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 June 30, 2017

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)

Irish
(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, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth 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 ☐
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 July 28, 2017: 163,354,268.
PART I. FINANCIAL INFORMATION

Item 1. Financial Statements
Condensed Consolidated Balance Sheets as of June 30, 2017 and as of December 31, 2016 (Unaudited) 1
Condensed Consolidated Statements of Comprehensive (Loss) Income for the Three and Six Months Ended June 30, 2017 and 2016 (Unaudited) 2
Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2017 and 2016 (Unaudited) 3
Notes to Unaudited Condensed Consolidated Financial Statements 5

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations 44

Item 3. Quantitative and Qualitative Disclosures About Market Risk 62

Item 4. Controls and Procedures 63

PART II. OTHER INFORMATION

Item 1. Legal Proceedings 64
Item 1A. Risk Factors 64
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 110
Item 6. Exhibits 111
Signatures 112
## 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 June 30, 2017</th>
<th>As of December 31, 2016</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>$554,269</td>
<td>$509,055</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>7,266</td>
<td>7,095</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>390,844</td>
<td>305,725</td>
</tr>
<tr>
<td>Inventories, net</td>
<td>102,244</td>
<td>174,788</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>45,988</td>
<td>49,619</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td>1,100,611</td>
<td>1,046,282</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>22,657</td>
<td>23,484</td>
</tr>
<tr>
<td>Developed technology, net</td>
<td>2,580,875</td>
<td>2,767,184</td>
</tr>
<tr>
<td>Other intangible assets, net</td>
<td>5,846</td>
<td>6,251</td>
</tr>
<tr>
<td>Goodwill</td>
<td>427,944</td>
<td>445,579</td>
</tr>
<tr>
<td>Deferred tax assets, net</td>
<td>2,163</td>
<td>911</td>
</tr>
<tr>
<td><strong>Other assets</strong></td>
<td>29,845</td>
<td>2,368</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>$4,169,941</td>
<td>$4,292,059</td>
</tr>
</tbody>
</table>

|                      |                     |                         |
| **LIABILITIES AND SHAREHOLDERS’ EQUITY** |                     |                         |
| **CURRENT LIABILITIES:** |                     |                         |
| Long-term debt—current portion | $8,500             | $7,750                  |
| Accounts payable       | 81,884              | 52,479                  |
| Accrued expenses       | 112,452             | 182,765                 |
| Accrued trade discounts and rebates | 413,201         | 297,556                 |
| Accrued royalties—current portion | 61,575           | 61,981                  |
| Deferred revenues—current portion | 4,254            | 3,321                   |
| **Total current liabilities** | 681,866          | 605,852                 |

|                      |                     |                         |
| **LONG-TERM LIABILITIES:** |                     |                         |
| Exchangeable notes, net | 306,022            | 298,002                 |
| Long-term debt, net, net of current | 1,577,822       | 1,501,741               |
| Accrued royalties, net of current | 268,144          | 272,293                 |
| Deferred revenues, net of current | 7,856            | 7,763                   |
| Deferred tax liabilities, net | 210,821          | 296,568                 |
| Other long-term liabilities | 88,642           | 46,061                  |
| **Total long-term liabilities** | 2,459,307        | 2,422,428               |

|                      |                     |                         |
| **COMMITMENTS AND CONTINGENCIES** |                     |                         |
| **SHAREHOLDERS’ EQUITY:** |                     |                         |
| Ordinary shares, $0.0001 nominal value; 300,000,000 shares authorized: |                     |                         |
| 163,698,457 and 162,004,956 shares issued at June 30, 2017 and December 31, 2016, respectively | 16              | 16                      |
| 163,314,091 and 161,620,590 shares outstanding at June 30, 2017 and December 31, 2016, respectively | (4,585)        | (4,585)                 |
| Treasury stock, 384,366 ordinary shares at June 30, 2017 and December 31, 2016 | (4,585)        | (4,585)                 |
| Additional paid-in capital | 2,177,377         | 2,119,455               |
| Accumulated other comprehensive loss | (2,132)         | (3,086)                 |
| **Accumulated deficit** | (1,141,908)       | (848,021)               |
| **Total shareholders’ equity** | 1,028,768         | 1,263,779               |

|                      |                     |                         |
| **TOTAL LIABILITIES AND SHAREHOLDERS’ EQUITY** |                     |                         |
| **$** | 4,169,941 | $4,292,059 |

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

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended June 30,</th>
<th>For the Six Months Ended June 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>$289,507</td>
<td>$257,378</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>130,150</td>
<td>81,126</td>
</tr>
<tr>
<td>Gross profit</td>
<td>159,357</td>
<td>176,252</td>
</tr>
<tr>
<td>OPERATING EXPENSES:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>163,101</td>
<td>11,210</td>
</tr>
<tr>
<td>Selling, general and administrative</td>
<td>181,923</td>
<td>133,575</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>345,024</td>
<td>144,785</td>
</tr>
<tr>
<td>Operating (loss) income</td>
<td>(185,667)</td>
<td>31,467</td>
</tr>
<tr>
<td>OTHER EXPENSE, NET:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(31,608)</td>
<td>(19,228)</td>
</tr>
<tr>
<td>Foreign exchange gain (loss)</td>
<td>151</td>
<td>15</td>
</tr>
<tr>
<td>Gain on divestiture</td>
<td>5,856</td>
<td>—</td>
</tr>
<tr>
<td>Loss on debt extinguishment</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Other expense, net</td>
<td>(35)</td>
<td>(26)</td>
</tr>
<tr>
<td>Total other expense, net</td>
<td>(25,636)</td>
<td>(19,239)</td>
</tr>
<tr>
<td>(Loss) income before benefit for income taxes</td>
<td>(211,303)</td>
<td>12,228</td>
</tr>
<tr>
<td>BENEFIT FOR INCOME TAXES</td>
<td>(1,767)</td>
<td>(2,756)</td>
</tr>
<tr>
<td>NET (LOSS) INCOME</td>
<td>$ (209,536)</td>
<td>$14,984</td>
</tr>
<tr>
<td>NET (LOSS) INCOME PER ORDINARY SHARE—Basic</td>
<td>$ (1.29)</td>
<td>$ 0.09</td>
</tr>
<tr>
<td>WEIGHTED AVERAGE ORDINARY SHARES OUTSTANDING—Basic</td>
<td>162,931,930</td>
<td>160,468,146</td>
</tr>
<tr>
<td>NET (LOSS) INCOME PER ORDINARY SHARE—Diluted</td>
<td>$ (1.29)</td>
<td>$ 0.09</td>
</tr>
<tr>
<td>WEIGHTED AVERAGE ORDINARY SHARES OUTSTANDING—Diluted</td>
<td>162,931,930</td>
<td>163,920,581</td>
</tr>
<tr>
<td>OTHER COMPREHENSIVE INCOME (LOSS), NET OF TAX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign currency translation adjustments</td>
<td>626</td>
<td>161</td>
</tr>
<tr>
<td>Other comprehensive income (loss)</td>
<td>626</td>
<td>161</td>
</tr>
<tr>
<td>COMPREHENSIVE (LOSS) INCOME</td>
<td>$ (208,910)</td>
<td>$15,145</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these condensed consolidated financial statements.
## CASH FLOWS FROM OPERATING ACTIVITIES:

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss</td>
<td>$(300,106)</td>
<td>$(30,422)</td>
</tr>
<tr>
<td><strong>Adjustments to reconcile net loss to net cash provided by operating activities:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization expense</td>
<td>143,014</td>
<td>102,525</td>
</tr>
<tr>
<td>Equity-settled share-based compensation</td>
<td>57,960</td>
<td>55,418</td>
</tr>
<tr>
<td>Royalty accretion</td>
<td>25,694</td>
<td>19,028</td>
</tr>
<tr>
<td>Royalty liability remeasurement</td>
<td>(2,944)</td>
<td>—</td>
</tr>
<tr>
<td>In-process research and development expense</td>
<td>148,609</td>
<td>—</td>
</tr>
<tr>
<td>Impairment of non-current asset</td>
<td>22,270</td>
<td>—</td>
</tr>
<tr>
<td>Loss on debt extinguishment</td>
<td>388</td>
<td>—</td>
</tr>
<tr>
<td>Payments related to term loan refinancing</td>
<td>(3,940)</td>
<td>—</td>
</tr>
<tr>
<td>Amortization of debt discount and deferred financing costs</td>
<td>10,629</td>
<td>8,932</td>
</tr>
<tr>
<td>Gain on divestiture</td>
<td>(2,635)</td>
<td>—</td>
</tr>
<tr>
<td>Deferred income taxes</td>
<td>(79,486)</td>
<td>(5,362)</td>
</tr>
<tr>
<td>Foreign exchange and other adjustments</td>
<td>613</td>
<td>159</td>
</tr>
<tr>
<td><strong>Changes in operating assets and liabilities:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>(85,323)</td>
<td>(83,932)</td>
</tr>
<tr>
<td>Inventories</td>
<td>67,736</td>
<td>13,777</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>2,434</td>
<td>(16,626)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>29,823</td>
<td>42,278</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>116,950</td>
<td>35,480</td>
</tr>
<tr>
<td>Accrued expenses and accrued royalties</td>
<td>(98,179)</td>
<td>(43,527)</td>
</tr>
<tr>
<td>Deferred revenues</td>
<td>384</td>
<td>(418)</td>
</tr>
<tr>
<td>Other non-current assets and liabilities</td>
<td>14,755</td>
<td>4,174</td>
</tr>
<tr>
<td><strong>Net cash provided by operating activities</strong></td>
<td>68,646</td>
<td>101,484</td>
</tr>
</tbody>
</table>

## CASH FLOWS FROM INVESTING ACTIVITIES:

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payments for acquisitions, net of cash acquired</td>
<td>(167,850)</td>
<td>(520,405)</td>
</tr>
<tr>
<td>Proceeds from divestiture, net of cash divested</td>
<td>69,072</td>
<td>—</td>
</tr>
<tr>
<td>Change in restricted cash</td>
<td>(170)</td>
<td>(1,309)</td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td>(2,628)</td>
<td>(12,776)</td>
</tr>
<tr>
<td><strong>Net cash used in investing activities</strong></td>
<td>(101,576)</td>
<td>(534,490)</td>
</tr>
</tbody>
</table>

## CASH FLOWS FROM FINANCING ACTIVITIES:

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net proceeds from term loans</td>
<td>847,768</td>
<td>—</td>
</tr>
<tr>
<td>Repayment of term loans</td>
<td>(770,790)</td>
<td>(2,000)</td>
</tr>
<tr>
<td>Proceeds from the issuance of ordinary shares in connection with warrant exercises</td>
<td>11</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from the issuance of ordinary shares through ESPP programs</td>
<td>3,856</td>
<td>3,235</td>
</tr>
<tr>
<td>Proceeds from the issuance of ordinary shares in connection with stock option exercises</td>
<td>1,297</td>
<td>1,658</td>
</tr>
<tr>
<td>Payment of employee withholding taxes related to share-based awards</td>
<td>(5,202)</td>
<td>(4,734)</td>
</tr>
<tr>
<td>Repurchase of ordinary shares</td>
<td>(992)</td>
<td>—</td>
</tr>
<tr>
<td><strong>Net cash provided by (used in) financing activities</strong></td>
<td>75,948</td>
<td>(1,841)</td>
</tr>
<tr>
<td>Effect of foreign exchange rate changes on cash and cash equivalents</td>
<td>2,196</td>
<td>(244)</td>
</tr>
</tbody>
</table>

### NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net increase (decrease) in cash and cash equivalents</strong></td>
<td>45,214</td>
<td>(435,091)</td>
</tr>
<tr>
<td><strong>CASH AND CASH EQUIVALENTS, beginning of the period</strong></td>
<td>509,055</td>
<td>859,616</td>
</tr>
<tr>
<td><strong>CASH AND CASH EQUIVALENTS, end of the period</strong></td>
<td>$554,269</td>
<td>$424,525</td>
</tr>
</tbody>
</table>
### Supplemental cash flow information:

<table>
<thead>
<tr>
<th>Description</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash paid for interest</td>
<td>$58,396</td>
<td>$29,791</td>
</tr>
<tr>
<td>Net cash payments for income taxes</td>
<td>1,519</td>
<td>18,059</td>
</tr>
<tr>
<td>Cash paid for debt extinguishment</td>
<td>145</td>
<td>—</td>
</tr>
</tbody>
</table>

### Supplemental non-cash flow information:

<table>
<thead>
<tr>
<th>Description</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchases of property and equipment included in accounts payable</td>
<td>939</td>
<td>2,189</td>
</tr>
<tr>
<td>and accrued expenses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchases of acquired in-process research and development</td>
<td>859</td>
<td>—</td>
</tr>
<tr>
<td>included in accounts payable and accrued expenses</td>
<td></td>
<td></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 six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017. The December 31, 2016 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by GAAP.

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. 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.

On January 13, 2016, the Company completed its acquisition of Crealta Holdings LLC (“Crealta”) for approximately $539.7 million, including $24.9 million of cash acquired and $70.9 million paid to settle Crealta’s outstanding debt. Following completion of the acquisition, Crealta became a wholly owned subsidiary of the Company and was renamed as Horizon Pharma Rheumatology LLC.

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. The total consideration was $860.8 million, including $24.9 million of cash acquired and $56.0 million paid to settle Raptor’s outstanding debt. Following completion of the acquisition, Raptor became a wholly owned subsidiary of the Company and converted to a limited liability company, changing its name to Horizon Pharmaceutical LLC.

On May 8, 2017, the Company acquired River Vision Development Corp. (“River Vision”) for upfront cash payments totaling $151.9 million, including $6.3 million of cash acquired, and subject to other customary purchase price adjustments for working capital, and potential future milestone and royalty payments contingent on the satisfaction of certain regulatory milestones and sales thresholds. Following completion of the acquisition, River Vision became a wholly owned subsidiary of the Company and was renamed as Horizon Pharma Tepro, Inc.

On June 23, 2017, the Company sold its European subsidiary that owned the marketing rights to PROCYSBI® (cysteamine bitartrate) delayed-release capsules and QUINSAIR™ (levofloxacin inhalation solution) in Europe, the Middle East and Africa (“EMEA”) regions (“the Chiesi divestiture”) to Chiesi Farmaceutici S.p.A. (“Chiesi”) for an upfront payment of $72.2 million, including $3.1 million of cash divested, with additional potential milestone payments based on sales thresholds.

On June 30, 2017, the Company completed its acquisition of certain rights to interferon gamma-1b from Boehringer Ingelheim International GmbH (“Boehringer Ingelheim International”) in all territories outside of the United States, Canada and Japan, as the Company previously held marketing rights to interferon gamma-1b in these territories. Boehringer Ingelheim International commercialized interferon gamma-1b under the trade names IMUKIN®, IMUKINE®, IMMUKIN® and IMMUKINE® ("IMUKIN") in an estimated thirty countries, primarily in Europe and the Middle East. In May 2016, the Company paid Boehringer Ingelheim International €5.0 million ($5.6 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1132) for such rights and upon closing in June 2017, the Company paid Boehringer Ingelheim International an additional €19.5 million ($22.3 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1406). The Company markets interferon gamma-1b as ACTIMMUNE® in the United States.

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

Beginning in the first quarter of 2017, the Company modified its presentation of certain operating expenses. Previously, the Company presented “general and administrative” expenses as one line item in its condensed consolidated statement of comprehensive (loss) income, and “selling and marketing” expenses as another. For current-period presentation and prior-period comparisons, the Company now combines these two line items into one line item, titled “selling, general and administrative” expenses.
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:

**Orphan Business Unit**
- ACTIMMUNE® (interferon gamma-1b); marketed as IMUKIN® outside the United States
- BUPHENYL® (sodium phenylbutyrate) Tablets and Powder; marketed as AMMONAPS® in certain European countries and Japan
- PROCYSBI® (cysteamine bitartrate) delayed-release capsules
- QUINSAIR™ (levofloxacin inhalation solution)
- RAVICTI® (glycerol phenylbutyrate) Oral Liquid

**Rheumatology Business Unit**
- KRYSTEXXA® (pegloticase)
- RAYOS® (prednisone) delayed-release tablets; marketed as LODOTRA® outside the United States

**Primary Care Business Unit**
- DUEXIS® (ibuprofen/famotidine)
- MIGERGOT® (ergotamine tartrate & caffeine suppositories)
- PENNSAID® (diclofenac sodium topical solution) 2% w/w (“PENNSAID 2%”)
- VIMOVO® (naproxen/esomeprazole magnesium)

Recent Accounting Pronouncements

From time to time, the Company adopts new accounting pronouncements issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies.

Effective January 1, 2017, the Company elected to early adopt ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* (“ASU No. 2017-01”). The amendments in ASU No. 2017-01 clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill and consolidation. The adoption did not have a material impact on the Company’s condensed consolidated financial statements and related disclosures.

Effective January 1, 2017, the Company adopted ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* (“ASU No. 2016-09”). The update requires excess tax benefits and tax deficiencies, which arise due to differences between the measure of compensation expense and the amount deductible for tax purposes, to be recorded directly through earnings as a component of income tax expense. Previously, these differences were generally recorded in additional paid-in capital and thus had no impact on net income. The change in treatment of excess tax benefits and tax deficiencies also impacts the computation of diluted earnings per share, and the cash flows associated with those items are classified as operating activities on the condensed consolidated statements of cash flows. Additionally, ASU No. 2016-09 permits entities to make an accounting policy election for the impact of forfeitures on the recognition of expense for share-based payment awards. Forfeitures can be estimated, as allowed under previous standards, or recognized when they occur. As a result of the adoption, $7.2 million of excess tax benefits that had not previously been recognized, as the related tax deduction had not reduced current taxes payable, were recorded on a modified retrospective basis through a cumulative effect adjustment to its accumulated deficit as of January 1, 2017. During the three and six months ended June 30, 2017, the Company recognized an excess tax deficiency of $0.1 million and $0.4 million, respectively. The Company elected not to change its policy on accounting for forfeitures and will continue to estimate a requisite forfeiture rate. Additional amendments to the accounting for income taxes and minimum statutory withholding requirements had no impact on the Company’s results of operations and related disclosures.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* (“ASU No. 2017-09”). The amendment amends the scope of modification accounting for share-based payment arrangements, provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. The ASU is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2017-09 on its condensed consolidated financial statements and related disclosures.
In February 2017, the FASB issued ASU No. 2017-05, (“Subtopic 610-20”), Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets (“ASU No. 2017-05”) which provides clarification regarding the scope of the asset derecognition guidance and accounting for partial sales of nonfinancial assets. The update defines an in-substance nonfinancial asset and clarifies that an entity should identify each distinct nonfinancial asset or in-substance nonfinancial asset promised to a counterparty and derecognize each asset when a counterparty obtains control of it. All businesses and nonprofit activities within the scope of Subtopic 610-20 are excluded from the amendments in this update. This guidance will be effective for annual and interim periods beginning after December 15, 2017 and is required to be applied at the same time as ASU No. 2014-09 (described below) is applied. The guidance can be applied using one of two methods: retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the guidance recognized against retained earnings as of the beginning of the fiscal year of adoption. The Company is currently evaluating the effect that this guidance may have on its condensed consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment (“ASU No. 2017-04”), to eliminate the second step of the goodwill impairment test. ASU No. 2017-04 requires an entity to measure a goodwill impairment loss as the amount by which the carrying value of a reporting unit exceeds its fair value. Additionally, an entity should include the income tax effects from any tax deductible goodwill on the carrying value of the reporting unit when measuring a goodwill impairment loss, if applicable. ASU No. 2017-04 is effective for fiscal years beginning after December 15, 2019 and interim periods within those years. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company does not expect the adoption of ASU No. 2017-04 to have a material impact on the Company’s condensed consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash ("ASU No. 2016-18"), which addresses diversity in practice related to the classification and presentation of changes in restricted cash on the statement of cash flows. ASU No. 2016-18 will require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU No. 2016-18 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption is permitted. The Company does not expect the adoption of ASU No. 2016-18 to have a material impact on the Company’s condensed consolidated financial statements and related disclosures.

In October 2016, the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory ("ASU No. 2016-16"). ASU No. 2016-16 was issued to improve the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Current GAAP prohibits the recognition of current and deferred income taxes for an intra-entity asset transfer until the asset has been sold to an outside party which has resulted in diversity in practice and increased complexity within financial reporting. ASU No. 2016-16 would require an entity to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs and does not require new disclosures. ASU No. 2016-16 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those annual periods. Early adoption is permitted and the adoption of ASU No. 2016-16 should be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2016-16 on its condensed 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 ("ASU No. 2016-15"). 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 in ASU No. 2016-15 are effective for reporting periods beginning after December 15, 2017, with early adoption permitted. The Company does not expect the adoption of ASU No. 2016-15 to have a material impact on the Company’s condensed consolidated financial statements and related disclosures.
In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU No. 2016-02”). 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. Lessees 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 condensed consolidated financial statements and related disclosures.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (“ASU No. 2014-09”). 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, April 2016 and December 2016, the FASB issued ASU No. 2016-08, Revenue From Contracts with Customers (Topic 606): Principal Versus Agent Considerations, ASU No. 2016-10, Revenue From Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue From Contracts with Customers, 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 No. 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. The Company expects to elect the modified retrospective method and expects to identify similar performance obligations under ASU No. 2014-09 as compared with deliverables and separate units of account previously identified. As a result, the Company expects the timing of the majority of its revenue to remain the same. Certain of the Company’s contracts for sales outside the United States include contingent amounts of variable consideration that the Company was precluded from recognizing because of the requirement for amounts to be “fixed or determinable”. However, the Company anticipates that ASU No. 2014-09 will require it to estimate these amounts and as a result, the Company expects to recognize the majority of its revenue under such contracts earlier under ASU No. 2014-09 than it would have recognized under current guidance. The Company’s total deferred revenue as of June 30, 2017 was $12.1 million. Otherwise, the adoption is not expected to have a material impact on the condensed consolidated financial statements and related disclosures.

Other recent authoritative guidance issued by the FASB (including technical corrections to the Accounting Standards Codification), the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not, or are not expected to, have a material impact on the Company’s condensed 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 six months ended June 30, 2017 and 2016 (in thousands, except share and per share data):

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended June 30</th>
<th>For the Six Months Ended June 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic net (loss) income per share calculation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net (loss) income</td>
<td>$ (209,536)</td>
<td>$ 14,984</td>
</tr>
<tr>
<td>Weighted average ordinary shares outstanding</td>
<td>162,931,930</td>
<td>160,468,146</td>
</tr>
<tr>
<td>Basic net (loss) income per share</td>
<td>$ (1.29)</td>
<td>$ 0.09</td>
</tr>
</tbody>
</table>

The following table presents diluted net (loss) income per share for the three and six months ended June 30, 2017 and 2016 (in thousands, except share and per share data):

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended June 30</th>
<th>For the Six Months Ended June 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diluted net (loss) income per share calculation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net (loss) income</td>
<td>$ (209,536)</td>
<td>$ 14,984</td>
</tr>
<tr>
<td>Weighted average ordinary shares outstanding</td>
<td>162,931,930</td>
<td>163,920,581</td>
</tr>
<tr>
<td>Diluted net (loss) income per share</td>
<td>$ (1.29)</td>
<td>$ 0.09</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 (loss) income per share reflects the potential dilution beyond shares for basic net (loss) 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 21.5 million and 18.0 million equity awards and warrants for the three and six months ended June 30, 2017, respectively, and 14.0 million and 13.4 million equity awards and warrants for the three and six months ended June 30, 2016, 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. There was no calculated spread added to the denominator for the three and six months ended June 30, 2017 and 2016.

NOTE 3 – DIVESTITURES, ACQUISITIONS AND OTHER ARRANGEMENTS

Divestiture of PROCYSBI and QUINSAIR rights in EMEA Regions

On June 23, 2017, the Company completed the Chiesi divestiture for an upfront payment of $72.2 million, including $3.1 million of cash divested, with additional potential milestone payments based on sales thresholds.

Pursuant to ASU No. 2017-01, the Company accounted for the Chiesi divestiture as a sale of a business. The Company determined that the sale of the business and its assets in connection with the Chiesi divestiture did not constitute a strategic shift and that it did not and will not have a major effect on its operations and financial results. Accordingly, the operations associated with the Chiesi divestiture are not reported in discontinued operations.

The gain on divestiture was determined as follows (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash proceeds</td>
<td>$72,163</td>
</tr>
<tr>
<td>Add reimbursement of royalties</td>
<td>27,101</td>
</tr>
<tr>
<td>Less net assets sold:</td>
<td></td>
</tr>
<tr>
<td>Developed technology</td>
<td>(47,261)</td>
</tr>
<tr>
<td>Goodwill</td>
<td>(16,285)</td>
</tr>
<tr>
<td>Other</td>
<td>(24,482)</td>
</tr>
<tr>
<td>Less transaction and other costs</td>
<td>(5,380)</td>
</tr>
<tr>
<td>Gain on divestiture</td>
<td>$5,856</td>
</tr>
</tbody>
</table>

Under the terms of its agreement with Chiesi, the Company will continue to pay third parties for the royalties on sales of PROCYSBI and QUINSAIR in EMEA, and Chiesi will reimburse the Company for those royalties. The Company recorded an asset of $27.1 million to “other assets”, which represents the estimated amounts that are expected to be reimbursed from Chiesi for the PROCYSBI and QUINSAIR royalties. These estimated royalties are accrued in “other long-term liabilities”.

Transaction and other costs primarily relate to professional and license fees attributable to the divestiture.
Acquisitions

Acquisition of River Vision

On May 8, 2017, the Company acquired 100% of the equity interests in River Vision for upfront cash payments totaling $151.9 million, including $6.3 million of cash acquired, and subject to other customary purchase price adjustments for working capital, potential future milestone and royalty payments contingent on the satisfaction of certain regulatory milestones and sales thresholds. Pursuant to ASC 805 (as amended by ASU No. 2017-01), the Company accounted for the River Vision acquisition as the purchase of an in-process research and development (“IPR&D”) asset and, pursuant to ASC 730, recorded the purchase price as research and development expense during the three months ended June 30, 2017. Further, the Company recognized approximately $13.1 million of federal net operating losses, $2.8 million of state net operating losses and $5.8 million of federal tax credits. The acquired tax attributes were set up as deferred tax assets which were further netted within the net deferred tax liabilities of the U.S. group, offset by a deferred credit recorded in long-term liabilities.

Acquisition of Additional Rights to Interferon Gamma-1b

On June 30, 2017, the Company completed its acquisition of certain rights to interferon gamma-1b from Boehringer Ingelheim International in all territories outside of the United States, Canada and Japan, as the Company previously held marketing rights to interferon gamma-1b in these territories. Boehringer Ingelheim International commercialized interferon gamma-1b as IMUKIN in an estimated thirty countries, primarily in Europe and the Middle East. In May 2016, the Company paid Boehringer Ingelheim International €5.0 million ($5.6 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1132) for such rights and upon closing in June 2017, the Company paid Boehringer Ingelheim International an additional €19.5 million ($22.3 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1406). The Company currently markets interferon gamma-1b as ACTIMMUNE in the United States. The €5.0 million upfront amount paid in May 2016 had initially been included in “other assets” in the Company’s condensed consolidated balance sheet. Following the discontinuation of the development of ACTIMMUNE in Friedreich’s ataxia (“FA”) in December 2016, the Company recorded an impairment charge of €5.0 million ($5.3 million when converted using a Euro-to-Dollar exchange rate at date of impairment of 1.052) to fully write off the asset in its condensed consolidated statements of comprehensive loss during the year ended December 31, 2016 as projections for future net sales of IMUKIN in these territories did not exceed the related costs. Upon closing, the Company recorded the additional €19.5 million payment ($22.3 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1406) as a “selling, general and administrative” expense in its condensed consolidated statement of comprehensive loss.

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. 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 limited liability company, changing its name to Horizon Pharmaceutical LLC. The Company financed the transaction through $300.0 million of 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, as described in Note 16, and cash on hand. The total consideration for the acquisition was approximately $860.8 million, including $24.9 million of cash acquired and $56.0 million paid to settle Raptor’s outstanding debt, and was composed of the following (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash</td>
<td>$841,494</td>
</tr>
<tr>
<td>Net settlements on the exercise of stock options and restricted stock units</td>
<td>19,268</td>
</tr>
<tr>
<td><strong>Total consideration</strong></td>
<td><strong>$860,762</strong></td>
</tr>
</tbody>
</table>

During the three and six months ended June 30, 2017, the Company incurred $4.0 million and $11.4 million, respectively, in Raptor acquisition-related costs including advisory, legal, accounting, severance, retention bonuses and other professional and consulting fees. During the three and six months ended June 30, 2017, $3.7 million and $10.8 million, respectively, were accounted for as “selling, general and administrative” expenses, and $0.3 million and $0.6 million, respectively, were accounted for as “research and development” expenses in the condensed consolidated statements of comprehensive (loss) income.
Pursuant to ASC 805, the Company accounted for the Raptor acquisition as a business combination using the acquisition method of accounting. Identifiable assets and liabilities of Raptor, 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 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 three months ended June 30, 2017, the Company recorded a measurement period adjustment related to accrued trade discounts and rebates as a result of new information, which resulted in a net decrease to goodwill of $1.4 million.

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 adjustment (in thousands):

<table>
<thead>
<tr>
<th>(Liabilities assumed) and assets acquired:</th>
<th>Before</th>
<th>Adjustment</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accounts payable</td>
<td>$ (4,572)</td>
<td>—</td>
<td>$ (4,572)</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>(23,773)</td>
<td>—</td>
<td>(23,773)</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>(6,377)</td>
<td>1,350</td>
<td>(5,027)</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>(237,166)</td>
<td>—</td>
<td>(237,166)</td>
</tr>
<tr>
<td>Contingent royalty liability</td>
<td>(102,000)</td>
<td>—</td>
<td>(102,000)</td>
</tr>
<tr>
<td>Accrued royalties</td>
<td>(2,705)</td>
<td>—</td>
<td>(2,705)</td>
</tr>
<tr>
<td>Other non-current liability</td>
<td>(25,500)</td>
<td>—</td>
<td>(25,500)</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>24,897</td>
<td>—</td>
<td>24,897</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>1,350</td>
<td>—</td>
<td>1,350</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>17,767</td>
<td>—</td>
<td>17,767</td>
</tr>
<tr>
<td>Inventories</td>
<td>74,463</td>
<td>—</td>
<td>74,463</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>4,194</td>
<td>—</td>
<td>4,194</td>
</tr>
<tr>
<td>Property and equipment</td>
<td>3,373</td>
<td>—</td>
<td>3,373</td>
</tr>
<tr>
<td>Developed technology</td>
<td>946,000</td>
<td>—</td>
<td>946,000</td>
</tr>
<tr>
<td>Other non-current assets</td>
<td>1,765</td>
<td>—</td>
<td>1,765</td>
</tr>
<tr>
<td>Goodwill</td>
<td>189,046</td>
<td>(1,350)</td>
<td>187,696</td>
</tr>
<tr>
<td>Fair value of consideration paid</td>
<td>$ 860,762</td>
<td>—</td>
<td>$ 860,762</td>
</tr>
</tbody>
</table>

Inventories acquired included raw materials, work-in-process and finished goods for PROCYSBI and QUINSAIR. 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 $67.0 million was recorded in connection with the acquisition. During the three and six months ended June 30, 2017, the Company recorded inventory step-up expense of $14.5 million and $44.0 million, respectively, related to PROCYSBI and QUINSAIR, of which $3.2 million was recorded to “gain on divestiture” in the condensed consolidated statement of comprehensive loss during the three months ended June 30, 2017.

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 liability of $25.5 million represents the fair value of an assumed contingent liability, arising from contingent payments associated with development, regulatory and commercial milestones following Raptor’s acquisition of QUINSAIR.

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 Raptor’s rights to PROCYSBI. 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 Raptor’s medicines. Indications of value were developed by discounting these benefits to their acquisition-date worth at a discount rate of 12.5%. The fair value of the PROCYSBI developed technology was capitalized as of the Raptor acquisition date and is subsequently being amortized over approximately thirteen years and nine years for the U.S. rights and ex-U.S. rights, respectively, which are the periods in which over 90% of the estimated cash flows are expected to be realized. The Company assigned no preliminary fair value to QUINSAIR developed technology as projections of future net sales do not exceed the related costs. See Note 7 for details of developed technology sold in the Chiesi divestiture.

The Company has assigned a preliminary fair value of $102.0 million to a contingent liability for royalties potentially payable under previously existing agreements related to PROCYSBI. The royalties for PROCYSBI are payable under the terms of an amended and restated license agreement with the Regents of the University of California, San Diego ("UCSD"). See Note 14 for details of the percentages of royalties payable under this agreement. 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.

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. Raptor’s developed technology as of the acquisition date was located primarily in the United States where an estimated U.S. tax rate of 36.6% is being utilized and a significant deferred tax liability is recorded. 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.

**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 $24.9 million of cash acquired and $70.9 million paid to settle Crealta’s outstanding debt, and was composed of the following (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash</td>
<td>$536,206</td>
</tr>
<tr>
<td>Net settlements on the exercise of stock options and restricted stock units</td>
<td>3,526</td>
</tr>
<tr>
<td><strong>Total consideration</strong></td>
<td><strong>$539,732</strong></td>
</tr>
</tbody>
</table>

During the three and six months ended June 30, 2017, the Company incurred zero and $0.5 million, respectively, in Crealta acquisition-related costs including legal, retention bonuses and other professional and consulting fees, which were accounted for as “selling, general and administrative” expenses. During the three and six months ended June 30, 2016, the Company incurred $1.6 million and $11.7 million, respectively, in Crealta acquisition-related costs including advisory, legal, accounting, valuation, severance, retention bonuses and other professional and consulting fees, of which $1.1 million and $11.0 million were accounted for as “selling, general and administrative”, respectively, $0.3 million and $0.3 million were accounted for as “research and development”, respectively, and $0.2 million and $0.4 million were accounted for as “costs of goods sold”, respectively, in the condensed consolidated statements of comprehensive income (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 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 were based on reasonable estimates and assumptions.

