid to Client. The Annual Shortfall, if any, will be disclosed by Patheon on the reconciliation report form.

(d) [...]  

(e) **No Material Breach.** It will not be a material breach of this Agreement by Patheon under Section 8.2(a) if the Actual Annual Yield is less than the Target Yield.

**ARTICLE 3**

**CLIENT'S OBLIGATIONS**

3.1 **Payment.**

Client will pay Patheon for performing the Manufacturing Services according to the Prices specified in Schedules B and C. These prices may be subject to adjustment under other parts of this Agreement. [...] Notwithstanding anything to the contrary, Patheon will not purchase nor will Client be obligated to reimburse Patheon for any cost items not included in Schedule B, [...], without the prior written approval of Client.

3.2 **Active Materials.**

Client will [...] deliver the Active Materials to Patheon (in accordance with Section 2.1(f)) sufficient for Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If applicable, Patheon and the Client will reasonably cooperate to permit the import of the Active Materials into the United States. Client's obligation will include obtaining the proper release of the Active Materials from U.S. Customs and the FDA. Client or Client's designated broker will be the "Importer of Record" for Active Materials imported into the United States. The Active Materials will be held by Patheon on behalf of Client as set forth in this Agreement. Title to the Active Materials will at all times remain the property of Client. Any Active Materials received by Patheon will only be used by Patheon to perform the Manufacturing Services.
ARTICLE 4
CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing.

The […] Price and annual stability Price for the Products for the first Year are listed in Schedules B and C and are subject to the adjustments set forth in Sections 4.2 and 4.3.

4.2 Price Adjustments — Subsequent Years' Pricing.

[...***...], Patheon may adjust the Price effective […***…] as follows:

(a) Manufacturing Costs. Patheon may adjust the Price […***…]. On or about […***…], Patheon will give Client a statement setting forth the […] in calculating the Price […] provided that no Prices may be increased until at least […] after completion of all validation and test batches of the Products.

(b) Component Costs. If Patheon incurs an increase in Component costs […] it may increase the Price for the next […] to pass through the additional Component costs. On or about […] Patheon will give Client information about the increase in Component costs which will be applied to the calculation of the Price for the next Year to demonstrate that the Price increase is justified. Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers, provided that Patheon demonstrates using non-confidential means that the Price increase is justified.

(c) […]

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- 11 -
4.3 **Price Adjustments — Current Year Pricing**

During any Year of this Agreement, the Prices set out in Schedule B will be adjusted as follows:

**Extraordinary Increases in Component Costs.** If, at any time, market conditions result in Patheon's cost of Components being materially greater than normal forecasted increases, then Patheon will be entitled to an adjustment to the Price for any affected Product to compensate it for the increased Component costs. Changes materially greater than normal forecasted increases will have occurred if: [...***...]. If Component costs have been previously adjusted to reflect an increase in the cost of one or more Components, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Components. Notwithstanding the foregoing, no Prices may be increased until [...***...].

For a Price adjustment under this Section 4.3, Patheon will deliver to Client a revised Schedule B and budgetary pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. The revised Price will be effective for any Product delivered on or after the [...***...] following Client's receipt of the revised Schedule B.

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**- 12 -**
4.4 **Adjustments Due to Technical Changes**

Amendments to the Specifications or the Quality Agreement requested by Client will only be implemented following a technical and cost review by Patheon and are subject to Client and Patheon reaching agreement on Price changes required because of the amendment. Amendments to the Specifications, the Quality Agreement, or the Manufacturing Site requested by Patheon will only be implemented following the written approval of Client, the approval not to be unreasonably withheld. If Client accepts a proposed Price change, the proposed change in the Specifications will be implemented, and the Price change will become effective, only for those orders of Products that are manufactured under the revised Specifications. 

Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 will be cancelled where possible and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Client if the Components cannot be used by other Patheon customers.

4.5 **Multi-Country Packaging Requirements.**

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional Component costs and the change over fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

**ARTICLE 5**

**ORDERS, SHIPMENT, INVOICING, PAYMENT**

5.1 **Orders and Forecasts.**

(a) **Rolling [...] Forecast.** When this Agreement is executed, Client will give Patheon a non-binding [...] forecast of the volume of Product that Client expects to order in the first [...] of commercial manufacture of the Product. This forecast will then be updated by Client on or before the [...] on a rolling forward basis. Client will update the forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than [...]. The most recent [...] forecast will prevail.

(b) **Firm Orders for Initial Manufacturing [...]**. At least [...] before the start of commercial manufacture of the Product, Client will update the rolling forecast for the first [...] of manufacture of the Product (the "Initial Manufacturing Period"). The [...] of this updated forecast ("Initial Manufacturing Month") will constitute a firm written order in the form of a purchase order or otherwise ("First Firm Order") by Client to purchase and,
when accepted by Patheon, for Patheon to manufacture the quantity of the Product. If manufacturing has not
started, Client may cancel any Batches from the First Firm Order at no cost if notice of cancellation is received
by Patheon [...] or more before the scheduled Delivery Date under the First Firm Order. If manufacturing
has not started, Client may cancel any Batches from the First Firm Order if notice of cancellation is received
by Patheon [...] before the scheduled Delivery Date under the First Firm Order, [...]. The parties
agree that this payment will be considered liquidated damages for Patheon's loss of manufacturing capacity
due to the Client's cancellation of manufacturing and will not be considered a penalty. If the First Firm Order is
changed or adjusted as described above then the initial rolling [...] forecast will also be adjusted as
necessary.

(c) Firm Orders Thereafter. Before and during the Initial Manufacturing Period, and on a rolling basis during the
term of this Agreement, Client will issue an updated [...] forecast on or before [...]. The first [...] of this updated forecast will be a firm order in the form of a purchase order or otherwise ("Firm Order") by
Client to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity
of the Products on a date not less than [...] from the [...] immediately following the date that the Firm
Order is submitted. Firm Orders submitted to Patheon will specify Client's Manufacturing Services purchase
order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to
ensure the timely manufacture and shipment of the Products. The quantities of Products ordered in those
written orders will be firm and binding on Client and may not be reduced by Client unless otherwise provided in
this Agreement.

(d) [...] Forecast. On or before the [...], Client will give Patheon a written non-binding [...] forecast,
broken down by [...] for the [...] of the forecast, of the volume of each Product Client then anticipates
will be required to be manufactured and delivered to Client during the [...]..

(e) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within
[...] of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from the
Client, the Delivery Date for the Product ordered. The Delivery Date may be amended by agreement of the
Parties or as set forth in Sections 2.1(f) or 5.1(b). Patheon will accept all Firm Orders submitted by Client up to
[...] of the quantities specified in the most recent forecast submitted by Client for the applicable period
subject to the availability of Materials and API.

5.2 Reliance by Patheon.

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted
under Sections 5.1(a), (b), and (c) in ordering the Components required to meet the Firm Orders. In addition, Client understands
that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in sufficient volumes to meet
the production requirements for Products during part or all of the forecasted

- 14 -
periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components to satisfy the Manufacturing Services requirements for Products for the first [...***...] contemplated in the most recent forecast given by Client under Section 5.1(a). Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties. The Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon. If Components ordered by Patheon under Firm Orders or this Section 5.2 are not included in finished Products manufactured for Client, or in any third party products manufactured by Patheon, [...***...] after the forecasted month for which the purchases have been made (or for a longer period as the parties may agree) or if the Components have expired during the period, then Client will pay to Patheon its costs therefor (including all costs incurred by Patheon for the purchase and handling of the Components). But if these Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

(b) If Client fails to take possession or arrange for the destruction of Components within [...***...] of purchase or, in the case of finished Product, within [...***...] of manufacture, Client will pay Patheon $[...***...] thereafter for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at $[...***...]. Storage fees are subject to a [...***...] minimum charge [...***...]. Patheon may ship finished Product held by it longer than [...***...] to the Client at Client's expense on [...***...] written notice to the Client.

5.3 Minimum Orders.

Client may only order Manufacturing Services for batches of Products in multiples of the Minimum Run Quantities as set out in Schedule B.

5.4 Shipments.

Shipments of Products will be made [...***...] Patheon's shipping point unless otherwise mutually agreed. Risk of loss or of damage to Products will remain with Patheon until [...***...]. Patheon will, in accordance with Client's instructions and as agent for Client, (i) arrange for shipping to be paid by Client and (ii) at Client's risk and expense, obtain any export licence or other official authorization necessary to export the Products. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications.

5.5 On Time Delivery.

(a) Patheon and the Client understand that there may be uncertainties and necessary adjustments in production schedules during the initial Manufacturing Period. The parties agree that they will work together closely to expedite deliveries and manage the scheduling of the initial Product launch.
If after the Initial Manufacturing Period, Patheon is unable to deliver the quantity of Product ordered under a Firm Order on the Delivery Date due to an act or omission by Patheon (a “Late Delivery”), Client will receive a credit from Patheon for the Late Delivery that will be applied against the purchase price under the next Firm Order. The credit will be [***...***].

A Late Delivery will not be a material breach of this Agreement by Patheon for the purposes of Section 8.2 unless the Products are delivered more than [***...***] after the Delivery Date.

For clarity, a Late Delivery will not include any delay in shipment of Product caused by events outside of Patheon's reasonable control, such as [***...***].

Patheon will not ship Products to Client or its agents in advance of a scheduled delivery date, without Client's prior approval.

No shipment will be deemed complete until all ordered Product SKUs have been delivered in accordance with Client's instructions and a certificate of compliance has been issued by Patheon. Partial shipment must be authorized by Client.

5.6 **Invoices and Payment.**

Invoices will be sent by fax or email to the fax number or email address given by Client to Patheon in writing. Invoices will be sent when the Product is manufactured and released by Patheon to the Client. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all undisputed invoices for accepted Products within [***...***] of the date thereof. No payment or other obligations of Client will accrue on partial or incomplete shipments. Interest on past due accounts will accrue at [***...***]. The Late Delivery credits set forth in this Section 5 are only available to Client if all outstanding undisputed invoices have been paid in full or are within [***...***] outstanding from the invoice date when the Late Delivery arose.

ARTICLE 6

**PRODUCT CLAIMS AND RECALLS**

6.1 **Product Claims.**

(a) **Product Claims.** Client has the right to reject any portion of any shipment of Products that deviates from the Specifications, cGMPs, or Applicable Laws without invalidating any remainder of the shipment. Client will inspect the Products manufactured by Patheon upon receipt and will give Patheon written notice (a "Deficiency Notice") of all claims for Products that deviate from the Specifications, cGMPs, or Applicable Laws within [***...***] after Clients

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- 16 -
receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within [...***...]
after discovery by Client, [...***...]). Should Client fail to give Patheon the Deficiency Notice within the applicable [...***...], then the
delivery will be deemed to have been accepted by Client on the [...***... after delivery or discovery, as applicable. Except as set
out in Section 6.3, Patheon will have no liability for any deviations for which it has not received notice within the applicable [...***...]
period.

(b) **Determination of Deficiency.** Upon receipt of a Deficiency Notice, Patheon will have [...***... to advise Client
by notice in writing that it disagrees with the contents of the Deficiency Notice. If Client and Patheon fail to agree within [...***...]
after Patheon’s notice to Client as to whether any Products identified in the Deficiency Notice deviate from the Specifications,
cGMPs, or Applicable Laws, then the parties will mutually select an independent laboratory to evaluate if the Products deviate from
the Specifications, cGMPs, or Applicable Laws. This evaluation will be binding on the parties. If the evaluation certifies that any
Products deviate from the Specifications, cGMPs, or Applicable Laws, Client may reject those Products in the manner
contemplated in this Section 6.1 and Patheon will be responsible for the cost of the evaluation. If the evaluation does not so certify
for any of the Products, then Client will be deemed to have accepted delivery of the Products on the [...***... after delivery (or, in
the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the [...***... after discovery
thereof by Client, but not after the expiration date of the Product) and Client will be responsible for the cost of the evaluation.

(c) **Shortages.** Claims for shortages in the amount of Products shipped by Patheon will be dealt with by
reasonable agreement of the parties.

6.2 **Product Recalls and Returns.**

(a) **Records and Notice.** Patheon and Client will each maintain records necessary to permit a Recall of any
Products delivered to Client or customers of Client. Each party will promptly notify the other of any information which might affect
the marketability, safety or effectiveness of the Products or which might result in the Recall or seizure of the Products. Upon
receiving this notice or upon this discovery, each party will stop making any further shipments of any Products in its possession or
control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a
Recall or to take some other corrective action, if any, will be made and implemented by Client. “Recall” will mean any action (i) by
Client to recover title to or possession of quantities of the Products sold or shipped to third parties (including, without limitation, the
voluntary withdrawal of Products from the market); or (ii) by any regulatory authorities to detain or destroy any of the Products.
Recall will also include any action by either Party to refrain from selling or shipping quantities of the Products to third parties which
would have been subject to a Recall if sold or shipped.

(b) **Recalls.** If (i) any governmental or regulatory authority issues a directive, order or, following the issuance of a
safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders
a Recall, or (iii) Client determines that any Product should be Recalled or that a “Dear Doctor” letter is required relating the
restrictions on the use of any Product, Patheon will co-operate as reasonably required by Client, having regard to all applicable
laws and regulations.
(c) **Product Returns.** Client will have the responsibility for handling customer returns of the Products. Patheon will give Client any assistance that Client may reasonably require to handle the returns.

6.3 **Patheon's Responsibility for Defective and Recalled Products.**

(a) **Defective Product.** If Client rejects Products under Section 6.1 and the deviation is determined to have arisen from Patheon's failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will credit Client's account for Patheon's invoice price for the defective Products. If Client previously paid for the defective Products, Patheon will promptly, at Client's election, either: (i) refund the invoice price for the defective Products; (ii) offset the amount paid against other amounts due to Patheon hereunder; or (iii) replace the Products with conforming Products without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all Active Materials required for the manufacture of the replacement Products. For greater certainty, Patheon's responsibility for any loss of Active Materials in defective Product will be captured and calculated in the Active Materials Yield under Section 2.2.

(b) **Recalled Product.** If a Recall or return results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will be responsible for the documented out-of-pocket expenses of the Recall or return and will use its commercially reasonable efforts to replace the Recalled or returned Products with new Products as soon as possible, contingent upon the receipt from Client of all Active Materials required for the manufacture of the replacement Products. For greater certainty, Patheon's responsibility for any loss of Active Materials in Recalled Product will be captured and calculated in the Active Materials Yield under Section 2.2. If Patheon is unable to replace the Recalled or returned Products (except where this inability results from a failure to receive the required Active Materials), then Client may request Patheon to reimburse Client for the price that Client paid to Patheon for Manufacturing Services for the affected Products. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense.

(c) Except as set forth in Sections 6.3(a) and (b) above, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it, (collectively, **“Product Claims”**). For greater certainty, Patheon will have no obligation for any Product Claims to the extent the Product Claim [...***...].

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6.4 **Disposition of Defective or Recalled Products.**

Client will not dispose of any damaged, defective, returned, or Recalled Products for which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.3. […]***…

6.5 **Healthcare Provider or Patient Questions and Complaints.**

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client's customer's, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will give Client all mutually agreed upon information that will enable Client to respond properly to questions or complaints about the Products as set forth in the Quality Agreement. Unless it is determined that the cause of the complaint resulted from a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, all costs incurred under this Section 6.5 will be borne by Client.

6.6 […]***…

ARTICLE 7

**CO-OPERATION**

7.1 […]***…] **Review.**

Each party will forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet not less than […]***…] to review the current status of the business relationship and manage any issues that have arisen.

7.2 **Governmental Agencies.**

Subject to Section 7.8, each party may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Products, regarding the Products if, in the opinion of that party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any law, governmental order or regulation. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a party will permit the other party to accompany and take part in any communications with the agency, and to receive copies of all communications from the agency.

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- 19 -
7.3 **Records and Accounting by Patheon.**

Patheon will keep records of the manufacture, testing, and shipping of the Products, and retain samples of the Products as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for a period of one year following the date of Product expiry, or longer if required by law or the Quality Agreement, at which time Client will be contacted concerning the delivery and destruction of the documents and/or samples of Products. Client is responsible for retaining samples of the Products necessary to comply with the legal/regulatory requirements applicable to Client.

7.4 **Inspection.**

Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, but a Patheon representative must be present during the inspection.

7.5 **Access.**

Patheon will give Client reasonable access at mutually agreeable times to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws. But, with the exception of “for-cause” audits, Client will be limited each Year to [...***...], lasting no more than [...***...], and involving no more than [...***...] auditors. Client may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of a fee of [...***...]. The right of access set forth in this Section 7.5 will not include a right to access or inspect Patheon's financial records.

7.6 **Notification of Regulatory Inspections.**

Patheon will notify Client within one Business Day of any inspections by any governmental agency specifically involving the Products. Patheon will also notify Client of receipt of any form 483's or warning letters or any other significant regulatory action which Patheon's quality assurance group determines could impact the regulatory status of the Products.

7.7 **Reports.**

Patheon will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA. At the Client's request, Patheon will provide a copy of the Annual Product Review Report to the Client at no additional cost. Any additional report requested by Client beyond the scope of cGMPs and customary FDA requirements will be subject to an additional fee to be agreed upon between Patheon and the Client.
7.8 FDA Filings.

(a) Regulatory Authority. Client will have the sole responsibility for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture of the Products. Patheon will assist Client, to the extent consistent with Patheon’s obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible.

(b) Verification of Data. At least [...] prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, Client will give Patheon a copy of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and regulatory validity of those documents as they relate to Patheon generated data.

(c) Verification of CMC. At least [...] prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA’s Chemistry and Manufacturing Controls (“CMC”) related to any Marketing Authorization, such as a New Drug Application or Abbreviated New Drug Application, Client will give Patheon a copy of the CMC as well as all supporting documents which have been relied upon to prepare the CMC. This disclosure will permit Patheon to verify that the CMC accurately describes the work that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Client will give Patheon copies of all FDA filings at the time of submission which contain CMC information regarding the Product.

(d) Deficiencies. If, in Patheon’s sole discretion, acting reasonably, Patheon determines that any of the information given by Client under clauses (b) and (c) above is inaccurate or deficient in any manner whatsoever (the “Deficiencies”), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to any pre-approval inspection.

(e) Client Responsibility. For clarity, the parties agree that in reviewing the documents referred to in clause (b) above, Patheon’s role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Patheon. Subject to the foregoing, Patheon will not assume any responsibility for the accuracy of any application for approval of products pending approval by a regulatory authority. The Client is solely responsibility for the preparation and filing of the application for approval by the regulatory authorities and any relevant costs will be borne by the Client.

(f) Inspection by Regulatory Authorities. If Client does not give Patheon the documents requested under clause (b) above within the time specified and if Patheon reasonably believes that Patheon’s standing with a regulatory authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the regulatory authority until Patheon has reviewed the requested documents and is satisfied with their contents.

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- 21 -
ARTICLE 8
TERM AND TERMINATION

8.1 Initial Term

This Agreement will become effective as of the Effective Date and will continue until December 31, 2017 (the “Initial Term”), unless terminated earlier by one of the parties in accordance herewith. This Agreement will automatically continue after the Initial Term for successive terms of two years each unless either party gives written notice to the other party of its intention to terminate this Agreement at least 18 months prior to the end of the then current term.