12
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>Allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accounts payable and accrued expenses</td>
<td>$ (4,543)</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>(1,424)</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>(20,141)</td>
</tr>
<tr>
<td>Other non-current liabilities</td>
<td>(6,900)</td>
</tr>
<tr>
<td>Contingent royalty liabilities</td>
<td>(51,300)</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>24,893</td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>10,014</td>
</tr>
<tr>
<td>Inventories</td>
<td>149,363</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>1,382</td>
</tr>
<tr>
<td>Developed technology</td>
<td>428,200</td>
</tr>
<tr>
<td>Other non-current assets</td>
<td>275</td>
</tr>
<tr>
<td>Goodwill</td>
<td>9,913</td>
</tr>
<tr>
<td>Fair value of consideration paid</td>
<td>$ 539,732</td>
</tr>
</tbody>
</table>

Inventories acquired included raw materials, work-in-process and finished goods for KRYSSTEXXA and MIGERGOT. Inventories were recorded at their 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 $144.3 million was recorded in connection with the acquisition. During the three and six months ended June 30, 2017, the Company recorded inventory step-up expense of $19.3 million and $33.7 million, respectively, related to KRYSSTEXXA and MIGERGOT.

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 year ended December 31, 2016.

Identifiable intangible assets and liabilities acquired include developed technology and contingent royalties. The estimated 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 fair value of Crealta’s rights to KRYSSTEXXA and MIGERGOT. 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 Crealta’s medicines. Indications of value were developed by discounting these benefits to their acquisition-date worth at a discount rate of 27% for KRYSSTEXXA and 23% for MIGERGOT. The fair value of the KRYSSTEXXA and MIGERGOT developed technologies were capitalized as of the Crealta acquisition date and are subsequently being amortized over approximately twelve and ten 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 fair value of $51.3 million to a contingent liability for royalties potentially payable under previously existing agreements related to KRYSSTEXXA and MIGERGOT. The royalties for KRYSSTEXXA are payable under the terms of a license agreement with Duke University (“Duke”) and Mountain View Pharmaceuticals (“MVP”). See Note 14 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 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 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.
Other Arrangements

Collaboration and option agreement

On November 8, 2016, the Company entered into a collaboration and option agreement with a privately held life-science entity. Under the terms of the agreement, the privately held life-science entity will conduct certain research and pre-clinical and clinical development activities. Upon execution of the agreement, the Company paid $0.1 million for the option to acquire certain assets of the privately held life-science entity for $25.0 million, which is exercisable on specified key dates. Under the collaboration and option agreement, the Company is required to pay up to $9.8 million upon the attainment of various milestones, primarily to fund clinical development costs for the medicine. The Company paid $0.2 million in the fourth quarter of 2016 and $0.9 million in the first quarter of 2017 related to milestones. The initial upfront amount paid of $0.1 million has been included in “other assets” in the Company’s condensed consolidated balance sheet as of December 31, 2016 and June 30, 2017 and the milestone amounts of $1.1 million paid in the fourth quarter of 2016 and the first quarter of 2017 were recorded as “research and development” expenses in the condensed consolidated statement of comprehensive loss during the year ended December 31, 2016. In July 2017, the Company paid a further $1.5 million under the terms of the collaboration and option agreement. The Company has determined that the privately held life-science entity is a variable interest entity (“VIE”) as it does not have enough equity to finance its activities without additional financial support. As the Company does not have the power to direct the activities of the VIE that most significantly affect its economic performance, it is not the primary beneficiary of, and does not consolidate the results of the VIE. The Company will reassess the appropriate accounting treatment for this arrangement throughout the life of the agreement and modify these accounting conclusions accordingly.

Pro Forma Information

The table below represents the condensed consolidated financial information for the Company for the six months ended June 30, 2016 on a pro forma basis, assuming that the Crealta and Raptor acquisitions occurred as of January 1, 2016. The historical financial information has been adjusted to give effect to pro forma items that are directly attributable to the Crealta and Raptor 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.

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>For the Six Months Ended June 30, 2016</th>
<th>As reported (Unaudited)</th>
<th>Pro forma adjustments (Unaudited)</th>
<th>Pro forma (Unaudited)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>$462,068</td>
<td>$61,705</td>
<td>$523,773</td>
</tr>
<tr>
<td>Net loss</td>
<td>$(30,422)</td>
<td>$(84,253)</td>
<td>$(114,675)</td>
</tr>
</tbody>
</table>

The Company’s unaudited condensed consolidated statements of comprehensive loss for the six months ended June 30, 2016 include KRYSTEXXA and MIGERGOT net sales as a result of the acquisition of Crealta of $36.0 million and $2.0 million, respectively.

Crealta and Raptor have been 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 June 30, 2017 and December 31, 2016 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2017</th>
<th>December 31, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw materials</td>
<td>$14,272</td>
<td>$10,233</td>
</tr>
<tr>
<td>Work-in-process</td>
<td>44,105</td>
<td>85,022</td>
</tr>
<tr>
<td>Finished goods</td>
<td>43,867</td>
<td>79,533</td>
</tr>
<tr>
<td>Inventories, net</td>
<td>$102,244</td>
<td>$174,788</td>
</tr>
</tbody>
</table>

14
Because inventory step-up expense is acquisition-related, will not continue indefinitely and has a significant effect on the Company’s gross profit, gross margin percentage and net income (loss) for all affected periods, the Company discloses balance sheet and income statement amounts related to inventory step-up within the notes to the condensed consolidated financial statements.


During the three and six months ended June 30, 2017 the Company recorded $19.3 million and $33.7 million, respectively, of KRYSTEXXA and MIGERGOT inventory step-up expense. During the three and six months ended June 30, 2016, the Company recorded $9.1 million and $16.5 million, respectively, of KRYSTEXXA and MIGERGOT inventory step-up expense.

The Company expects that the KRYSTEXXA inventory step-up will be fully expensed by the end of the first quarter of 2018. Following that period, the Company expects the costs of goods sold related to KRYSTEXXA to decrease significantly to levels consistent with the historical cost of goods sold of Crealta.

During the three and six months ended June 30, 2017, the Company recorded $14.5 million and $40.8 million, respectively, of PROCYSBI and QUINSAIR inventory step-up expense. In addition, during the three months ended June 30, 2017, the Company recorded $3.2 million of inventory step-up expense to “gain on divestiture” relating to PROCYSBI and QUINSAIR in connection with the Chiesi divestiture. Finished goods at December 31, 2016 included $38.1 million of stepped-up PROCYSBI and QUINSAIR inventory. Work-in-process at December 31, 2016 included $5.9 million of stepped-up PROCYSBI and QUINSAIR inventory.

NOTE 5 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets as of June 30, 2017 and December 31, 2016 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2017</th>
<th>December 31, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine samples inventory</td>
<td>$ 15,043</td>
<td>$ 10,192</td>
</tr>
<tr>
<td>Prepaid income taxes</td>
<td>10,049</td>
<td>9,155</td>
</tr>
<tr>
<td>Rabbi trust assets</td>
<td>5,045</td>
<td>3,073</td>
</tr>
<tr>
<td>Other prepaid expenses</td>
<td>15,851</td>
<td>19,398</td>
</tr>
<tr>
<td>Deferred charge for taxes on intra-group profit</td>
<td>—</td>
<td>7,801</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>$ 45,988</td>
<td>$ 49,619</td>
</tr>
</tbody>
</table>

NOTE 6 – PROPERTY AND EQUIPMENT

Property and equipment as of June 30, 2017 and December 31, 2016 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2017</th>
<th>December 31, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software</td>
<td>$ 10,591</td>
<td>$ 10,876</td>
</tr>
<tr>
<td>Leasehold improvements</td>
<td>9,351</td>
<td>9,184</td>
</tr>
<tr>
<td>Machinery and equipment</td>
<td>4,931</td>
<td>4,566</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>2,260</td>
<td>3,069</td>
</tr>
<tr>
<td>Other</td>
<td>2,690</td>
<td>2,664</td>
</tr>
<tr>
<td></td>
<td>29,823</td>
<td>30,359</td>
</tr>
<tr>
<td>Less accumulated depreciation</td>
<td>(10,985)</td>
<td>(8,319)</td>
</tr>
<tr>
<td>Construction in process</td>
<td>86</td>
<td>17</td>
</tr>
<tr>
<td>Software implementation in process</td>
<td>3,733</td>
<td>1,427</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>$ 22,657</td>
<td>$ 23,484</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 June 30, 2017 and December 31, 2016 was 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 $1.8 million and $1.1 million for the three months ended June 30, 2017 and 2016, respectively, and was $3.6 million and $2.1 million for the six months ended June 30, 2017 and 2016, respectively.

NOTE 7 – GOODWILL AND INTANGIBLE ASSETS

Goodwill

The gross carrying amount of goodwill as of June 30, 2017 was as follows (in thousands):

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at December 31, 2016</td>
<td>$445,579</td>
</tr>
<tr>
<td>Divestiture during the period</td>
<td>(16,285)</td>
</tr>
<tr>
<td>Measurement period adjustment</td>
<td>(1,350)</td>
</tr>
<tr>
<td>Balance at June 30, 2017</td>
<td>$427,944</td>
</tr>
</tbody>
</table>

During the three and six months ended June 30, 2017, in connection with the Chiesi divestiture, the Company recorded a reduction to goodwill of $16.3 million and a corresponding amount to “gain on divestiture” in the condensed consolidated statements of comprehensive loss. In addition, the Company recorded a measurement period adjustment to goodwill of $1.4 million related to the Raptor acquisition during the three and six months ended June 30, 2017.

During the year ended December 31, 2016, the Company recognized goodwill of $9.9 million and $189.1 million in connection with the Crealta and Raptor acquisitions, respectively, which represented the excess of the purchase prices over the fair value of the net assets acquired.

As of June 30, 2017, there were no accumulated goodwill impairment losses. See Note 3 for further details of goodwill acquired and disposed of in business acquisitions and divestitures.

Intangible Assets

As of June 30, 2017, the Company’s intangible assets consisted of developed technology related to ACTIMMUNE, BUPHENYL, KRYSTEXXA, MIGERGOT, PENNSAID 2%, PROCYSBI, RAVICTI, RAYOS and VIMOVO in the United States, and AMMONAPS, BUPHENYL, LODOTRA and PROCYSBI outside the United States, as well as customer relationships for ACTIMMUNE.

During the year ended December 31, 2016, in connection with the acquisition of Crealta, the Company capitalized $402.2 million of developed technology related to KRYSTEXXA and $26.0 million of developed technology related to MIGERGOT.

During the year ended December 31, 2016, in connection with the acquisition of Raptor, the Company capitalized $946.0 million of developed technology related to PROCYSBI.

During the three and six months ended June 30, 2017, in connection with the Chiesi divestiture, the Company recorded a reduction in the net book value of developed technology related to PROCYSBI of $47.3 million and a corresponding amount to “gain on divestiture” in the condensed consolidated statements of comprehensive loss.

See Note 3 for further details of intangible assets acquired in business acquisitions and disposed of in business divestitures.
Prior to the fourth quarter of 2016, the Company had IPR&D of $66.0 million related to one research and development project to evaluate ACTIMMUNE in the treatment of FA. The fair value of the IPR&D was recorded as an indefinite-lived intangible asset and was being tested for impairment at least annually until completion or abandonment of the research and development efforts associated with the project. On December 8, 2016, the Company announced that the Phase 3 trial, STEADFAST, evaluating ACTIMMUNE for the treatment of FA did not meet its primary endpoint of a statistically significant change from baseline in the modified Friedreich’s Ataxia Rating Scale at twenty-six weeks versus treatment with placebo. In addition, the secondary endpoints did not meet statistical significance. No new safety findings were identified on initial review of data other than those already noted in the ACTIMMUNE prescribing information for approved indications. The Company, in conjunction with the independent Data Safety Monitoring Board, the principal investigator and the Friedreich’s Ataxia Research Alliance Collaborative Clinical Research Network in FA, determined that, based on the trial results, the STEADFAST program would be discontinued, including the twenty-six week extension study and the long-term safety study. The IPR&D had no alternative use or economic value as a result of the cancellation of the project, and the Company recorded an impairment charge of $66.0 million to “impairment of in-process research and development” in its condensed consolidated statements of comprehensive loss during the year ended December 31, 2016 to fully write off the value of the asset on its condensed consolidated balance sheet.

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, except for IPR&D as described above, was impaired at June 30, 2017 or December 31, 2016.

| Intangible assets as of June 30, 2017 and December 31, 2016 consisted of the following (in thousands): |
|---------------------------------------------------------------|-------------------|-------------------|
| Developed technology                                           | 3,115,695         | 3,166,695         |
| Customer relationships                                         | 8,100             | 8,100             |
| Total intangible assets                                        | 3,123,795         | 3,174,795         |

Amortization expense for the three months ended June 30, 2017 and 2016 was $69.8 million and $50.8 million, respectively, and was $139.5 million and $100.4 million for the six months ended June 2017 and 2016, respectively. As of June 30, 2017 estimated future amortization expense was as follows (in thousands):

<table>
<thead>
<tr>
<th>2017 (July to December)</th>
<th>$137,332</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>274,084</td>
</tr>
<tr>
<td>2019</td>
<td>261,092</td>
</tr>
<tr>
<td>2020</td>
<td>261,068</td>
</tr>
<tr>
<td>2021</td>
<td>253,373</td>
</tr>
<tr>
<td>Thereafter</td>
<td>1,399,772</td>
</tr>
<tr>
<td>Total</td>
<td>2,586,721</td>
</tr>
</tbody>
</table>

### NOTE 8 – ACCRUED TRADE DISCOUNTS AND REBATES

Accrued trade discounts and rebates as of June 30, 2017 and December 31, 2016 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2017</th>
<th>December 31, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accrued wholesaler fees and commercial rebates</td>
<td>$163,597</td>
<td>$47,460</td>
</tr>
<tr>
<td>Accrued co-pay and other patient assistance</td>
<td>177,050</td>
<td>188,504</td>
</tr>
<tr>
<td>Accrued government rebates and chargebacks</td>
<td>72,554</td>
<td>61,592</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>413,201</td>
<td>297,556</td>
</tr>
<tr>
<td>Invoiced wholesaler fees and commercial rebates, co-pay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>and other patient assistance, and government rebates and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>chargebacks in accounts payable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>55,313</td>
<td>16,830</td>
</tr>
<tr>
<td>Total customer-related accruals and allowances</td>
<td>$468,514</td>
<td>$314,386</td>
</tr>
</tbody>
</table>
The following table summarizes changes in the Company’s customer-related accruals and allowances from December 31, 2016 to June 30, 2017 (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, 2016</td>
<td>$47,651</td>
<td>$205,143</td>
<td>$61,592</td>
<td>$314,386</td>
</tr>
<tr>
<td>Measurement period adjustment</td>
<td>—</td>
<td>—</td>
<td>(1,350)</td>
<td>(1,350)</td>
</tr>
<tr>
<td>Current provisions relating to sales during the six months ended June 30, 2017</td>
<td>303,360</td>
<td>957,477</td>
<td>162,588</td>
<td>1,423,425</td>
</tr>
<tr>
<td>Adjustments relating to prior-year sales</td>
<td>5,935</td>
<td>(59)</td>
<td>(4,905)</td>
<td>971</td>
</tr>
<tr>
<td>Payments relating to sales during the six months ended June 30, 2017</td>
<td>(139,830)</td>
<td>(730,876)</td>
<td>(84,748)</td>
<td>(955,454)</td>
</tr>
<tr>
<td>Payments relating to prior-year sales</td>
<td>(53,043)</td>
<td>(205,084)</td>
<td>(55,337)</td>
<td>(313,464)</td>
</tr>
<tr>
<td>Balance at June 30, 2017</td>
<td>$164,073</td>
<td>$226,601</td>
<td>$77,840</td>
<td>$468,514</td>
</tr>
</tbody>
</table>

**NOTE 9 – ACCRUED EXPENSES**

Accrued expenses as of June 30, 2017 and December 31, 2016 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2017</th>
<th>December 31, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payroll-related expenses</td>
<td>$41,460</td>
<td>$66,417</td>
</tr>
<tr>
<td>Consulting and professional services</td>
<td>29,494</td>
<td>33,614</td>
</tr>
<tr>
<td>Accrued interest</td>
<td>14,746</td>
<td>18,938</td>
</tr>
<tr>
<td>Accrued other</td>
<td>26,752</td>
<td>31,296</td>
</tr>
<tr>
<td>Litigation settlement</td>
<td>—</td>
<td>32,500</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>$112,452</td>
<td>$182,765</td>
</tr>
</tbody>
</table>

Accrued payroll-related expenses at June 30, 2017 and December 31, 2016 included $5.1 million and $15.0 million, respectively, of severance and employee costs as a result of the Raptor acquisition. The Company anticipates that a significant amount of the Raptor acquisition-related cash payments will be complete by the fourth quarter of 2017.

Accrued litigation settlement at December 31, 2016 included $32.5 million in relation to a litigation settlement with Express Scripts, Inc., which was paid in two equal installments in January 2017 and April 2017.

Accrued other as of June 30, 2017 and December 31, 2016 included $6.4 million and $9.5 million, respectively, related to a loss on inventory purchase commitments. During the year ended December 31, 2016, the Company committed to purchase additional units of ACTIMMUNE from Boehringer Ingelheim RCV GmbH & Co KG (“Boehringer Ingelheim”). These additional units of ACTIMMUNE were intended to cover anticipated demand if the results of the STEADFAST study of ACTIMMUNE for the treatment of FA had been successful. Following the discontinuation of the STEADFAST program during the year ended December 31, 2016, the Company recorded a loss of $14.3 million in “cost of goods sold” in the condensed consolidated statement of comprehensive loss for firm, non-cancellable and unconditional purchase commitments for quantities in excess of the Company’s current forecasts for future demand. During the three and six months ended June 30, 2017, the Company renegotiated its purchase commitments with Boehringer Ingelheim and recorded a reduction of $3.1 million to the loss on inventory purchase commitments in “cost of goods sold”. “Other long-term liabilities” as of June 30, 2017 and December 31, 2016 included $3.9 million and $4.8 million, respectively, related to this loss on inventory purchase commitments. Accrued other as of June 30, 2017 and December 31, 2016 also included $2.0 million and $4.0 million, respectively, related to costs to be incurred to discontinue the clinical trial.
NOTE 10 – ACCRUED ROYALTIES

During the six months ended June 30, 2017, 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, 2016</td>
<td>$334,274</td>
</tr>
<tr>
<td>Reclassification to other long-term liabilities</td>
<td>(5,233)</td>
</tr>
<tr>
<td>Remeasurement of royalty liabilities</td>
<td>(2,944)</td>
</tr>
<tr>
<td>Royalty payments</td>
<td>(22,360)</td>
</tr>
<tr>
<td>Accretion expense</td>
<td>25,694</td>
</tr>
<tr>
<td>Other royalty expense</td>
<td>288</td>
</tr>
<tr>
<td>Balance as of June 30, 2017</td>
<td>329,719</td>
</tr>
<tr>
<td>Accrued royalties - current portion as of June 30, 2017</td>
<td>61,575</td>
</tr>
<tr>
<td>Accrued royalties, net of current as of June 30, 2017</td>
<td>$268,144</td>
</tr>
</tbody>
</table>

The reclassification to other long-term liabilities in the table above relates to the reclassification of a contingent royalty liability for PROCYSBI to other long-term liabilities as a result of the Chiesi divestiture.

NOTE 11 – OTHER LONG-TERM LIABILITIES

Included in other long-term liabilities at June 30, 2017 and December 31, 2016, is $49.1 million and $25.5 million, respectively, representing the preliminary fair value of the contingent liability for royalties potentially payable under previously existing agreements related to PROCYSBI and QUINSAIR.

NOTE 12- SEGMENT AND OTHER INFORMATION

The following table presents the amount and percentage of gross sales from customers that represented more than 10% of the Company’s gross sales included in its single operating segment, and all other customers as a group (in thousands, except percentages):

For the Three Months Ended June 30,

<table>
<thead>
<tr>
<th>Customer</th>
<th>Amount</th>
<th>% of Gross Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer A</td>
<td>$337,770</td>
<td>32%</td>
</tr>
<tr>
<td>Customer B</td>
<td>321,639</td>
<td>30%</td>
</tr>
<tr>
<td>Customer C</td>
<td>144,241</td>
<td>13%</td>
</tr>
<tr>
<td>Other Customers</td>
<td>268,034</td>
<td>25%</td>
</tr>
<tr>
<td>Gross Sales</td>
<td>$1,071,684</td>
<td>100%</td>
</tr>
</tbody>
</table>

For the Six Months Ended June 30,

<table>
<thead>
<tr>
<th>Customer</th>
<th>Amount</th>
<th>% of Gross Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer A</td>
<td>$588,859</td>
<td>29%</td>
</tr>
<tr>
<td>Customer B</td>
<td>627,191</td>
<td>31%</td>
</tr>
<tr>
<td>Customer C</td>
<td>283,465</td>
<td>14%</td>
</tr>
<tr>
<td>Other Customers</td>
<td>500,742</td>
<td>26%</td>
</tr>
<tr>
<td>Gross Sales</td>
<td>$2,000,257</td>
<td>100%</td>
</tr>
</tbody>
</table>
NOTE 13 – 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 June 30, 2017, 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 and other long-term liabilities recorded at fair value on a recurring basis are composed of investments held in a rabbi trust and the related deferred liability for deferred compensation arrangements. Quoted prices for this investment, primarily in mutual funds, are available in active markets. Thus, the Company’s investments related to deferred compensation arrangements and the related long-term liability 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 during the three and six months ended June 30, 2017 and 2016.

**Assets and liabilities measured at fair value on a recurring basis**

The following tables set forth the Company’s financial assets and liabilities at fair value on a recurring basis as of June 30, 2017 and December 31, 2016 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bank time deposits</td>
<td>$—</td>
<td>$3,000</td>
<td>$—</td>
<td>$3,000</td>
</tr>
<tr>
<td>Money market funds</td>
<td>$478,000</td>
<td>—</td>
<td>—</td>
<td>$478,000</td>
</tr>
<tr>
<td>Other current assets</td>
<td>$5,045</td>
<td>—</td>
<td>—</td>
<td>$5,045</td>
</tr>
<tr>
<td><strong>Liabilities:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other long-term liabilities</td>
<td>$(5,045)</td>
<td>—</td>
<td>—</td>
<td>$(5,045)</td>
</tr>
<tr>
<td><strong>Total assets and liabilities at fair value</strong></td>
<td>$478,000</td>
<td>$3,000</td>
<td>$—</td>
<td>$481,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bank time deposits</td>
<td>$—</td>
<td>$3,000</td>
<td>$—</td>
<td>$3,000</td>
</tr>
<tr>
<td>Money market funds</td>
<td>$170,000</td>
<td>—</td>
<td>—</td>
<td>$170,000</td>
</tr>
<tr>
<td>Other current assets</td>
<td>$3,038</td>
<td>—</td>
<td>—</td>
<td>$3,038</td>
</tr>
<tr>
<td><strong>Liabilities:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other long-term liabilities</td>
<td>$(3,038)</td>
<td>—</td>
<td>—</td>
<td>$(3,038)</td>
</tr>
<tr>
<td><strong>Total assets and liabilities at fair value</strong></td>
<td>$170,000</td>
<td>$3,000</td>
<td>$—</td>
<td>$173,000</td>
</tr>
</tbody>
</table>

20
NOTE 14 – COMMITMENTS AND CONTINGENCIES

Lease Obligations

The Company has the following office space 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>Novato, California (2)</td>
<td>61,000</td>
<td>August 31, 2021</td>
</tr>
<tr>
<td>Deerfield, Illinois (3)</td>
<td>32,300</td>
<td>June 30, 2018</td>
</tr>
<tr>
<td>Brisbane, California</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 $2.0 million letter of credit to the landlord, through a commercial bank.

(2) During March 2017, the Company vacated an area of the office space in Novato, California. During April 2017, the Company entered into a sublease arrangement for a portion of this space with a third party.

(3) During January 2016, the Company vacated the premises in Deerfield, Illinois and began occupying the premises in Lake Forest, Illinois. During April 2017, the Company entered into a sublease arrangement for a portion of this space with a third party. During June 2017, the Company terminated a portion of the lease, resulting in 32,300 square footage remaining.

Following the Chiesi divestiture in June 2017, the Company ceased to hold a lease obligation in Utrecht in the Netherlands.

Purchase Commitments

In August 2007, the Company entered into a manufacturing and supply agreement with Jagotec AG (“Jagotec”), which was amended in March 2011 and in January 2017. Under the agreement, Jagotec or its affiliates are required to manufacture and supply RAYOS/LODOTRA exclusively to the Company in bulk. The earliest the agreement can expire is December 31, 2023, and the minimum purchase commitment is in force until December 2023. At June 30, 2017, the minimum purchase commitment based on tablet pricing in effect under the agreement was $7.0 million through December 2023. Additionally, purchase orders relating to the manufacture of RAYOS/LODOTRA of $0.3 million were outstanding at June 30, 2017.

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. The agreement term extends until May 2019, and automatically renews for successive two-year terms unless terminated by either party upon two years prior written notice. At June 30, 2017, the Company had a binding purchase commitment to Sanofi-Aventis U.S. for DUEXIS of $5.5 million, which is to be delivered through December 2017.
In July 2013, Vidara Therapeutics International Public Limited Company (“Vidara”) and Boehringer Ingelheim entered into an exclusive supply agreement, which the Company assumed in September 2014 and amended effective as of September 5, 2014 and June 1, 2015. That supply agreement was replaced with an exclusive global supply agreement between the Company and Boehringer Ingelheim Biopharmaceuticals GmbH (“Boehringer Ingelheim Biopharmaceuticals”) effective June 30, 2017. Under the agreement, Boehringer Ingelheim Biopharmaceuticals is required to manufacture and supply ACTIMMUNE and IMUKIN to the Company. The Company is required to purchase minimum quantities of finished medicine per annum through July 2024. During the year ended December 31, 2016, the Company committed to purchase additional amounts of ACTIMMUNE from Boehringer Ingelheim. These additional amounts were intended to cover anticipated demand if the results of the STEADFAST study of ACTIMMUNE for the treatment of FA had been successful. As of June 30, 2017, the minimum binding purchase commitment to Boehringer Ingelheim Biopharmaceuticals was $24.8 million (converted using a Dollar-to-Euro exchange rate of 1.1427) through July 2024. Following the discontinuation of the STEADFAST program, the Company recorded a loss of $14.3 million in “cost of goods sold” in the condensed consolidated statement of comprehensive loss during the year ended December 31, 2016 for a portion of this commitment which represented firm, non-cancellable and unconditional purchase commitments for quantities in excess of the Company’s current forecasts for future demand. During the six months ended June 30, 2017 the Company renegotiated the purchase commitment due to Boehringer Ingelheim and recorded $3.1 million as a reduction to “cost of goods sold”. During the year ended December 31, 2016, the Company also committed to incur an additional $14.9 million for the harmonization of the drug substance manufacturing process with Boehringer Ingelheim. These additional costs will be incurred during the years 2017 through 2021. During the six months ended June 30, 2017 the Company recorded $6.5 million in its condensed consolidated statement of comprehensive loss related to the harmonization of the drug substance manufacturing process.

In November 2013, the Company entered into a long-term master 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 twelve-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 June 30, 2017, the Company had a binding purchase commitment with Patheon for VIMOVO of $0.6 million which is to be delivered through September 2017.

In October 2014, in connection with the acquisition of the U.S. rights to PENNSAID 2% from Nuvo Research Inc., (“Nuvo”), the Company and Nuvo entered into an exclusive supply agreement. Under the supply agreement, which was amended in February 2016, 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 ninety 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 June 30, 2017, the Company had a binding purchase commitment with Nuvo for PENNSAID 2% of $2.4 million through September 2017.

In November 2010, Raptor and Patheon entered into a manufacturing services agreement, which the Company assumed as a result of its acquisition of Raptor. Under the agreement, which was amended in April 2012 and June 2013, Patheon is obligated to manufacture PROCYSBI for the Company through December 31, 2019. The Company must provide Patheon with rolling, non-binding forecasts of PROCYSBI, with a portion of the forecast being a firm written order. In November 2010, Raptor and Cambrex Profarmaco Milano (“Cambrex”) entered into an active pharmaceutical ingredient (“API”) supply agreement, which the Company assumed as a result of its acquisition of Raptor. Under the agreement, which was amended in April 2013 and August 2016, Cambrex is obligated to manufacture PROCYSBI API for the Company through November 30, 2020. The Company must provide Cambrex with rolling, non-binding forecasts, with a portion of the forecast being the minimum floor of the firm order that must be placed. At June 30, 2017, the Company had a binding purchase commitment with Patheon for PROCYSBI of $1.6 million through September 2017 and with Cambrex for PROCYSBI API of $3.1 million through December 2020.
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. Under this agreement, the Company has agreed to purchase certain minimum annual order quantities and is obligated to purchase at least eighty 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. The Company issues eighteen-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 June 30, 2017, the Company had a binding purchase commitment with BTG Israel for KRYSTEXXA of $53.0 million through December 31, 2026. Additionally, other binding commitments relating to the manufacture of KRYSTEXXA of $1.8 million were outstanding at June 30, 2017.

Excluding the above, additional purchase orders relating to the manufacture of BUPHENYL, MIGERGOT, QUINSAIR and RAVICTI of $8.5 million were outstanding at June 30, 2017.

Royalty Agreements

RAYOS/LODOTRA

In connection with an August 2004 development and license agreement with SkyPharma AG, who subsequently entered into a business combination with Vectura Group plc (“Vectura”), and Jagotec, a wholly owned subsidiary of Vectura, regarding certain proprietary technology and know-how owned by Vectura, Jagotec is entitled to receive a single digit percentage royalty on net sales of RAYOS/LODOTRA and on any sub-licensing income, such as license fees, lump sums and milestone payments.

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 Aralez Pharmaceuticals Inc. (“Aralez”). Under this agreement, the Company is required to pay Aralez 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 Aralez’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 Aralez 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.

In November 2013, the Company, AstraZeneca AB (“AstraZeneca”) and Aralez entered into a letter agreement. Under the letter agreement, the Company and AstraZeneca agreed to pay Aralez milestone payments upon the achievement by the Company and AstraZeneca, collectively, of certain annual aggregate global net sales thresholds ranging from $550.0 million to $1.25 billion with respect to VIMOVO. The aggregate milestone payment amount that may be owed by AstraZeneca and the Company, collectively, under the letter agreement is $260.0 million, with the amount payable by each of the Company and AstraZeneca with respect to each milestone to be based upon the proportional sales achieved by each of the Company and AstraZeneca, respectively, in the applicable year.

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:

• For the period from November 26, 2014 through May 5, 2018, a royalty in the 20% to 30% range for the first $3.7 million in net sales achieved in any calendar year and in the 1% to 9% range for all additional net sales in any year; 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.
Under the terms of an assignment and option agreement with Connetics Corporation (which was the predecessor parent company to InterMune Pharmaceuticals Inc. and is now part of GlaxoSmithKline), (“Connetics”), the Company is obligated to pay low single-digit royalties to Connetics on the Company’s net sales of ACTIMMUNE in the United States.

RAVICTI

Under the terms of an asset purchase agreement with Ucyclyd Pharma, Inc. (“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.

KRYSTEXXA

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 KRYSTEXXA and a royalty of between 5% and 15% on any global sublicense revenue. The Company is also obligated to pay MVP a mid single-digit royalty on its net sales of KRYSTEXXA outside of the United States and a royalty of between 5% and 15% on any sublicense revenue outside of the United States.

PROCYSBI

Under the terms of an amended and restated license agreement with UCSD, the Company is obligated to pay to UCSD tiered low to mid single-digit royalties on its net sales of PROCYSBI.

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 $15.1 million and $27.1 million was recorded in cost of goods sold for the three and six months ended June 30, 2017, respectively, and $10.9 million and $21.4 million was recorded in cost of goods sold for the three and six months ended June 30, 2016, respectively.

Other Agreements

On November 8, 2016, the Company entered into a collaboration and option agreement with a privately held life-science entity. Under the terms of the agreement, the privately held life-science entity will conduct certain research and pre-clinical and clinical development activities. Upon execution of the agreement, the Company paid $0.1 million for the option to acquire certain of the privately held life-science entity’s assets for $25.0 million, which is exercisable on specified key dates. Under the collaboration and option agreement, the Company is required to pay up to $9.8 million upon the attainment of various milestones, primarily to fund clinical development costs for the medicine. The Company paid $0.2 million in the fourth quarter of 2016 and $0.9 million during the three and six months ended June 30, 2017. During July 2017, the Company paid a further $1.5 million under the terms of the collaboration and option agreement.

On May 8, 2017, the Company acquired River Vision for upfront cash payments totaling $151.9 million, including $6.3 million of cash acquired, and subject to other customary purchase price adjustments for working capital, and potential future milestone and royalty payments contingent on the satisfaction of certain regulatory milestones and sales thresholds. Under the agreement, the Company is required to pay up to $325.0 million upon the attainment of various milestones related to FDA approval and net sales thresholds. The agreement also includes a royalty payment of three percent of the portion of annual worldwide net sales exceeding $300.0 million (if any).

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, 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 will continue to 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.

**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 15 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 15 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 have also entered into separate indemnification agreements with Horizon Pharma, Inc. (“HPI”) prior to the Company’s merger transaction with Vidara (the “Vidara Merger”).

**NOTE 15 - LEGAL PROCEEDINGS**

**RAYOS**

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. The court entered the stipulation of dismissal 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.

25
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 Actavis Laboratories UT, 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 is the current owner of the ANDA. The lawsuit alleged that Actavis had infringed U.S. Patents 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").