8.2 Termination for Cause; Client Termination.

(a) Either party at its sole option may terminate this Agreement upon written notice where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement within [***] following receipt of a written notice (the “Remediation Period”) of the breach that expressly states that it is a notice under this Section 8.2(a) (a “Breach Notice”).

(b) Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate this Agreement as to any Product upon [***] prior written notice if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product or if Client is unable to secure a license for Patheon to manufacture the Product without infringing third party rights in the Product. But if this occurs, Client will still fulfill all of its obligations under Section 8.4 below [and under any Capital Equipment Agreement regarding this Product].

(d) Patheon may terminate this Agreement upon [***] prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement to an assignee that, in the opinion of Patheon acting reasonably, is: (i) not a credit worthy substitute for Client; or (ii) a competitor of Patheon; or (iii) an entity with whom Patheon has had prior unsatisfactory business relations.

(e) Client may terminate this Agreement upon [***] prior written notice to Patheon if Client enters into a strategic arrangement with a third party that does not compete with Patheon by principally providing contract manufacturing services to third parties, and if the written notice of termination to Patheon is made within [***] after the Effective Date of this Agreement.

8.3 Product Discontinuation.

Client may terminate this agreement with at least [***] advance notice to Patheon if it intends to no longer order Manufacturing Services for a Product due to (i) Client’s ***Confidential Treatment Requested
termination of sales of the Product in the Territory, or (ii) termination of clinical trials for the Product.

8.4 **Obligations on Termination.**

If this Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

(a) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged under a Firm Order according to the terms of this Agreement, at the price in effect at the time the Firm Order was placed;

(b) Client will purchase, at Patheon's cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), the Inventory applicable to the Products which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders;

(c) Client will satisfy the purchase price payable under Patheon's orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders;

(d) Patheon will return to Client all unused Active Materials (with shipping and related expenses, if any, to be borne by Client); and

(e) Client acknowledges that no competitor of Patheon will be permitted access to the Manufacturing Site.

(f) Patheon will, at its own expense, remove from Patheon site(s) and deliver to Client, within [...***...], all of Client's Components, Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control ("Client Property"). If Client requests that the Client Property be stored at Patheon, following the completion, termination, or expiration of the Agreement Client will pay Patheon [...***...] thereafter for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.6 of this Agreement.

Any termination or expiration of this Agreement will not affect any outstanding obligations or payments due hereunder prior to the termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement [or any related Capital Equipment Agreement]. For greater certainty, termination of this Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 10 and 11 and Sections 5.4, 5.6, 8.4, 13.1, 13.2, 13.3, and 13.15, all of which survive any termination.

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- 23 -
ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

9.2 Client Warranties.

Client covenants, represents, and warrants that:

(a) Non-Infringement.

(i) the Specifications for each of the Products are its or its Affiliate’s property and that Client may lawfully disclose the Specifications to Patheon;

(ii) any Client Intellectual Property, used by Patheon in performing the Manufacturing Services according to the Specifications (A) is Clients or its Affiliates unencumbered property, (B) may be lawfully used as directed by Client, and (C) to the knowledge of Client, does not infringe and will not infringe any Third Party Rights;

(iii) to the knowledge of Client, the performance of the Manufacturing Services by Patheon for any Product under this Agreement or the use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement does not and will not infringe any Third Party Rights;

(iv) there are no actions or other legal proceedings, concerning the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Components, or the sale, use, or other disposition of any Product made in accordance with the Specifications;

(b) Quality and Compliance.

(i) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws;

(ii) on the date of shipment, the API will conform to the specifications for the API that Client has given to Patheon and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container;

(iii) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets the Products after separate approval, and (ii) to the knowledge of Client, will be safe for human consumption.
9.3 **Patheon Warranties.**

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in a professional and workmanlike manner and in accordance with the Specifications, cGMPs, and Applicable Laws,

(b) Patheon and its personnel performing the Manufacturing Services have the requisite experience, skills, knowledge, and expertise necessary to perform the Manufacturing Services in a competent manner;

(c) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliates unencumbered property, (ii) may be lawfully used by Patheon, and (iii) to the knowledge of Patheon, does not infringe and will not infringe any Third Party Rights; and

(d) the Products will be delivered free of all liens and encumbrances

9.4 **Debarred Persons.**

Patheon represents and warrants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the Federal Food, Drug, and Cosmetic Act (United States).

9.5 **Permits.**

Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

Patheon will maintain at all relevant times all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

9.6 **No Warranty.**

NEITHER PATHEON NOR CLIENT MAKE ANY WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. NEITHER PATHEON NOR CLIENT MAKES ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY FOR THE PRODUCTS.
ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages.

Except for a party's indemnification obligations under this Agreement, or due to a breach of Article 11, under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

10.2 Limitation of Liability.

(a) Active Materials. Except as expressly set forth in Section 2 2, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials. [...***…]

(b) [...***…]

10.3 Patheon.

Patheon agrees to defend, indemnify, and hold Client, its officers, employees, and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any [...***…].

If a claim occurs, Client will: (a) promptly notify Patheon of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim, (c) reasonably cooperate with Patheon in the defense of the claim: and (d) permit Patheon to control the defense and settlement of the claim, all at Patheon's cost and expense.

10.4 Client.

Client agrees to defend, indemnify, and hold Patheon, its officers, employees, and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any [...***…]

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If a claim occurs, Patheon will: (a) promptly notify Client of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Client in the defense of the claim; and (d) permit Client to control the defense and settlement of the claim, all at Client's cost and expense.

10.5 **Reasonable Allocation of Risk.**

This Agreement (including, without limitation, this Article 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Products. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Products because Client has developed and holds the marketing approval for the Products, Client requires Patheon to manufacture and label the Products strictly in accordance with the Specifications, and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Products.

**ARTICLE 11**

**CONFIDENTIALITY**

11.1 **Confidentiality.**

The Confidentiality Agreement will apply to all confidential information disclosed by the parties under this Agreement. If the Confidentiality Agreement expires or is terminated prior to the expiration or termination of this Agreement, the terms of the Confidentiality Agreement will continue to govern the parties’ obligations of confidentiality for any confidential or proprietary information disclosed by the parties hereunder, for the term of this Agreement, as though the Confidentiality Agreement remained in full force and effect.

**ARTICLE 12**

**DISPUTE RESOLUTION**

12.1 **Commercial Disputes.**

If any dispute arises out of this Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined herein), the parties will first try to resolve it amicably. In that regard, any party may send a notice of dispute to the other, and each party will appoint, within [...***…] from receipt of the notice of dispute, a single representative having full power and authority to solve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within one month from their appointment, or if a party fails to appoint a representative within the [...***…] period set forth above, the dispute will immediately be referred to the Chief Operating Officer (or another officer as he/she may designate) of each party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the parties fail to reach a resolution...
under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.15.

12.2 Technical Dispute Resolution.

If a dispute arises (other than disputes under Sections 6.1(b) or 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement (a “Technical Dispute”), the parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, senior representatives of each party will, as soon as practicable and in any event no later than [...***...] after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within [...***...] of the written request, the Technical Dispute will, at the request of either party, be referred for determination to an expert in accordance with Schedule E. If the parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Schedule E) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

ARTICLE 13

MISCELLANEOUS

13.1 Inventions.

(a) For the term of this Agreement, Client hereby grants to Patheon a limited, non-exclusive, paid-up, royalty-free, non-transferable, non-sublicensable license of Client's Intellectual Property which Patheon must use in order to perform the Manufacturing Services solely for use by Patheon in performing the Manufacturing Services.

(b) All Intellectual Property generated or derived by Patheon while performing the Manufacturing Services, to the extent it is specific to the development, manufacture, use, and sale of Client's Product that is the subject of the Manufacturing Services, will be the exclusive property of Client, and Patheon hereby assigns all of its right, title, and interest in and to such Intellectual Property to Client.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, sublicensable, transferable license to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services or otherwise incorporated into the Products to make, use, sell, offer for sale, import, export, distribute, create derivative works of, and otherwise use the Product(s) in any manner as contemplated under this Agreement.

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

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Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Products or processes or technology owned or otherwise controlled by the party.

13.2 Intellectual Property.

Subject to Section 13.1, all Client Intellectual Property will be owned by Client and all Patheon Intellectual Property will be owned by Patheon. Neither party has, nor will it acquire, any interest in any of the other party’s Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13.3 Insurance.

Each party will maintain [...***...], insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of [...***...]. If requested each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of [...***...], written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will forthwith notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors.

The parties are independent contractors and this Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.5 No Waiver.

Either party’s failure to require the other party to comply with any provision of this Agreement will not be deemed a waiver of the provision or any other provision of this Agreement, with the exception of Sections 6.1 and 8.2.

13.6 Assignment.

(a) Patheon may not assign this Agreement or any of its rights or obligations hereunder without the written consent of Client, this consent not to be unreasonably withheld. But Patheon may arrange for subcontractors to perform specific testing services arising under this Agreement without the consent of Client.

***Confidential Treatment Requested
Subject to Section 8.2(d), Client may assign this Agreement or any of its rights or obligations hereunder without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement, and Client will remain liable hereunder. Any partial assignment will be subject to Patheon's cost review of the assigned Products and Patheon may terminate this Agreement or any assigned part thereof, on [...] written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time.

despite the foregoing provisions of this Section 13.6, and notwithstanding Section 8.2(d), either party may assign this Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound hereunder.

13.7 **Force Majeure.**

Neither party will be liable for the failure to perform its obligations under this Agreement if the failure is caused by an event beyond that party’s reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within colour of right (a “**Force Majeure Event**”) A party claiming a right to excused performance under this Section 13.7 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement.