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 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 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 9,132,110. All three patents, U.S. Patents 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 were consolidated with the case filed against Actavis on December 23, 2014.

On August 17, 2016, the district court issued a Markman opinion holding certain of the asserted claims of U.S. Patents 8,252,838, 8,563,613, 9,066,913 and 9,101,591 invalid as indefinite. On March 16, 2017, the court granted Actavis' motion for summary judgment of non-infringement of the asserted claims of U.S. Patents 8,546,450, 8,217,078 and 9,132,110. In view of the Markman and summary judgment decisions, a bench trial was held on March 21-30, 2017, regarding claim 12 of U.S. Patent 9,066,913. On May 14, 2017, the court issued its opinion upholding the validity of claim 12 of the '913 patent, which Actavis had previously admitted its proposed generic diclofenac sodium topical solution product would infringe. Actavis filed its Notice of Appeal on June 16, 2017. The Company filed its Notice of Appeal of the district court's rulings on certain claims of the '450, '078, '838, '613, '591, '304, '784, '913, and '110 patents on June 9, 2017.

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. Patents 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%. All claims from U.S. Patents 9,168,304, 9,168,305 and 9,220,784 asserted against Actavis were held invalid as indefinite by way of the court's August 17, 2016, Markman opinion. The court's rulings are currently on appeal to the Federal Circuit.

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. Patents 9,339,551, 9,339,552, 9,370,501 and 9,375,412. All four patents, U.S. Patents 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%.

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. Patents. 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 Delaware, respectively, against Paddock seeking an injunction to prevent the approval of the ANDA. The lawsuits alleged that Paddock has infringed U.S. Patents 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%. A stipulation of dismissal was entered by the district court on May 13, 2015.

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.

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. Patents 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 Lupin for patent infringement of U.S. Patent No. 9,220,784. On August 11, 2015, the Company received a Paragraph IV Patent Certification against Orange Book listed U.S. Patents 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956 and 8,871,809 from Lupin Ltd. advising that Lupin Ltd. had filed an ANDA with the FDA seeking approval for generic versions of PENNSAID 2%. On August 22, 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. Patents 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164 and 8,871,809 with respect to the strike of the lawsuit alleging that Lupin had infringed U.S. Patents 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 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 which finds 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 concerning U.S. Patent 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 9,132,110. All three patents, U.S. Patents 9,066,913, 9,101,591, and 9,132,110, 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 Lupin 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. Patents 9,339,551, 9,339,552, 9,370,501 and 9,375,412. All seven patents, U.S. Patents 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 Lupin remain pending, with certain claims of the '809, '913, '450, '110, '551, '552, '412 and '501 patents being asserted. The decisions reached by the court in the related Actavis actions regarding the '809, '913, '450, '110, '551, '552, '412 and '501 patents as described above, are expected to apply to the same claims asserted against Lupin in these actions. The court has not yet set a trial date for the Lupin actions.
The Company received from Teligent, Inc., formerly known as IGI Laboratories, Inc. ("Teligent"), a Paragraph IV Patent Certification dated March 24, 2015 against Orange Book listed U.S. Patents 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 advising that Teligent had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On May 21, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Teligent has infringed U.S. Patents 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 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 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 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. Patents 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. Patents 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 9,220,784. All three patents, U.S. Patents 9,168,304, 9,168,305 and 9,220,784 are listed in the Orange Book and have claims that cover PENNSAID 2%.

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. 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%. A stipulation of dismissal was entered by the district court on May 2, 2016.

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. 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 received from Amneal Pharmaceuticals LLC ("Amneal") a Paragraph IV Patent Certification dated April 2, 2015 against Orange Book listed U.S. Patents 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. Patents 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 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 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 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 9,132,110. All three patents, U.S. Patents 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. Patents 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 9,220,784. All three patents, U.S. Patents 9,168,304, 9,168,305 and 9,220,784, are listed in the Orange Book and have claims that cover PENNSAID 2%.

The Company received from Teligent, Inc., formerly known as IGI Laboratories, Inc. ("Teligent"), a Paragraph IV Patent Certification dated April 2, 2015 against Orange Book listed U.S. Patents 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. Patents 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 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 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 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 9,132,110. All three patents, U.S. Patents 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. Patents 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 9,220,784. All three patents, U.S. Patents 9,168,304, 9,168,305, and 9,220,784, are listed in the Orange Book and have claims that cover PENNSAID 2%.

28
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. 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%. A stipulation of dismissal was entered by the district court.

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%.

In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, the Company may be required to supply Amneal with 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 received from Apotex Inc. (“Apotex”) a Paragraph IV Patent Certification Notice Letter dated April 1, 2016, against Orange Book listed U.S. Patents 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. Patents 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 9,415,029, advising that Apotex had filed an ANDA with the FDA for a generic version of PENNSAID 2%. The Company also received from Apotex additional Paragraph IV Patent Certification Notice Letters dated April 20, 2017 and April 27, 2017 against Orange Book listed U.S. Patent 9,539,335 and 9,370,501.

VIMOVO

Currently, patent litigation is pending in the United States District Court for the District of New Jersey against three 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 Ltd. and Lupin Pharmaceuticals Inc. (collectively, “Lupin”); and (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, “Mylan”). Patent litigation in the United States District Court for the District of New Jersey against a fourth generic company, Actavis Laboratories FL., Inc. and Actavis Pharma, Inc. (collectively, “Actavis Pharma”), was dismissed on January 10, 2017 after the court granted Actavis’ motion to compel enforcement of a settlement agreement. On February 3, 2017, the Company appealed this dismissal decision to the Court of Appeals for the Federal Circuit. 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. The settlement agreement, however, has no effect on the Aralez 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 Aralez patents licensed to the Company under the amended and restated collaboration and license agreement for the United States with Aralez.

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 February 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. On December 6, 2016, the Company asserted U.S. Patent No. 9,393,208 (the “’208 patent”) against Lupin, Mylan, and Actavis in amended complaints, and against Dr. Reddy’s in a new complaint.
“Case I” consists of the cases asserting U.S. Patent Nos. 8,557,285 and 6,926,907. “Case II” consists of 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 III” consists of the cases asserting U.S. Patent Nos. 8,945,621, 9,220,698, 9,345,695, and the ’208 patent against Lupin and Mylan, and the case asserting U.S. Patent Nos. 8,945,621, 9,220,698, and 9,345,695 against Dr. Reddy’s. “Case IV” consisted of the case asserting the ’208 patent against Dr. Reddy’s, but has been consolidated with Case III.

The Case I cases were consolidated for discovery. The court issued a claim construction order for Case I and conducted trial beginning on January 12, 2017. 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.

On December 19, 2016, defendant Actavis filed a motion to compel enforcement of settlement agreement related to Cases I, II, and III. On December 22, 2016, Magistrate Judge Arpert entered a report and recommendation that Actavis’ motion to compel the enforcement of settlement be granted. On December 30, 2016, the Honorable Judge Mary Cooper ordered the adoption of the report and recommendation. On December 30, 2016, an order of dismissal was entered for all claims in Cases I, II and III. The Company appealed the district court’s order enforcing the settlement with Actavis to the Federal Circuit. Briefing before the Federal Circuit is ongoing.

On January 12, 2017, a six-day bench trial commenced against defendants Dr. Reddy’s and Mylan before Honorable Judge Mary Cooper in the District of New Jersey for Case I. The patents at issue in this trial included two Orange Book listed patents: U.S. Patent Nos. 6,926,907 and 8,557,285. Defendant Lupin formerly entered into a stay pending the entry of judgment in Case I. On June 26, 2017, the court issued its opinion upholding the validity of the ’285 and ’907 patents and finding that Dr. Reddy’s, Mylan’s, and Lupin’s proposed generic naproxen/esomeprazole magnesium products would all infringe at least one of the two patents. The court entered the final judgment on July 21, 2017. Any notice of appeal is due by August 21, 2017.

The Case II and Case III cases have been consolidated for discovery. On January 19, 2017, the court entered a scheduling order for Case II and Case III, which was subsequently updated. The court’s scheduling order requires, inter alia, filing and serving of the opening claim construction submissions by May 26, 2017. The court has not issued a claim construction order in Case II. A trial date for Cases II and III has not yet been set. On December 20, 2016, Mylan filed a motion to dismiss the Company’s first amended complaint for patent infringement in Case III. On April 28, 2017, Dr. Reddy’s filed a motion to dismiss for lack of jurisdiction in Case III, and the Company is awaiting final ruling.

The Company understands the cases arise from Paragraph IV 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 patents-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, March 12, 2014 and July 26, 2016; 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, May 29, 2015, 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 was held on November 16, 2016. The PTAB issued a final written decision finding the ’621 patent valid on February 21, 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 were both held on November 29, 2016. On February 28, 2017, the Patent Trial and Appeal Board issued final written decisions on the IPRs of the ‘996 and ‘190 patents, upholding the validity of both patents.

RAVICTI

On March 17, 2014, Hyperion Therapeutics, Inc. (“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, which extends the expiration date to July 28, 2018. 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 lawsuit alleges that Par Pharmaceutical has infringed the ‘559 patent, 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 Par New Jersey action has been stayed pending the resolution of the PTAB’s IPR of the ‘559 patent.

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 did not 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 December 29, 2016, Par filed a notice of appeal with the Federal Circuit to appeal the final written decision of the PTAB concerning the patentability of the ‘012 patent. Par’s opening brief is due on October 16, 2017.
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 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 expiration of the ’966 patent. The subject patents are listed in the Orange Book. The Lupin New Jersey actions have been stayed pending the resolution of the PTAB’s IPR of the ’559 patent.

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. On March 27, 2017, Lupin filed a Petition to request an IPR of the ’278 patent and a Petition to request an IPR of the ’966 patent. The Company filed its response on the ’966 patent on July 6, 2017. The Company’s preliminary patent owner response for the ’278 patent was filed on July 24, 2017.

Other

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 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 attorneys’ fees. On November 14, 2016, all defendants moved to dismiss the plaintiffs’ amended complaint. Plaintiffs’ filed their opposition to the motion to dismiss on December 21, 2016. Briefing on the motion to dismiss was completed on January 27, 2017 and the parties await the court’s ruling.
NOTE 16 – DEBT AGREEMENTS

The Company’s outstanding debt balances as of June 30, 2017 and December 31, 2016 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2017</th>
<th>December 31, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017 Term Loan Facility</td>
<td>$847,875</td>
<td>—</td>
</tr>
<tr>
<td>2015 Term Loan Facility</td>
<td>—</td>
<td>394,000</td>
</tr>
<tr>
<td>2016 Incremental Loan Facility</td>
<td>—</td>
<td>375,000</td>
</tr>
<tr>
<td>2023 Senior Notes</td>
<td>475,000</td>
<td>475,000</td>
</tr>
<tr>
<td>2024 Senior Notes</td>
<td>300,000</td>
<td>300,000</td>
</tr>
<tr>
<td>Exchangeable Senior Notes</td>
<td>400,000</td>
<td>400,000</td>
</tr>
<tr>
<td>Total face value</td>
<td>2,022,875</td>
<td>1,944,000</td>
</tr>
<tr>
<td>Debt discount</td>
<td>(118,351)</td>
<td>(126,352)</td>
</tr>
<tr>
<td>Deferred financing fees</td>
<td>(12,180)</td>
<td>(10,155)</td>
</tr>
<tr>
<td>Total long-term debt</td>
<td>1,892,344</td>
<td>1,807,493</td>
</tr>
<tr>
<td>Less: current maturities</td>
<td>8,500</td>
<td>7,750</td>
</tr>
<tr>
<td>Long-term debt, net of current maturities</td>
<td>$1,883,844</td>
<td>$1,799,743</td>
</tr>
</tbody>
</table>

2017 Term Loan Facility

On March 29, 2017, HPI and Horizon Pharma USA, Inc. (“HPUSA” and, together with HPI, in such capacity, the “Borrowers”), wholly-owned subsidiaries of the Company, borrowed $850.0 million aggregate principal amount of loans (the “Refinancing Loans”) pursuant to an amendment (the “Refinancing Amendment”) to the Credit Agreement, dated as of May 7, 2015 (as amended by the 2016 Amendment described below, the “Existing Credit Agreement” and, the Existing Credit Agreement as amended by the Refinancing Amendment, the “Credit Agreement”), by and among the Borrowers, the Company and certain of its subsidiaries as guarantors, the lenders party thereto from time to time and Citibank, N.A., as administrative agent and collateral agent (the “2017 Term Loan Facility”). The Credit Agreement provides for (i) the Refinancing Loans, (ii) one or more uncommitted additional incremental loan facilities subject to the satisfaction of certain financial and other conditions, and (iii) one or more uncommitted refinancing loan facilities with respect to loans thereunder. The Credit Agreement allows for the Company and certain of its subsidiaries to become borrowers under incremental or refinancing facilities.

The Refinancing Loans were incurred as a separate new class of term loans under the Credit Agreement with substantially the same terms as the previously outstanding senior secured term loans incurred on May 7, 2015 (the “2015 Loans”) and the outstanding senior secured term loans incurred on October 25, 2016 (the “2016 Loans” and, together with the 2015 Loans, the “Refinanced Loans”), except as described below. The Refinancing Loans bear interest, at the Borrowers’ option, at a rate equal to either the London Inter-Bank Offer Rate (“LIBOR”), plus an applicable margin of 3.75% per year (subject to a LIBOR floor of 1.00%), or the adjusted base rate plus 2.75%. The adjusted base rate is defined as the greater of (a) LIBOR (using one-month interest period) plus 1.00%, (b) prime rate, (c) fed funds plus ½ of 1.00%, and (d) 2.00%. The Borrowers used a portion of the proceeds of the Refinancing Loans to repay the Refinanced Loans, which totaled $769.0 million.

The Company elected to exercise its reinvestment rights under the mandatory prepayment provisions of the Credit Agreement with respect to the net proceeds from the Chiesi divestiture. To the extent the Company does not apply such net proceeds to permitted acquisitions (including the acquisition of rights to products and products lines) and/or the acquisition of capital assets within 365 days of the receipt thereof (or commit to so apply and then apply within 180 days after the end of such 365-day period), the Borrowers under the Credit Agreement would be required to make a mandatory prepayment under the Credit Agreement in an amount equal to the unapplied net proceeds. Until such time, the net proceeds are not legally restricted for use. As of June 30, 2017, the Company had applied a portion of such net proceeds to the acquisition of additional rights to interferon gamma-1b. See Note 3 for further details of this acquisition.
The obligations under the Credit Agreement (including obligations in respect of the Refinancing Loans) and any swap obligations and cash management obligations owing to a lender (or an affiliate of a lender) thereunder are guaranteed by the Company and each of the Company’s existing and subsequently acquired or formed 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 (including obligations in respect of the Refinancing Loans) and any such swap and cash management obligations are secured, subject to customary permitted liens and other agreements 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). The Borrowers and the guarantors under the Credit Agreement are individually and collectively referred to herein as a “Loan Party” and the “Loan Parties,” as applicable.

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 Refinancing Loans, a 1.00% premium will apply to a repayment of the Refinancing 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 six months following March 29, 2017. The Borrowers are required to make mandatory prepayments of loans under the Credit Agreement (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) 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 or 1.75:1, respectively). The Refinancing Loans will amortize in equal quarterly installments beginning on June 30, 2017 in an aggregate annual amount equal to 1.00% of the original principal amount thereof, with any remaining balance payable on March 29, 2024, the final maturity date of the Refinancing Loans.

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.

Events of default under the Credit Agreement include: (i) the failure by any Borrower to timely make payments due under the Credit Agreement; (ii) material misrepresentations or misstatements in any representation or warranty by any Loan Party when made; (iii) failure by any Loan Party to comply with the covenants under the Credit Agreement and other related agreements; (iv) certain defaults under a specified amount of other indebtedness of the Company or its subsidiaries; (v) insolvency or bankruptcy-related events with respect to the Company or any of its material subsidiaries; (vi) certain undischarged judgments against the Company or any of its restricted subsidiaries; (vii) certain ERISA-related events reasonably expected to have a material adverse effect on the Company and its restricted subsidiaries taken as a whole; (viii) certain security interests or liens under the loan documents ceasing to be, or being asserted by the Company or its restricted subsidiaries not to be, in full force and effect; (ix) any loan document or material provision thereof ceasing to be, or any challenge or assertion by any Loan Party that such loan document or material provision is not, in full force and effect; and (x) the occurrence of a change of control. If one or more events of default occurs and continues beyond any applicable cure period, the administrative agent may, with the consent of the lenders holding a majority of the loans and commitments under the facilities, or will, at the request of such lenders, terminate the commitments of the lenders to make further loans and declare all of the obligations of the Loan Parties under the Credit Agreement to be immediately due and payable.

The Company was, as of June 30, 2017, and is currently in compliance with the Credit Agreement.

As of June 30, 2017, the fair value of the 2017 Term Loan Facility was approximately $852.1 million, categorized as a Level 2 instrument, as defined in Note 13.

2016 Incremental Loan Facility and 2015 Term Loan Facility

On May 7, 2015, HPI, as borrower, and the Company and certain of its subsidiaries, as guarantors, entered into a credit agreement (the “2015 Credit Agreement”) with Citibank, N.A., as administrative and collateral agent, and the lenders from time to time party thereto providing for (i) a 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. The 2015 Loans under the 2015 Term Loan Facility bore interest, at each borrower’s option, at a rate equal to either the LIBOR, plus an applicable margin of 3.50% per year (subject to a 1.00% LIBOR floor), or the adjusted base rate plus 2.50%. The adjusted base rate was defined as the greater of (a) LIBOR (using one-month interest period) plus 1.00%, (b) prime rate, (c) fed funds plus ½ of 1.00%, and (d) 2.00%. HPI borrowed the full $400.0 million available on the 2015 Term Loan Facility on May 7, 2015 as a LIBOR-based borrowing.
On October 25, 2016 and in connection with the financing for the acquisition of Raptor, HPI and HPUSA (together, in such capacity, the “Incremental Borrowers”) entered into an amendment to the 2015 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 2015 Credit Agreement with the same terms as the loans under the 2015 Term Loan Facility, except as described below.

The 2016 Loans under the 2016 Incremental Loan Facility bore interest, at the 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 1.00%), or the adjusted base rate plus 3.50%. The terms of 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 2016 Loans minus 0.50%. Consequently, the issuance of the 2016 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 1.00% (an initial interest rate of 5.00%).

On March 29, 2017, the Borrowers used the proceeds of the Refinancing Loans under the 2017 Term Loan Facility to repay the 2015 Loans and 2016 Loans, which collectively totaled $769.0 million.

The 2015 Loans and the 2016 Loans were repaid, and a portion of the repayment was accounted for as a debt modification and a portion was accounted for as a debt extinguishment. Under debt extinguishment accounting, the Company recorded a charge of $0.5 million to “loss on debt extinguishment” in the condensed consolidated statements of comprehensive loss, which reflected the write-off of the unamortized portion of debt discount and deferred financing costs previously incurred and a one percent prepayment penalty fee. Under debt modification accounting, the Company capitalized an incremental $5.8 million of debt discount and deferred financing fees.

2024 Senior Notes

On October 25, 2016, HPI and HPUSA (together, in such capacity, the “2024 Issuers”), completed a private placement of $300.0 million aggregate principal amount of the 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 net proceeds from the offering of the 2024 Senior Notes were approximately $291.9 million, after deducting the initial purchasers’ discount and offering expenses payable by the 2024 Issuers.

The obligations under the 2024 Senior Notes are the 2024 Issuers’ general unsecured senior obligations and are fully and unconditionally guaranteed on a senior unsecured basis by the Company and all of the Company’s direct and indirect subsidiaries that are guarantors from time to time under the Credit Agreement.

The Company used the net proceeds from the offering of the 2024 Senior Notes as well as $375.0 million principal amount of 2016 Loans under the 2016 Incremental Loan Facility to fund a portion of the acquisition of Raptor, repay Raptor’s outstanding debt, and pay any prepayment premiums, fees and expenses in connection with the foregoing.

The 2024 Senior Notes accrue interest at an annual rate of 8.750% 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 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 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.

The Company was, as of June 30, 2017, and is currently in compliance with the indenture governing the 2024 Senior Notes.

As of June 30, 2017, the fair value of the 2024 Senior Notes was approximately $303.0 million, categorized as a Level 2 instrument, as defined in Note 13.

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. The net proceeds from the offering of the 2023 Senior Notes were approximately $462.3 million, after deducting the initial purchasers’ discount and offering expenses payable by Horizon Financing.

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. The obligations under the 2023 Senior Notes are fully and unconditionally guaranteed on a senior unsecured basis by the Company and all of the Company’s direct and indirect subsidiaries that are guarantors from time to time under the Credit Agreement.

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 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 aggregate principal amount thereof, plus accrued and unpaid interest to the repurchase date.

If the Company ceases to be an investment-grade rated public company, the 2023 Senior Notes may be redeemed in whole or in part at a price equal to 100% of the aggregate principal amount thereof, plus accrued and unpaid interest to, but not including, the redemption 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 June 30, 2017, and is currently in compliance with the indenture governing the 2023 Senior Notes.

As of June 30, 2017, the fair value of the 2023 Senior Notes was approximately $446.5 million, categorized as a Level 2 instrument, as defined in Note 13.
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 certain 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 twenty trading days whether or not consecutive) during any thirty 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 twenty trading days (whether or not consecutive) during the period of thirty 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 June 30, 2017, 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 June 30, 2017, the fair value of the Exchangeable Senior Notes was approximately $344.8 million, categorized as a Level 2 instrument, as defined in Note 13.

NOTE 17 – SHAREHOLDERS’ EQUITY

During the six months ended June 30, 2017, the Company issued an aggregate of:

- 206,090 ordinary shares in connection with the exercise of stock options and received $1.3 million in proceeds; and
- 597,292 ordinary shares in net settlement of vested restricted stock units.

During the six months ended June 30, 2017, warrants to purchase an aggregate of 2,500 ordinary shares of the Company were exercised and proceeds of $11,425 were received. In addition, warrants to purchase an aggregate of 704,185 ordinary shares of the Company were exercised in cashless exercises, resulting in the issuance of 523,459 ordinary shares. As of June 30, 2017, there were outstanding warrants to purchase 665,975 ordinary shares of the Company.

During the six months ended June 30, 2017, the Company made payments of $5.2 million for employee withholding taxes relating to share-based awards.

On January 1, 2017, the Company adopted ASU No. 2016-09. As a result of the adoption, $7.2 million of excess tax benefits that had not previously been recognized, as the related tax deduction had not reduced current taxes payable, were recorded on a modified retrospective basis through a cumulative effect adjustment to its accumulated deficit as of January 1, 2017.

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. In May 2017, the Company’s board of directors reauthorized a share repurchase program pursuant to which the Company may repurchase up to 16,000,000 of its ordinary shares. As of June 30, 2017, the Company had repurchased 100,000 of its ordinary shares under this repurchase program, for a total consideration of $1.0 million. The timing and amount of future repurchases, if any, 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 Credit Agreement and market conditions.

NOTE 18 – 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 June 30, 2017, an aggregate of 3,361,928 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.

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 June 30, 2017, an aggregate of 4,013,780 and 667,871 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 six months ended June 30, 2017:

<table>
<thead>
<tr>
<th>Stock Option Activity</th>
<th>Options (in thousands)</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, 2016</td>
<td>13,627,519</td>
<td>$18.17</td>
<td>7.60</td>
<td>$35,157</td>
</tr>
<tr>
<td>Granted</td>
<td>1,746,384</td>
<td>16.96</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercised</td>
<td>(206,090)</td>
<td>6.10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forfeited</td>
<td>(403,133)</td>
<td>18.62</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expired</td>
<td>(106,577)</td>
<td>19.66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outstanding as of June 30, 2017</td>
<td>14,658,103</td>
<td>18.17</td>
<td>7.31</td>
<td>16,285</td>
</tr>
<tr>
<td>Exercisable as of June 30, 2017</td>
<td>8,414,791</td>
<td>$16.60</td>
<td>6.49</td>
<td>$15,486</td>
</tr>
</tbody>
</table>

Stock options typically have a contractual term of ten 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 six months ended June 30, 2017 and 2016, and assumptions used to value stock options, are as follows:

<table>
<thead>
<tr>
<th>For the Six Months Ended June 30,</th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dividend yield</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Risk-free interest rate</td>
<td>1.9%-2.0%</td>
<td>1.3% - 1.8%</td>
</tr>
<tr>
<td>Weighted average expected volatility</td>
<td>49.1%</td>
<td>73.8%</td>
</tr>
<tr>
<td>Expected life (in years)</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>Weighted average grant-date fair value per share of options granted</td>
<td>$8.24</td>
<td>$11.78</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 Credit Agreement, as well as the indentures governing the 2024 Senior Notes and the 2023 Senior Notes (each as described in Note 16 above), 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.

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. The Company adopted ASU No. 2016-09 on January 1, 2017 and has elected to retain a forfeiture rate after adoption.

Restricted Stock Units

The following table summarizes restricted stock unit activity for the six months ended June 30, 2017:

<table>
<thead>
<tr>
<th>Description</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, 2016</td>
<td>3,367,871</td>
<td>$18.45</td>
</tr>
<tr>
<td>Granted</td>
<td>2,048,187</td>
<td>12.16</td>
</tr>
<tr>
<td>Vested</td>
<td>(943,070)</td>
<td>16.38</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(343,528)</td>
<td>18.15</td>
</tr>
<tr>
<td>Outstanding as of June 30, 2017</td>
<td>4,129,460</td>
<td>$15.83</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 awards (“PSUs”) activity for the six months ended June 30, 2017:

<table>
<thead>
<tr>
<th>Description</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, 2016</td>
<td>12,045,656</td>
<td>$12.81</td>
<td>7.3%</td>
<td>$11.87</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(158,336)</td>
<td>$12.81</td>
<td></td>
<td>$11.87</td>
</tr>
<tr>
<td>Outstanding as of June 30, 2017</td>
<td>11,887,320</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 twenty 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.

41
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></th>
<th>For the Six Months Ended June 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2017</td>
</tr>
<tr>
<td>Valuation date stock price</td>
<td>N/A</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>N/A</td>
</tr>
<tr>
<td>Risk free rate</td>
<td>N/A</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>Grouping</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>8,889,656</td>
<td>$15.15</td>
<td>18.9%</td>
<td>$12.29</td>
</tr>
<tr>
<td>Non-executive committee members</td>
<td>2,972,664</td>
<td>13.59</td>
<td>7.3%</td>
<td>12.60</td>
</tr>
<tr>
<td></td>
<td>11,862,320</td>
<td>$14.76</td>
<td>16.2%</td>
<td>$12.37</td>
</tr>
</tbody>
</table>

During the six months ended June 30, 2017 and 2016, the Company recorded an expense of $23.9 million and $24.3 million, respectively, 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 $15.8 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 twenty 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 a result, the Monte Carlo simulation model is applied and the fair value is revalued at each reporting period. As of June 30, 2017 and December 31, 2016, the estimated fair value was $2.0 million and $4.8 million, respectively. For the six months ended June 30, 2017, the Company recorded a reduction in the expense of $1.7 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 June 30, 2017 include:

- Valuation Date Stock Price - $11.87
- Expected Volatility - The expected volatility assumption of 82.27% is based on the Company’s historical volatility over the 0.35 year period ending June 30, 2017, based upon daily stock price observations.
- Risk Free Rate - 1.07%, which is based upon the yield on U.S. Treasury Separate Trading of Registered Interest and Principal Securities with a remaining term of 0.35 years as of June 30, 2017.
Share-Based Compensation Expense

The following table summarizes share-based compensation expense included in the Company’s condensed consolidated statements of operations for the six months ended June 30, 2017 and 2016 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>For the Six Months Ended June 30,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2017</td>
<td>2016</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>$1,001</td>
<td>$—</td>
</tr>
<tr>
<td>Research and development</td>
<td>4,362</td>
<td>4,363</td>
</tr>
<tr>
<td>Selling, general and administrative</td>
<td>50,874</td>
<td>51,246</td>
</tr>
<tr>
<td>Total share-based compensation expense</td>
<td>$56,237</td>
<td>$55,609</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 June 30, 2017, the Company estimates that pre-tax unrecognized compensation expense of $171.1 million for all unvested share-based awards, including stock options, restricted stock units and PSUs, will be recognized through the second quarter of 2021. 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 19 – INCOME TAXES

The Company accounts for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are recognized for deductible temporary differences, and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by 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 for income taxes for the three and six months ended June 30, 2017 and 2016 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended June 30,</th>
<th></th>
<th>For the Six Months Ended June 30,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Loss) income before benefit for income taxes</td>
<td>$ (211,303)</td>
<td>$ 12,228</td>
<td>$ (349,426)</td>
<td>$ (34,621)</td>
</tr>
<tr>
<td>Benefit for income taxes</td>
<td>(1,767)</td>
<td>(2,756)</td>
<td>(49,320)</td>
<td>(4,199)</td>
</tr>
<tr>
<td>Net (loss) income</td>
<td>$ (209,536)</td>
<td>$ 14,984</td>
<td>$ (300,106)</td>
<td>$ (30,422)</td>
</tr>
</tbody>
</table>

During the three and six months ended June 30, 2017, the Company recorded a benefit for income taxes of $1.8 million and $49.3 million, respectively, compared to $2.8 million and $4.2 million during the three and six months ended June 30, 2016, respectively. The increase in benefit for income taxes for the six months ended June 30, 2017 compared to the six months ended June 30, 2016 resulted from an increase in pre-tax losses incurred in higher tax rate jurisdictions.

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.
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.

Beginning in the first quarter of 2017, we modified our presentation of certain operating expenses. Previously, we presented “general and administrative” expenses as one line item in our condensed consolidated statement of comprehensive (loss) income, and “selling and marketing” expenses as another. For current-period presentation and prior-period comparisons, we now combine these two line items into one line item, titled “selling, general and administrative” expenses.

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:

**Orphan Business Unit**
- ACTIMMUNE® (interferon gamma-1b); marketed as IMUKIN® outside the United States
- BUPHENYL® (sodium phenylbutyrate) Tablets and Powder; marketed as AMMONAPS® in certain European countries and Japan
- PROCYSBI® (cysteamine bitartrate) delayed-release capsules
- QUINSAIR™ (levofloxacin inhalation solution)
- RAVICTI® (glycerol phenylbutyrate) Oral Liquid

**Rheumatology Business Unit**
- KRYSTEXXA® (pegloticase)
- RAYOS® (prednisone) delayed-release tablets; marketed as LODOTRA® outside the United States

**Primary Care Business Unit**
- DUEXIS® (ibuprofen/famotidine)
- MIGERGOT® (ergotamine tartrate & caffeine suppositories)
- PENNSAID® (diclofenac sodium topical solution) 2% w/w, or PENNSAID 2%
- VIMOVO® (naproxen/esomeprazole magnesium)

On January 13, 2016, we completed our acquisition of Crealta Holdings LLC, or Crealta, for approximately $539.7 million, including $24.9 million of cash acquired and $70.9 million paid to settle Crealta’s outstanding debt. Following completion of the acquisition, Crealta became our wholly owned subsidiary and was renamed as Horizon Pharma Rheumatology LLC.

On October 25, 2016, we completed our acquisition of Raptor Pharmaceutical Corp., or Raptor, in which we acquired all of the issued and outstanding shares of Raptor’s common stock for $9.00 per share in cash. The total consideration was $860.8 million, including $24.9 million of cash acquired and $56.0 million paid to settle Raptor’s outstanding debt. Following completion of the acquisition, Raptor became our wholly owned subsidiary and converted to a limited liability company, changing its name to Horizon Pharmaceutical LLC.
On May 8, 2017, we acquired River Vision Development Corp., or River Vision, for upfront cash payments totaling $151.9 million, including $6.3 million of cash acquired, and subject to other customary purchase price adjustments for working capital, and potential future milestone and royalty payments contingent on the satisfaction of certain regulatory milestones and sales thresholds. Following completion of the acquisition, River Vision became our wholly owned subsidiary and was renamed as Horizon Pharma Tepro, Inc.

On June 23, 2017, we sold our European subsidiary which owned the marketing rights to PROCYSBI and QUINSAIR in Europe, the Middle East and Africa regions, or the Chiesi divestiture, to Chiesi Farmaceutici S.p.A., or Chiesi, for an upfront payment of $72.2 million, including $3.1 million of cash divested, with additional potential milestone payments based on sales thresholds.

On June 30, 2017, we completed the acquisition of certain rights to interferon gamma-1b from Boehringer Ingelheim International GmbH, or Boehringer Ingelheim International, in all territories outside of the United States, Canada and Japan, as we previously held marketing rights to interferon gamma-1b in these territories. Boehringer Ingelheim International commercialized interferon gamma-1b under the trade names IMUKIN®, IMUKINE®, IMMUKIN® and IMMUKINE®, or IMUKIN, in an estimated thirty countries, primarily in Europe and the Middle East. In May 2016, we paid Boehringer Ingelheim International €5.0 million ($5.6 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1132) for such rights and upon closing in June 2017, we paid Boehringer Ingelheim International an additional €19.5 million ($22.3 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1406). We market interferon gamma-1b as ACTIMMUNE® in the United States.

On December 8, 2016, we announced that the Phase 3 trial, Safety, Tolerability and Efficacy of ACTIMMUNE Dose Escalation in Friedreich’s Ataxia study, or STEADFAST, evaluating ACTIMMUNE for the treatment of Friedreich’s ataxia, or FA, did not meet its primary endpoint of a statistically significant change from baseline in the modified Friedreich’s Ataxia Rating Scale at twenty-six weeks versus treatment with placebo and that the secondary endpoints did not meet statistical significance, or the FA announcement. No new safety findings were identified on initial review of data other than those already noted in the ACTIMMUNE prescribing information for approved indications. We, in conjunction with the independent Data Safety Monitoring Board, the principal investigator and the Friedreich’s Ataxia Research Alliance Collaborative Clinical Research Network in FA, determined that, based on the trial results, the STEADFAST program would be discontinued, including the twenty-six week extension study and the long-term safety study.