13.8 **Additional Product.**

Additional products may be added to this Agreement and the additional products will be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by amendments to Schedules A, B, and C as applicable.

13.9 **Notices.**

Any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery, by telecopy, facsimile communication, or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses, telecopy or facsimile numbers or electronic mail addresses set forth below:
If to Client:

- Attention: ●
- Telecopier No.: ●
- Email address:

If to Patheon:

Patheon Pharmaceuticals Inc.
2110 East Galbraith Road
Cincinnati, OH 45237-1625
Attention: Director of Legal Services
Telecopier No 513-948-6927

Email address: [Frank.McCune@patheon.com]

With a copy to:

Patheon Inc.
4721 Emperor Boulevard
Research Triangle Park,
NC 27703
Attention: General Counsel
Telecopier No.: 919-474-2269

Email address: [Doaa.Fathallah@patheon.com]

or to any other addresses, telecopy or facsimile numbers or electronic mail addresses given to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery, telecopy, facsimile, or electronic mail will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner.

13.10 Severability.

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions hereof, because each provision is separate, severable, and distinct.

13.11 Entire Agreement.

This Agreement, together with the Quality Agreement and the Confidentiality Agreement, constitutes the full, complete, final and integrated agreement between the parties.
relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Quality Agreement, and the Confidentiality Agreement.

13.12 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement and is signed by both parties.

13.13 No Third Party Benefit or Right.

For greater certainty, nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement.

13.14 Execution in Counterparts.

This Agreement may be executed in two or more counterparts, by original or facsimile signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.15 Use of Client Name.

Patheon will not make any use of Client's name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client, which consent will not be unreasonably withheld. Despite this, Client agrees that Patheon may include Client's name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon's Manufacturing Services.

13.16 Governing Law.

This Agreement will be construed and enforced in accordance with the laws of the State of Ohio and the laws of the United States of America applicable therein and subject to the exclusive jurisdiction of the courts thereof. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.
IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the date first written above.

PATHEON PHARMACEUTICALS INC.

By: /s/ Eric Evans
Name: Eric Evans
Title: Chief Financial Officer

RAPTOR THERAPEUTICS, INC.

By: /s/ Thomas E. Daley
Name: Thomas E. Daley
Title: President
SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

[...***...]

***Confidential Treatment Requested
SCHEDULE B

MINIMUM RUN QUANTITY, ANNUAL VOLUME, AND PRICE

[...***...]

***Confidential Treatment Requested
SCHEDULE C

ANNUAL STABILITY TESTING

[...***...]

***Confidential Treatment Requested
SCHEDULE D

[…***…]
SCHEDULE E

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 will be resolved in the following manner

1. **Appointment of Expert.** Within […***…] after a party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the parties are unable to so agree within the […***…] period, or in the event of disclosure of a conflict by an expert under Paragraph 2 hereof which results in the parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.

2. **Conflicts of Interest.** Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the parties will, after the disclosure, have confirmed his appointment.

3. **Not Arbitrator.** No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert’s determination or the procedure by which the expert reaches his determination under this Schedule E.

4. **Procedure.** Where an expert is appointed

   (a) **Timing.** The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and that he issues the authorizations to the parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within […***…] (or another other date as the parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.

   (b) **Disclosure of Evidence.** The parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within […***…] of a written request from the relevant expert to do so.

   (c) **Advisors.** Each party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the parties will cooperate and seek to narrow and limit the issues to be determined.

   (d) **Appointment of New Expert.** If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment,
a new expert may (at the request of either party) be appointed and the appointment of the existing expert will thereupon cease for the purposes of determining the matter at issue between the parties save this if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.

(e) Final and Binding. The determination of the expert will, except for fraud or manifest error be final and binding upon the parties.

(f) Costs. Each party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

For greater certainty, the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Schedule E) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.
SCHEDULE G (Reserved)
SCHEDULE H

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

[...***...]

***Confidential Treatment Requested
SCHEDULE I

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION
AND CALCULATION OF ACTUAL ANNUAL YIELD

[...***...]
SCHEDULE J (Reserved)
Amendment to Manufacturing Services Agreement

between Patheon Pharmaceuticals Inc., and Raptor Therapeutics, Inc.

Background: Patheon Pharmaceuticals Inc., (“Patheon”) and Raptor Therapeutics, Inc., (“Raptor”) entered into a Manufacturing Services Agreement dated November 15, 2010 (the “Agreement”). Patheon and Raptor wish to amend the Agreement to revise Schedule B.

NOW THEREFORE in consideration of the premises hereof and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, the parties agree to amend the Agreement as follows:

1. Amendment to Agreement:
   Schedule B to the Agreement is deleted in its entirety and is replaced with a new Schedule B as attached to this Amendment.

2. No Other Modifications. The “Background” section of this document is incorporated into the Amendment. Except as modified by this Amendment, the terms and conditions of the Agreement remain unchanged.

IN WITNESS WHEREOF, the parties have caused this Amendment to be duly executed by their authorized representatives, effective as of April 5, 2012.

RAPTOR THERAPEUTICS, INC.

By: /s/ Thomas E. Daley  
Name: Thomas E. Daley  
Title: President

PATHEON PHARMACEUTICALS INC.

By: /s/ Francis P. McCune  
Name: Francis P. McCune  
Title: Secretary

APPROVED BY LEGAL

FPM  4-13-12
Initials  Date
SCHEDULE B
(as revised by the Amendment to the Agreement effective April 5, 2012)

MINIMUM RUN QUANTITY, ANNUAL VOLUME, AND PRICE

[...***…]

***Confidential Treatment Requested

2
Second Amendment to Manufacturing Services Agreement
between Patheon Pharmaceuticals Inc., and Raptor Pharmaceuticals Inc.

Background: Patheon Pharmaceuticals Inc., (“Patheon”) and Raptor Pharmaceuticals Inc., (formerly known as Raptor Therapeutics, Inc.), (“Raptor”) entered into a Manufacturing Services Agreement dated November 15, 2010, as amended on April 5, 2012 (the “Agreement”). Patheon and Raptor wish to further amend the Agreement to add Raptor Pharmaceuticals Europe B.V., a wholly owned subsidiary of RPTP European Holdings C.V. (a wholly-owned subsidiary of Raptor) as an additional party to the Agreement and to update the Pricing in Schedule B.

NOW THEREFORE in consideration of the premises hereof and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the parties, the parties agree to amend the Agreement as follows:

1. Second Amendment to Agreement:

   (a) Raptor Pharmaceuticals Europe B.V. located at Naritaweg 165, Telestone-Teleport, 1043 BW Amsterdam, the Netherlands, is hereby added as a party to the Agreement and will thereupon have all the rights and obligations of the “Client” thereunder. All references to “Client” in the Agreement shall refer to Raptor and/or Raptor Pharmaceuticals Europe B.V., as applicable.

   (b) Schedule B to the Agreement is deleted in its entirety and is replaced in its entirety with the Schedule B attached to this Second Amendment.

2. No Other Modifications. The “Background” section of this document is incorporated into this Second Amendment. Except as expressly amended by this Second Amendment, the terms and conditions of the Agreement shall remain in full force and effect.

3. Counterparts. This Second Amendment may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument.

   [Signature page to follow]
IN WITNESS WHEREOF, the parties have caused this Second Amendment to be duly executed by their authorized representatives, effective as of June 21, 2013.

RAPTOR PHARIVI ACEUTICALS INC.

By: /s/ Julie Smith
Name: Julie Smith
Title: EVP Strategy & COO

PATHEON PHARMACEUTICALS INC.

By: /s/ Francis P. McCune
Name: Francis P. McCune
Title: Secretary

RAPTOR PHARMACEUTICALS EUROPE B.V.

By: /s/ Kim R. Tsuchimoto
Name: Kim R. Tsuchimoto
Title: Director A

APPROVED BY LEGAL

FPM 4-13-12
Initials Date

RAPTOR PHARMACEUTICALS EUROPE B.V.

By: /s/ Henk Doude van Troostwijk
Name: Henk Doude van Troostwijk
Title: Director B
SCHEDULE B

(as revised by the Second Amendment to the Agreement effective June 21, 2013)

MINIMUM ORDERING QUANTITY AND PRICE

[...***...]

***Confidential Treatment Requested
CONFIDENTIAL SETTLEMENT AGREEMENT AND MUTUAL RELEASE

This Confidential Settlement Agreement and Mutual Release (this “Agreement”) is entered into as of September 26, 2016 by and between (a) EXPRESS SCRIPTS, INC. (“EXPRESS SCRIPTS”) and (b) HORIZON PHARMA USA, INC., ("HORIZON"). Collectively, EXPRESS SCRIPTS and HORIZON shall be referred to as the “Parties” or singularly, a “Party.”

RECITALS

WHEREAS, effective November 1, 2012, the Parties entered into a Preferred Savings Grid Rebate Program Agreement (“Rebate Agreement”), as amended, whereby HORIZON agreed to pay EXPRESS SCRIPTS rebates and administrative fees with respect to certain utilization of Horizon’s products, under specified conditions, and in exchange for related administrative services;

WHEREAS, (a) Express Scripts contends that Horizon agreed to pay rebates under the Rebate Agreement to Express Scripts for the drugs Duexis, Rayos, and Vimovo, and that Horizon has breached the Rebate Agreement by failing to pay such rebates, and (b) Horizon contends that Express Scripts agreed to perform certain services under the Rebate Agreement, that Express Scripts breached the Rebate Agreement by failing to perform such services, and that Horizon terminated the Rebate Agreement effective August 30, 2014 such that rebates under it were no longer due and owing (collectively, the “Dispute”).