Following the FA announcement, we recorded certain amounts in our condensed consolidated statement of comprehensive loss during the year ended December 31, 2016. Refer to Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 for details. We recorded $14.3 million in our condensed consolidated statement of comprehensive loss during the year ended December 31, 2016 for firm, non-cancellable and unconditional purchase commitments for quantities of ACTIMMUNE in excess of our current forecasts for future demand. During the three months ended June 30, 2017, we renegotiated the amounts due to Boehringer Ingelheim RCV GmbH & Co KG, or Boehringer Ingelheim, and recorded a reduction to “cost of goods sold” of $3.1 million. During the year ended December 31, 2016, we also committed to incur an additional $14.9 million for the harmonization of the drug substance manufacturing process with Boehringer Ingelheim, of which $0.7 million and $6.5 million was recorded in our condensed consolidated statements of comprehensive loss during the three and six months ended June 30, 2017, respectively.

Strategy
Our strategy is to continue the transformation of Horizon Pharma plc into a balanced, diversified, sustainable-growth biopharmaceutical company predominantly focused on rare disease medicines. We are executing on our strategy by accelerating the growth of our rare disease medicine portfolio through differentiated commercial strategies, business development efforts, and the expansion of our pipeline with post-marketing and development-stage programs. We are strongly committed to helping ensure patient access to their medicines and support services, and by investing in the further development of medicines for patients with rare or underserved diseases.
**Orphan Business Unit**

Our marketed rare disease medicines in our orphan business unit are ACTIMMUNE, BUPHENYL, PROCYSBI, QUINSAIR and RAVICTI. Our strategy for RAVICTI is to drive growth through increased awareness and diagnosis of urea cycle disorders and to drive conversion from older-generation nitrogen scavengers to RAVICTI, based on the medicine’s differential benefits. With respect to PROCYSBI, our strategy is to drive conversion of patients from older-generation immediate-release capsules of cysteamine bitartrate, increase the uptake of diagnosed but untreated patients and to identify previously undiagnosed patients who are suitable for treatment. Although we no longer have EMEA marketing rights to PROCYSBI and QUINSAIR after the Chiesi divestiture, we retain marketing rights for both medicines in the United States, Canada, Latin America and Asia. Our strategy with respect to ACTIMMUNE includes driving growth by increasing awareness and diagnosis of chronic granulomatous disease, increasing the length of treatment, establishing ACTIMMUNE as a cornerstone for treatment for a broader range of patients and evaluating opportunities for combination therapy with PD-1 and PD-L1 inhibitors in treatment of certain cancers through investigator-initiated studies.

With our May 2017 acquisition of River Vision, we added the late-stage rare disease biologic medicine teprotumumab to our pipeline. Teprotumumab, which recently successfully completed its Phase 2 clinical trial, targets the treatment of moderate-to-severe thyroid eye disease, a debilitating autoimmune condition that presents in patients with Graves’ disease. Our strategy for teprotumumab is to support its continued clinical development and pursue regulatory approval. The River Vision acquisition further demonstrates our commitment to rare disease medicines and expands and diversifies our rare disease medicine pipeline to support sustainable longer-term growth.

**Rheumatology Business Unit**

Our marketed rare disease rheumatology medicine is KRYSTEXXA. We are focused on optimizing and maximizing KRYSTEXXA’s peak sales potential by expanding our commercialization efforts, as well as investing in education, patient and physician outreach, and investigation programs that demonstrate KRYSTEXXA as an effective treatment of refractory chronic gout. In May 2017, we announced increased investment in KRYSTEXXA as part of the program to optimize its sales potential, with the goal of nearly doubling the commercial organization by the end of 2017. We believe that KRYSTEXXA represents a significant opportunity and potential growth driver for our rheumatology business unit. The rheumatology business unit also includes RAYOS.

**Primary Care Business Unit**

Our strategy for the primary care business unit, which includes DUEXIS, VIMOVO and PENNSAID 2%, is to educate physicians about these clinically differentiated medicines and the benefits they offer. Patients are able to fill prescriptions for these medicines through pharmacies participating in our HorizonCares patient access program, as well as other pharmacies. In addition, we have evolved our commercial strategy to enter into business arrangements with pharmacy benefit managers, or PBMs, and other payers to secure formulary status and reimbursement of our medicines. The business arrangements with the PBMs generally require us to pay administrative fees and rebates to the PBMs and other payers for qualifying prescriptions. The primary care business unit also includes MIGERGOT.

We market our medicines in the United States through our field sales force, which numbered approximately 385 representatives across our three business units as of June 30, 2017 compared to approximately 460 representatives as of March 31, 2017. During the second quarter of 2017, we effected a workforce reduction in the primary care business unit. Additionally, we revised our methodology of classifying the sales force to more closely align with those who participate in our sales incentive compensation program.
RESULTS OF OPERATIONS

Comparison of Three Months Ended June 30, 2017 and 2016

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 June 30, 2017, compared to the three months ended June 30, 2016.

<table>
<thead>
<tr>
<th>For the Three Months Ended June 30</th>
<th>2017</th>
<th>2016</th>
<th>Increase / Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>$289,507</td>
<td>$257,378</td>
<td>$32,129</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>130,150</td>
<td>81,126</td>
<td>49,024</td>
</tr>
<tr>
<td>Gross profit</td>
<td>159,357</td>
<td>176,252</td>
<td>(16,895)</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>163,101</td>
<td>11,210</td>
<td>151,891</td>
</tr>
<tr>
<td>Selling, general and administrative</td>
<td>181,923</td>
<td>133,575</td>
<td>48,348</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>345,024</td>
<td>144,785</td>
<td>200,239</td>
</tr>
<tr>
<td>Operating (loss) income</td>
<td>(185,667)</td>
<td>31,467</td>
<td>(217,134)</td>
</tr>
<tr>
<td>Other expense, net:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(31,608)</td>
<td>(19,228)</td>
<td>(12,380)</td>
</tr>
<tr>
<td>Foreign exchange gain</td>
<td>151</td>
<td>15</td>
<td>136</td>
</tr>
<tr>
<td>Gain on divestiture</td>
<td>5,856</td>
<td>—</td>
<td>5,856</td>
</tr>
<tr>
<td>Other expense, net</td>
<td>(35)</td>
<td>(26)</td>
<td>(9)</td>
</tr>
<tr>
<td>Total other expense, net</td>
<td>(25,636)</td>
<td>(19,239)</td>
<td>(6,397)</td>
</tr>
<tr>
<td>(Loss) income before benefit for income taxes</td>
<td>(211,303)</td>
<td>12,228</td>
<td>(223,531)</td>
</tr>
<tr>
<td>Benefit for income taxes</td>
<td>(1,767)</td>
<td>(2,756)</td>
<td>989</td>
</tr>
<tr>
<td>Net (loss) income</td>
<td>(209,536)</td>
<td>14,984</td>
<td>(224,520)</td>
</tr>
</tbody>
</table>

Net sales. Net sales increased $32.1 million, or 12%, to $289.5 million during the three months ended June 30, 2017, from $257.4 million during the three months ended June 30, 2016.

The following table presents a summary of net sales attributed to geographic sources for the three months ended June 30, 2017 and 2016 (in thousands):

<table>
<thead>
<tr>
<th>Three Months Ended June 30, 2017</th>
<th>Amount</th>
<th>% of Total Net Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>$279,012</td>
<td>96%</td>
</tr>
<tr>
<td>Rest of world</td>
<td>10,495</td>
<td>4%</td>
</tr>
<tr>
<td>Net sales</td>
<td>$289,507</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Three Months Ended June 30, 2016</th>
<th>Amount</th>
<th>% of Total Net Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>$254,656</td>
<td>99%</td>
</tr>
<tr>
<td>Rest of world</td>
<td>2,722</td>
<td>1%</td>
</tr>
<tr>
<td>Net sales</td>
<td>$257,378</td>
<td></td>
</tr>
</tbody>
</table>

The following table reflects net sales by medicine for the three months ended June 30, 2017 and 2016:

<table>
<thead>
<tr>
<th>Three Months Ended June 30</th>
<th>2017</th>
<th>2016</th>
<th>Change</th>
<th>Change %</th>
</tr>
</thead>
<tbody>
<tr>
<td>PENNSAID 2%</td>
<td>$51,221</td>
<td>$72,665</td>
<td>$(21,444)</td>
<td>(30%)</td>
</tr>
<tr>
<td>RAVICTI</td>
<td>47,239</td>
<td>39,353</td>
<td>7,886</td>
<td>20%</td>
</tr>
<tr>
<td>DUEXIS</td>
<td>43,603</td>
<td>45,517</td>
<td>(1,914)</td>
<td>(4%)</td>
</tr>
<tr>
<td>KRYSTEXXA</td>
<td>38,301</td>
<td>19,872</td>
<td>18,429</td>
<td>93%</td>
</tr>
<tr>
<td>PROCYSBI</td>
<td>36,679</td>
<td>—</td>
<td>36,679</td>
<td>*</td>
</tr>
<tr>
<td>ACTIMMUNE</td>
<td>28,819</td>
<td>30,038</td>
<td>(1,219)</td>
<td>(4%)</td>
</tr>
<tr>
<td>VIMOVO</td>
<td>21,130</td>
<td>31,420</td>
<td>(10,290)</td>
<td>(33%)</td>
</tr>
<tr>
<td>RAYOS</td>
<td>11,643</td>
<td>12,134</td>
<td>(491)</td>
<td>(4%)</td>
</tr>
<tr>
<td>BUPHENYL</td>
<td>6,231</td>
<td>4,049</td>
<td>2,182</td>
<td>54%</td>
</tr>
<tr>
<td>LODOTRA</td>
<td>1,804</td>
<td>1,195</td>
<td>609</td>
<td>51%</td>
</tr>
<tr>
<td>MIGERGOT</td>
<td>1,430</td>
<td>1,135</td>
<td>295</td>
<td>26%</td>
</tr>
<tr>
<td>QUINSAIR</td>
<td>1,407</td>
<td>—</td>
<td>1,407</td>
<td>*</td>
</tr>
<tr>
<td>Net sales</td>
<td>$289,507</td>
<td>$257,378</td>
<td>$32,129</td>
<td>12%</td>
</tr>
</tbody>
</table>

* Percentage change is not meaningful.
The increase in net sales during the three months ended June 30, 2017 was primarily due to the recognition of PROCYSBI sales following the acquisition of Raptor in October 2016 and higher net sales of KRYSTEXXA and RAVICTI, offset by lower net sales of PENNSAID 2% and VIMOVO.

**PENNSAID 2%**. Net sales decreased $21.4 million, or 30%, to $51.2 million during the three months ended June 30, 2017, from $72.7 million during the three months ended June 30, 2016. Net sales decreased by approximately $21.3 million due to lower net pricing and approximately $0.1 million resulting from lower prescription volume.

**RAVICTI**. Net sales increased $7.9 million, or 20%, to $47.2 million during the three months ended June 30, 2017, from $39.3 million during the three months ended June 30, 2016. Net sales increased by approximately $7.0 million resulting from prescription volume growth and approximately $0.9 million due to higher net pricing.

**DUEXIS**. Net sales decreased $1.9 million, or 4%, to $43.6 million during the three months ended June 30, 2017, from $45.5 million during the three months ended June 30, 2016. Net sales decreased by approximately $3.3 million due to lower net pricing, offset by an increase of approximately $1.4 million resulting from prescription volume growth.

**KRYSTEXXA**. Net sales increased $18.4 million, or 93%, to $38.3 million during the three months ended June 30, 2017, from $19.9 million during the three months ended June 30, 2016. Net sales increased by approximately $9.5 million resulting from higher net pricing and approximately $8.9 million resulting from prescription volume growth.

**PROCYSBI**. Net sales were $36.7 million during the three months ended June 30, 2017. We began recognizing PROCYSBI sales following our acquisition of Raptor in October 2016.

**ACTIMUME**. Net sales decreased $1.2 million, or 4%, to $28.8 million during the three months ended June 30, 2017, from $30.0 million during the three months ended June 30, 2016. Net sales decreased by approximately $3.5 million resulting from lower prescription volume, offset by an increase of approximately $2.3 million due to higher net pricing.

**VIMOVO**. Net sales decreased $10.3 million, or 33%, to $21.1 million during the three months ended June 30, 2017, from $31.4 million during the three months ended June 30, 2016. Net sales decreased by approximately $7.5 million due to lower net pricing and approximately $2.8 million resulting from lower prescription volume.

**RAYOS**. Net sales decreased $0.5 million, or 4%, to $11.6 million during the three months ended June 30, 2017, from $12.1 million during the three months ended June 30, 2016. Net sales decreased by approximately $5.8 million due to lower net pricing, partially offset by an increase of approximately $5.3 million resulting from prescription volume growth.

**BUPHENYL**. Net sales increased $2.2 million, or 54%, to $6.2 million during the three months ended June 30, 2017, from $4.0 million during the three months ended June 30, 2016. Net sales increased by approximately $1.1 million resulting from prescription volume growth and $1.1 million due to higher net pricing.

**LODOTRA**. Net sales increased $0.6 million, or 51%, to $1.8 million during the three months ended June 30, 2017, from $1.2 million during the three months ended June 30, 2016. 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 increased $0.3 million, or 26%, to $1.4 million during the three months ended June 30, 2017, from $1.1 million during the three months ended June 30, 2016. Net sales increased by approximately $0.5 million resulting from higher net pricing, partially offset by approximately $0.2 million resulting from lower prescription volume.

**QUINSAIR**. Net sales were $1.4 million during the three months ended June 30, 2017. We began recognizing QUINSAIR sales following our acquisition of Raptor in October 2016.
The table below reconciles our gross to net sales for the three months ended June 30, 2017 and 2016 (in millions):

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amount</td>
<td>% of Gross Sales</td>
<td>Amount</td>
<td>% of Gross Sales</td>
</tr>
<tr>
<td>Gross sales</td>
<td>$1,071.7</td>
<td>100.0%</td>
<td>$792.0</td>
<td>100.0%</td>
</tr>
<tr>
<td>Adjustments to gross sales:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prompt pay discounts</td>
<td>(21.3)</td>
<td>(2.0)%</td>
<td>(16.3)</td>
<td>(2.1)%</td>
</tr>
<tr>
<td>Medicine returns</td>
<td>(15.0)</td>
<td>(1.4)%</td>
<td>(1.1)</td>
<td>(0.1)%</td>
</tr>
<tr>
<td>Co-pay and other patient assistance</td>
<td>(497.0)</td>
<td>(46.4)%</td>
<td>(428.2)</td>
<td>(54.1)%</td>
</tr>
<tr>
<td>Wholesaler fees and commercial rebates</td>
<td>(168.3)</td>
<td>(15.7)%</td>
<td>(26.5)</td>
<td>(3.3)%</td>
</tr>
<tr>
<td>Government rebates and chargebacks</td>
<td>(80.6)</td>
<td>(7.5)%</td>
<td>(62.5)</td>
<td>(7.9)%</td>
</tr>
<tr>
<td>Total adjustments</td>
<td>(782.2)</td>
<td>(73.0)%</td>
<td>(534.6)</td>
<td>(67.5)%</td>
</tr>
<tr>
<td>Net sales</td>
<td>$289.5</td>
<td>27.0%</td>
<td>$257.4</td>
<td>32.5%</td>
</tr>
</tbody>
</table>

During the three months ended June 30, 2017, wholesaler fees and commercial rebates, as a percentage of gross sales, increased to 15.7% from 3.3% during the three months ended June 30, 2016, and co-pay and other patient assistance, as a percentage of gross sales, decreased to 46.4% from 54.1% during the three months ended June 30, 2016. During the second half of 2016, we entered into business arrangements with PBMs and other payers in an effort to secure formulary status and reimbursement of our medicines, such as our arrangements with Express Scripts, CVS Caremark and Prime Therapeutics LLC, which resulted in lower co-pay and other patient assistance costs as a percentage of gross sales during the three months ended June 30, 2017. The mix of PBM healthcare plans that adopted our primary care medicines onto their formulary during 2017 was more heavily weighted towards those plans for which we pay a higher commercial rebate. In addition, we also recorded a higher rate of managed care control in our non-contracted business, which resulted in significantly lower net pricing during the three months ended June 30, 2017 when compared to the three months ended June 30, 2016.

Cost of Goods Sold. Cost of goods sold increased $49.0 million to $130.2 million during the three months ended June 30, 2017, from $81.2 million during the three months ended June 30, 2016. As a percentage of net sales, cost of goods sold was 45.0% during the three months ended June 30, 2017, compared to 31.5% during the three months ended June 30, 2016. The increase in cost of goods sold was primarily attributable to a $24.8 million increase in inventory step-up expense, a $19.0 million increase in intangible amortization expense, a $3.1 million increase in royalty accretion, a $2.3 million increase in salary and wages, partially offset by a reduction of $3.1 million in cost of goods sold following a reduction in our excess inventory purchase commitments with Boehringer Ingelheim.

Because inventory step-up expense is acquisition-related, will not continue indefinitely and has a significant effect on our gross profit, gross margin percentage and net income (loss) for all affected periods, we disclose balance sheet and income statement amounts related to inventory step-up within the notes to the condensed consolidated financial statements. The increase in inventory step-up expense of $24.8 million recorded to cost of goods sold during the three months ended June 30, 2017 compared to the prior year period was due to KRYSTEMXXA and MIGERGOT inventory step-up expense of $19.3 million (acquired in January 2016) and PROCYSBI and QUINSAIR inventory step-up expense of $14.5 million (acquired in October 2016) recorded during the three months ended June 30, 2017, compared to KRYSTEMXXA and MIGERGOT inventory step-up expense of $9.0 million recorded during the three months ended June 30, 2016.

The increase in intangible amortization of $19.0 million during the three months ended June 30, 2017 compared to the prior year period was primarily due to the amortization of developed technology of $18.8 million related to PROCYSBI, which was acquired in October 2016.

Research and Development Expenses. Research and development expenses increased $151.9 million to $163.1 million during the three months ended June 30, 2017, from $11.2 million during the three months ended June 30, 2016. The increase was primarily attributable to $147.7 million related to the acquisition of River Vision during the three months ended June 30, 2017. Pursuant to ASC 805 (as amended by ASU No. 2017-01), we accounted for the River Vision acquisition as the purchase of an in-process research and development, or IPR&D, asset and, pursuant to ASC 730, recorded the purchase price of Boehringer Ingelheim International upon closing of the acquisition of certain rights to interferon gamma-1b during the three months ended June 30, 2017, a $7.2 million increase in consulting expense, a $9.3 million increase in employee costs and a $9.1 million increase in marketing programs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $48.3 million to $181.9 million during the three months ended June 30, 2017, from $133.6 million during the three months ended June 30, 2016. The increase was primarily attributable to $22.3 million paid to Boehringer Ingelheim International upon closing of the acquisition of certain rights to interferon gamma-1b during the three months ended June 30, 2017, a $7.2 million increase in consulting expense, a $9.3 million increase in employee costs and a $9.1 million increase in marketing programs.

49
Interest Expense, Net. Interest expense, net, increased $12.4 million to $31.6 million during the three months ended June 30, 2017, from $19.2 million during the three months ended June 30, 2016. The increase was primarily due to higher borrowings in connection with the acquisition of Raptor, including our $300.0 million aggregate principal amount of 8.75% Senior Notes due 2024, or the 2024 Senior Notes, and our $850.0 million principal amount of secured loans under our 2017 term loan facility, compared to the $397.0 million principal amount of secured loans from previous borrowings under our senior secured loan facility.

Gain on divestiture. During the three months ended June 30, 2017, we completed the Chiesi divestiture for an upfront payment of $72.2 million, including $3.1 million of cash divested, with additional potential milestone payments based on sales thresholds and we recorded a gain of $5.9 million on the divestiture.

Benefit for Income Taxes. During the three months ended June 30, 2017, we recorded a benefit for income taxes of $1.8 million compared to $2.8 million during the three months ended June 30, 2016. The decrease in benefit for income taxes during the three months ended June 30, 2017, compared to the three months ended June 30, 2016, resulted from a greater tax benefit limitation driven by an increase in the proportion of losses incurred for the three months ended June 30, 2017 compared to the proportion of losses incurred for the three months ended June 30, 2016.
Comparison of Six Months Ended June 30, 2017 and 2016

The table below should be referenced in connection with a review of the following discussion of our results of operations for the six months ended June 30, 2017, compared to the six months ended June 30, 2016.

<table>
<thead>
<tr>
<th>For the Six Months Ended June 30,</th>
<th>Increase / (Decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2017 (in thousands)</td>
</tr>
<tr>
<td><strong>Net sales</strong></td>
<td>$510,366</td>
</tr>
<tr>
<td><strong>Cost of goods sold</strong></td>
<td>269,266</td>
</tr>
<tr>
<td><strong>Gross profit</strong></td>
<td>241,100</td>
</tr>
<tr>
<td><strong>Operating expenses:</strong></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>176,162</td>
</tr>
<tr>
<td>Sales, general and administrative</td>
<td>355,988</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td>532,150</td>
</tr>
<tr>
<td><strong>Operating (loss) income</strong></td>
<td>(291,050)</td>
</tr>
<tr>
<td><strong>Other expense, net:</strong></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(63,591)</td>
</tr>
<tr>
<td>Foreign exchange gain (loss)</td>
<td>(108)</td>
</tr>
<tr>
<td>Gain on divestiture</td>
<td>5,856</td>
</tr>
<tr>
<td>Loss on debt extinguishment</td>
<td>(533)</td>
</tr>
<tr>
<td><strong>Other expense, net</strong></td>
<td>(58,376)</td>
</tr>
<tr>
<td><strong>Loss before benefit for income taxes</strong></td>
<td>(349,426)</td>
</tr>
<tr>
<td><strong>Benefit for income taxes</strong></td>
<td>(49,320)</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>$ (300,106)</td>
</tr>
</tbody>
</table>

Net sales. Net sales increased $48.3 million, or 11%, to $510.4 million during the six months ended June 30, 2017, from $462.1 million during the six months ended June 30, 2016.

The following table presents a summary of net sales attributed to geographic sources for six months ended June 30, 2017 and 2016 (in thousands):

<table>
<thead>
<tr>
<th>Six Months Ended June 30, 2017</th>
<th>% of Total Net Sales</th>
<th>Six Months Ended June 30, 2016</th>
<th>% of Total Net Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>$489,897</td>
<td>96%</td>
<td>$456,306</td>
</tr>
<tr>
<td>Rest of world</td>
<td>20,469</td>
<td>4%</td>
<td>5,762</td>
</tr>
<tr>
<td><strong>Total Net Sales</strong></td>
<td>$510,366</td>
<td></td>
<td>$462,068</td>
</tr>
</tbody>
</table>

The following table reflects the components of net sales for the six months ended June 30, 2017 and 2016:

<table>
<thead>
<tr>
<th>Six Months Ended June 30, 2017</th>
<th>2016</th>
<th>Change $</th>
<th>Change %</th>
</tr>
</thead>
<tbody>
<tr>
<td>PENNSAID 2%</td>
<td>$92,831</td>
<td>$127,658</td>
<td>$(34,827)</td>
</tr>
<tr>
<td>RAVICTI</td>
<td>91,114</td>
<td>76,423</td>
<td>14,691</td>
</tr>
<tr>
<td>PROCYSB1</td>
<td>70,959</td>
<td>—</td>
<td>70,959</td>
</tr>
<tr>
<td>KRYSTEXXA</td>
<td>69,915</td>
<td>36,028</td>
<td>33,887</td>
</tr>
<tr>
<td>DUEXIS</td>
<td>61,332</td>
<td>75,165</td>
<td>(13,833)</td>
</tr>
<tr>
<td>ACTIMMUNE</td>
<td>55,021</td>
<td>55,550</td>
<td>(529)</td>
</tr>
<tr>
<td>VIMOVO</td>
<td>26,012</td>
<td>56,871</td>
<td>(30,859)</td>
</tr>
<tr>
<td>RAYOS</td>
<td>21,901</td>
<td>22,643</td>
<td>(742)</td>
</tr>
<tr>
<td>BUPHENYL</td>
<td>12,555</td>
<td>7,793</td>
<td>4,762</td>
</tr>
<tr>
<td>QUINSAIR</td>
<td>3,200</td>
<td>—</td>
<td>3,200</td>
</tr>
<tr>
<td>MIGERGOT</td>
<td>2,854</td>
<td>2,042</td>
<td>812</td>
</tr>
<tr>
<td>LODOTRA</td>
<td>2,672</td>
<td>1,895</td>
<td>777</td>
</tr>
<tr>
<td><strong>Total Net Sales</strong></td>
<td>$510,366</td>
<td>$462,068</td>
<td>$48,298</td>
</tr>
</tbody>
</table>
The increase in net sales during the six months ended June 30, 2017 was primarily due to the recognition of PROCYSBI sales following the acquisition of Raptor in October 2016 and higher net sales of KRYSTEXXA and RAVICTI, offset by lower net sales of PENNSAID 2%, VIMOVO and DUEXIS.

**PENNSAID 2%**. Net sales decreased $34.8 million, or 27%, to $92.8 million during the six months ended June 30, 2017, from $127.6 million during the six months ended June 30, 2016. Net sales decreased by approximately $26.8 million due to lower net pricing and $8.0 million due to prescription volume decreases.

**RAVICTI**. Net sales increased $14.7 million, or 19%, to $91.1 million during the six months ended June 30, 2017, from $76.4 million during the six months ended June 30, 2016. Net sales increased by approximately $14.8 million resulting from prescription volume growth, offset by a decrease of approximately $0.1 million due to lower net pricing.

**PROCYSBI**. Net sales were $71.0 million during the six months ended June 30, 2017. We began recognizing PROCYSBI sales following our acquisition of Raptor in October 2016.

**KRYSTEXXA**. Net sales increased $33.9 million, or 94%, to $69.9 million during the six months ended June 30, 2017, from $36.0 million during the six months ended June 30, 2016. Net sales increased by approximately $17.2 million due to higher net pricing and approximately $16.7 million resulting from prescription volume growth.

**DUEXIS**. Net sales decreased $13.8 million, or 18%, to $61.3 million during the six months ended June 30, 2017, from $75.1 million during the six months ended June 30, 2016. Net sales decreased by approximately $14.3 million due to lower net pricing, offset by approximately $0.5 million resulting from prescription volume growth.

**ACTIMMUNE**. Net sales decreased $0.5 million, or 1%, to $55.0 million during the six months ended June 30, 2017, from $55.5 million during the six months ended June 30, 2016. Net sales decreased by approximately $4.9 resulting from prescription volume decreases, offset by an increase of $4.5 million due to higher net pricing.

**VIMOVO**. Net sales decreased $30.9 million, or 54%, to $26.0 million during the six months ended June 30, 2017, from $56.9 million during the six months ended June 30, 2016. Net sales decreased by approximately $20.6 million due to lower net pricing and approximately $10.3 million resulting from prescription volume decreases.

**RAYOS**. Net sales decreased $0.7 million, or 3%, to $21.9 million during the six months ended June 30, 2017, from $22.6 million during the six months ended June 30, 2016. Net sales decreased by approximately $8.7 million due to lower net pricing, offset by an increase of $8.0 million resulting from prescription volume growth.

**BUPHENYL**. Net sales increased $4.8 million, or 61%, to $12.6 million during the six months ended June 30, 2017, from $7.8 million during the six months ended June 30, 2016. Net sales increased by approximately $5.0 million due to higher net pricing, offset by a decrease of approximately $0.2 million resulting from prescription volume decreases.

**QUINSAIR**. Net sales were $3.2 million during the six months ended June 30, 2017. We began recognizing QUINSAIR sales following our acquisition of Raptor in October 2016.

**MIGERGOT**. Net sales increased $0.8 million, or 40%, to $2.9 million during the six months ended June 30, 2017, from $2.1 million during the six months ended June 30, 2016. Net sales increased by approximately $0.9 million due to higher net pricing, offset by a decrease of approximately $0.1 million resulting from prescription volume decreases.

**LODOTRA**. Net sales increased $0.8 million, or 41%, to $2.7 million during the six months ended June 30, 2017, from $1.9 million during the six months ended June 30, 2016. 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.
The table below reconciles our gross to net sales for the six months ended June 30, 2017 and 2016 (in millions):

<table>
<thead>
<tr>
<th></th>
<th>Gross sales</th>
<th>Adjustments to gross sales:</th>
<th>Net sales</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$ 2,000.3</td>
<td>Prompt pay discounts (39.7)</td>
<td>$ 510.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medicine returns (25.8)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Co-pay and other patient assistance (957.4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wholesaler fees and commercial rebates (309.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Government rebates and chargebacks (157.7)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$ 1,484.6</td>
<td>Total adjustments (1,489.9)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>% of Gross Sales 100.0%</td>
<td>% of Gross Sales 31.1%</td>
</tr>
</tbody>
</table>

During the six months ended June 30, 2017, wholesaler fees and commercial rebates, as a percentage of gross sales, increased to 15.4% from 3.7% during the six months ended June 30, 2016, and co-pay and other patient assistance, as a percentage of gross sales, decreased to 47.9% from 55.1% during the six months ended June 30, 2016. During the second half of 2016, we entered into business arrangements with PBMs and other payers in an effort to secure formulary status and reimbursement of our medicines, such as our arrangements with Express Scripts, CVS Caremark and Prime Therapeutics LLC, which resulted in lower co-pay and other patient assistance costs as a percentage of gross sales during the six months ended June 30, 2017. The mix of PBM healthcare plans that adopted our primary care medicines onto their formulary during 2017 was more heavily weighted towards those plans for which we pay a higher commercial rebate. In addition, we also recorded a higher rate of managed care control in our non-contracted business, which resulted in significantly lower net pricing during the six months ended June 30, 2017 when compared to the six months ended June 30, 2016.

Cost of Goods Sold. Cost of goods sold increased $110.9 million to $269.3 million during the six months ended June 30, 2017, from $158.4 million during the six months ended June 30, 2016. As a percentage of net sales, cost of goods sold was 52.8% during the six months ended June 30, 2017 compared to 34.3% during the six months ended June 30, 2016. The increase in cost of goods sold was primarily attributable to a $57.9 million increase in inventory step-up expense, an increase in intangible amortization expense of $39.0 million, higher royalty accretion expense of $6.7 million, $6.5 million in drug substance harmonization costs and a $4.5 million increase in employee costs, partially offset by a reduction of $3.1 million in cost of goods sold following a reduction in our excess inventory purchase commitments with Boehringer Ingelheim.

Because inventory step-up expense is acquisition-related, will not continue indefinitely and has a significant effect on our gross profit, gross margin percentage and net income (loss) for all affected periods, we disclose balance sheet and income statement amounts related to inventory step-up within the notes to the condensed consolidated financial statements. The increase in inventory step-up expense of $57.9 million recorded to cost of goods sold during the six months ended June 30, 2017 compared to the prior year period was due to KRYSTEXXA and MIGERGOT inventory step-up expense of $33.7 million (acquired in January 2016) and PROCYSBI and QUINSAIR inventory step-up expense of $40.8 million (acquired in October 2016) recorded during the six months ended June 30, 2017 compared to KRYSTEXXA and MIGERGOT inventory step-up expense of $16.6 million recorded during the six months ended June 30, 2016.

The increase in intangible amortization of $39.0 million during the six months ended June 30, 2017 compared to the prior year period was primarily due to the amortization of developed technology of $37.6 million related to PROCYSBI, which was acquired in October 2016.

Research and Development Expenses. Research and development expenses increased $152.2 million to $176.2 million during the six months ended June 30, 2017, from $24.0 million during the six months ended June 30, 2016. The increase was primarily attributable to $147.7 million related to the acquisition of River Vision during the six months ended June 30, 2017. Pursuant to ASC 805 (as amended by ASU No. 2017-01), we accounted for the River Vision acquisition as the purchase of an IPR&D asset and, pursuant to ASC 730, recorded the purchase price as a research and development expense during the six months ended June 30, 2017.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $80.5 million to $356.0 million during the six months ended June 30, 2017, from $275.5 million during the six months ended June 30, 2016. The increase was primarily attributable to $22.3 million paid to Boehringer Ingelheim International upon closing of the acquisition of certain rights to interferon gamma-1b during the six months ended June 30, 2017, an increase of $15.4 million in employee costs as a result of an increased workforce, an increase of $12.7 million in consulting costs and an increase of $18.6 million in marketing programs.
Interest Expense, Net. Interest expense, net, increased $24.9 million to $63.6 million during the six months ended June 30, 2017, from $38.7 million during the six months ended June 30, 2016. The increase was primarily due to higher borrowings in connection with the acquisition of Raptor, including our $300.0 million aggregate principal amount of our 2024 Senior Notes and our $850.0 million principal amount of secured loans under our 2017 term loan facility, compared to the $397.0 million principal amount of secured loans from previous borrowings under our senior secured loan facility.

Gain on divestiture. During the six months ended June 30, 2017, we completed the Chiesi divestiture for an upfront payment of $72.2 million, including $3.1 million of cash divested, with additional potential milestone payments based on sales thresholds and we recorded a gain of $5.9 million on the divestiture.

Loss on Induced Conversion and Debt Extinguishment. During the six months ended June 30, 2017, we entered into a refinancing amendment for our term loans. We accounted for a portion of the repayment as a debt extinguishment and recorded a loss on debt extinguishment of $0.5 million in the condensed consolidated statements of comprehensive loss, which reflected the write-off of the unamortized portion of debt discount and deferred financing costs previously incurred and a one percent prepayment penalty fee.