WHEREAS, on November 10, 2015, EXPRESS SCRIPTS filed a Complaint against HORIZON in the Superior Court of the State of Delaware, Case No. N15C-11-054 (CCLD) asserting claims for breach of contract, breach of the implied covenant of good faith and fair dealing, unjust enrichment, and declaratory relief arising from Rebate Agreement.

WHEREAS, on January 11, 2016, HORIZON answered the Complaint, denying EXPRESS SCRIPTS’ claims and filed a Counterclaim against EXPRESS SCRIPTS for breach of contract, breach of the implied covenant of good faith and fair dealing, and declaratory relief arising from EXPRESS SCRIPTS’ alleged breach of the Rebate Agreement (the “Litigation”).

WHEREAS, without either Party conceding the validity or correctness of the position of the other, in order to avoid the costs, uncertainty, and vexation of additional legal proceedings, the Parties want to finally and conclusively resolve their differences, including any and all causes of action and claims either Party has or may have against the
other in connection with the Litigation, and the Rebate Agreement that is the subject of that Litigation.

Now, therefore, in consideration of the foregoing recitals (which are hereby incorporated into this Agreement), and the following terms and conditions, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties hereby covenant and agree as follows:

**AGREED TERMS**

1. **Settlement Payment by HORIZON.** HORIZON will pay EXPRESS SCRIPTS in the amount of $[***] and in the amount of $[***] for Express Scripts’ attorneys’ fees and litigation costs and expenses, for a total of $65,000,000 (the “Settlement Payment”) as provided herein by wiring the Settlement Payment to an account designated by Express Scripts. The Settlement Payment shall be paid as follows:

   (a) No later than 60 business days after EXPRESS SCRIPTS and HORIZON exchange fully executed copies of this Agreement, HORIZON will make an initial installment payment of $32,500,000, inclusive of $[***] in payment of EXPRESS SCRIPTS’ attorneys’ fees and litigation costs and expenses;

   (b) $16,250,000 payable on or before January 15, 2017; and

   (c) $16,250,000 payable on or before April 15, 2017.

The Settlement Payment shall constitute the Parties’ full release for any amounts allegedly owed to each other arising from the 2012 Rebate Agreement.

In the event HORIZON defaults on any part of the Settlement Payment, EXPRESS SCRIPTS shall provide HORIZON notice of such default and ten (10) business days to cure such default. If HORIZON fails to cure its default within this ten (10)-day period, all remaining Settlement Payment amounts will become immediately due and owing.

2. **Attorneys’ Fees and Expenses.** Except as expressly provided in this Agreement, each side shall bear its respective attorneys’ fees, costs, and expenses of any kind or nature whatsoever related to the Litigation and the preparation of this Agreement.

3. **Taxes.** EXPRESS SCRIPTS shall be solely responsible for, and is legally bound to make payment of, any taxes determined to be due and owing (including penalties and interest related thereto) by it to any federal, state, local or regional taxing authority as a result of the Settlement Payment. EXPRESS SCRIPTS understands that HORIZON has not made, and it does not rely upon, any representations regarding the tax treatment of the sums paid pursuant to this Agreement. Moreover, EXPRESS SCRIPTS agrees to indemnify and hold HORIZON harmless in the event that any governmental taxing ***Confidential Treatment Requested***
authority asserts against HORIZON any claim for unpaid taxes, failure to withhold taxes, penalties or interest based upon the payment of the Settlement Payment.

4. **Mutual Release.** The Parties, on behalf of themselves, their predecessors, successors, direct and indirect parent companies, direct and indirect subsidiary companies, companies under common control with any of the foregoing, affiliates and assigns, and its and their past, present and future officers, directors, shareholders, interest holders, members, partners, attorneys, agents, employees, managers, representatives, assigns and successors in interest, and all persons acting by, through, under or in concert with them, and each of them, hereby release and discharge the other Party, together with their predecessors, successors, direct and indirect parent companies, direct and indirect subsidiary companies, companies under common control with any of the foregoing, affiliates and assigns and its and their past, present and future officers, directors, shareholders, interest holders, members, partners, attorneys, agents, employees, managers, representatives, assigns and successors in interest, and all persons acting by, through, under or in concert with them, and each of them, from all known and unknown charges, complaints, claims, grievances, liabilities, obligations, promises, agreements, controversies, damages, actions, causes of action, suits, rights, demands, costs, losses, debts, penalties, fees, wages, medical costs, pain and suffering, mental anguish, emotional distress, expenses (including attorneys’ fees and costs actually incurred) and punitive damages, of any nature whatsoever, known or unknown, which either Party has, or may have had, against the other Party, whether or not apparent or yet to be discovered, or which may hereafter develop, for any acts or omissions related to or arising from:

(a) the Dispute;

(b) the Litigation; and/or

(c) the Rebate Agreement.

This Agreement resolves any claim for relief that is, or could have been alleged, no matter how characterized, including, without limitation, compensatory damages, damages for breach of contract, bad faith damages, reliance damages, liquidated damages, damages for humiliation and embarrassment, punitive damages, costs and attorneys’ fees related to or arising from the Dispute. Notwithstanding anything herein to the contrary, this Agreement does not release HORIZON or EXPRESS SCRIPTS from their obligations provided for in this Agreement, which shall remain in full force and effect according to its terms.

5. **No Admission of Liability.** The Parties acknowledge that the Settlement Payment was agreed upon as a compromise and final settlement of disputed claims and that payment of the Settlement Payment is not, and may not be construed as, an admission of liability by HORIZON and is not to be construed as an admission that HORIZON engaged in any wrongful, tortious or unlawful activity. HORIZON specifically disclaims
and denies (a) any liability to EXPRESS SCRIPTS and (b) engaging in any wrongful, tortious or unlawful activity.

6. **Dismissal of Litigation.** The Parties shall take whatever actions are necessary to ensure that the Litigation is dismissed in its entirety as to both Parties, with prejudice and without costs or fees, within three (3) days of HORIZON’s delivery of the initial installment of the Settlement Payment, as described in Paragraph 1(a). Nothing in this Agreement, specifically including Paragraphs 4 and 6, is intended to release or limit any Party’s right to enforce the terms of this Agreement, including the payment obligations in Paragraph 1. The stipulation of dismissal and proposed order shall provide that the Superior Court of the State of Delaware will retain jurisdiction to enforce this Agreement.

7. **Confidentiality of Agreement.** The fact of settlement, and the Settlement Payment, will be a matter of public record pursuant to Paragraph 8 below. The Parties expressly understand and agree, however, that this Agreement will remain CONFIDENTIAL, except as provided herein.

A Party may disclose this Agreement: (a) to the extent necessary to enforce the Party’s rights under the Agreement; (b) as required by law, including, but not limited to, in response to an order or subpoena issued by a court of competent jurisdiction, a duly constituted arbitration panel, or a local, state, or federal governmental agency, so long as advance notice, in writing, is immediately given to all the Parties, prior to any such disclosure; and (c) only to the extent reasonably necessary, to persons providing auditing, tax, insurance, actuarial, or financial services to a Party, provided those persons are bound by confidentiality obligations no less restrictive than those set forth herein and except as required by law or order of court. Each Party shall be liable for any breaches of confidentiality by persons to whom such Party has disclosed this Agreement in accordance with clause (c) of the preceding sentence. If a Party is compelled by any law, regulation or court order to disclose this Agreement, such Party shall provide written notice to the other Party before making such disclosure. Notwithstanding the foregoing, EXPRESS SCRIPTS also has the right to notify its clients of the settlement, the Settlement Payment and its structured payment terms, in connection with any payment of a client’s share of the settlement monies for rebates and other fees related to the Horizon products in accordance with a client’s contract, that are the subject of the Rebate Agreement.

8. **Public Disclosure of Agreement.** Concurrent with the exchange between the Parties of fully executed copies of this Agreement, as described in Paragraph 18 below, HORIZON will issue an 8K report with the Securities and Exchange Commission (“SEC”) relating to the settlement and the dismissal of the Litigation. A copy of the 8K report is attached hereto as Exhibit A. The Parties will not provide any comments to the general public through news media (“Public Disclosure”) relating to the settlement and the dismissal of the Litigation. The Parties further agree that, unless required to do so by
legal process, their officers and directors will not make any Public Disclosure of any disparaging statements or representations related to this Dispute and/or this Litigation.

9. [...***...].

10. **Agreement is Legally Binding.** The Parties intend this Agreement to be legally binding upon and shall inure to the benefit of each of them and their respective successors, assigns, executors, administrators, heirs and estates. Moreover, the persons and entities referred to in paragraph 4 above, but not a Party, are third-party beneficiaries of this Agreement.

11. **Entire Agreement.** The recitals set forth at the beginning of this Agreement are incorporated by reference and made a part of this Agreement. This Agreement constitutes the entire agreement and understanding of the Parties and supersedes all prior negotiations and/or agreements, proposed or otherwise, written or oral, concerning the subject matter hereof. Furthermore, no modification of this Agreement shall be binding unless in writing and signed by each of the parties hereto.

12. **New or Different Facts: No Effect.** Except as provided herein, this Agreement shall be, and remain, in effect despite any alleged breach of this Agreement or the discovery or existence of any new or additional fact, or any fact different from that which either Party now knows or believes to be true. Notwithstanding the foregoing, nothing in this Agreement shall be construed as, or constitute, a release of any Party’s rights to enforce the terms of this Agreement.

13. **Interpretation.** Should any provision of this Agreement be declared or be determined by any court to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this Agreement. The headings within this Agreement are purely for convenience and are not to be used as an aid in interpretation. Moreover, this Agreement shall not be construed against either Party as the author or drafter of the Agreement.