Benefit for Income Taxes. During the six months ended June 30, 2017, we recorded a benefit for income taxes of $49.3 million compared to $4.2 million during the six months ended June 30, 2016. The increase in benefit for income taxes during the six months ended June 30, 2017, compared to the six months ended June 30, 2016, resulted from an increase in pre-tax losses incurred in higher tax rate jurisdictions.
NON-GAAP FINANCIAL MEASURES

EBITDA, or earnings before interest, taxes, depreciation and amortization, adjusted EBITDA, non-GAAP net income and non-GAAP earnings per share are used and provided by us as non-GAAP financial measures. 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 costs, an upfront fee for a license of a patent, drug substance harmonization costs, fees related to term loan refinancing and Primary Care business unit realignment costs, as well as non-cash items such as share-based compensation, inventory step-up expense, depreciation and amortization, remeasurement of royalties for medicines acquired through business combinations, royalty accretion, non-cash interest expense, non-current asset impairment charges, gain on divestiture 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 2017 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.

Reconciliations of reported GAAP net loss 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>GAAP Net (Loss) Income</th>
<th>For the Three Months Ended June 30,</th>
<th>For the Six Months Ended June 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depreciation</td>
<td>1,755</td>
<td>1,091</td>
</tr>
<tr>
<td>Amortization, accretion and step-up:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intangible amortization expense</td>
<td>69,776</td>
<td>50,792</td>
</tr>
<tr>
<td>Accretion of royalty liabilities</td>
<td>12,735</td>
<td>9,669</td>
</tr>
<tr>
<td>Amortization of deferred revenue</td>
<td>(207)</td>
<td>(213)</td>
</tr>
<tr>
<td>Inventory step-up expense</td>
<td>33,895</td>
<td>9,102</td>
</tr>
<tr>
<td>Interest expense, net (including amortization of debt discount and deferred financing costs)</td>
<td>31,608</td>
<td>19,228</td>
</tr>
<tr>
<td>Benefit for income taxes</td>
<td>(1,767)</td>
<td>(2,756)</td>
</tr>
<tr>
<td>EBITDA</td>
<td>(61,741)</td>
<td>101,897</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>—</td>
<td>—</td>
</tr>
<tr>
<td>Acquisition-related costs</td>
<td>153,385</td>
<td>281</td>
</tr>
<tr>
<td>Upfront fee for license of global patent</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Primary Care business unit realignment costs</td>
<td>5,193</td>
<td>—</td>
</tr>
<tr>
<td>Gain on divestiture</td>
<td>(5,856)</td>
<td>—</td>
</tr>
<tr>
<td>Loss on debt extinguishment</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Fees related to term loan refinancing</td>
<td>(45)</td>
<td>—</td>
</tr>
<tr>
<td>Share-based compensation</td>
<td>27,768</td>
<td>27,997</td>
</tr>
<tr>
<td>Charges relating to discontinuation of Friedreich's ataxia program (1)</td>
<td>19,167</td>
<td>—</td>
</tr>
<tr>
<td>Drug substance harmonization costs (2)</td>
<td>745</td>
<td>—</td>
</tr>
<tr>
<td>Royalties for medicines acquired through business combinations</td>
<td>(11,622)</td>
<td>(9,095)</td>
</tr>
<tr>
<td>Total of non-GAAP adjustments</td>
<td>188,735</td>
<td>19,183</td>
</tr>
<tr>
<td>Adjusted EBITDA</td>
<td>$ 126,994</td>
<td>$ 121,080</td>
</tr>
</tbody>
</table>
GAAP Net (Loss) Income

Non-GAAP Adjustments:

<table>
<thead>
<tr>
<th>Description</th>
<th>2017</th>
<th>2016</th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remeasurement of royalties for medicines acquired through business combinations</td>
<td>—</td>
<td>—</td>
<td>(2,944)</td>
<td>—</td>
</tr>
<tr>
<td>Acquisition-related costs</td>
<td>153,385</td>
<td>281</td>
<td>163,424</td>
<td>11,297</td>
</tr>
<tr>
<td>Upfront fee for license of global patent</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>2,000</td>
</tr>
<tr>
<td>Fees related to term loan refinancing</td>
<td>(45)</td>
<td>—</td>
<td>4,098</td>
<td>—</td>
</tr>
<tr>
<td>Primary Care business unit realignment costs</td>
<td>5,193</td>
<td>—</td>
<td>5,193</td>
<td>—</td>
</tr>
<tr>
<td>Gain on divestiture</td>
<td>(5,856)</td>
<td>—</td>
<td>(5,856)</td>
<td>—</td>
</tr>
<tr>
<td>Loss on debt extinguishment</td>
<td>—</td>
<td>—</td>
<td>533</td>
<td>—</td>
</tr>
</tbody>
</table>

Amortization, accretion and step-up:

<table>
<thead>
<tr>
<th>Description</th>
<th>2017</th>
<th>2016</th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intangible amortization expense</td>
<td>69,776</td>
<td>50,792</td>
<td>139,453</td>
<td>100,442</td>
</tr>
<tr>
<td>Amortization of debt discount and deferred financing costs</td>
<td>5,206</td>
<td>4,507</td>
<td>10,629</td>
<td>8,932</td>
</tr>
<tr>
<td>Accretion of royalty liabilities</td>
<td>12,735</td>
<td>9,669</td>
<td>25,694</td>
<td>19,028</td>
</tr>
<tr>
<td>Inventory step-up expense</td>
<td>33,895</td>
<td>9,102</td>
<td>74,490</td>
<td>16,548</td>
</tr>
<tr>
<td>Share-based compensation</td>
<td>27,768</td>
<td>27,997</td>
<td>56,237</td>
<td>55,609</td>
</tr>
<tr>
<td>Depreciation expense</td>
<td>1,755</td>
<td>1,091</td>
<td>3,561</td>
<td>2,083</td>
</tr>
<tr>
<td>Charges relating to discontinuation of Friedreich’s ataxia program (1)</td>
<td>19,167</td>
<td>—</td>
<td>19,167</td>
<td>—</td>
</tr>
<tr>
<td>Drug substance harmonization costs (2)</td>
<td>745</td>
<td>—</td>
<td>5,044</td>
<td>—</td>
</tr>
<tr>
<td>Royalties for medicines acquired through business combinations (11,622)</td>
<td>(9,095)</td>
<td>(22,939)</td>
<td>(17,595)</td>
<td></td>
</tr>
</tbody>
</table>

Total pre-tax non-GAAP adjustments                                         | 312,102| 94,344 | 475,784| 198,344|

Income tax effect of pre-tax non-GAAP adjustments (3)                       | (34,272)| (18,064)| (72,375)| (35,338)|

Total non-GAAP adjustments                                                  | 277,830| 76,280 | 403,409| 163,006|

Non-GAAP Net Income

<table>
<thead>
<tr>
<th>Description</th>
<th>2017</th>
<th>2016</th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>GAAP (loss) earnings per share – Basic</td>
<td>(1.29)</td>
<td>0.09</td>
<td>(1.85)</td>
<td>(0.19)</td>
</tr>
<tr>
<td>Non-GAAP adjustments</td>
<td>1.71</td>
<td>0.48</td>
<td>2.49</td>
<td>1.02</td>
</tr>
<tr>
<td>Non-GAAP earnings per share – Basic</td>
<td>0.42</td>
<td>0.57</td>
<td>0.64</td>
<td>0.83</td>
</tr>
</tbody>
</table>

Non-GAAP Adjustments – Diluted

<table>
<thead>
<tr>
<th>Description</th>
<th>2017</th>
<th>2016</th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>GAAP (loss) earnings per share – Diluted</td>
<td>(1.29)</td>
<td>0.09</td>
<td>(1.85)</td>
<td>(0.19)</td>
</tr>
<tr>
<td>Non-GAAP adjustments</td>
<td>1.71</td>
<td>0.47</td>
<td>2.49</td>
<td>1.02</td>
</tr>
<tr>
<td>Diluted earnings per share effect of ordinary share equivalents (0.01)</td>
<td>—</td>
<td>—</td>
<td>(0.01)</td>
<td>(0.02)</td>
</tr>
<tr>
<td>Non-GAAP earnings per share – Diluted</td>
<td>0.41</td>
<td>0.56</td>
<td>0.63</td>
<td>0.81</td>
</tr>
</tbody>
</table>

(1) Charges relating to discontinuation of Friedreich’s ataxia program include $22.3 million relating to the impairment of a non-current asset recorded following payment to Boehringer Ingelheim International for the acquisition of certain rights to interferon gamma-1b, and a $3.1 million reduction in “cost of goods sold”, relating to the renegotiation of a contract with Boehringer Ingelheim related to the purchase of additional units of ACTIMMUNE.

(2) During the year ended December 31, 2016, we committed to spend $14.9 million related to the harmonization of the manufacturing processes for ACTIMMUNE and IMUKIN drug substance. During the three and six months ended June 30, 2017, we incurred $0.7 million and $6.5 million, respectively, of this spend, including costs of $0.7 million and $5.0 million, respectively, that qualify for exclusion in our non-GAAP financial measures under our non-GAAP cost policy.

(3) Adjustment to the GAAP tax benefit 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.

LIQUIDITY, FINANCIAL POSITION AND CAPITAL RESOURCES

We have incurred losses since our inception in June 2005 and, as of June 30, 2017, we had an accumulated deficit of $1,141.9 million. We do not expect our current operations to achieve operating profitability in 2017 and expect to fund our operations for the remainder of 2017 primarily through net sales and available cash resources.
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 June 30, 2017, we had $554.3 million in cash and cash equivalents and total debt with a book value of $1,892.3 million and face value of $2,022.9 million. Cash at June 30, 2017 reflects our use of cash on hand of approximately $145.6 million, net of $63.3 million of cash acquired, to fund our acquisition of River Vision on May 8, 2017 and $32.5 million paid during the six months ended June 30, 2017 in relation to the litigation settlement with Express Scripts, and includes $60.1 million received following the Chiesi divestiture in June 2017, net of cash divested. 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 twelve months from the issuance of these financial statements. 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.

On March 29, 2017, Horizon Pharma, Inc., or HPI, our wholly owned subsidiary, and Horizon Pharma USA, Inc., our wholly owned subsidiary, or HPUSA and together with HPI in such capacity, the Borrowers, borrowed $850.0 million aggregate principal amount of loans, or the Refinancing Loans, pursuant to an amendment, or the Refinancing Amendment, to the Credit Agreement, dated as of May 7, 2015 (as amended by Amendment No. 1, dated as of October 25, 2016, or the 2016 Amendment), by and among the Borrowers, us and certain of our subsidiaries as guarantors, the lenders party thereto from time to time and Citibank, N.A., as administrative agent and collateral agent. As used herein, all references to the “2015 Credit Agreement” are references to the Credit Agreement, dated as of May 7, 2015, by and among HPI, us and certain of our subsidiaries as guarantors, the lenders party thereto from time to time and Citibank, N.A., as administrative agent and collateral agent, all references to the “Existing Credit Agreement” are references to the 2015 Credit Agreement, as amended by the 2016 Amendment, and all references to the “Credit Agreement” are references to Existing Credit Agreement, as amended by the Refinancing Amendment.

The Refinancing Loans were incurred as a separate new class of term loans under the Credit Agreement with substantially the same terms as the previously outstanding senior secured term loans incurred on May 7, 2015 under the 2015 Credit Agreement, or the 2015 Loans, and the outstanding senior secured term loans incurred on October 25, 2016 under the Existing Credit Agreement, or the 2016 Loans and, together with the 2015 Loans, the Refinanced Loans, except as described below. The Refinancing Loans bear interest, at the Borrowers’ option, at a rate equal to either the London Inter-Bank Offer Rate, or LIBOR, plus an applicable margin of 3.75% per year (subject to a LIBOR floor of 1.0%), or the adjusted base rate plus 2.75%. 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 Borrowers used the proceeds of the Refinancing Loans to repay the Refinanced Loans, which totaled $769 million. The Credit Agreement provides for (i) the Refinancing Loans, (ii) one or more uncommitted additional incremental loan facilities subject to the satisfaction of certain financial and other conditions, and (iii) one or more uncommitted refinancing loan facilities with respect to loans thereunder. The Credit Agreement allows for us and certain of our subsidiaries to become borrowers under incremental or refinancing facilities.

The obligations under the Credit Agreement (including obligations in respect of the Refinancing Loans) and any swap obligations and cash management obligations owing to a lender (or an affiliate of a lender) thereunder are guaranteed by us and each of our existing and subsequently acquired or formed 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 (including obligations in respect of the Refinancing Loans) 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). The Borrowers and the guarantors under the Credit Agreement are individually and collectively referred to herein as a “Loan Party” and the “Loan Parties,” as applicable.

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 Refinancing Loans, a 1% premium will apply to a repayment of the Refinancing 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 six months following March 29, 2017. The Borrowers are required to make mandatory prepayments of loans under the Credit Agreement (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) 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 or 1.75:1, respectively). The Refinancing Loans will amortize in equal quarterly installments beginning on June 30, 2017 in an aggregate annual amount equal to 1% of the original principal amount thereof, with any remaining balance payable on March 29, 2024, the final maturity date of the Refinancing Loans.
We elected to exercise our reinvestment rights under the mandatory prepayment provisions of the Credit Agreement with respect to the net proceeds from the Chiesi divestiture. To the extent we do not apply such net proceeds to permitted acquisitions (including the acquisition of rights to products and products lines) and/or the acquisition of capital assets within 365 days of the receipt thereof (or commit to so apply and then apply within 180 days after the end of such 365-day period), we would be required to make a mandatory prepayment under the Credit Agreement in an amount equal to the unapplied net proceeds. Until such time, the net proceeds are not legally restricted for use. As of June 30, 2017, we had applied a portion of such net proceeds to the acquisition of additional rights to interferon gamma-1b.

On October 25, 2016, HPI and HPUSA, or 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 obligations under the 2024 Senior Notes are the 2024 Issuers’ general unsecured senior obligations and are fully and unconditionally guaranteed on a senior unsecured basis by us and all of our direct and indirect subsidiaries that are guarantors from time to time under the Credit Agreement.

We used the net proceeds from the offering of the 2024 Senior Notes as well as $375.0 million principal amount of 2016 Loans under the Existing Credit Agreement to fund a portion of the acquisition of Raptor, repay Raptor’s outstanding debt, and pay any prepayment premiums, fees and expenses in connection with the foregoing.

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 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 April 29, 2015, Horizon Pharma Financing Inc., our wholly owned subsidiary, or Horizon Financing, completed a private placement of $475.0 million aggregate principal amount of 6.625% Senior Notes due 2023, or 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. The obligations under the 2023 Senior Notes are fully and unconditionally guaranteed by us and all of our direct and indirect subsidiaries that are guarantors from time to time under the Credit Agreement.

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 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 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 March 13, 2015, Horizon Pharma Investment Limited, our wholly owned subsidiary, or Horizon Investment, completed a private placement of $400.0 million aggregate principal amount of 2.50% Exchangeable Senior Notes due 2022, or the 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 on a senior unsecured basis, or the Guarantee. 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).

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 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 six months ended June 30, 2017, we issued an aggregate of:

- 206,090 ordinary shares in connection with the exercise of stock options and received $1.3 million in proceeds; and
- 597,292 ordinary shares in net settlement of vested restricted stock units.

During the six months ended June 30, 2017, warrants to purchase an aggregate of 2,500 shares of the Company were exercised and proceeds of $11,425 were received. In addition, warrants to purchase an aggregate of 704,185 ordinary shares were exercised in cashless exercises, resulting in the issuance of 523,459 ordinary shares. As of June 30, 2017, there were outstanding warrants to purchase 665,975 ordinary shares.

During the six months ended June 30, 2017, we made payments of $5.2 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. In May 2017, our board of directors reauthorized a share repurchase program pursuant to which we may repurchase up to 16,000,000 of our ordinary shares. As of June 30, 2017, we have purchased 100,000 of our ordinary shares under this repurchase program, for a total consideration of $1.0 million. The timing and amount of future repurchases, if any, will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, our cash resources, restrictions under the Credit Agreement and market conditions.

**Sources and Uses of Cash**

The following table provides a summary of our cash position and cash flows as of and for the six months ended June 30, 2017 and 2016 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$554,269</td>
<td>$424,525</td>
</tr>
<tr>
<td>Cash provided by (used in):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating activities</td>
<td>68,646</td>
<td>101,484</td>
</tr>
<tr>
<td>Investing activities</td>
<td>(101,576)</td>
<td>(534,490)</td>
</tr>
<tr>
<td>Financing activities</td>
<td>75,948</td>
<td>(1,841)</td>
</tr>
</tbody>
</table>

**Operating Cash Flows**

During the six months ended June 30, 2017, net cash provided by operating activities was $68.6 million compared to $101.5 million during the six months ended June 30, 2016. The decrease in net cash provided by operating activities was primarily attributable to cash payments of $58.4 million for interest during the six months ended June 30, 2017 compared to $29.8 million during the six months ended June 30, 2016, and $32.5 million paid during the six months ended June 30, 2017 in relation to the litigation settlement with Express Scripts.

**Investing Cash Flows**

During the six months ended June 30, 2017, net cash used in investing activities was $101.6 million compared to $534.5 million during the six months ended June 30, 2016. The net cash used in investing activities during the six months ended June 30, 2017 was primarily associated with $145.6 million of payments for the acquisition of River Vision, net of cash acquired, and $22.3 million relating to the payment for certain rights for interferon gamma-1b. This was partially offset by $69.1 million proceeds received from the Chiesi divestiture, net of cash divested.

Net cash used in investing activities during the six months ended June 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 rights to interferon gamma-1b and $12.8 million of payments for purchases of property and equipment.

**Financing Cash Flows**

During the six months ended June 30, 2017, net cash provided by financing activities was $75.9 million compared to net cash used in financing activities of $1.8 million during the six months ended June 30, 2016. Net cash provided by financing activities during the six months ended June 30, 2017 was primarily attributable to the net proceeds of $847.8 million from term loans, offset in part by repayment of term loans of $770.8 million.

**Financial Condition as of June 30, 2017 Compared to December 31, 2016**

Accounts receivable, net. Accounts receivable, net, increased $85.1 million, from $305.7 million as of December 31, 2016 to $390.8 million as of June 30, 2017. The increase was due to growth in gross sales of our medicines and increases due to the timing of cash receipts.

Inventories, net. Inventories, net, decreased $72.6 million, from $174.8 million as of December 31, 2016 to $102.2 million as of June 30, 2017. The decrease was primarily due to $74.5 million of inventory step-up expense recorded during the six months ended June 30, 2017 ($33.7 million related to KRYSTEXXA and MIGERGOT and $40.8 million related to PROCYSBI and QUINSAIR). Additionally, during the six months ended June 30, 2017, we recorded $3.2 million of inventory step-up expense to “gain on divestiture” following the sale of inventory to Chiesi in connection with the Chiesi divestiture.

Developed technology, net. Developed technology, net, decreased $186.3 million, from $2,767.2 million as of December 31, 2016 to $2,580.9 million as of June 30, 2017. The decrease was due to the amortization of $139.0 million of developed technology during the six months ended June 30, 2017 and developed technology with a net book value of $47.3 million disposed of in the Chiesi divestiture.
Goodwill. Goodwill decreased $17.7 million from $445.6 million as of December 31, 2016 to $427.9 million as of June 30, 2017. The decrease was due to $16.3 million written off in connection with the Chiesi divestiture and a $1.4 million measurement period adjustment related to the Raptor acquisition, which was recorded during the six months ended June 30, 2017.

Other assets. Other assets increased $27.5 million as of December 31, 2016 to $29.9 million as of June 30, 2017. The increase was primarily due to an indemnification asset recorded in connection with the Chiesi divestiture during the six months ended June 30, 2017, which represents the future estimated amount receivable from Chiesi in respect of PROCYSBI and QUINSAIR contingent royalty liabilities.

Accounts payable. Accounts payable increased $29.4 million, from $52.5 million as of December 31, 2016 to $81.9 million as of June 30, 2017. This increase was primarily due to $55.3 million of trade discount and rebate invoices included in accounts payable at June 30, 2017, compared to $16.8 million at December 31, 2016.

Accrued expenses. Accrued expenses decreased $70.3 million, from $182.8 million as of December 31, 2016 to $112.5 million as of June 30, 2017. This was primarily due to the payment of $32.5 million during the six months ended June 30, 2017 pursuant to our settlement agreement with Express Scripts, a decrease of $19.3 million in accrued incentive compensation following payments made during the six months ended June 30, 2017, a decrease of $4.2 million in accrued interest and a decrease of $3.1 million in relation to excess purchase commitment liabilities.

Accrued trade discounts and rebates. Accrued trade discounts and rebates increased $115.7 million, from $297.5 million as of December 31, 2016 to $413.2 million as of June 30, 2017. This was primarily due to a $116.1 million increase in accrued wholesaler fees and commercial rebates and an $11.0 million increase in accrued government rebates and chargebacks, partially offset by an $11.4 million decrease in co-pay and other patient assistance costs.

Deferred tax liabilities, net. Deferred tax liabilities, net, decreased $85.8 million, from $296.6 million as of December 31, 2016 to $210.8 million as of June 30, 2017. This was primarily due to the benefit for income taxes of $49.3 million recorded during the six months ended June 30, 2017 and deferred tax assets of $21.6 million acquired in the River Vision acquisition. Additionally, we prospectively adopted ASU No. 2016-09 on January 1, 2017 and recorded a decrease of $7.2 million in deferred tax liabilities and a corresponding increase in accumulated deficit during the six months ended June 30, 2017.

Other long-term liabilities. Other long-term liabilities increased $42.5 million, from $46.1 million as of December 31, 2016 to $88.6 million as of June 30, 2017. This was primarily due to $23.7 million recorded in connection with the Chiesi divestiture during the six months ended June 30, 2017, which represents the preliminary fair value of the contingent liability for PROCYSBI and QUINSAIR royalties potentially payable on EMEA sales, and $21.6 million recorded during the six months ended June 30, 2017, which represents long-term liabilities offsetting the deferred tax assets recorded following the River Vision acquisition.

Long-term debt, net, net of current. Long-term debt, net, net of current increased $76.1 million from $1,501.7 million as of December 31, 2016 to $1,577.8 million as of June 30, 2017. The increase was primarily related to the $850.0 million Refinancing Loans, which replaced the $394.0 million 2015 Term Loan Facility and the $375.0 million 2016 Incremental Loan Facility, resulting in an increase of $81.0 million of principal amount of our outstanding debt. This increase was offset in part by certain charges related to the Refinancing Loans and amortization of debt discount and deferred financing fees and a repayment of $2.1 million during the six months ended June 30, 2017.

Contractual Obligations

During the three months ended June 30, 2017, 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, 2016, except as disclosed below.

On May 8, 2017, we acquired River Vision for upfront cash payments totaling $151.9 million, including $6.3 million of cash acquired, and subject to other customary purchase price adjustments for working capital, and potential future milestone and royalty payments contingent on the satisfaction of certain regulatory milestones and sales thresholds. Under the agreement, we are required to pay up to $325.0 million upon the attainment of various milestones related to FDA approval and net sales thresholds. The agreement also includes a royalty payment of three percent of the portion of annual worldwide net sales exceeding $300.0 million (if any).
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, 2016. There have been no significant changes in our application of our critical accounting policies during the six months ended June 30, 2017.

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 14, “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 Credit Agreement and our investment in money market accounts which bear a variable interest rate. Loans under the Credit Agreement bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 3.75% per annum (subject to a 1.00% LIBOR floor), or the adjusted base rate plus 2.75%. 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%. Our $850.0 million of Refinancing Loans are based on LIBOR. The current LIBOR rate is 1.25%, and as a result, the interest rate on our borrowings are currently 5.00% per annum.

An increase in the LIBOR of 100 basis points above the current LIBOR rate would increase our interest expense related to the Credit Agreement by $8.5 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 Biopharmaceuticals GmbH and 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.

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. As of June 30, 2017 and December 31, 2016, our top three customers accounted for approximately 82% and 78%, respectively, of our total outstanding 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 June 30, 2017, the end of the period covered by this report.

Changes in Internal Control Over Financial Reporting. During the quarter ended June 30, 2017, 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 15, 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, 2016, 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;
• 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 immediate-release cysteamine therapy to PROCYSBI and to identify additional patients with nephropathic cystinosis. 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 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 commercial strategy 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 business unit medicines, ACTIMMUNE, BUPHENYL, PROCYSBI, QUINSAIR and RAVICTI, and with respect to our rheumatology business unit 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 for advanced urothelial carcinoma and renal cell carcinoma, and price increases but we cannot be certain that our pricing strategy will not result in downward pressure on sales or that we or others will be able to successfully complete clinical trials and obtain regulatory approvals in additional indications. With respect to PROCYSBI and RAVICTI, 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. Our strategy with respect to KRYSTEXXA includes the continued enhancement of the 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 more recently included 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 or that expected volume growth will sufficiently offset the rebates and fees paid to PBMs or that our existing agreements with PBMs will have the intended impact on formulary access. Net pricing for DUEXIS, VIMOVO and PENNSAID 2% was significantly below expectations during the first half of 2017 due to higher patient assistance costs and higher commercial rebate levels compared to our expectations. This was due to lower-than-anticipated adoption rates of our primary care medicines onto certain healthcare plan formularies during the period which resulted in higher patient assistance costs than expectations. In addition, the mix of PBH healthcare plans that adopted our primary care medicines onto their formulary was more heavily weighted towards those plans for which we pay a higher commercial rebate, which resulted in higher commercial rebate costs to us than we anticipated. If we are unable to realize the expected benefits of our contractual arrangements with the PBMs we may continue to experience reductions in net sales from our primary care business unit. 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.
Our strategy for RAYOS in the United States is to focus on the rheumatology indications approved for RAYOS, including our collaboration with the Alliance for Lupus Research, or ALR, to study the effect of RAYOS on the fatigue experienced by systemic lupus erythematosus, or SLE, patients.

Our overall commercialization strategy also includes plans to expand sales in Europe and other countries outside the United States directly or through distributors 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, or EEA, namely Norway, Iceland and Liechtenstein, for the medicine to be placed on the market. In June 2016, we partnered with Clinigen Group plc’s Ids managed access division to initiate a managed access program in selected European countries, which agreement terminated on April 10, 2017 and after which we partnered with Swedish Orphan Biovitrum AB, or SOBI, to continue our managed access program in selected European countries. While we expect to commercially launch RAVICTI in Europe in 2017 through an exclusive distribution agreement with SOBI, we cannot guarantee we will be able to successfully implement our commercial plans for RAVICTI in Europe. 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 outside the United States 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. In order to commercialize any approved medicines, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. During the second quarter of 2017, we effected a workforce reduction in the primary care business unit. We also revised our methodology of classifying the sales force to more closely align with those who participate in our sales incentive compensation program. Based on the workforce reduction and new methodology, as of June 30, 2017, we had approximately 385 sales representatives in the field, consisting of approximately 25 orphan disease sales representatives, 100 rheumatology sales specialists and 260 primary care sales representatives, compared to approximately 460 sales representatives as of March 31, 2017, consisting of approximately 25 orphan disease sales representatives, 95 rheumatology sales specialists and 340 primary care sales representatives. We cannot be certain that we will be able to adequately market our primary care medicines following the reduction in our sales force or that we will be able to continue retaining the current members of our primary care sales force. 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 focus on hiring sales representatives for our primary care and rheumatology business units 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 continue to acquire additional medicines through acquisition transactions, the members of our sales force may have limited experience promoting certain of our medicines. To the extent we employ an acquired entity’s original sales forces to promote acquired medicines, we may not be successful in continuing to retain these employees and we otherwise will 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 increase formulary access and reimbursement for our medicines 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 previously placed DUEXIS and VIMOVO on their formulary exclusion lists. 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 our HorizonCares program. In addition, the HorizonCares program is not available to federal health care program (such as Medicare and Medicaid) beneficiaries. We have also contracted with certain 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 business relationships with two of the largest PBMs, Express Scripts and CVS Caremark, that have resulted in DUEXIS and VIMOVO being removed from the Express Scripts and CVS Caremark 2017 exclusion lists, as well as a rebate agreement with another PBM, Prime Therapeutics LLC, 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. Despite our agreements with PBMs, the extent of formulary status and reimbursement will ultimately depend to a large extent upon individual healthcare plan formulary decisions. If healthcare plans that contract with PBMs with which we have agreements do not adopt formulary changes recommended by the PBMs with respect to our medicines, we may not realize the expected access and reimbursement benefits from these agreements. In addition, we generally pay higher rebates for prescriptions covered under plans that adopt a PBM-chosen formulary than for plans that adopt custom formularies. Consequently, the success of our PBM contracting strategy will depend not only on our ability to expand formulary adoption among healthcare plans, but also upon the relative mix of healthcare plans that have PBM-chosen formularies versus custom formularies. For example, during the first half of 2017, the adoption rates of our primary care medicines onto certain healthcare plan formularies during the period were lower than we had anticipated and as a result, we incurred higher patient assistance costs than we expected, and the mix of healthcare plans adopting our primary care medicines onto their formularies was more heavily weighted towards plans that use PBM-chosen formularies, which resulted in higher rebate costs than we expected. If we are unable to realize the expected benefits of our contractual arrangements with the PBMs we may continue to experience reductions in net sales from our primary care business unit. 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, particularly with healthcare plans that use custom formularies, our ability to achieve net sales growth for our primary care business unit would be impaired.

There has been negative publicity and inquiries from Congress and enforcement authorities 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 negative publicity and interest from Congress and enforcement authorities 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 comprehensive 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 have incurred and anticipate that we may continue to incur significant costs in connection with the investigation, regardless of the outcome. We may also become subject to similar investigations by other governmental agencies or Congress. 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, exclusion, additional reporting requirements and/or oversight or other administrative sanctions against us.

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. While we believe that our recent arrangements with PBMs will 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 and their effectiveness will ultimately depend to a large extent upon individual healthcare plan formulary decisions that are beyond the control of the PBMs. If our arrangements with PBMs and other payers do not result in increased prescripions 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 continue to 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.

Mundipharma International Corporation Limited, or Mundipharma, is our exclusive distributor for LODOTRA in Europe, Asia and Latin America. 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 these medicines in our markets. In the event that Mundipharma or our current ex-U.S. distributors for BUPHENYL may 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. 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, QUINSAIR, RAVICTI 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, or MAA, for marketing new drugs in Europe, must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable 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.

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 June 19, 2017, we received a notice of compliance, from Health Canada, or HC, for PROCYSBI for the treatment of nephropathic cystinosis in adults and children two years of age and older. PROCYSBI is the only cystine-depleting agent approved in Canada for the treatment of nephropathic cystinosis.

If we are unable to obtain any further approvals for PROCYSBI in the United States, Canada, Latin America and Asia-Pacific region, or determine that commercializing PROCYSBI outside the United States, Canada, Latin America and Asia-Pacific region is not economically viable, the market potential of PROCYSBI may be limited.

With respect to QUINSAIR, the FDA has indicated in previous written and verbal communications with Raptor Pharmaceutical Corp., or Raptor, and with the drug’s previous sponsor that it believes the data submitted in connection with EMA’s subsequent approval of QUINSAIR for the management of chronic pulmonary infections due to Pseudomonas aeruginosa in adults with cystic fibrosis does not provide substantial evidence of efficacy and safety to support FDA approval of QUINSAIR for treatment of patients with cystic fibrosis. On October 27, 2016, the FDA expressed its recommendation that an additional clinical trial should be conducted, and noted that if Raptor submits a new drug application, or NDA, without conducting an additional clinical trial, the FDA will review the submission to determine whether it is acceptable for filing. Based upon the FDA’s feedback, we have made the decision not to pursue an NDA for U.S. approval of QUINSAIR as a treatment of Pseudomonas aeruginosa in adults with cystic fibrosis at this time.
Prior to our acquisition of Raptor, Raptor planned to pursue the development of QUINSAIR for use in the indication of bronchiectasis, or BE, not associated with cystic fibrosis. Raptor submitted a protocol to FDA on August 18, 2016 for a Phase 2, placebo-controlled study of QUINSAIR in adults with BE. Feedback from FDA was received on October 17, 2016 requesting additional information and changes to the proposed study protocol. 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 has been generated with QUINSAIR in patients with BE or with NTM infections, either by Raptor, subsequently by Horizon 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 medicine sales in 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 our medicines 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 medicine registration and continued compliance with current good manufacturing practices, or cGMPs, 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 medicine, suspend or withdraw medicine approvals, revoke necessary licenses or suspend medicine 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 medicines or require us to initiate a medicine recall; and/or
• commence criminal investigations and prosecutions.

71
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 medicines, and our medicine 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 APIs 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.*

Following our sale of the rights to PROCYSBI and QUINSAIR in the Europe, Middle East and Africa, or EMEA, regions to Chiesi Farmaceutici S.p.A., or Chiesi, in June 2017, or the Chiesi divestiture, Chiesi has marketing and distribution rights to PROCYSBI and QUINSAIR in EMEA. 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 granted to SOBI and Orphan Pacific, Inc., or Orphan Pacific. Similarly, Nuvo Research Inc., or Nuvo, has retained its rights to PENNSAID 2% in territories outside of the United States and in March 2017, Nuvo announced that it had entered into an exclusive license agreement with Sayre Therapeutics Pvt Ltd. to distribute, market and sell PENNSAID 2% in India, Sri Lanka, Bangladesh and Nepal. Nuvo also announced that it expects to complete PENNSAID 2% out-licensing agreements for other territories throughout 2017 and 2018. We have little or no control over Chiesi’s activities with respect to PROCYSBI and QUINSAIR in EMEA, over AstraZeneca’s activities with respect to VIMOVO outside the United States, over SOBI’s activities with respect to BUPHENYL in Europe, certain Middle Eastern and North African countries, over Orphan Pacific’s activities with respect to AMMONAPS in Japan or over Nuvo’s or its existing and 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 these medicines. For example, Chiesi or its assignees, AstraZeneca or its assignees or Nuvo or its assignees can make statements or use promotional materials with respect to PROCYSBI, QUINSAIR, 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 these medicines 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 them. We also rely on Chiesi, AstraZeneca, SOBI and Nuvo or their assignees to provide us with timely and accurate safety information regarding the use of these medicines outside of the United States, 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 Biopharmaceuticals GmbH, or Boehringer Ingelheim Biopharmaceuticals, for manufacturing and supply of ACTIMMUNE. ACTIMMUNE is manufactured by starting with cells from working cell bank samples which are derived from a master cell bank. We and Boehringer Ingelheim Biopharmaceuticals separately store multiple vials of the master cell bank. In the event of catastrophic loss at our or Boehringer Ingelheim Biopharmaceuticals’ 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 KRYSTEXXA. If NOF failed to supply such PEGylation agent, it may lead to KRYSTEXXA supply constraints.