***Confidential Treatment Requested***
14. **Governing Law and Choice of Forum.** This Agreement is made and entered into within and shall be governed by, construed, interpreted and enforced in accordance with the laws of the Delaware, without regard to the principles of conflicts of laws. Any action to enforce this Agreement shall be brought only in a Delaware state court.

15. **Reliance on Own Counsel.** In entering into this Agreement, the Parties acknowledge that they have relied upon the legal advice of their respective attorneys, who are the attorneys of their own choosing, that such terms are fully understood and voluntarily accepted by them, and that, other than the consideration set forth herein, no promises or representations of any kind have been made to them by the other Party. The Parties represent and acknowledge that in executing this Agreement they did not rely, and have not relied, upon any representation or statement, whether oral or written, made by the other Party or by that other Party’s agents, representatives or attorneys with regard to the subject matter, basis or effect of this Agreement or otherwise.

16. **Counterparts.** This Agreement may be executed by the Parties in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Several signature pages may be collected and annexed to one or more documents to form a complete counterpart. Photocopies, facsimiles, and/or PDFs of executed copies of this Agreement may be treated as originals.

17. **Authority to Execute Agreement.** By signing below, each Party warrants and represents that the person signing this Agreement on its behalf has authority to bind that Party and that the Party’s execution of this Agreement is not in violation of any by-law, covenants and/or other restrictions placed upon them by their respective entities.

18. **Effective Date.** The terms of the Agreement will be effective only when fully executed copies of this Agreement are exchanged between the Parties (the “Effective Date”).

19. **Headings.** The various headings used in this Agreement are solely for the Parties’ convenience and may not be used to interpret this Agreement. The headings do not define, limit, extend or describe the Parties’ intent or the scope of this Agreement.

**READ THE FOREGOING DOCUMENT CAREFULLY. IT INCLUDES A RELEASE OF KNOWN AND UNKNOWN CLAIMS.**

[Signature page follows]
IN WITNESS WHEREOF, and intending to be legally bound, each of the Parties hereto has caused this Agreement to be executed as of the date(s) set forth below.

/s/ Julia Brncic  
for EXPRESS SCRIPTS, INC.  
Title: VP and Associate General Counsel  
Dated: 9/26/16

/s/ Timothy P. Walbert  
for HORIZON PHARMA USA, INC.  
Title: Chairman, President and CEO  
Dated: 9/24/16

7
EXECUTIVE EMPLOYMENT AGREEMENT BY AND BETWEEN HORIZON PHARMA, INC., HORIZON PHARMA USA, INC. AND DAVID A. HAPPEL

This Executive Employment Agreement (hereinafter referred to as the “Agreement”), is entered into by and between Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation, each having a principal place of business at 150 S. Saunders Road, Lake Forest, IL 60045 (hereinafter referred to together as the “Company”) and David A. Happel (hereinafter referred to as the “Executive”). The terms of this Agreement shall be effective commencing October 25, 2016 (the “Effective Date”).

RECITALS

WHEREAS, the Executive previously entered into an amended and restated employment agreement with Raptor Pharmaceuticals Corp. (“Raptor”) on October 13, 2014 and a Change in Control Severance Agreement with Raptor dated March 8, 2016 (together, the “Prior Agreement”);

WHEREAS, the Company’s parent entity, Horizon Pharma Public Limited Company (“Horizon plc”) acquired Raptor on October 25, 2016, and Raptor became a wholly owned subsidiary of Horizon plc;

WHEREAS, the Company desires assurance of the continued association and services of the Executive in order to continue to retain the Executive’s experience, skills, abilities, background and knowledge, and is willing to continue to engage the Executive’s services on the terms and conditions set forth in this Agreement, which as of the Effective Date shall replace supersede in its entirety the terms of the Prior Agreement; and

WHEREAS, Executive desires to be in the employ of the Company, and is willing to accept such employment on the terms and conditions set forth in this Agreement and the letter agreement by and between the Executive and Raptor dated October 13, 2016 (the “Transition Services Agreement”) the terms of which will continue in full force and effect following the Effective Date.

WHEREAS, nothing herein is intended to alter Executive’s right to receive the retention bonus amount of $196,219 that was approved for Executive by Raptor’s compensation committee in September 2016.

AGREEMENT

1. Employment.

1.1 Term. Executive’s employment will be transferred from Raptor to the Company as of the Effective Date. The Company hereby agrees to employ the Executive, and the Executive hereby accepts employment by the Company, upon the terms and conditions set forth in this Agreement. Executive’s employment shall be
governed under the terms set forth in this Agreement beginning on the Effective Date and shall continue until it is terminated pursuant to Section 4 herein (hereinafter referred to as the “Term”).

1.2 Title. From and after the Effective Date the Executive will have the title of Executive Vice President, Global Orphan Business (such position held by Executive during such period is hereinafter referred to as “EVP GOB”) and Executive shall continue to serve in such other capacity or capacities commensurate with his position as EVP GOB as the President and CEO of the Company may from time to time prescribe.

1.3 Duties. The Executive shall do and perform all services, acts or things necessary or advisable to manage and conduct the business of the Company and shall have the authority and responsibilities which are generally associated with the position of EVP GOB including being responsible for the Company’s international operations and the U.S. orphan business unit. The Executive shall report to the President and CEO.

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

1.5 Location. The Executive shall perform the services the Executive is required to perform pursuant to this Agreement in Novato California. The Company may from time to time require the Executive to travel temporarily to other locations outside of the Novato California area in connection with the Company’s business.

2. Loyalty of Executive.

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

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

2.3 Agreement not to Participate in Company’s Competitors. During the Term of this Agreement, the Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by Executive to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise or in any company, person or entity that is, directly or indirectly, in competition with the business of the Company or any of its affiliates. Notwithstanding the foregoing,
Executive may invest and/or maintain investments in any public or private entity up to an amount of 2% of an entity’s fully diluted shares and on a passive basis.

3. **Compensation to Executive.**

3.1 **Base Salary.** The Company shall pay the Executive a base salary at the initial annualized rate of five hundred thousand dollars ($500,000) per year, subject to standard deductions and withholdings, or such higher rate as may be determined from time to time by the Board or the compensation committee thereof (hereinafter referred to as the “Base Salary”). Such Base Salary shall be paid in accordance with the Company’s standard payroll practice. Payments of salary installments shall be made no less frequently than once per month. Executive’s Base Salary will be reviewed annually each December and Executive shall be eligible to receive a salary increase (but not decrease) annually in an amount to be determined by the Board or the compensation committee thereof in its sole and exclusive discretion. Once increased, the new salary shall become the Base Salary for purposes of this Agreement and shall not be reduced without the Executive’s written consent. Any material reduction in the Base Salary of the Executive, without his written consent, may be deemed Good Reason as set forth in and subject to Section 4.5.2 of this Agreement.

3.2 **Discretionary Bonus.** Executive’s eligibility to receive a bonus for the 2016 calendar year will be governed by the terms of Transition Services Agreement. Provided the Executive meets the conditions stated in this Section 3.2, commencing with the 2017 calendar year the Executive shall be eligible for an annual discretionary bonus (hereinafter referred to as the “Bonus”) with a target amount of fifty percent (50%) of the Executive’s Base Salary, subject to standard deductions and withholdings, based on the Board’s determination, in good faith, and based upon the Executive’s individual achievement and company performance objectives as set by the Board or the compensation committee thereof, of whether the Executive has met such performance milestones as are established for the Executive by the Board or the compensation committee thereof, in good faith, in consultation with the Executive (hereinafter referred to as the “Performance Milestones”). The Performance Milestones will be based on certain factors including, but not limited to, the Executive’s performance and the Company’s financial performance. The Executive’s Bonus target will be reviewed annually and may be adjusted by the Board or the compensation committee thereof in its discretion, provided however, that the Bonus target may only be materially reduced upon Executive’s written consent. The Executive must be employed on the date the Bonus is awarded to be eligible for the Bonus, subject to the termination provisions thereof. The Bonus shall be paid during the calendar year following the performance calendar year.

3.3 **Horizon Retention Agreement.** Concurrently with the execution of this Agreement, the Executive shall execute the Retention Agreement, a copy of which is attached as Exhibit D (the “Horizon Retention Agreement”). Subject to Executive’s timely acceptance and execution of this Agreement and the Horizon Retention Agreement, Executive will be eligible to earn a retention bonus on the terms and conditions set forth in the Horizon Retention Agreement.
3.4 Equity Awards.

3.4.1 Equity Grants. Subject to Executive’s timely acceptance and execution of this Agreement, on the Effective Date the Executive was granted the following equity awards pursuant to and subject to the terms of the Horizon Pharma Public Limited Company 2014 Equity Incentive Plan (“2014 Equity Incentive Plan”) and its form of stock option and restricted stock unit award agreements, in the forms provided to Executive concurrently with this Agreement (collectively the “Equity Plan Documents”) and compliance with applicable securities laws:

(i) Option. A stock option to purchase up to 50,674 ordinary shares of Horizon plc (the “Option”). The Option has an exercise price equal to the fair market value of Horizon plc’s ordinary shares on the applicable date of grant, which is October 25, 2016. The Option will be an incentive stock option to the maximum extent permitted by applicable tax laws. Any portion of the Option that does not qualify as an incentive stock option will be a nonstatutory stock option. Subject to Executive’s continued provision of services to the Company through the applicable vesting dates, the Option shall vest as follows: 25% of the total number of shares subject to the Option shall vest on the first anniversary of the date of grant (the “Vesting Commencement Date”) and 1/36 of the remaining number of shares subject to the Option shall vest on each monthly anniversary thereafter so that the Option would fully vest on the four (4) year anniversary of the Vesting Commencement Date subject to Executive’s continued services with the Company through such date.