73
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, Pharmaceu
tics International, Inc., or Pii, our manufacturer of BUPHENYL, was found to be non-compliant for cGMPs by the Medicines and Healthcare Products Regulatory Agency, or the MHRA, which could restrict Pii 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 Pii, which was initially valid until June 30, 2017. Following reinspection of Pii and progress made since the MHRA’s initial inspection, this certificate was extended until June 30, 2018. 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 and packaging of our medicines, our manufacturers may not perform as agreed or may terminate their agreements with us. We currently rely on single source suppliers for certain of our medicines. If our manufacturers terminate their agreements with us, we may have to qualify new back-up manufacturers. 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.

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, development program 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 June 30, 2017, we employed approximately 935 full-time employees, including approximately 385 sales representatives, representing a substantial change to the size of our organization. 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.

Our 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 plans to launch RAVICTI in Europe through an exclusive distribution agreement with SOBI, we may continue expanding our operations and add commercial personnel in Europe. We may not be successful in 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.

We are also broadening our acquisition strategy to potentially include development-stage assets or programs, which entails additional risk to us. For example, if we are unable to identify programs that ultimately result in approved medicines, we may spend material amounts of our capital and other resources evaluating, acquiring and developing medicines that ultimately do not provide a return on our investment. We have less experience evaluating development-stage assets and may be at a disadvantage compared to other entities pursuing similar opportunities. Regardless, development-stage programs generally have a high rate of failure and we cannot guarantee that any such programs will ultimately be successful. We will also need to enhance our clinical development and regulatory functions to properly evaluate and develop earlier-stage opportunities, which may include recruiting personnel that are knowledgeable in therapeutic areas we have not yet pursued. If we are unable to acquire promising development-stage assets or eventually obtain marketing approval for them, we may not be able to create a meaningful pipeline of new medicines and eventually realize a return on our investments.
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 KRYSTEXXA 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 KRYSTEXXA and if effective, could reduce the target patient population for KRYSTEXXA. PROCYSBI 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 cystic fibrosis, TOBI Podhaler, Cyston 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. We granted a non-exclusive license (that is only royalty-bearing in some circumstances), to manufacture and commercialize a generic version of DUEXIS in the United States after January 1, 2023, or earlier under certain circumstances. We granted non-exclusive licenses to manufacture and commercialize generic versions of PENNSAID 2% in the United States after January 10, 2029, or earlier under certain circumstances. We granted a non-exclusive license to manufacture and commercialize a generic version of RAYOS tablets in the United States after December 23, 2022, or earlier under certain circumstances.
Actavis has filed an ANDA with the FDA for a generic version of RAVICTI. 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 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 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; and (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc., or collectively Mylan. Patent litigation is currently pending before the Court of Appeals for the Federal Circuit against a fourth generic company, Actavis Laboratories FL., Inc. 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 and Mylan advising each had filed an ANDA with the FDA seeking approval to market generic versions of RAVICTI prior to the expiration of the patents-in-suit.

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, Apolgen 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 Ib/II 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, KRYSTEXXA and PROCYSBI have been granted orphan drug exclusivity by the FDA, which we expect will provide orphan drug marketing exclusivity in the United States until February 2020, September 2017 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, KRYSTEXXA or PROCYSBI, we could be subject to generic competition and revenues from RAVICTI, KRYSTEXXA or PROCYSBI could decrease materially. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as RAVICTI, KRYSTEXXA or PROCYSBI despite orphan drug exclusivity, we may face increased competition and lose market share with respect to these medicines. KRYSTEXXA 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.

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 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 previously in litigation with 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 paid Express Scripts $65.0 million.

Litigation related to these disputes may be costly and time-consuming and could materially and adversely impact our financial position and results of operations if resolved against us.
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 Biotech Ltd). Moreover, Grünenthal S.A. is in the registration process for the commercialization of DUEXIS in Latin America. BPHENYL is currently marketed in various territories outside the United States by third-party distributors. RAVICTI received marketing authorization from HC in March 2016 and marketing approval in the EU in November 2015. We launched RAVICTI in Canada in November 2016 and plan to begin commercializing RAVICTI in Europe in 2017. QUINSAIR received marketing authorization from HC in June 2015 and we launched QUINSAIR in Canada in December 2016. PROCYSBI received marketing authorization from HC in June 2017 and we plan to launch PROCYSBI in Canada in the fourth quarter of 2017. 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-United Kingdom, or 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 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 our acquisition of Hyperion Therapeutics Inc., or 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 contractual obligations under agreements with Tripex Pharmaceuticals, LLC, or Tripex, and PARI Pharma GmbH, or 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 submitting an NDA for approval of QUINSAIR in the United States for use 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 submit an NDA for U.S. approval in the cystic fibrosis patient population, during the time periods specified in the 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 and to spend a specified minimum amount per year on development activities in the United States until submission 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 an amended and restated license agreement with the Regents of the University of California, San Diego, or UCSD, with respect to PROCYSBI, including obligations to consider engaging in the development of PROCYSBI for the treatment of non-alcoholic steatohepatitis, or NASH, and related diligence obligations if we undertake such development. Under the amended and restated license agreement with UCSD, we also are subject to diligence obligations to identify a third party to undertake development of PROCYSBI for the treatment of Huntington’s disease. 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 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.

82
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 Therapeutics International Public Limited Company, or Vidara, and such transaction, 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 agreements, 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 and growth prospects.

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., or HPI, and Vidara.*

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 of the Code 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 of the Code, 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 HPI owned (within the meaning of Section 7874 of the Code) 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 the IRS will agree with the position that the ownership test was satisfied. 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.

Further, there can be no assurance that the IRS will agree with the position that the ownership test was satisfied. 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.

On April 4, 2016, the U.S. Treasury and the IRS issued temporary regulations and in January 2017 issued final regulations that expand the scope of transactions subject to the rules designed to eliminate the U.S. tax benefits of so-called inversion transactions. 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 Secretary of the United States Treasury recently announced that the U.S. Treasury will review every significant regulation issued over the past year and a half, including certain inversion regulations, but, at present, it is unclear what the outcome of Treasury’s review will be or what impact it may have on us.
The U.S. Treasury and the IRS also issued proposed regulations on April 4, 2016 as well as final and temporary regulations in October 2016 that address whether an interest in a related corporation is debt or equity for United States federal income tax purposes. These regulations could result in recharacterization of inter-company debt to equity for certain of our inter-company debt and such a recharacterization could result in more of our future income being taxed by the United States and thereby increase our effective tax rate. We are continuing to evaluate the impact that these regulations may have and will reflect such impact on our financial statements as required.

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. The status of the recommendations from the International Tax Bipartisan Tax Working Group, including regulations aimed at curbing earnings stripping, as well as the status of United States tax reform in general, is subject to significant uncertainty as President Trump and both houses of Congress are considering several material tax reform proposals. These proposals include, among other items, a significant reduction to the U.S. corporate tax rate and a possible “border adjustment tax” that would effectively increase the economic cost of imports. Consideration of various tax reform proposals continues to evolve. In July 2017, the Speaker of the House, Majority Leader of the Senate, Chairmen of the House of Representatives Committee on Ways and Means, Finance Committee, Secretary of the Treasury and Director of the National Economic Council issued a joint statement setting aside the idea of a border adjustment tax and called for tax reform legislation that “reduces tax rates as much as possible, allows unprecedented capital expensing, places a priority on permanence, and creates a system that encourages American companies to bring back jobs and profits trapped overseas”. At this point in time it is not possible to determine all of the possible consequences to us of the various tax reform proposals that are under consideration. However, any tax reform could significantly impact our U.S. and worldwide tax liabilities.

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. On June 7, 2017, several countries, including many countries that we operate and have subsidiaries in, participated in the signing ceremony adopting the Organization for Economic Cooperation and Development’s Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting, commonly referred to as the MLI. The MLI is intended to provide countries with a tool through which they can amend their income tax treaties. Although not yet effective, the MLI may modify thousands of tax treaties making it more difficult for us to obtain advantageous tax-treaty benefits. 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.

The U.S. federal government has called for substantial changes to U.S. tax policy and laws and President Trump has released an outline of a proposed tax plan which would significantly alter the U.S. tax code if enacted. We do not currently have sufficient information that would allow us to predict what U.S. tax reform, if any, may be enacted in the future or what impact any such changes would have on our business. Changes to U.S. tax laws could significantly impact our business, financial condition, results of operations, or cash flows.

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, Chief Administrative 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, Primary Care Business Unit, George Hampton; our Executive Vice President, Orphan Business Unit, Dave Happel; our Executive Vice President, Technical Operations, Michael A. DesJardin and our Senior Vice President, Rheumatology Business Unit, Vikram Karnani. 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, cGCPs, 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. 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. In May 2017, the FDA approved our supplemental new drug application, or sNDA, 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, which requirement was fulfilled in May 2017. We are in the process of closing out the study and drafting the final report.

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;

85
• 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.

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 therapeutics, 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 Express Scripts and CVS Caremark 2017 exclusion lists, we cannot guarantee that Express Scripts or CVS Caremark will not later add these medicines back to their exclusion lists or that we will be able to otherwise expand formulary access for DUEXIS and VIMOVO under health plans that contract with Express Scripts and/or CVS Caremark. 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 IMUKIN, 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. The majority of LODOTRA sales are in Germany and Italy where reimbursement has been approved. BUPHENYL is marketed in select countries throughout Europe, the Middle East and the Asia-Pacific region. We launched RAVICTI in Canada in November 2016 and we expect to begin commercializing RAVICTI in Europe in 2017 through an exclusive distribution agreement with SOBI. QUINSAIR was recently launched in Canada and we plan to launch PROCYSBI in Canada in the fourth quarter of 2017. We cannot be certain that existing reimbursement in such 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, 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, the ACA increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization and increased the types of entities eligible for the federal 340B drug discount program. On January 30, 2017, the White House Office of Management and Budget withdrew the draft August 2015 Omnibus Guidance document that was issued by the Department of Health and Human Services Health Resources and Services Administration, or HRSA, that addressed a broad range of topics including, among other items, the definition of a patient’s eligibility for 340B drug pricing. However, as concerns continue to grow over the need for tighter oversight, there remains the possibility that HRSA or other agency under the Department of Health and Human Services, or HHS, will propose a similar regulation or that Congress will explore changes to the program through legislation. For example, the Centers for Medicare & Medicaid Services has issued a proposed rule that would revise the Medicare hospital outpatient prospective payment system, including a new reimbursement methodology for drugs purchased under the 340B program for Medicare patients. In addition, HHS has currently set October 1, 2017 for implementation of the final rule setting forth the calculation of the ceiling price and application of civil monetary penalties under the 340B program. A material portion of KRYSEXXA prescriptions are written by healthcare providers that are eligible for 340B drug pricing and therefore any reduction in 340B pricing, whether in the form of the final rule or otherwise, or an expansion of healthcare providers eligible for 340B drug pricing, would likely have a negative impact on our net sales from KRYSEXXA.

There may be additional pressure by payers, healthcare providers, federal regulators and 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 United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to regulate and to change the healthcare system in ways that could affect our ability to sell our 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.

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, additional reporting requirements and/or oversight 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.

In January 2017, the United States House of Representatives and Senate passed legislation, the concurrent budget resolution for fiscal year 2017, which initiates actions that would repeal certain aspects of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA, to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In May 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act, which, if enacted, will amend and repeal significant portions of the ACA. However, the U.S. Senate is unlikely to adopt the American Health Care Act as passed by the U.S. House of Representatives. The U.S. Senate considered but did not adopt other legislation to amend and/or replace elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, drug pricing by pharmaceutical companies has recently come under increased scrutiny. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the out-of-pocket cost of prescription drugs, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies. Moreover, President Trump has discussed the need for federal legislation, regulation or Executive Order to regulate the prices of medicines. The majority of our medicines are purchased by private payers, and much of the focus of pending legislation is on government program reimbursement. However, we cannot know what form any such action may take, the likelihood it would be executed, enacted, effectuated or implemented 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 (involving 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 trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA, among other things, imposed 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 DUENIS, 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 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 SLE patients, we are collaborating with the ALR. 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 academic research organizations 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 medicine 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, our results of operations and the commercial prospects for our medicines and medicine candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs or collaborators can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO or collaborator commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs and collaborators, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition or prospects.
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 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. Also, on December 8, 2016, we announced that the Phase 3 trial, Safety, Tolerability and Efficacy of ACTIMMUNE Dose Escalation in Friedreich’s Ataxia study evaluating ACTIMMUNE for the treatment of Friedreich’s ataxia, or FA, did not meet its primary endpoint of a statistically significant change from baseline in the modified Friedreich’s Ataxia Rating Scale at twenty-six weeks versus treatment with placebo. In addition, the secondary endpoints did not meet statistical significance. We, in conjunction with the independent Data Safety Monitoring Board, the principal investigator and the Friedreich’s Ataxia Research Alliance Collaborative Clinical Research Network in FA, determined that, based on the trial results, the STEADFAST program would be discontinued, including the twenty-six week extension study and the long-term safety study.

With respect to the investigator-initiated study to evaluate ACTIMMUNE in combination with OPDIVO® (nivolumab) in advanced solid tumors and the planned Phase 3 pivotal clinical trial of teprotumumab in thyroid eye disease that we expect to begin in the second half of 2017, 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.

*See footnote*
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 $125 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.*

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 $291.1 million for the six months ended June 30, 2017, an operating loss of $147.2 million for the year ended December 31, 2016, operating income of $55.4 million for the year ended December 31, 2015 and an operating loss of $8.5 million for the year ended December 31, 2014. We had a net loss of $300.1 million for the six months ended June 30, 2017, a net loss of $166.8 million for the year ended December 31, 2016, net income of $39.5 million for the year ended December 31, 2015 and a net loss of $263.6 million for the year ended December 31, 2014. As of June 30, 2017, we had an accumulated deficit of $1,141.9 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 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.

94
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;
• 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 June 30, 2017, we had $1,892.3 million book value, or $2,022.9 million principal amount, of indebtedness, including $847.9 million in secured indebtedness. In March 2017, we borrowed $850.0 million in principal amount of secured loans pursuant to our credit agreement. 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. 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. In March 2015, we issued $400.0 million aggregate principal amount of 2.50% Exchangeable Senior Notes due 2022, or the Exchangeable Senior Notes. 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 incur additional indebtedness.

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 to offset U.S. income taxes 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. 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 $14.7 million for 2017 and $7.7 million for 2018 through 2028. During the third quarter of 2016, we also recognized additional net operating losses and federal and state tax credits as a result of our acquisition of Raptor on October 25, 2016 in the amount of approximately $97.3 million of federal net operating losses, state operating losses of approximately $177.5 million and approximately $22.4 million of federal and state tax credits. We continue to carry forward the annual limitation related to Hyperion of $50 million resulting from the last ownership change date in 2014. In addition, in the second quarter of 2017, we recognized $37.4 million of federal net operating losses, $43.2 million of state net operating losses and $5.8 million of federal tax credits following our acquisition of River Vision Development Corp. These acquired federal net operating losses and credits are subject to an annual limitation of $8.1 million for the 2017 year and $12.5 million from 2018 through 2021. 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.*

From time to time, global credit and financial markets have experienced extreme disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. 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 equity and credit markets deteriorate, 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 an economic down-turn, which could directly affect our ability to attain our operating goals on schedule and on budget.

97
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. The tax consequences of the U.K.’s withdrawal from the EU are uncertain as well. 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 June 30, 2017, we had $554.3 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 June 30, 2017, no assurance can be given that 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. 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.**

Accounting principles generally accepted in the United States, or 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 our 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 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; and (iii) Mylan. Patent litigation against a fourth generic company, Actavis, is currently pending in the Court of Appeals for the Federal Circuit. The cases arise from Paragraph IV Patent Certification notice letters from each of Dr. Reddy’s, Lupin, and Mylan. Patent litigation against a fourth generic company, Actavis, is currently pending in the Court of Appeals for the Federal Circuit. The cases arise from Paragraph IV Patent Certification notice letters from each of Dr. Reddy’s, Lupin, and Mylan 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 January 12, 2017, a six-day bench trial commenced against defendants Dr. Reddy’s and Mylan before Honorable Judge Mary Cooper in the District of New Jersey for Case I. The patents at issue in this trial included two Orange Book listed patents: U.S. Patent Nos. 6,926,907 and 8,557,285. Defendant Lupin formerly entered into a stay pending the entry of judgment in Case I. On June 26, 2017, the court issued its opinion upholding the validity of the ‘285 and ‘907 patents and finding that Dr. Reddy’s, Mylan’s, and Lupin’s proposed generic naproxen/esomeprazole magnesium products would all infringe at least one of the two patents. The court entered the final judgment on July 21, 2017. Any notice of appeal is due by August 21, 2017.
On January 19, 2017, the court entered a scheduling order for Case II and Case III, which was subsequently updated. The court’s scheduling order requires, inter alia, filing and serving of the opening claim construction submissions by May 26, 2017. The court has not issued a claim construction order in Case II. A trial date for Cases II and III has not yet been set. On December 20, 2016, Mylan filed a motion to dismiss the Company’s first amended complaint for patent infringement in Case III. On April 28, 2017, Dr. Reddy’s filed a motion to dismiss for lack of jurisdiction in Case III, and we are awaiting final ruling.

On August 19, 2015, Lupin filed Petitions for inter partes review, or IPR, of U.S. Patent No. 8,858,996, or 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 Patent Trial and Appeal Board, or the PTAB, issued decisions to institute the IPRs for the ‘996 patent and the ‘190 patent. 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. Also on March 1, 2016, the PTAB denied the Petition for IPR for U.S. Patent No. 8,852,636. The PTAB bearings for the ‘996 and ‘190 patents were both held on November 29, 2016. On February 28, 2017, the Patent Trial and Appeal Board issued final written decisions on the IPRs of the ‘996 and ‘190 patents, upholding the validity of both patents.

Patent litigation is currently pending in the United States District Court for the District of New Jersey against two 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 Orange Book listed U.S. Patents 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, 8,781,809, 9,066,913, 9,101,591, 9,132,110, 9,168,304, 9,168,305, 9,220,784, 9,339,551 and 9,339,552.


On October 27, 2015, we filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of U.S. Patents 9,168,304 and 9,168,305. On February 5, 2016, we 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%. All claims from U.S. Patents 9,168,304 and 9,168,305 and 9,220,784 asserted against Actavis were held invalid as indefinite by way of the court’s August 17, 2016, Markman opinion and the court’s January 6, 2017, order denying our motion for reconsideration. The court’s rulings are currently on appeal to the Federal Circuit.

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

On March 18, 2015, we received a Paragraph IV Patent Certification against Orange Book listed U.S. Patents 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, we filed suit in the United States District Court for the District of New Jersey against Lupin Limited and Lupin Pharmaceuticals Inc., collectively referred to as Lupin, seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Lupin has infringed U.S. Patents 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 our 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 which finds that the subject patents are not infringed or are invalid.

On June 30, 2015, we filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patent 9,066,913. On August 11, 2015, we filed an amended complaint in the United States District Court for the District of New Jersey against Lupin that added U.S. Patent 9,101,591 to the litigation pending on U.S. Patent 9,066,913. On September 17, 2015, we filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patent 9,132,110. All three patents, U.S. Patents 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, we filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patents 9,168,304 and 9,168,305. On February 5, 2016, we filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patent 9,220,784. On August 18, 2016, we filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of U.S. Patents 9,339,551, 9,339,552, 9,370,501 and 9,375,412. All seven patents, U.S. Patents 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 Lupin remain pending, with certain claims of the '809, '913, '450, '110, '551, '552, '412 and '501 patents being asserted. The decisions reached by the court in the related Actavis actions regarding the ’809, ’450, ’110, ’551, ’552, ’412 and ’501 patents as described above, are expected to apply to the same claims asserted against Lupin in these actions. The court has not yet set a trial date for the Lupin actions.

We have received from Apotex Paragraph IV Patent Certification Notice Letters dated April 1, 2016, June 30, 2016, September 21, 2016, April 20, 2017 and April 27, 2017 against Orange Book listed U.S. Patents 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, 9,415,029, 9,539,335 and 9,370,501 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.

On April 29, 2015, Par Pharmaceutical filed Petitions for IPR of U.S. Patent 8,404,215 and U.S. Patent 8,642,012, two of the patents involved in the above mentioned RAVICTI cases. On November 4, 2015, the PTAB issued decisions instituting such IPRs and on December 14, 2015, the District Court Judge Roy Payne issued a stay pending a final written decision from the PTAB with respect to such IPRs. On September 29, 2016, the PTAB found all of the claims in U.S. Patent 8,404,215 to be unpatentable. We did not appeal the PTAB’s final written decision with respect to U.S. Patent 8,404,215. On November 3, 2016, the PTAB issued a final written decision holding all of the claims of U.S. Patent 8,642,012 patentable. On December 29, 2016, Par filed a notice of appeal with the Federal Circuit to appeal the final written decision of the PTAB concerning the patentability of U.S. Patent 8,642,012. Par’s opening brief is due on October 16, 2017.

On April 1, 2016, Lupin filed a Petition for IPR of U.S. Patent 9,095,559, a patent currently at issue in the Lupin RAVICTI case. On September 30, 2016, the PTAB issued a decision instituting the IPR. The PTAB must issue a final written decision on the IPR no later than September 30, 2017. On March 27, 2017, Lupin filed a Petition to request an IPR of the ’278 patent and a Petition to request an IPR of the ’966 patent. We filed our response on the ’966 patent on July 6, 2017. Our preliminary patent owner response for the ’278 patent was filed on July 24, 2017.

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 which party 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 for this patent under the Drug Price Competition and Patent Term Restoration Act and received notice that the United States Patent and Trademark Office, or the U.S. PTO, extended the expiration date of the patent to July 28, 2018. 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. 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 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 submitting an NDA for approval of QUINSAIR in the United States for use 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 submit an NDA for U.S. approval in the cystic fibrosis patient population, during the time periods specified in the 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 and to spend a specified minimum amount per year on development activities in the United States until submission 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 amended and restated license agreement with UCSD, with respect to PROCYSBI, including obligations to consider engaging in the development of PROCYSBI for the treatment of NASH and related diligence obligations if we undertake such development. Under the amended and restated license agreement with UCSD, we are also subject to diligence obligations to identify a third party to undertake development of PROCYSBI for the treatment of Huntington’s disease. 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 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;
• additions 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 our credit agreement and the indentures governing 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 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. 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 Rule 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.

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:

- 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. In November 2016, defendants filed motions to dismiss plaintiffs’ consolidated amended complaint, which are fully briefed but have not yet been decided by the court. Even if we are successful in defending against this action or any similar claims that may be brought in the future, such 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

(a) Recent Sales of Unregistered Securities

We completed the following issuances of unregistered securities during the three months ended June 30, 2017:

• In June 2017, we issued an aggregate of 2,500 ordinary shares to Baraboo Growth upon the cash exercise of warrants and we received proceeds of $11,425 representing the aggregate exercise price of such warrants.

(b) Use of Proceeds

• None

(c) Issuer Purchases of Equity Securities

The following table summarizes purchases of our ordinary shares made by or on behalf of us or any of our “affiliated purchasers” as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934, as amended, during each fiscal month during the three month period ended June 30, 2017:

<table>
<thead>
<tr>
<th>Month</th>
<th>Total Number of Shares Purchased</th>
<th>Average Price Paid per Share (1)</th>
<th>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (2)</th>
<th>Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1 – April 30, 2017</td>
<td>—</td>
<td>$ —</td>
<td>—</td>
<td>16,000,000</td>
</tr>
<tr>
<td>May 1 – May 31, 2017</td>
<td>100,000</td>
<td>9.93</td>
<td>100,000</td>
<td>15,900,000</td>
</tr>
<tr>
<td>June 1 – June 30, 2017</td>
<td>—</td>
<td>$ —</td>
<td>—</td>
<td>15,900,000</td>
</tr>
<tr>
<td>Total</td>
<td>100,000</td>
<td>$ 9.93</td>
<td>100,000</td>
<td>15,900,000</td>
</tr>
</tbody>
</table>

(1) Average price paid per ordinary share includes brokerage commissions.

(2) The ordinary shares reported in the table above were purchased pursuant to our publicly announced share repurchase program. 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. In May 2017, our board of directors reauthorized a share repurchase program pursuant to which we may repurchase up to 16,000,000 of our ordinary shares.

(3) The share amount shown represents as of the end of each period, the number of ordinary shares that may yet be purchased under our publicly announced share repurchase program. The timing and amount of repurchases, if any, 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.
ITEM 6. EXHIBITS

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

HORIZON PHARMA PLC

Date: August 7, 2017

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

Date: August 7, 2017

By: /s/ Paul W. Hoelscher
   Paul W. Hoelscher
   Executive Vice President, Chief Financial Officer
   (Principal Financial Officer)

112
<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(13)</td>
<td>Amendment No. 2, dated March 29, 2017, to Credit Agreement, dated May 7, 2015 (as amended by Amendment No. 1, dated October 25, 2016), by and among Horizon Pharma, Inc., as Borrower, Horizon Pharma USA, Inc., as an Additional 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>10.2(14)</td>
<td>Transition services letter agreement, dated April 21, 2017, between Horizon Pharma plc and David Happel.</td>
</tr>
<tr>
<td>10.3*</td>
<td>Global Supply Agreement, dated June 30, 2017, by and between Horizon Pharma Ireland Limited and Boehringer Ingelheim Biopharmaceuticals GmbH.</td>
</tr>
<tr>
<td>10.4*</td>
<td>Amended and Restated License Agreement, dated May 31, 2017, by and between Horizon Orphan LLC and The Regents of the University of California.</td>
</tr>
<tr>
<td>10.5+</td>
<td>Executive Employment Agreement, effective as of February 1, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Vikram Karnani.</td>
</tr>
<tr>
<td>10.6+</td>
<td>Second Amendment to Amended and Restated Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D.</td>
</tr>
<tr>
<td>10.7+</td>
<td>First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Paul W. Hoelscher.</td>
</tr>
<tr>
<td>10.8+</td>
<td>First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Barry Moze.</td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Document</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>10.9+</td>
<td>First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Brian Beeler.</td>
</tr>
<tr>
<td>10.10+</td>
<td>First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and David A. Happel.</td>
</tr>
<tr>
<td>10.11+</td>
<td>First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and George P. Hampton.</td>
</tr>
<tr>
<td>10.12+</td>
<td>First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Robert F. Carey.</td>
</tr>
<tr>
<td>10.13+</td>
<td>Second Amendment to Amended and Restated Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Timothy P. Walbert.</td>
</tr>
<tr>
<td>31.1</td>
<td>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.</td>
</tr>
<tr>
<td>31.2</td>
<td>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.</td>
</tr>
<tr>
<td>32.1</td>
<td>Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.</td>
</tr>
<tr>
<td>32.2</td>
<td>Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.</td>
</tr>
<tr>
<td>101.INS</td>
<td>XBRL Instance Document</td>
</tr>
<tr>
<td>101.SCH</td>
<td>XBRL Taxonomy Extension Schema Document</td>
</tr>
<tr>
<td>101.CAL</td>
<td>XBRL Taxonomy Extension Calculation Linkbase Document</td>
</tr>
<tr>
<td>101.DEF</td>
<td>XBRL Taxonomy Extension Definition Linkbase Document</td>
</tr>
<tr>
<td>101.LAB</td>
<td>XBRL Taxonomy Extension Label Linkbase Document</td>
</tr>
<tr>
<td>101.PRE</td>
<td>XBRL Taxonomy Extension Presentation Linkbase Document</td>
</tr>
</tbody>
</table>

+ Indicates management contract or compensatory plan.
† 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.
*** Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(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.

Incorporated by reference to Horizon Pharma, Inc.’s Current Report on Form 8-K, filed on March 1, 2012.

Incorporated by reference to Horizon Pharma, Inc.’s Current Report on Form 8-K, filed on September 20, 2012.


GLOBAL SUPPLY AGREEMENT

This Global Supply Agreement (the “AGREEMENT”), is made effective as of June 30, 2017 (the “EFFECTIVE DATE”) by and between

Horizon Pharma Ireland Limited
Connaught House
1 Burlington Road, Dublin 4
Ireland

(hereinafter referred to as “HORIZON”)

and

Boehringer Ingelheim Biopharmaceuticals GmbH
Binger Straße 173
55216 Ingelheim am Rhein
Germany

(hereinafter referred to as “BI”),

Hereinafter HORIZON and BI may be referred to herein each individually as a “Party” and jointly as the “Parties”.

Page 1 of 138
# Table of Content

1. **INTRODUCTION AND RECITALS** 
2. **DEFINITIONS** 
3. **GENERAL** 
4. **MANUFACTURE AND SUPPLY** 
5. **PRICES AND PAYMENT** 
6. **QUALITY ASSURANCE AND COMPLIANCE WITH LAW** 
7. **CO OPERATION AND CO-ORDINATION BETWEEN THE PARTIES** 
8. **INTELLECTUAL PROPERTY AND LICENSES** 
9. **COMPLAINTS; ADVERSE EVENTS; RECALLS** 
10. **REPRESENTATIONS AND WARRANTIES** 
11. **INDEMNIFICATION** 
12. **LIMITATIONS ON LIABILITY** 
13. **CONFIDENTIALITY** 
14. **DURATION AND TERMINATION** 
15. **MISCELLANEOUS**
1. INTRODUCTION AND RECITALS

Whereas, InterMune, Inc. ("InterMune") and Boehringer Ingelheim RCV GmbH & Co KG ("BI RCV"), an AFFILIATE (as defined hereafter) of BI, entered into a previous supply agreement relating to the commercial supply of Actimmune® (as described below) dated 29 June, 2007 ("RESTATED SUPPLY AGREEMENT") pursuant to the Termination Agreement dated 6 June 2007 ("TERMINATION AGREEMENT") terminating the Data Transfer, Clinical Trial and Market Supply Agreement dated 27 January 2000, as amended (the "ORIGINAL SUPPLY AGREEMENT"); and

Whereas, Vidara Therapeutics Research Limited ("VIDARA") (now HORIZON, as described below) and BI RCV entered into a consolidated supply agreement effective as of 31 July 2013, as amended (the "CONSOLIDATED SUPPLY AGREEMENT"); and

Whereas, the CONSOLIDATED SUPPLY AGREEMENT was assigned from BI RCV to its AFFILIATE BI, effective as of 1 January 2014, via an assignment letter acknowledged by VIDARA on 13 December 2013; and

Whereas, Vidara Therapeutics International plc, the parent company of VIDARA merged with Horizon Pharma Public Limited Company, an AFFILIATE of HORIZON, on 19 September 2014, and as of this date VIDARA was renamed and traded as HORIZON; and

Whereas, HORIZON’s AFFILIATE Horizon Pharma Plc and BI entered into a technology transfer and development agreement, effective as of 9 February 2015 ("LYOPHILISATION DEVELOPMENT AGREEMENT") as [***...***] the CONSOLIDATED SUPPLY AGREEMENT; and

Whereas, HORIZON terminated the LYOPHILISATION DEVELOPMENT AGREEMENT for convenience with termination letter of 15 September 2015 and effective as of 30 September 2016; and

Whereas, HORIZON is expected to become the exclusive licensee of and the holder of an exclusive sublicense under a license from [***...***]; and

Whereas, BII (as defined hereafter) had originally obtained exclusive licenses from GENENTECH to manufacture, use and sell INTERFERON GAMMA 1b in Europe and certain other territories under the trade-mark Imukin®, Immukin®, Imukine® and/or Immukine® ("BI-
GENENTECH LICENSE AGREEMENTS”). BII and HORIZON’s AFFILIATE HZNP Limited entered into an asset purchase agreement (“ASSET PURCHASE AGREEMENT”), effective as of May 18, 2016, as amended, under which HORIZON acquired all rights, title and interest from BII to INTERFERON GAMMA 1b, including the relevant confidential information and trademarks, in the BII territory.

Whereas, in connection with the ASSET PURCHASE AGREEMENT, BII and HZNP Limited anticipate that [...***...].

Whereas, BII and HORIZON, in connection with the ASSET PURCHASE AGREEMENT, entered into a Transition Service Agreement (“TRANSITION SERVICE AGREEMENT”) effective as of 30 June 2017, covering transitional services to be provided by BII and/or its AFFILIATES until such time as HORIZON makes HORIZON-labelled PRODUCT available to patients; and

Whereas, BII and its AFFILIATES BI RCV and BI Pharma KG (as defined hereinafter) own facilities specialised for cGMP manufacture of biopharmaceuticals and have been manufacturing and supplying the ACTIMMUNE PRODUCT (as defined hereinafter) and IMUKIN PRODUCT (as defined hereinafter) to BII and HORIZON, as applicable; and

Whereas, HORIZON and BII agreed in amendment No. 2 to the CONSOLIDATED SUPPLY AGREEMENT with an effective date of 1 June 2015 (“CSA AMENDMENT NO. 2”) to harmonise the current MANUFACTURING PROCESS (Exhibit 1a, 1b of CSA AMENDMENT NO. 2) for DRUG SUBSTANCE manufacture and the manufacturing process for PRODUCT manufacture [...***...];

Whereas, the Parties wish to enter into this GLOBAL SUPPLY AGREEMENT (“AGREEMENT”) to replace the CONSOLIDATED SUPPLY AGREEMENT setting forth the terms and conditions pursuant to which BII will on a going forward basis manufacture and supply to HORIZON, and HORIZON will purchase from BII, DRUG SUBSTANCE and PRODUCT to meet HORIZON’s needs with respect thereto.