(ii) Restricted Stock Unit Award. A restricted stock unit award in respect of 31,813 ordinary shares of Horizon plc (the “RSU Award”). Subject to Executive’s continued provision of services to the Company through the applicable vesting dates, the RSU Award shall vest as follows: 25% of the total number of units subject to the RSU Award shall vest on the first anniversary of the Vesting Commencement Date, and thereafter 25% of the total number of units subject to the RSU Award shall vest on each anniversary thereafter, so that the RSU Award would fully vest on the fourth anniversary of the Vesting Commencement Date, subject to Executive’s continued services with the Company through such date.

3.4.2 Legal Review. Upon the Executive’s submission of appropriate itemized proof and verification of reasonable and customary legal fees incurred by the Executive in obtaining legal advice associated with the review, preparation, approval, and execution of this Agreement, the Company shall pay for up to $10,000.00 of such legal fees subject to receipt of appropriate proof and verification of such legal fees no later than sixty (60) days of receipt of an invoice for legal services from the Executive and/or his attorneys. To be eligible for reimbursement, the invoice must be submitted no later than ninety (90) days after the legal fees are incurred.

3.5 Changes to Compensation. The Executive’s compensation may be changed from time to time by mutual agreement of the Executive and the Company. In the event that the Executive’s base salary is materially decreased without his written consent, said decrease will be Good Reason for the Executive to terminate the Agreement as set forth in and subject to Section 4.5.2 of this Agreement.

3.6 Taxes. All amounts paid under this Agreement to the Executive by the Company will be paid less applicable tax withholdings and any other withholdings required by law or authorized by the Executive.
3.7 Benefits. The Executive shall, in accordance with Company policy and the terms of the applicable plan documents, be eligible to participate in benefits under any executive benefit plan or arrangement which may be in effect from time to time and made available to the Company’s executives or key management employees, provided, however, that the Executive shall be entitled to at least four (4) weeks of paid vacation annually.

4. Termination.

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

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

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

4.1.3 Termination by the Company Without Cause. The Company may terminate the Executive’s employment under this Agreement at any time and for any reason or no reason subject to the requirements set out in Section 4.4 of this Agreement. Such termination shall be effective on the date the Executive is so informed or as otherwise specified by the Company, pursuant to notice requirements set forth in Section 6 of this Agreement.

4.2 Termination By The Executive. The Executive may terminate his employment with the Company at any time and for any reason or no reason, including, but not limited, to the following conditions:

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

4.2.2 Without Good Reason. The Executive may terminate the Executive’s employment hereunder for other than Good Reason upon thirty (30) days written notice to the Company.
4.3 Termination by Mutual Agreement of the Parties. The Executive’s employment pursuant to this Agreement may be terminated at any time upon a mutual agreement in writing of the parties. Any such termination of employment shall have the consequences specified in such mutual agreement.

4.4 Compensation to Executive Upon Termination. In connection with any termination of the Executive’s employment for any reason, the Executive or the Executive’s estate, as applicable, shall be entitled to any amounts payable to the Executive or the Executive’s beneficiaries subject to and accordance with the terms of the Company’s employee welfare benefit plans or policies (excluding any severance pay).

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

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

4.4.3 Without Cause or For Good Reason.

(i) Not in Connection With a Change in Control. If the Company terminates the Executive’s employment without Cause or the Executive terminates his employment for Good Reason, and Section 4.4.3(ii) below does not apply, the Company shall pay the Accrued Amounts subject to standard deductions and withholdings, to be paid as a lump sum no later than thirty (30) days after the date of termination. In addition, subject to the limitations stated in this Agreement and upon the Executive’s furnishing to the Company an executed waiver and release of claims (the form of which is attached hereto as Exhibit A) (the “Release”) within the applicable time period set forth therein, but in no event later than forty-five days following termination of employment and permitting such Release to become effective in accordance with its terms (the “Release Effective Date”), and subject to Executive entering into no later than the Release Effective Date a non-competition agreement to be effective during the
Severance Period (as defined below), substantially similar to Section 2.3, and continuing to abide by its terms during the Severance Period, the Executive shall be entitled to:

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

(b) in the event the Executive timely elects continued coverage under COBRA, the Company will continue to pay the same portion of Executive’s COBRA health insurance premium as the percentage of health insurance premiums that it paid during the Executive’s employment, including any amounts that Company paid for benefits to the qualifying family members of the Executive, following the date of termination up until the earlier of either (i) the last day of the Severance Period or, (ii) the date on which the Executive begins full-time employment with another company or business entity which offers comparable health insurance coverage to the Executive (such period, the “COBRA Payment Period”). Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive a taxable cash amount, which payment shall be made regardless of whether the Executive or his qualifying family members elect COBRA continuation coverage (the “Health Care Benefit Payment”). The Health Care Benefit Payment shall be paid in monthly or bi-weekly installments on the same schedule that the COBRA premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the COBRA Payment Period.

(ii) In Connection With a Change in Control. If the Company (or its successor) terminates the Executive’s employment without Cause or the Executive terminates his employment for Good Reason within the period commencing ninety (90) days immediately prior to a Change in Control of the Company and ending eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the Executive shall receive the Accrued Amounts subject to standard deductions and withholdings, to be paid as a lump sum no later than thirty (30) days after the date of termination. In addition, subject to the limitations stated in this Agreement and upon the Executive’s furnishing to the Company (or its successor) an executed Release within the applicable time period set forth therein, but in no event later than forty-five days following termination of employment and permitting such Release to become effective in accordance with its terms, and subject to Executive entering into no later than the Release Effective Date a non-competition agreement to be effective during the Severance Period, substantially similar to Section 2.3, and continuing to abide by its terms during the Severance Period, then in lieu of (and not additional to) the benefits provided pursuant to Section 4.4.3(i) above, the
Executive shall be entitled to:

(a) the equivalent of the Executive’s Base Salary in effect at the time of termination will continue to be paid during the Severance Period, less standard deductions and withholdings, to be paid during the Severance Period according to the Company’s regular payroll practices, subject to any delay in payment required by Section 4.6 in connection with the Release Effective Date;

(b) Executive’s target Bonus in effect at the time of termination, or if none, the last target Bonus in effect for Executive, less standard deductions and withholdings, to be paid in a lump sum within ten (10) days following the later of (i) the Release Effective Date, or (ii) the effective date of the Change in Control; and

(c) in the event the Executive timely elects continued coverage under COBRA, the Company will continue to pay the same portion of Executive’s COBRA health insurance premium as the percentage of health insurance premiums that it paid during the Executive’s employment, including any amounts that Company paid for benefits to the qualifying family members of the Executive, following the date of termination until the expiration of the COBRA Payment Period. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive the Health Care Benefit Payment, which payment shall be made regardless of whether the Executive or his qualifying family members elect COBRA continuation coverage. The Health Care Benefit Payment shall be paid in monthly or bi-weekly installments on the same schedule that the COBRA premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the COBRA Payment Period.

(iii) No Duplication of Benefits. For the avoidance of doubt, in no event will Executive be entitled to benefits under Section 4.4.3(i) and Section 4.4.3(ii). If Executive commences to receive benefits under Section 4.4.3(i) due to a qualifying termination prior to a Change in Control and thereafter becomes entitled to benefits under Section 4.4.3(ii), any benefits previously provided to Executive under Section 4.4.3(i) shall offset the benefits to be provided to Executive under Section 4.4.3(ii) and shall be deemed to have been provided to Executive pursuant to Section 4.4.3(ii).

4.4.4 Equity Award Acceleration.

(i) In Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason within the ninety (90) days immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of the Option, the RSU Award and any other time-based vesting Company equity awards granted to Executive shall be fully accelerated such that
on the effective date of such termination (or, if later, the date of the Change in Control) one hundred percent (100%) of the equity award shares granted to Executive prior to such termination shall be fully vested and immediately exercisable, if applicable, by the Executive.

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

4.5 Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

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

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

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

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

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

(iv) a material breach by the Company of Section 1.2 of this Agreement.
Provided, however that, such termination by the Executive shall only be deemed for Good Reason pursuant to the foregoing definition if (i) the Company is given written notice from the Executive within sixty (60) days following the first occurrence of the condition that he considers to constitute Good Reason describing the condition and the Company fails to satisfactorily remedy such condition within thirty (30) days following such written notice, and (ii) the Executive terminates employment within thirty (30) days following the end of the period within which the Company was entitled to remedy the condition constituting Good Reason but failed to do so.

4.5.3 Cause. “Cause” for the Company to terminate Executive’s employment hereunder shall mean the occurrence of any of the following events, as determined reasonably and in good faith by the Board or a committee designated by the Board:

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

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

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

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

4.5.4 Change in Control. For purposes of this Agreement, “Change in Control” means: (i) a sale of all or substantially all of the assets of the Company; (ii) a merger or consolidation in which the Company is not the surviving entity and in which the holders of the Company’s outstanding voting stock immediately prior to such transaction own, immediately after such transaction, securities representing less than fifty percent (50%) of the voting power of the entity surviving such transaction or, where the surviving entity is a wholly-owned subsidiary of another entity, the surviving entity’s parent; (iii) a reverse merger in which the Company is the surviving entity but the shares of Common Stock outstanding immediately preceding the merger are converted by virtue of the merger into other property, whether in the form of securities of the surviving entity’s parent, cash or otherwise, and in which the holders of the Company’s outstanding voting stock immediately prior to such transaction own, immediately after such transaction, securities representing less than fifty percent (50%) of the voting power of the Company or, where the Company is a wholly-owned subsidiary of another entity, the Company’s parent; or (iv) an acquisition by any person, entity or group (excluding any employee benefit plan, or related trust, sponsored or maintained by the Company or subsidiary of the Company or other entity controlled by the Company) of the beneficial
ownership of securities of the Company representing at least seventy-five percent (75%) of the combined voting power entitled to vote in the election of Directors; provided, however, that nothing in this paragraph shall apply to a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

4.6 Application of Internal Revenue Code Section 409A. Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under this Agreement (the “Severance Benefits”) that constitute “deferred compensation” within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the “Code”) and the regulations and other guidance thereunder and any state law of similar effect (collectively “Section 409A”) shall not commence in connection with Executive’s termination of employment unless and until Executive has also incurred a “separation from service” (as such term is defined in Treasury Regulation Section 1.409A-1(h) (“Separation From Service”), unless the Company reasonably determines that such amounts may be provided to Executive without causing Executive to incur the additional 20% tax under Section 409A.

It is intended that each installment of the Severance Benefits payments provided for in this Agreement is a separate “payment” for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the Severance Benefits set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulation Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Company (or, if applicable, the successor entity thereto) determines that the Severance Benefits constitute “deferred compensation” under Section 409A and Executive is, on the termination of service, a “specified employee” of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance Benefit payments shall be delayed until the earlier to occur of: (i) the date that is six months and one day after Executive’s Separation From Service, or (ii) the date of Executive’s death (such applicable date, the “Specified Employee Initial Payment Date”), the Company (or the successor entity thereto, as applicable) shall (A) pay to Executive a lump sum amount equal to the sum of the Severance Benefit payments that Executive would otherwise have received through the Specified Employee Initial Payment Date if the commencement of the payment of the Severance Benefits had not been so delayed pursuant to this Section and (B) commence paying the balance of the Severance Benefits in accordance with the applicable payment schedules set forth in this Agreement.
Notwithstanding anything to the contrary set forth herein, Executive shall receive the Severance Benefits described above, if and only if Executive duly executes and returns to the Company within the applicable time period set forth therein, but in no event more than forty-five days following Separation From Service, the Company’s standard form of release of claims in favor of the Company (attached to this Agreement as Exhibit A) (the “Release”) and permits the release of claims contained therein to become effective in accordance with its terms (such latest permitted date, the “Release Deadline”). If the severance benefits are not covered by one or more exemptions from the application of Section 409A and the Release could become effective in the calendar year following the calendar year in which Executive separates from service, the Release will not be deemed effective any earlier than the Release Deadline. Notwithstanding any other payment schedule set forth in this Agreement, none of the Severance Benefits will be paid or otherwise delivered prior to the effective date (or deemed effective date) of the Release. Except to the extent that payments may be delayed until the Specified Employee Initial Payment Date pursuant to the preceding paragraph, on the first regular payroll pay day following the effective date of the Release, the Company will pay Executive the Severance Benefits Executive would otherwise have received under the Agreement on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the Severance Benefits being paid as originally scheduled.

The severance benefits are intended to qualify for an exemption from application of Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences under Section 409A, and any ambiguities herein shall be interpreted accordingly.

4.7 Application of Internal Revenue Code Section 280G. If any payment or benefit Executive would receive pursuant to a Change in Control from the Company or otherwise (“Payment”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then such Payment shall be equal to the Reduced Amount. The “Reduced Amount” shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive’s receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting “parachute payments” is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

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

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

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

4.8 Indemnification Agreements. Concurrently with the execution of this Agreement, the Company and the Executive shall enter into indemnification agreements, copies of which are attached hereto as Exhibit B-1 and Exhibit B-2.

4.9 Confidential Information and Invention Assignment Agreement. Concurrently with the execution of this Agreement, the Executive shall execute the Company’s Confidential Information and Invention Assignment Agreement, a copy of which is attached as Exhibit C.

4.10 No Mitigation or Offset. The Executive shall not be required to seek or accept other employment, or otherwise to mitigate damages, as a condition to receipt of the Severance Benefits, and the Severance Benefits shall not be offset by any amounts received by the Executive from any other source, except to the extent that the Executive’s rights to the benefits described in Sections 4.4.3(i)(b) or 4.4.3(ii)(c), as applicable, are terminated by reason of the Executive obtaining full-time employment with another company or business entity which offers comparable health insurance coverage.

5. Assignment and Binding Effect.

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


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

If to the Company:

Horizon Pharma, Inc.
150 S. Saunders Road
Lake Forest, IL 60045
Attention: Timothy P. Walbert, Chairman, President & CEO
Fax: 847-572-1372

If to the Executive:

David A. Happel
2362 Caballo Ranchero Drive
Diablo, CA 94528

Any such written notice shall be deemed given on the earlier of the date on which such notice is personally delivered or five (5) days after its deposit in the United States mail as specified above. Either Party may change its address for notices by giving written notice to the other Party in the manner specified in this section.

7. Choice of Law.

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

This Agreement, including Exhibit A, Exhibit B, Exhibit C, Exhibit D, the 2014 Equity Incentive Plan, and the Transition Services Agreement contains the complete, final and exclusive agreement of the parties relating to the terms and conditions of the Executive’s employment and the termination of Executive’s employment, and supersedes all prior and contemporaneous oral and written employment agreements or arrangements between the parties, including but not limited to the Prior Agreement. By executing this Agreement, Executive hereby agrees that Executive’s Prior Agreement is terminated and superseded in its entirety by this Agreement as of the Effective Date and that Executive waives any right that Executive may have and/or is not entitled to severance benefits under the Prior Agreement.

9. **Amendment.**

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

10. **Waiver.**

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

11. **Severability.**

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

12. **Interpretation; Construction.**

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

13. **Execution by Facsimile Signatures and in Counterparts.**

The parties agree that facsimile signatures shall have the same force and effect as original signatures. This Agreement may be executed in one or more counterparts, each
of which shall be deemed an original but all of which together shall constitute one and the same instrument.

14. **Survival.**

    The provisions of this Agreement, and of all other agreements referenced herein, shall survive the termination of this Agreement, and of the Executive’s employment by the Company for any reason, to the extent necessary to enable the parties to enforce their respective rights hereunder.

    [Remainder of Page Intentionally Left Blank]
IN WITNESS WHEREFORE, the parties have signed this Agreement on the date first written above.

COMPANY:

HORIZON PHARMA, INC.
HORIZON PHARMA USA, INC.

By:

Title: Chairman, President & CEO

Print Name: Timothy P. Walbert

/s/ Timothy P. Walbert

Signature:

As authorized agent of the Company

November 4, 2016

Date

EXECUTIVE:

David A. Happel

/s/ David A. Happel

David A. Happel, individually

November 4, 2016

Date
EXHIBIT A

RELEASE AND WAIVER OF CLAIMS

In consideration of the payments and other benefits set forth in Section 4.4 of the Executive Employment Agreement dated October 25, 2016, (the “Employment Agreement”), to which this form is attached, I, David A. Happel, hereby furnish Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (together the “Company”), with the following release and waiver (“Release and Waiver”).

In exchange for the consideration provided to me by the Employment Agreement that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, Affiliates, and assigns from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring relating to my employment or the termination thereof prior to my signing this Release and Waiver. This general release includes, but is not limited to: (1) all claims arising out of or in any way related to my employment with the Company or the termination of that employment; (2) all claims related to my compensation or benefits from the Company, including, but not limited to, salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including, but not limited to, claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including, but not limited to, claims for discrimination, harassment, retaliation, attorneys’ fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) (“ADEA”), the California Labor Code (as amended), the California Family Rights Act, and the California Fair Employment and Housing Act (as amended). Notwithstanding the foregoing, this Release and Waiver, shall not release or waive my rights: to indemnification under the articles and bylaws of the Company or applicable law; to payments under Sections ___ of the Employment Agreement; under any provision of the Employment Agreement that survives the termination of that agreement; under any applicable workers’ compensation statute; under any option, restricted share or other agreement concerning any equity interest in the Company; as a shareholder of the Company or any other right that is not waivable under applicable law.

I acknowledge that, among other rights, I am waiving and releasing any rights I may have under ADEA, that this Release and Waiver is knowing and voluntary, and
that the consideration given for this Release and Waiver is in addition to anything of value to which I was already entitled as an executive of the Company. If I am 40 years of age or older upon execution of this Release and Waiver, I further acknowledge that I have been advised, as required by the Older Workers Benefit Protection Act, that: (a) the release and waiver granted herein does not relate to claims under the ADEA which may arise after this Release and Waiver is executed; (b) I should consult with an attorney prior to executing this Release and Waiver; and (c) I have twenty-one (21) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier); (d) I have seven (7) days following the execution of this Release and Waiver to revoke my consent to this Release and Waiver; and (e) this Release and Waiver shall not be effective until the seven (7) day revocation period has expired unexercised. If I am less than 40 years of age upon execution of this Release and Waiver, I acknowledge that I have the right to consult with an attorney prior to executing this Release and Waiver (although I may choose voluntarily to do so); and (c) I have five (5) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier).

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

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

Date:

By:

David A. Happel
Exhibit 31.1

Certification of Chief Executive Officer

I, Timothy P. Walbert, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Horizon Pharma PLC (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 7, 2016

/s/ Timothy P. Walbert
Timothy P. Walbert
Chairman, President and Chief Executive Officer
(Principal Executive Officer)
I, Paul W. Hoelscher, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Horizon Pharma PLC (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 7, 2016

/s/ Paul W. Hoelscher
Paul W. Hoelscher
Executive Vice President, Chief Financial Officer
(Principal Financial 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 PLC (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, 2016 (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 7, 2016

/s/ Timothy P. Walbert
Timothy P. Walbert
Chairman, President and Chief Executive Officer
(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, 1, Paul W. Hoelscher, Executive Vice President and Chief Financial Officer of Horizon Pharma PLC (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, 2016 (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 7, 2016

/s/ Paul W. Hoelscher

Paul W. Hoelscher
Executive Vice President, Chief Financial Officer
(Principal Financial 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.