Now, Therefore, in consideration of the foregoing recitals which are hereby incorporated by reference herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

***Confidential Treatment Requested
2. DEFINITIONS

The following capitalized definitions will apply throughout this AGREEMENT:

2.1 ACTIMMUNE PRODUCT means the liquid formulation of INTERFERON GAMMA 1b currently sold under the trademark Actimmune® and that is manufactured and supplied under this AGREEMENT by BI as further described in Exhibit 6.

2.2 AFFILIATE means (i) any corporation or business entity fifty percent (50%) or more of the voting stock of which is and continues to be owned directly or indirectly by any party hereto; (ii) any corporation or business entity which directly or indirectly owns fifty percent (50%) or more of the voting stock of any party hereto; or (iii) any corporation or business entity under the direct or indirect control of such corporation or business entity as described in (i) or (ii).

2.3 AGREEMENT means this GLOBAL SUPPLY AGREEMENT as set forth in the recitals above of this AGREEMENT.

2.4 APPROVAL means a regulatory approval required from a HEALTH AUTHORITY in order to manufacture DRUG SUBSTANCE or PRODUCT for use in clinical trials or market supply as applicable, in the applicable jurisdiction.

2.5 ASSET PURCHASE AGREEMENT has the meaning ascribed to it in the recitals above of this AGREEMENT.

2.6 BACKGROUND IP means all INFORMATION and INTELLECTUAL PROPERTY RIGHTS (i) owned or CONTROLLED by a Party or any of its AFFILIATES as of the EFFECTIVE DATE, or (ii) developed by a Party or any of its AFFILIATES or subcontractors during the term of this AGREEMENT independently and with no reference to the other Party’s CONFIDENTIAL INFORMATION and outside of the scope of this AGREEMENT.

2.7 BATCH has the meaning as set forth in the QAA.

2.8 BATCH RECORDS have the meaning as set forth in the QAA.

2.9 BI BACKGROUND IP means all BACKGROUND IP owned or CONTROLLED by BI or any of its AFFILIATES as of the EFFECTIVE DATE which is used, applied or otherwise employed by BI in the performance under this AGREEMENT. For the avoidance of doubt, BI BACKGROUND IP specifically excludes all INFORMATION and INTELLECTUAL PROPERTY RIGHTS included in the DIVESTED ASSETS, including the DRUG SUBSTANCE MANUFACTURING PROCESS as described in Exhibit 7 (a and b).

2.10 BI-GENENTECH LICENSE AGREEMENTS has the same meaning as the “Genentech Agreements” as defined in 1.1.(ii) of the ASSET PURCHASE AGREEMENT.
2.11 **BII** means BI’s AFFILIATE Boehringer Ingelheim International GmbH, Binger Straße 173, 55216 Ingelheim am Rhein, Germany.

2.12 **BI IMPROVEMENTS** mean all IMPROVEMENTS that BI, its AFFILIATES or subcontractors discovers, develops, conceives or reduces to practice under this AGREEMENT, individually or jointly among themselves, but excluding all HORIZON IMPROVEMENTS. BI IMPROVEMENTS include, but are not limited to, any such IMPROVEMENTS that are generally applicable to the development and manufacture of biopharmaceutical products (i.e. applicable to at least one biopharmaceutical product other than INTERFERON GAMMA 1b).

2.13 **BI PHARMA KG** means BI’s AFFILIATE Boehringer Ingelheim Pharma GmbH & Co. KG, 88397 Biberach an der Riss, Birkendorfer Straße 65, Germany, owning an FDA inspected and cGMP-certified facility.

2.14 **BI RCV** has the meaning ascribed to it in the recitals above of this AGREEMENT.

2.15 **BLA** means HORIZON’s approved Biologics License Application for the PRODUCT in the United States of America.

2.16 **BUSINESS CONTINUITY PLAN** has the meaning as set forth in Section 4.8.

2.17 **cGMP** means the current Good Manufacturing Practices of all applicable HEALTH AUTHORITIES, including without limitation the FDA (US) as set forth in more detail in the QAA.

2.18 **CHANGE OF CONTROL** means, with respect to a particular Party, occurrence of any one or more of the following events with respect to such Party: (i) the acquisition by any entity, that is not an Affiliate of such Party, of a majority of the total outstanding voting securities of the Party; (ii) the merger of such Party with a third party in a transaction under which the holders of the outstanding voting shares of such Party, as of just prior to such merger, own less than fifty percent (50%) of the outstanding voting shares of the combined entity as of just after such event; (iii) the acquisition by a third Party of beneficial ownership of more than fifty percent (50%) of the outstanding voting shares of such Party and/or all its Affiliates; or (iv) any sale (other than in the ordinary course of business), exchange, transfer, acquisition or disposition, of all or substantially all of the assets of the Party relating to the PRODUCT (i.e., assets of the Party having a fair market value equal to more than eighty percent (80%) of the total fair market value of all of the assets of the Party at such time) to an entity that is not an Affiliate of such Party.

2.19 **CHANGE ORDER / CO** means a written document between the Parties setting forth the scope, objectives, deliverables, timelines, costs, fees and other details of each and any additional development work or additional commercial service(s) to be performed by BI under this AGREEMENT, the agreed form of which shall be signed by the Parties. Each fully-executed CHANGE ORDER shall be incorporated by reference into this AGREEMENT.
2.20 **CMC** means the Chemistry, Manufacturing, and Controls content of a submission to a HEALTH AUTHORITY.

2.21 **COA** means a Certificate of Analysis, a document listing testing parameters, specifications and test results (in a format and detail as listed in Exhibit 3) and as further set forth in the QAA.

2.22 **COC** means a Certificate of Compliance confirming compliance with cGMP regulations and signed by BI RCV’s authorised Qualified Person, the Head of Production and the Head of Quality Assurance (in a format and such detail as listed in Exhibit 4) and as further set forth in the QAA.

2.23 **COMPONENTS** means, collectively, all raw materials, consumables, resins, and equipment dedicated to the DELIVERED MATERIALS, and materials required to process and package for shipment the DELIVERED MATERIALS in accordance with the DELIVERED MATERIAL SPECIFICATIONS.

2.24 **CONFIDENTIAL INFORMATION** means any proprietary INFORMATION (a) disclosed by one Party to the other from and after the effective date of the ORIGINAL SUPPLY AGREEMENT (including, without limitation, disclosed in connection with the CONSOLIDATED SUPPLY AGREEMENT), or (b) developed by either Party pursuant to this AGREEMENT, except in each case INFORMATION which (i) is already in the public domain at the time of its disclosure to the receiving Party; (ii) becomes part of the public domain through no wrongful action or omission of the receiving Party after disclosure to the receiving Party; (iii) is already known to the receiving Party at the time of disclosure as evidenced by the receiving Party’s written records; or (iv) is independently developed by the receiving Party without the use or application of the disclosing Party’s proprietary INFORMATION. For clarity, all Divested Confidential Information (as defined in the ASSET PURCHASE AGREEMENT) will be deemed to be HORIZON’s CONFIDENTIAL INFORMATION, such that HORIZON will be deemed to be the disclosing Party, BI will be deemed to be the receiving Party, and subclause (b)(iii) above shall not apply with respect thereto.

2.25 **CONFORMING** when used in reference to any DELIVERED MATERIAL means DELIVERED MATERIAL that has been manufactured in accordance with cGMP, the QAA and DELIVERED MATERIAL SPECIFICATIONS.

2.26 **CONSOLIDATED SUPPLY AGREEMENT** has the meaning ascribed to it in the recitals above of this AGREEMENT.

2.27 **CONTROLLED** means, with respect to any material, INFORMATION or INTELLECTUAL PROPERTY RIGHT possession of the ability by a Party to grant access, a license, or a sublicense to such material, INFORMATION or INTELLECTUAL PROPERTY RIGHT as provided for herein (a) without violating an agreement with a Third Party and (b) without obligation to make any payments to a Third Party as a result of such grant the other Party of such access, license or sublicense or the exercise thereof by such other Party unless such other
Party has agreed in writing to reimburse the granting Party for such payments. The granting Party, at the time such access, license or sublicense is required to be granted hereunder, will notify the other Party in writing of any payment obligation under subclause (b) above.

2.28 CSA AMENDMENT NO. 2 has the meaning ascribed to it in the recitals above of this AGREEMENT.

2.29 DELIVERED MATERIAL means EXCESS MATERIAL or PRODUCT, as applicable.

2.30 DELIVERED MATERIAL SPECIFICATIONS means DRUG SUBSTANCE SPECIFICATIONS or PRODUCT SPECIFICATIONS, as applicable.

2.31 DIVESTED ASSETS has the meaning ascribed in the ASSET PURCHASE AGREEMENT.

2.32 DRUG SUBSTANCE means a bulk form of the PRODUCT. This bulk form is the […***…].

2.33 DRUG SUBSTANCE MANUFACTURING PROCESS means the processes for fermentation and purification of DRUG SUBSTANCE, as described in Exhibit 7 (a and b), which the Parties intend to replace with the process described in Exhibit 7(c) […***…]. The DRUG SUBSTANCE MANUFACTURING PROCESS does however not encompass the filling of the DRUG SUBSTANCE to PRODUCT, or the labelling and packaging of PRODUCT.

2.34 DRUG SUBSTANCE SPECIFICATIONS mean all the specifications and tests, analytical methods and/or limits, and the results thereof, as applicable, for DRUG SUBSTANCE agreed to by the Parties and listed in Exhibit 2 and to which DRUG SUBSTANCE has to conform.

2.35 EMA means the European Medicines Agency and any successor agency thereto.

2.36 EQUIPMENT means all plant, columns, vessels, machines and in general all equipment of any kind used in the manufacture or storage of the DRUG SUBSTANCE or the PRODUCT.

2.37 EURO means a euro, which is the European unit of currency.

2.38 EXCESS MATERIAL means any excess DRUG SUBSTANCE from DRUG SUBSTANCE BATCHES manufactured by BI for the supply of PRODUCT to HORIZON to be determined by BI after HORIZON’s annual commercial purchase obligations for each commercial year under the AGREEMENT have been met.

***Confidential Treatment Requested
2.39 **FACILITY** shall mean the biotech buildings and all other buildings located at Dr. Boehringer Gasse 5-11, 1121 Vienna, Austria and at Birkendorfer Str. 65, 88397 Biberach, Germany and used by BI in the performance of BI’s obligations under this AGREEMENT.

2.40 **FDA** means the United States Food and Drug Administration and any successor agency thereto.

2.41 **FD&C ACT** means the United States Food, Drug & Cosmetic Act as amended from time to time and any supplements thereunder, and any equivalent regulation of any HEALTH AUTHORITIES.

2.42 **FINAL RELEASE** means (a), with respect to PRODUCT, the release of PRODUCT by HORIZON or its licensees for clinical trial use or market supply, as applicable, and (b) with respect to DRUG SUBSTANCE, the release of DRUG SUBSTANCE by HORIZON or its licensees.

2.43 **GENENTECH** means Genentech, Inc. with its principal place of business at 1 DNA Way, South San Francisco, CA, 94080-4990, USA.

2.44 […***…].

2.45 **HEALTH AUTHORITIES** mean all regulatory authorities having jurisdiction over the manufacture, use and/or sale of the PRODUCT in the TERRITORY, including but not limited to the FDA and the EMA.

2.46 **HORIZON BACKGROUND IP** means all INFORMATION and BACKGROUND IP that was or is owned or CONTROLLED either by InterMune or HORIZON (or previously by VIDARA) and required for the performance by BI of its obligations under this AGREEMENT. HORIZON BACKGROUND IP includes (a) all INFORMATION and INTELLECTUAL PROPERTY RIGHTS included in the DIVESTED ASSETS, and (b) all INFORMATION and INTELLECTUAL PROPERTY RIGHTS relating to the manufacture, use or sale of INTERFERON GAMMA 1b […***…], including without limitation the MANUFACTURING PROCESS as described in Exhibit 7 (a and b) and the PRODUCT MANUFACTURING PROCESS as described Exhibit 16.

2.47 **HORIZON IMPROVEMENTS** mean all IMPROVEMENTS to HORIZON BACKGROUND IP relating specifically to the PRODUCT and/or DRUG SUBSTANCE that BI, its AFFILIATES or subcontractors (whether solely or jointly with HORIZON, its AFFILIATES or subcontractors) discover, develop, conceive or reduce to practice under this AGREEMENT, but excluding any such IMPROVEMENTS that are generally applicable to the development and manufacture of biopharmaceutical products (i.e. applicable to at least one biopharmaceutical product other than INTERFERON GAMMA 1b). Any IMPROVEMENTS of the DRUG SUBSTANCE MANUFACTURING PROCESS and/or PRODUCT

***Confidential Treatment Requested***
Page 9 of 138
MANUFACTURING PROCESS shall be HORIZON IMPROVEMENTS only to the extent that they directly relate to the DRUG SUBSTANCE and/or PRODUCT.

2.48 IMPROVEMENTS mean all INFORMATION and INTELLECTUAL PROPERTY RIGHTS, and all modifications, derivatives and improvements of BACKGROUND IP or new uses thereof (whether or not protectable under patent, trademark, copyright or similar laws) that are discovered, developed, conceived or reduced to practice in the performance of this AGREEMENT.

2.49 IMUKIN PRODUCT means the liquid formulation of INTERFERON GAMMA 1b, currently traded under the trademarks Imukin®, Immukin®, Imukine® and Immukine®, that is manufactured and supplied under this AGREEMENT by BI as further described in Exhibit 6.

2.50 INFORMATION means (a) techniques, data, discoveries, inventions, practices, methods, knowledge, know-how, skill, experience, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, regulatory submissions, correspondence and communications, marketing, pricing, distribution, cost, sales, manufacturing, patent, patent applications and legal data or descriptions, compositions of matter, assays and biological materials, and (b) all INTELLECTUAL PROPERTY RIGHTS in and to any of the foregoing.

2.51 INTELLECTUAL PROPERTY RIGHTS mean any and all now known or hereafter existing: (i) rights associated with works of authorship, including copyrights and moral rights; (ii) trade secret rights; (iii) patent rights, including patent applications, and industrial property rights; (iv) other proprietary rights in all inventions (whether or not patentable), discoveries, methods, processes, techniques, specifications, protocols, schematics, diagrams, reagents, compounds, samples, formulation, data, circuit designs, design layout, databases, data, and other forms of technology; and (v) all registrations, applications, renewals, and extensions of the foregoing, in each case in any jurisdiction throughout the world, including, but not limited to, inventor’s certificates, utility models, substitutions, confirmations, reissues, re-examinations, renewals or any like governmental grants for protection of inventions; and any pending application for any of the foregoing, including any continuation, divisional, substitution, additions, continuations-in-part, provisional and converted provisional applications, as well as extensions and supplementary protection certificates based thereon.

2.52 INTERFERON-GAMMA 1b means the recombinant human Interferon-Gamma 1b derived from […***…]. The relevant amino acid sequence is set forth in Exhibit 5.

2.53 JOINT PROJECT TEAM means the team as described in Section 7.1.

***Confidential Treatment Requested
2.54 **LATENT DEFECT** means, with respect to a Non-CONFORMING DELIVERED MATERIAL, that such non-conformance hereof is not visible or easily detectable without any analysis in a laboratory.

2.55 **MANUFACTURER’S RELEASE** shall mean BI’s release through its qualified person of a BATCH of DRUG SUBSTANCE or PRODUCT, conducted in accordance with the specified procedures and requirements defined in the QUALITY ASSURANCE AGREEMENT and applicable cGMP, which release signifies that the BATCH meets the MANUFACTURER’S RELEASE (DRUG SUBSTANCE or PRODUCT, as applicable) SPECIFICATIONS.

2.56 **MANUFACTURER’S RELEASE SPECIFICATIONS** shall mean the defined list of analytical test methods that BI is responsible for performing, and acceptance criteria for a PRODUCT and DRUG SUBSTANCE, as set forth in Exhibit 1 and Exhibit 2, as applicable, to all of which a PRODUCT or DRUG SUBSTANCE must conform in order to be considered acceptable for the disposition of the PRODUCT or DRUG SUBSTANCE for the intended use. Such MANUFACTURER’S RELEASE SPECIFICATIONS may be amended, supplemental or otherwise modified by the Parties from time to time in accordance with the terms of this AGREEMENT and the QUALITY ASSURANCE AGREEMENT as applicable.

2.57 **MANUFACTURING PROCESS** means the DRUG SUBSTANCE MANUFACTURING PROCESS or the PRODUCT MANUFACTURING PROCESS, as applicable.

2.58 **MASTER BATCH RECORD** means controlled documents of BI, approved by authorized technical and quality representatives of BI, that provides written instructions for the respective MANUFACTURING PROCESS and includes all relevant MANUFACTURING PROCESS parameters to be followed and Equipment and raw materials to be used.

2.59 **MATERIAL SUPPLY BREACH** means a failure of BI: (a) to supply to HORIZON at [...] of HORIZON’s binding forecasted requirements of DRUG SUBSTANCE or PRODUCT (or actual orders, if less) that are due for shipment by the designated shipment date during the then-current calendar half-year; or (b) to repeatedly [...] materially violate against cGMP.

2.60 **Non-CONFORMING** means, with respect to any DELIVERED MATERIAL, that such DELIVERED MATERIAL is not CONFORMING.

2.61 **OBVIOUS DEFECT** means, with respect to any Non-CONFORMING DELIVERED MATERIAL, that such non-conformance is visible or easily detectable without any analysis in a laboratory.

2.62 **ORIGINAL SUPPLY AGREEMENT** has the meaning ascribed to it in the recitals above of this AGREEMENT.

***Confidential Treatment Requested***
2.63 **PRODUCT MANUFACTURING PROCESS** means the processes for the filling of the DRUG SUBSTANCE to PRODUCT, as well as the labelling and packaging of PRODUCT, as described in Exhibit 16.

2.64 **PERMITTED SUBCONTRACTORS** has the meaning as set forth in Section 4.3.6.

2.65 **PROCESS PACKAGE** means the package, for the applicable MANUFACTURING PROCESS, containing the documentation and materials set forth in Section 14.4.1 to the extent these documents and information are in existence as at the relevant transfer date and to the extent these are necessary and for the sole purpose that HORIZON or a secondary supplier may implement the MANUFACTURING PROCESS and analytical methods in order to manufacture and produce DRUG SUBSTANCE and PRODUCT.

2.66 **PRODUCT** means finished product(s) consisting of formulated INTERFERON GAMMA 1b as a [...***…] (the relevant amino acid sequence of the monomer is set forth in Exhibit 5) and filled into the designated vials or other agreed containers (which may be labelled by BI for the U.S. and/or Canadian market only, or unlabelled, as set forth in the applicable rolling forecast) for clinical supply or for market supply, as described in Exhibit 6, or alternatively shall mean finished product(s) of formulation buffer filled into the designated vials or other agreed containers for clinical supply (placebo).

2.67 **PRODUCT MANAGER** means the responsible person designated by each Party to be responsible for the communication of all information concerning this AGREEMENT. As of the EFFECTIVE DATE, the person designated as HORIZON’s PRODUCT MANAGER and the person designated as BI’s PRODUCT MANAGER are listed in Exhibit 8. Either Party may change its own designated PRODUCT MANAGER by providing written notice thereof to the other Party.

2.68 **PRODUCT SPECIFICATIONS** mean all the specifications and tests, analytical methods and/or limits, and the results thereof, as applicable, for the PRODUCT agreed by the Parties and set forth in Exhibit 1 within which the PRODUCT has to conform to be considered acceptable by HORIZON.

2.69 **PRODUCT TEAM** means the team as listed in Exhibit 8 and described in Section 7.1.

2.70 **PROJECT LEADER** means the responsible person designated by each PARTY to be responsible for the communication of all INFORMATION concerning this AGREEMENT. Either Party may change its own designated PROJECT LEADER by providing written notice thereof to the other PARTY.

2.71 **QUALITY ASSURANCE AGREEMENT / QAA** means that Quality Assurance Agreement effective April 26, 2016 between the Parties, as amended.

***Confidential Treatment Requested***
2.72 **RELEVANT YEAR** shall mean (a) the calendar year in which the MANUFACTURER’S RELEASE of the PRODUCT which caused the damage occurred, or (b) in case the damage is not caused by the use of PRODUCT, the calendar year when the damage occurred.

2.73 **RESIDUAL SHELF LIFE** means, with respect to a vial of PRODUCT, the actual residual shelf life of such PRODUCT at the time of delivery to HORIZON hereunder, which in no event shall be shorter than the residual shelf life set forth in Section 4.4.5.

2.74 **RESTATE** **D SUPPLY AGREEMENT** has the meaning ascribed to it in the recitals above of this AGREEMENT.

2.75 **STEERING COMMITTEE** means the committee as listed in Exhibit 8 and as further described in Section 7.4.

2.76 **SOPs** means standard operating procedures.

2.77 **TECHNOLOGY TRANSFER** has the meaning as set forth in Section 14.4.1.

2.78 **TERMINATION AGREEMENT** has the meaning ascribed to it in the recitals above of this AGREEMENT.

2.79 **TERRITORY** means the countries set forth in Exhibit 12, as may be amended from time to time in accordance with Section 4.12.

2.80 **THIRD PARTY** means any person other than the Parties and their respective AFFILIATES.

2.81 **TRANSFER SUPPORT** has the meaning as set forth in Section 14.4.1.

2.82 **TRANSITION SERVICES AGREEMENT** has the meaning ascribed to it in the recitals above of this AGREEMENT.

2.83 **US** means the United States of America.

3. **GENERAL**

3.1 **HORIZON’s Tasks and Responsibilities**

3.1.1 **Support**

HORIZON shall timely send all documentation, and otherwise timely provide all information and other assistance, reasonably requested by BI for use under this AGREEMENT. HORIZON shall provide such reasonable technical support at its own expense, which support shall include...
access to HORIZON’s expert personnel upon reasonable notice and at such reasonable times as the Parties may agree.

3.1.2 Contact with Health Authorities

3.1.2.1 HORIZON and its AFFILIATES shall have the overall responsibility regarding all contacts with the HEALTH AUTHORITIES with respect to the PRODUCT and shall be solely responsible for filing all regulatory documents required by any HEALTH AUTHORITIES with respect to the PRODUCT, except as otherwise expressly set forth in the SDEA (as defined below), the TRANSITION SERVICES AGREEMENT or this AGREEMENT.

3.1.2.2 Under Section 14.1 of the ASSET PURCHASE AGREEMENT, HORIZON’s AFFILIATE HZNP Limited and BI’s AFFILIATE BII agreed to amend the Pharmacovigilance Agreement for Co-Marketing effective April 17, 2014 (the “SDEA”), which addresses the rights and obligations of the parties to the ASSET PURCHASE AGREEMENT in relation to global product safety. The Parties agree that all questions regarding the monitoring of and reporting to HEALTH AUTHORITIES on global product safety of DRUG SUBSTANCE and/or PRODUCT are subject to the terms of the then-current SDEA. Once all the marketing authorizations have been transferred to HZNP Limited, the Parties intend that the SDEA be amended to provide that HZNP Limited shall be solely responsible for the monitoring and reporting to HEALTH AUTHORITIES regarding the global product safety of the DRUG SUBSTANCE and/or the PRODUCT.

3.1.2.3 BI shall support HORIZON in all matters regarding the manufacturing and quality control of DRUG SUBSTANCE and PRODUCT as reasonably requested by HORIZON, but HORIZON shall be the leading party and thus be responsible for co-ordination of all regulatory matters. Notwithstanding the foregoing, as of the EFFECTIVE DATE and until registration of HORIZON as manufacturing authorisation holder for IMUKIN PRODUCT in each of the countries listed in Exhibit 12 (TERRITORY) where a manufacturing authorization exists, BI shall be responsible for all contacts with the HEALTH AUTHORITIES for IMUKIN PRODUCT in said country/countries in accordance with the terms of the TRANSITION SERVICES AGREEMENT. Following the registration of HORIZON as manufacturing authorisation holder for IMUKIN PRODUCT in a country, HORIZON shall be responsible for all contacts with the HEALTH AUTHORITIES for IMUKIN PRODUCT in such country.

3.1.2.4 HORIZON will notify BI in due time, but in no event later than [...***…] in advance of any meeting with any HEALTH AUTHORITIES with regard to manufacture, supply and quality control of the DRUG SUBSTANCE and/or PRODUCT manufactured by BI under this AGREEMENT. BI shall have the right to participate in such meetings with such HEALTH AUTHORITIES during the portion of such meetings relating to BI’s manufacture, supply and quality control of the DRUG SUBSTANCE and/or PRODUCT.

3.1.2.5 BI will be responsible for drawing up the annual report required by the HEALTH AUTHORITIES reasonably in advance of the due date, and will be responsible of matters

***Confidential Treatment Requested

Page 14 of 138
regarding the manufacture of PRODUCT. HORIZON shall submit such report to the HEALTH AUTHORITIES and shall provide BI with a copy of the finally submitted report.

3.1.3 Shipment of Material by HORIZON

Any materials, e.g. samples, sent by HORIZON (or by a Third Party on behalf of HORIZON) to BI under this AGREEMENT shall be made by shipment from HORIZON’s facility (or the Third Party's facility, as the case may be) to BI shall be made [***…***…] to the FACILITY in Vienna. Thus, shipping costs including insurance will be borne by HORIZON, and risk of loss in transit shall lie with HORIZON. Along with each shipment, HORIZON shall provide to BI, as applicable, shipping documents indicating [***…***…].

3.2 BI’s Tasks and Responsibilities

3.2.1 Regulatory Support

3.2.1.1 BI agrees to co-operate with HORIZON in obtaining and maintaining all governmental approvals and registrations in the TERRITORY relevant to the chemistry, manufacturing and control (“CMC”) section of the registration dossier (and their foreign equivalents) for the PRODUCT as requested by HORIZON.

3.2.1.2 The Parties shall consult with each other concerning the scope and content of all regulatory filings pertinent to BI’s responsibilities for manufacture and supply of PRODUCT, and shall jointly define the requirements for the necessary PRODUCT registration with the applicable HEALTH AUTHORITIES so that BI shall be able to fulfill its obligations under this AGREEMENT with respect to the CMC portion of such PRODUCT registration. With respect to any part of the CMC portion which contains INFORMATION of BI and/or its AFFILIATES, BI shall be provided an opportunity of twenty [***…***…] in accordance with Section 14.1.5 of the QAA, or such other period as the Parties may agree in writing (the “REVIEW PERIOD”), to review and approve in writing the CMC section(s) of any regulatory filing which contain any data generated by BI relating to the manufacture and testing of the Product at BI and/or the facility prior to submission of such filing by HORIZON to a HEALTH AUTHORITY, which approval shall not be unreasonably withheld, conditioned or delayed. If BI does not notify HORIZON in writing of any material objection to any CMC section(s) provided to BI in accordance with the preceding sentence within the REVIEW PERIOD, then BI shall be deemed to have approved such CMC section for provision to the applicable HEALTH AUTHORITIES. The foregoing BI review and prior approval shall not apply and a notification by HORIZON to BI shall be sufficient in the event that documents issued by BI for regulatory purposes are provided to any such Governmental Authority without further processing or changes by HORIZON. The Parties shall agree in good faith on the required time periods for such review and approval and for any compilation, review and approval of regulatory documents in general in the Quality Agreement or otherwise in writing.

***Confidential Treatment Requested
3.2.2 Format and Content of Documents

BI's Quality Management System demands a special format for certain documents (i.e. BATCH RECORDS, testing procedures, technical reports) which is binding. For those documents where a binding format is not obligatory, the Parties shall agree in writing on a master format. With respect to the dates contained in these documents, and in particular in all reports and when dates occur in connection with signatures, the European writing style shall apply. The order shall be as follows: dd / mm / yy (day/month/year).

3.3 Harmonised MANUFACTURING PROCESS

The Parties understand that BI's manufacturing and supply obligations hereunder are dependent on [...***...]. In the event that [...***...].

4. MANUFACTURE AND SUPPLY

4.1 Continuing Services from CONSOLIDATED SUPPLY AGREEMENT/CSA AMENDMENT NO. 2; Use of DRUG SUBSTANCE

The Parties agree that BI shall continue to conduct under this AGREEMENT the services agreed pursuant to CSA AMENDMENT NO. 2 and adapted in agreement between the PARTIES as set forth in Exhibit 17.

The DRUG SUBSTANCE and PRODUCT manufactured from the Process and Performance Qualification (PPQ) activities shall, [...***...], be used to provide HORIZON's commercial requirements of PRODUCT in the TERRITORY for the commercial years [...***...], and the Parties acknowledge that such PRODUCT from PPQ fill and finish Batches will be paid for as per the billing plan of Exhibit 9. BI shall perform additional fill and finish runs using DRUG SUBSTANCE manufactured under the harmonization program and HORIZON shall pay for the fill and finish services only, as set forth in Exhibit 10.

4.2 Scope Changes and Change Orders

4.2.1 In case HORIZON requests additional services beyond those described in Section 3 or Section 4.1, including but not limited to additional regulatory support, or extension of the scope of services or BATCHES, the Parties shall negotiate in good faith the detailed scope, timelines

***Confidential Treatment Requested
and prices of such service. Upon HORIZON's request BI shall prepare a proposal specifying the required services. Any agreed service shall be set forth in writing in the form of a CHANGE ORDER. Once a CHANGE ORDER is executed, such services or BATCH identified therein shall be subject to the terms and conditions of this AGREEMENT.

4.2.2 For clarity, HORIZON may request DRUG SUBSTANCE supply from BI under mutually acceptable terms, including but not limited to price, forecasting and minimum purchase order. HORIZON acknowledges that BI requires a minimum of […***…] prior notice to schedule additional BATCHES of DRUG SUBSTANCE, and BI agrees that it will manufacture such BATCHES within this time frame, under the condition that the Parties agree on the mutually acceptable terms for such BATCHES. The Parties shall negotiate in good faith such price and any other necessary terms for manufacture and shipment of additional BATCHES of DRUG SUBSTANCE.

4.3 General Provisions for the Services

4.3.1 BI shall […***…] (i) manufacture and supply to HORIZON EXCESS MATERIAL in bulk form and (ii) subject to Section 4.3.2, manufacture and supply to HORIZON PRODUCT […***…], using DRUG SUBSTANCE produced by BI or provided by HORIZON, to HORIZON. BI shall not supply DRUG SUBSTANCE or PRODUCT […***…]. However, provided that HORIZON’s rolling forecast according to Section 4.4 can be satisfied by BI, HORIZON shall not unreasonably withhold, delay or condition any request of BI or its AFFILIATES to use any PRODUCT to satisfy any of their own commitments towards HEALTH AUTHORITIES or other branches of governments located in jurisdictions that are not subject to the terms of the ASSET PURCHASE AGREEMENT. If BI manufactures and supplies PRODUCT using DRUG SUBSTANCE provided by HORIZON or that HORIZON has purchased separately from BI […***…].

4.3.2 HORIZON shall […***…] purchase from BI […***…] of HORIZON’s clinical trial supply and its market requirements for PRODUCT for the term of this AGREEMENT, subject to Section 4.9 (Continuity of Supply). In addition, subject to a minimum of […***…] prior notice and the Parties reaching written agreement on all matters set forth in Section 4.2.2, HORIZON shall […***…] purchase from BI […***…] of HORIZON’s requirements for DRUG SUBSTANCE for the term of this AGREEMENT, subject to Section 4.9 (Continuity of Supply). For clarity, the […***…] obligation in this Section 4.3.2 shall not apply to […***…].

4.3.3 All DRUG SUBSTANCE and PRODUCT manufactured for and/or supplied to HORIZON by BI hereunder shall be manufactured at the FACILITY in accordance with the DRUG SUBSTANCE SPECIFICATIONS and PRODUCT SPECIFICATIONS, respectively, the
cGMP requirements, the QUALITY ASSURANCE AGREEMENT and all applicable laws, regulations and ordinances in the jurisdictions in which such manufacture occurs. Provided that HORIZON is able to provide to BI storage and temperature log documentation showing that the DRUG SUBSTANCE or PRODUCT, as applicable, delivered to HORIZON has been stored under appropriate conditions, BI warrants (gewährleistet) that such PRODUCT shall meet the applicable stability specifications until the end of the residual shelf-life. It is understood that HORIZON is responsible for the compliance with applicable laws of the regulatory filings of the PRODUCT, and that changes and/or variations to the DRUG SUBSTANCE SPECIFICATIONS and/or PRODUCT SPECIFICATIONS affecting the BLA or other regulatory submissions to the BLA or any marketing authorization in the TERRITORY shall be initiated by HORIZON in accordance with the QUALITY ASSURANCE AGREEMENT and the TRANSITION SERVICE AGREEMENT; provided that BI shall promptly inform HORIZON in writing if updates are needed to the CMC sections of any regulatory submissions for the DRUG SUBSTANCE or PRODUCT if it is an update that has been requested by a HEALTH AUTHORITY or HORIZON, or if BI becomes aware of an issue that would have impact on the registration for the DRUG SUBSTANCE or PRODUCT (for example, as the result of a routine inspection and deficiency noted that needs to be improved).

4.3.4 The Parties agree that that the minimum campaign length is […] of PRODUCT and thus that BI will not offer any […] campaigns.

4.3.5 Supply of Excess Drug Substance

In the event of any EXCESS MATERIAL being available, HORIZON may purchase under a CHANGE ORDER order from BI such EXCESS MATERIAL, to be supplied in accordance with the price set forth in Exhibit 10. For clarity, EXCESS MATERIAL produced pursuant to CSA AMENDMENT NO. 2 shall be used for development or clinical activities, including but not limited to new PRODUCT applications, or as otherwise permitted under the respective CHANGE ORDER, and the prices set forth in Exhibit 10 shall apply to such EXCESS MATERIAL. The terms and conditions of this AGREEMENT relevant for each supply of EXCESS MATERIAL shall apply hereto. Further, and in accordance with Section 10.7.1.1, HORIZON will in no event use any expired EXCESS MATERIAL in humans.

4.3.6 Subcontracting

Rights and obligations under this AGREEMENT may not be subcontracted by BI in whole or in part without the prior written consent of HORIZON. Notwithstanding the foregoing, HORIZON herewith gives express consent that BI may subcontract the services under this AGREEMENT in whole or in part to (a) its AFFILIATE BI RCV, (b) its AFFILIATE BI Pharma KG and (c) those subcontractors set forth in Exhibit 13 (the entities described in subclauses (a), (b) and (c) above, and any other subcontractor for which HORIZON gives its consent as set forth in this Section 4.3.6, collectively referred to as “PERMITTED SUBCONTRACTORS”). Notwithstanding the foregoing, no PERMITTED SUBCONTRACTOR shall perform any manufacturing activity under this AGREEMENT for which such PERMITTED SUBCONTRACTOR’s manufacturing facilities would be required to comply with cGMP under applicable laws unless and until BI and

***Confidential Treatment Requested

Page 18 of 138
HORIZON have entered into a written agreement with respect to ensuring such PERMITTED SUBCONTRACTOR’s compliance with cGMP.

BI shall be responsible and liable for all activities (including omissions) of any PERMITTED SUBCONTRACTORS in connection with this AGREEMENT as if such activities or omissions were performed or made by BI. BI shall ensure that any PERMITTED SUBCONTRACTORS shall be bound by written agreements consistent with this AGREEMENT and QUALITY ASSURANCE AGREEMENT and containing: (a) confidentiality obligations no less restrictive than those in this AGREEMENT and (b) provisions that are sufficient to enable BI to grant INTELLECTUAL PROPERTY RIGHTS granted to HORIZON under this AGREEMENT.

4.4 Forecasts

HORIZON shall provide a rolling forecast for [...***…] for PRODUCT in the format set forth in Exhibit 11. For clarity, [...***…].

4.4.1 [...***…]. From the EFFECTIVE DATE until [...***…] and the manufacturing process for PRODUCT (Exhibit 16), HORIZON agrees to order the PRODUCT in filling lot quantities or multiples thereof (available lot sizes as of the EFFECTIVE DATE are [...***…] vials, as follows: [...***…] of ACTIMMUNE PRODUCT and [...***…] of IMUKIN PRODUCT per [...***…].

4.4.2 [...***…]. After [...***…] and the PRODUCT MANUFACTURING PROCESS (Exhibit 16) with the FDA, HORIZON agrees to order the PRODUCT in filling lot quantities or multiples thereof of [...***…] vials. HORIZON shall be obligated to purchase amounts of PRODUCT in full lot size of [...***…] vials, under this AGREEMENT consistent with the binding/nonbinding rolling forecast set forth in Section 4.4 above. At minimum, HORIZON shall order [...***…] vials of PRODUCT per calendar year (prorated for partial calendar years). If HORIZON requires more PRODUCT than set forth in the current firm forecast, BI shall use commercially reasonable efforts in good faith to supply HORIZON with PRODUCT as requested; provided that for the amounts of PRODUCT in excess of such forecast which BI is unable to supply, despite such commercially reasonable

***Confidential Treatment Requested

Page 19 of 138
efforts, HORIZON may use a secondary source manufacturer for PRODUCT in accordance with the procedures set forth in Section 4.9.

4.4.3 If HORIZON reduces the forecast for [...***…], then HORIZON shall be obligated to pay for PRODUCT which was not ordered [...***…]. Similarly, if HORIZON reduces the forecast [...***…], then HORIZON shall be obligated to pay for PRODUCT which was not ordered [...***…]. BI shall mitigate HORIZON’s payment obligations under this Section 4.4.3 by allocating any available capacity resulting from HORIZON’s reduction of the forecast to a BI AFFILIATE or a THIRD PARTY.

4.4.4 BI shall guarantee that at the date of MANUFACTURER’S RELEASE all DELIVERED MATERIAL supplied to HORIZON shall have a minimum RESIDUAL SHELF LIFE of not less than [...***…] based on an approved shelf life of [...***…], provided that HORIZON shall strictly fulfill its contractual timelines regarding FINAL RELEASE as set forth in Sections 4.7 and 5.

4.4.5 Subject to Section 4.6, BI shall ship all EXCESS MATERIAL and/or PRODUCT by the date and in the quantities specified in the applicable purchase order. BI shall be obligated to accept any purchase order within the range of permitted variation in the forecasted quantities as set forth in Section 4.4.1 and 4.4.2. If BI does not accept such a purchase order with respect to PRODUCT, then HORIZON may use a secondary source manufacturer for such PRODUCT in accordance with the procedures set forth in Section 4.10. Any other purchase order shall be binding on BI only if it is accepted by BI, which acceptance shall not be unreasonably withheld.

4.4.6 HORIZON shall be obligated to buy and BI shall be obligated to sell only the quantities of EXCESS MATERIAL and/or PRODUCT which are subject to a purchase order accepted by BI; provided that BI shall accept sufficient purchase orders from HORIZON annually to meet its obligations pursuant to this Section 4.4 and in accordance with the rolling forecast model pursuant to Section 4.4. Any purchase order (or portion thereof) for which HORIZON has not received a written rejection from BI within [...***…] of BI’s receipt of such purchase order shall be deemed accepted by BI. With respect to PRODUCTS ordered by HORIZON for its clinical supply requirements, the number of vials supplied by BI shall not exceed the number of vials subject to the applicable purchase order submitted by HORIZON; provided, however, that if the number of vials BI is able to supply falls below the number of vials ordered by HORIZON in such purchase order and such lesser number is within a reasonable range of the number ordered by HORIZON, BI shall notify HORIZON in writing and inquire as to whether such lesser number of vials is acceptable and if not, whether BI should produce an additional BATCH of DRUG SUBSTANCE to produce enough vials to satisfy HORIZON’s purchase order. If HORIZON notifies BI that such lesser number of vials is acceptable to HORIZON, then the applicable purchase order shall be deemed to be amended to
4.4.7 provide for such lesser number of vials and BI shall be deemed to have accepted such purchase order in accordance with Section 4.4 and 4.5 (and HORIZON shall only be required to pay for the number of vials actually delivered). On the other hand, if HORIZON notifies BI that BI should manufacture an additional BATCH of DRUG SUBSTANCE to produce the number of vials ordered by HORIZON in its purchase order submitted to BI, then BI shall be obligated to produce the additional BATCH of DRUG SUBSTANCE, HORIZON shall be obligated to purchase any excess vials (above the amounts forecasted in accordance with Section 4.4) of PRODUCT from such additional BATCH of DRUG SUBSTANCE and the purchase order submitted to BI by HORIZON shall be deemed amended to account for any excess vials resulting from the additional BATCH of DRUG SUBSTANCE and such purchase order shall be deemed accepted by BI in accordance with Section 4.4 and 4.5. In the event HORIZON prefers to purchase any EXCESS MATERIAL of said additional BATCH, Section 4.3.5 shall apply.

4.4.8 For the avoidance of doubt, HORIZON shall supply separate forecasts and purchase orders according to Exhibits 10 and 11 in accordance with Sections 4.4 and 4.5.

4.4.9 For the sake of clarity, Section 4.4 sets forth HORIZON’s purchase obligations, whereas the purchase orders set forth in Section 4.5 serve financial transactional purposes only. Thus, in the unlikely event of a contradiction between Section 4.4 (Forecasts) and 4.5 (Purchase Orders) regarding HORIZON’s purchase obligations, Section 4.4 shall prevail.

4.5 Purchase Orders

4.5.1 For financial transaction purposes and to document the agreed shipment date when purchasing PRODUCT or EXCESS MATERIAL hereunder, HORIZON shall submit written purchase orders to BI in accordance with the binding forecast as set forth under Section 4.4 above. The Parties acknowledge that due to the internal guidelines, procedures or systems of a Party it might not be avoidable that communication or documents and the like are issued containing a reference to the general terms and conditions of such Party. Moreover, each Party acknowledges that the other Party for such reasons as outlined in the previous sentence might not be able to avoid the issuance of one or more purchase orders or acceptance documents (or the like) replicating what was already agreed upon in this AGREEMENT and which due to technical reasons of the system might contain a reference to such other Party’s general terms and conditions. Therefore, the Parties agree that the general terms and conditions of the Parties shall not apply, even if reference is made thereto in such purchase order (or the like) or any other communication or documents related to this AGREEMENT.

4.5.2 Purchase orders shall include (i) the ordered quantity of PRODUCT and/or EXCESS MATERIAL, as applicable, (ii) the agreed shipment date(s), (iii) the price, (iv) the designation of HORIZON’s carrier; and (v) any other information dictated by the circumstances of the order.

4.6 Shipment of Product and Material by BI

4.6.1 DELIVERED MATERIAL and all material (e.g. samples) shall be shipped […] at the FACILITY and shipped to HORIZON or as directed by HORIZON, in accordance with
with [...***...] and in accordance with the QUALITY ASSURANCE AGREEMENT. HORIZON’s designated carrier shall be used to ship DELIVERED MATERIAL to the site designated by HORIZON. BI shall use commercially reasonable efforts to notify HORIZON in writing upon loading of the DELIVERED MATERIAL onto such designated carrier. The Parties acknowledge and agree that [...***...] shall be responsible and bear the cost [...***...] the DELIVERED MATERIAL onto the [...***...] carrier such that [...***...] onto the HORIZON designated carrier. Risk of loss in transit by [...***...].

4.6.2 BI will provide or will have provided assistance to HORIZON regarding necessary procedures for exportation and/or importation of DELIVERED MATERIAL.

4.7 Testing and Rejection

4.7.1 HORIZON shall as soon as reasonable practicable and in any case within [...***...] (solely with respect to OBVIOUS DEFECTS that are readily apparent upon visual inspection) or [...***...] (for all other OBVIOUS DEFECTS), from the date of physical receipt of DELIVERED MATERIAL delivered to HORIZON hereunder, reject such delivery (in whole or in part) in the event that it is Non-CONFORMING due to an OBVIOUS DEFECT by written notice thereof to BI, indicating the relevant BATCH description and HORIZON’s reasons for rejection. If HORIZON fails to notify BI within said [...***...] time period, HORIZON shall be deemed to have accepted such delivery and HORIZON shall not be entitled to any remedies for such OBVIOUS DEFECTS under this AGREEMENT, including but not limited to this Section 4.7 and 11. Notwithstanding the foregoing, HORIZON shall have the right to revoke its acceptance of such DELIVERED MATERIAL if it later discovers LATENT DEFECTS not reasonably discoverable at the time of receipt, and retains all rights and remedies hereunder with respect to such LATENT DEFECTS, subject to the time limitations set forth in Section 4.7.3.

4.7.2 HORIZON shall have [...***...] from the date of discovery that the DELIVERED MATERIAL is Non-CONFORMING owing to a LATENT DEFECT, to reject such DELIVERED MATERIAL (in whole or in part) by written notice thereof to BI, indicating the relevant BATCH description and HORIZON’s reasons for rejection. If HORIZON fails to so notify BI within said [...***...] time period, HORIZON shall be deemed to have accepted such delivery of DELIVERED MATERIAL and HORIZON shall not be entitled to any remedies for such LATENT DEFECT under this under this AGREEMENT, including but not limited to this Section 4.7 and Section 11.

4.7.3 Notwithstanding the above, any and all remedies for Non-CONFORMING PRODUCT pursuant to this Section 4.7 shall be time-barred following expiration of the RESIDUAL SHELF LIFE of such PRODUCT. BI’s warranties under Section 4.3.3 with respect to such PRODUCT shall expire upon expiration of the RESIDUAL SHELF LIFE of such
PRODUCT, and BI shall have no liability under Section 11.1 with respect any product liability due to the use of any PRODUCT following the expiration of its RESIDUAL SHELF LIFE.

4.7.4 If BI receives a notice from HORIZON pursuant to Section 4.7.1 or 4.7.2 that HORIZON does not accept any DELIVERED MATERIAL supplied hereunder, then BI shall immediately start re-testing the DELIVERED MATERIAL using the retained samples in order to evaluate process issues and other reasons for such non-compliance.

4.7.5 If BI does not accept HORIZON’s assertion that the rejected DELIVERED MATERIAL is Non-CONFORMING:

   (i) BI will provide written notice to HORIZON that the rejection is not accepted stating in detail the reasons for BI’s assertion that the DELIVERED MATERIAL is CONFORMING. Such written notice by BI shall be provided to HORIZON within […] after receipt of HORIZON’s notice of rejection pursuant to Section 4.7.1 or 4.7.2; and

   (ii) both Parties will try to find a mutually acceptable solution through referral to the STEERING COMMITTEE in accordance with Section 7.2. If the STEERING COMMITTEE fails to find a mutually acceptable solution within […] after HORIZON’s receipt of BI’s notice under sub-Section 4.7.5(i) above, then:

   (iii) HORIZON shall immediately provide a representative sample of the DELIVERED MATERIAL from the relevant shipment received by HORIZON and/or related documentation to a mutually agreed upon, independent THIRD PARTY who shall be responsible for determining whether the relevant DELIVERED MATERIAL rejected by HORIZON is CONFORMING or Non-CONFORMING; and

   (iv) BI shall immediately provide to such mutually agreed upon, independent Third Party a representative sample of DELIVERED MATERIAL from the relevant shipment delivered to HORIZON and/or all documentation relating to the manufacture of the relevant DELIVERED MATERIAL that the independent THIRD PARTY deems necessary to fulfill its obligations.

Both Parties shall be bound by the determination of such independent THIRD PARTY (such determination to be made in accordance with the timelines as set forth in the investigation plan) which determination shall be made in writing and shall include reasoning, and the Party against which the determination is made shall bear all costs associated with such THIRD PARTY determination, including those of the Party in whose favour the THIRD PARTY determination is given. The independent THIRD PARTY shall be required to enter into written undertakings of confidentiality and non-use with respect to CONFIDENTIAL INFORMATION no less burdensome than those set forth in this AGREEMENT.

4.7.6 Whether or not BI accepts HORIZON’s assertion that the DELIVERED MATERIAL rejected by HORIZON in accordance with Section 4.7.1 or 4.7.2 is Non-CONFORMING and

***Confidential Treatment Requested
irrespective of the independent THIRD PARTY determination referred to in Section 4.7.5, BI shall, upon receipt of the notice of rejection, consult with HORIZON and use commercially reasonable efforts, as soon as reasonably practicable as mutually agreed by the Parties, to (i) provide a replacement shipment for the DELIVERED MATERIAL rejected by HORIZON, (ii) rework or reprocess (solely to the extent permitted under, and in accordance with, the QUALITY ASSURANCE AGREEMENT) the Non-CONFORMING DELIVERED MATERIAL in accordance with the Parties’ quality system procedures and the Parties’ mutual agreement thereto and deliver such reworked or reprocessed DELIVERED MATERIAL to HORIZON (which shall remain subject to the RESIDUAL SHELF LIFE provisions of Section 4.4.4) or (iii) issue a credit note for any payments made by HORIZON for the Non-CONFORMING DELIVERED MATERIAL.

4.7.7 If any DELIVERED MATERIAL rejected by HORIZON in accordance with Section 4.7.1 or 4.7.2 is ultimately determined to be Non-CONFORMING or BI accepts that the DELIVERED MATERIAL is Non-CONFORMING, BI shall bear all expenses (including raw materials) for any manufacture and shipment of replacement or reworked/reprocessed DELIVERED MATERIAL, provided that the replacement cost for a vial of a cell line shall be and not exceed [...***...] (with any costs in excess being at HORIZON’s expense). In addition, BI shall make arrangements for the return or disposal, at BI’s sole discretion, of the Non-CONFORMING DELIVERED MATERIAL, provided, however, that in the case of PRODUCT that has been distributed (whether commercially or for clinical trials), such PRODUCT shall be subject to Section 9.2. BI shall pay or reimburse HORIZON for any reasonable return shipping charges or out-of-pocket costs incurred by HORIZON for any return shipment or lawful disposal of such Non-CONFORMING DELIVERED MATERIAL in accordance with BI’s reasonable instructions.

4.7.8 If any Product rejected by HORIZON pursuant to Section 4.7.1 or 4.7.2 is ultimately determined to be CONFORMING, HORIZON shall either make payment to BI in accordance with Section 5 not only for the prices relating to the original shipment of the relevant PRODUCT now determined to be CONFORMING, but also for the prices relating to the replacement shipment of Product, or BI shall balance out the credit note issued pursuant to Section 4.7.6.

4.7.9 In addition to the provisions relating to the same set out in this AGREEMENT, acceptance and rejection, inspection and testing of DELIVERED MATERIAL shall be subject to each Parties’ rights and obligations as set out in the QAA.

4.7.10 If BI becomes aware that any shipment of PRODUCT to HORIZON is Non-CONFORMING, BI will promptly notify HORIZON in accordance with the QUALITY ASSURANCE AGREEMENT.

4.7.11 Sec. 377 of the German Commercial Code (HGB) is expressly excluded.

4.8 Risk Management and Business Continuity Plan
4.8.1 Risk Management. In order to ensure continuity of supply of PRODUCT and in connection with diligent risk management practices, BI will develop, implement and keep current a risk management program, including a Business Continuity Plan and business continuity plans with its suppliers of critical components. As used herein, a “critical component” means any component, item, material or service required to manufacture or transport DRUG SUBSTANCE or PRODUCT and for which no suitable replacement is readily available in time to meet obligations regarding shipment date, quantity or quality of DRUG SUBSTANCE or PRODUCT. […***…].

4.8.2 “Business Continuity Plan” shall mean a plan detailing strategies for responses to and recovery from a range of potential disruptive events and clearly defining and documenting a set of measures designed to (i) allow for a quick response to a disruptive event so that the business process is restored to the minimum required operational level and/or (ii) recover the business process in a defined time frame. Such plan shall cover in particular all key personnel, resources, services and actions which are required to manage the business continuity management process, and identify available alternative facilities, infrastructure and adequate inventories. Additionally, the Business Continuity Plan shall provide for security and protective measures necessary to ensure minimal impact of the range of potential disruptive events on HORIZON. The Business Continuity Plan is attached to this AGREEMENT as Exhibit 15 and may be revised from time to time by the Parties’ written agreement. HORIZON shall have the right to review the then-current Business Continuity Plan at the FACILITY.

4.8.3 BI shall have in place an adequate business continuity plan with its suppliers of critical components, which plan shall include, without limitation, retaining alternative back-up supply to the extent such back-up supply can be made available on commercially reasonable terms and regularly reviewing all such back-up supply and its ability to supply at short notice.

4.8.4 HORIZON shall have the right to inspect and review the Business Continuity Plan and the business continuity plans with its suppliers of critical components in the course of HORIZON’s scheduled visits at the FACILITY.

4.9 Continuity of Supply

4.9.1 BI acknowledges that it is critical that HORIZON be ensured continuity of supply of DRUG SUBSTANCE and PRODUCT for use in clinical trials and market supply. BI shall ensure continuity of supply of DRUG SUBSTANCE and PRODUCT for use in clinical trials and market supply. Nevertheless, due to the potentially growing market demand of PRODUCT, BI’s ability to manufacture and supply DRUG SUBSTANCE and PRODUCT shall be carefully observed by HORIZON.

4.9.2 BI shall supply the ordered quantities of DRUG SUBSTANCE to HORIZON in accordance with the respective HORIZON order. In the event of a MATERIAL SUPPLY BREACH, the matter of second source manufacture of DRUG SUBSTANCE and/or PRODUCT
and any potential next steps shall be discussed in good faith by the Parties’ executive officers, subject to the remainder of this Section 4.9.

4.9.3 Should at any time BI have any indication that continuity of supply for PRODUCT can not be ensured, BI shall immediately inform HORIZON thereof in writing. In event HORIZON or BI reasonably believes there may be an interruption in supply, the matter would be immediately forwarded to executive officers of each Party to discuss second source manufacture of PRODUCT reasonably and in good faith.

4.9.3.1 In the event the STEERING COMMITTEE decides that it is appropriate for HORIZON to establish a second source manufacturer for PRODUCT (e.g. in case of other PRODUCT formats not sourced from BI as described in Section 4.3.2), HORIZON agrees to provide the first opportunity to qualify as a second source manufacturer for PRODUCT to a BI AFFILIATE. Accordingly, BI shall promptly nominate a BI AFFILIATE as such a second source manufacturer and, if such BI AFFILIATE is approved by HORIZON, shall use its commercially reasonable efforts to qualify such BI AFFILIATE pursuant to timelines as mutually agreed by the Parties. If such an AFFILIATE is unable to demonstrate to HORIZON’s reasonable satisfaction that it will be able to supply HORIZON’s requirements then HORIZON shall be free to choose an alternate supplier for PRODUCT. In this case BI shall assist HORIZON in transferring the MANUFACTURING PROCESS for PRODUCT to a THIRD PARTY supplier by providing reasonable technical assistance and documentation as necessary for a transfer to a party well skilled in the manufacture of such biotech products at HORIZON’s cost.

4.9.4 In addition, the Parties, through the STEERING COMMITTEE, shall work together in good faith to develop a risk mitigation plan to minimise any risk of interruption in the supply PRODUCT for use in clinical trials and market supply, which plan may include, among other things, production of excess PRODUCT, DRUG SUBSTANCE or materials relating thereto that can be used as a buffer and/or the off-site storage of certain PRODUCT, DRUG SUBSTANCE or materials relating thereto.

4.10 Material Supply Breach

4.10.1 In the event of a MATERIAL SUPPLY BREACH, HORIZON shall provide BI written notification of such MATERIAL SUPPLY BREACH.

4.10.2 Upon BI’s receipt of such notice the Parties shall agree in writing upon a timetable and activity plan to cure such MATERIAL SUPPLY BREACH as promptly as possible (the “CURE PLAN”). If the Parties fail to agree upon such a CURE PLAN within [...***...] from the date of notice of such MATERIAL SUPPLY BREACH, or if BI fails to comply with such CURE PLAN, or if despite BI’s compliance with the CURE PLAN, BI cannot cure the MATERIAL SUPPLY BREACH, then HORIZON shall have the right to purchase from a second source manufacturer, to be agreed upon within the STEERING COMMITTEE in accordance with Section 7.4, such amounts of PRODUCT as necessary to offset BI’s shortfall in fulfilling HORIZON’s purchase orders for such PRODUCT (or the anticipated shortfall).
4.10.3 BI shall evaluate its capabilities and, as applicable, promptly nominate a BI AFFILIATE as a second source manufacturer and, if such BI AFFILIATE
is approved by HORIZON, shall use its commerically reasonable efforts to qualify such BI AFFILIATE as promptly as possible. In the event that:

(i) a BI AFFILIATE can not qualify as a second source manufacturer for PRODUCT or DRUG SUBSTANCE, as applicable, or such a BI AFFILIATE is
unable to demonstrate to HORIZON’s reasonable satisfaction that it will be able to supply HORIZON’s PRODUCT or DRUG SUBSTANCE requirements, and

(ii) provided that PRODUCT or DRUG SUBSTANCE supply as requested by HORIZON by a different second source manufacturer, a company experienced
in manufacturing of biopharmaceuticals derived from [...***…], and selected by HORIZON could demonstrably take place earlier than a MATERIAL
SUPPLY BREACH by BI could be remedied, BI shall assist HORIZON as requested in transferring the MANUFACTURING PROCESS to such a second
source supplier in accordance with Section 14.4.

4.10.4 In the event that BI reasonably anticipates that there is a substantial likelihood that a MATERIAL SUPPLY BREACH will occur, BI shall immediately
notify HORIZON in writing thereof. Upon receipt of such notice, the Parties shall immediately confer to discuss the circumstances and magnitude of such
potential MATERIAL SUPPLY BREACH, and to determine in good faith whether there are any steps that BI could take to avoid such MATERIAL SUPPLY
BREACH. If HORIZON is not reasonably satisfied that BI will be able to avoid such MATERIAL SUPPLY BREACH, then HORIZON shall forward this
issue to the STEERING COMMITTEE to determine whether it is necessary or desirable to establish a second source manufacturer to prevent such a
MATERIAL SUPPLY BREACH from occurring.

4.10.5 Nothing in this Section 4.10 shall affect HORIZON’s rights under Section 14 of this AGREEMENT or any right or remedy otherwise available to
HORIZON in connection with such MATERIAL SUPPLY BREACH.

4.11 Manufacturing [...***…] Commitment

BI shall maintain at all times during the term of this Agreement [...***…] manufacturing [...***…] at the FACILITY that has been approved by the
applicable HEALTH AUTHORITIES for the manufacture of PRODUCT. In the event a change in the fill and finish manufacturing [...***…] at the
FACILITY due to, e.g., state-of-the art upgrades, would be required after [...***…], the PARTIES shall agree on a transfer plan and associated work
packages for such fill and finish line transfer, FMEA (failure mode effect analysis) and drug product validation which would be covered by HORIZON as
CHANGE ORDER.

4.12 Extension of Territory
If HORIZON desires to extend the TERRITORY, e.g., to include […***…], the Parties shall in accordance with Section 15.9 negotiate in good faith an amendment to this AGREEMENT, which shall include agreement on the required measures and cGMP and associated costs.

5. PRICES AND PAYMENT

5.1 The price of PRODUCT for clinical and market supply are set forth in Exhibit 10. Commencing in […***…], the price for the PRODUCT as set forth in Exhibit 10 will be adjusted year by year in accordance with […***…]. Payments by HORIZON to BI under this AGREEMENT shall be in EUROS.

5.2 […***…] will be […***…] which are […***…] at the time such […***…]. […***…], BI shall only purchase and maintain at any given time such quantities of COMPONENTS as reasonably necessary to manufacture and supply the PRODUCT to HORIZON in accordance HORIZON’s forecast and this AGREEMENT and shall use reasonable efforts to maintain the level of inventory of COMPONENTS to a […***…]. […***…] shall be entitled […***…] selected by […***…], which […***…] on verification concerning […***…]. BI shall provide HORIZON with […***…] prior notice of any price adjustment.

5.3 BI shall submit to HORIZON appropriate invoices for the price of the DELIVERED MATERIAL and any fees for services agreed upon by the Parties; provided, however, that with respect to the price of the DELIVERED MATERIAL, BI shall submit invoices therefor only […***…] of DELIVERED MATERIAL by BI according to Section 4.6. The price for DELIVERED MATERIAL or any services agreed by the Parties shall be paid to BI no later than […***…] after the date that BI’s invoice is received by HORIZON. Payment of the invoice amounts shall be made in Germany, […***…], into an account as stated in the respective invoice, which account may change from time to time.

5.4 All payments owed to BI by HORIZON on the basis of accounts rendered shall be made in such a way that […***…] shall […***…] on such […***…]. In the event of a default in payment for whatever reason, default interest at a rate of […***…] p.a. shall be payable on the outstanding amount due. BI
reserves the right to claim any damage exceeding such amount that shall have been caused by such delay, subject to Section 12.1.

5.5 Fees for additional services. As consideration for any additional development work and/or additional commercial services pursuant to this AGREEMENT to be agreed upon by the Parties and covered in a CHANGE ORDER, HORIZON shall pay to BI the fees as set forth in such CHANGE ORDER and corresponding billing plan set forth in Exhibit 9.

6. QUALITY ASSURANCE AND COMPLIANCE WITH LAW

6.1 Quality Assurance Agreement. Simultaneously with the execution of this Agreement, or prior to such execution, the Parties shall amend and update the QUALITY ASSURANCE AGREEMENT. Such amended and updated QUALITY ASSURANCE AGREEMENT is hereby incorporated by reference herein and that it shall apply to any DRUG SUBSTANCE and PRODUCT produced under this AGREEMENT. The QUALITY ASSURANCE AGREEMENT shall in no way determine liability or financial responsibility of the Parties for the responsibilities set forth therein. In the event of a conflict between any of the provisions of this Agreement and the QUALITY ASSURANCE AGREEMENT in matters of business, financial or legal nature, the terms of this Agreement shall control and for matters of quality processes (including with respect to PRODUCT disposition), the terms of the Quality Agreement shall prevail. The QUALITY ASSURANCE AGREEMENT may be amended from time to time by the Parties only in accordance with Section 15.9.

6.2 Manufacturing Facilities

BI represents and warrants that it shall obtain all relevant APPROVALS required by the relevant HEALTH AUTHORITIES for the FACILITY and that its and its AFFILIATES’ respective manufacturing facilities conform, and will during the term of this AGREEMENT conform, to cGMP.

6.3 Compliance with Law

6.3.1 BI shall comply, and shall ensure that its AFFILIATES and PERMITTED SUBCONTRACTORS comply, with all applicable rules, laws and regulations in [***], as applicable to a biopharmaceutical manufacturer in [***] (including without limitation cGMP) in performing its obligations under this AGREEMENT. HORIZON shall comply with all applicable rules, laws and regulations in performing its obligations under this AGREEMENT.

6.3.2 All costs in connection with maintaining BI’s compliance with all applicable regulatory requirements applicable to a biopharmaceutical manufacturer in [***] and cGMP in performing under this AGREEMENT, including but not limited to the maintenance and upgrading of technical facilities and infrastructure and the training of personnel, shall be borne by [***]. [***]
6.3.3 If a HEALTH AUTHORITY requests or requires that a change be made to the DRUG SUBSTANCE SPECIFICATIONS, PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS, then BI shall make such changes in accordance with the QUALITY ASSURANCE AGREEMENT and SOPs (i.e., change control procedures) agreed in writing by HORIZON and BI. Those changes are subject to written approval of each Party, which approval shall not be unreasonably withheld, delayed or conditioned. In case that a request from a HEALTH AUTHORITY may be challenged by either Party, HORIZON and/or BI shall use commercially reasonable efforts to challenge the requests of the HEALTH AUTHORITY and shall assist each other in its communication with the pertinent HEALTH AUTHORITY requesting such a change. The costs for such a change shall be allocated between the Parties according to Section 6.3.2.

6.3.4 If HORIZON desires (for any reason other than a request or requirement by a HEALTH AUTHORITY), to change the DRUG SUBSTANCE SPECIFICATIONS, PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS, then BI shall use reasonable commercial efforts to accommodate such request, subject to the remainder of this Section 6.3.4 below.

6.3.4.1 HORIZON shall promptly advise BI in writing of any such change(s), and provide information necessary for BI to evaluate the effect of such change(s). BI shall promptly advise HORIZON as to scheduling changes, if any, which may result from such change(s). The notification and approval procedure shall be in accordance with SOPs (i.e. change control procedures) agreed by the Parties from time to time, as described in the QUALITY ASSURANCE AGREEMENT. The Parties shall hold a meeting in a timely manner to discuss such changes as appropriate.

6.3.4.2 Prior to implementation of any change(s), BI shall provide HORIZON with a quote of the price of the services (which price shall be reasonable in nature and consistent with industry standards) and COMPONENTS that will be provided and purchased by BI in order to implement any such change(s) to the DRUG SUBSTANCE SPECIFICATIONS, PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS, including, but not limited to, the price of BI’s validation and analytical services. If such changes will be implemented, then HORIZON shall pay the price of the services and COMPONENTS described in this Section.

6.3.4.3 BI shall make changes as described in this Section 6.3.4 in accordance with timelines agreed to by the Parties, except that BI shall have no obligation to make any such change where doing so, (i) in BI’s reasonable judgment after due consultation with legal counsel having experience in such matters, which shall be communicated in writing to HORIZON, would violate ***Confidential Treatment Requested
any applicable law or regulations, or (ii) has a material adverse effect upon any regulatory filings for other products of BI or (iii) would be incompatible with BI's established operations for biopharmaceuticals. For all changes requested by HORIZON, BI shall cooperate with HORIZON in good faith to implement all agreed upon changes to DRUG SUBSTANCE SPECIFICATIONS, PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS in accordance with the timelines agreed to by the Parties according to this Section 6.3.4.3.

6.3.5 HORIZON acknowledges and agrees that the Parties must agree in advance as of which point in time and to which manufacture of BATCHES of DRUG SUBSTANCE or PRODUCT changes to the DRUG SUBSTANCE SPECIFICATIONS, PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS apply. However, HORIZON acknowledges and agrees that changes to the DRUG SUBSTANCE SPECIFICATIONS, PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS during an ongoing campaign are not possible.

6.3.6 If any changes to the DRUG SUBSTANCE SPECIFICATIONS, PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS render obsolete or unusable any COMPONENTS and if and to the extent those COMPONENTS may not be returned to the appropriate vendor for a credit, BI shall either destroy or deliver to HORIZON, at HORIZON’s sole option, those obsolete or unusable COMPONENTS. HORIZON shall reimburse BI for the costs of such COMPONENTS destroyed or provided to HORIZON to the extent the amount of COMPONENTS that would have been reasonably required for BI to maintain in inventory in order to meet its obligations under this AGREEMENT (consistent with its obligations under Section 5.2 hereof with respect to the COMPONENTS).

6.3.7 HORIZON may request additional regulatory services support from BI (e.g., those set forth in Sections 3.1.2.3 and 3.2) with respect to the DRUG SUBSTANCE or PRODUCT, in support of either obtaining or maintaining regulatory approval in any country of the TERRITORY. In such event, BI shall provide a quote of the price of such services (which pricing shall be reasonable in nature and consistent with industry standards), and shall provide such additional regulatory services upon mutual agreement on the scope and price of such services. For purposes of clarity and notwithstanding anything to the contrary contained in this Agreement, for purposes of maintaining regulatory approvals existing as of the EFFECTIVE DATE of this Agreement in any country of the TERRITORY, BI will draw up the annual report required by the HEALTH AUTHORITIES pursuant to Section 3.1.2.5, [...***...], without additional cost or expense to HORIZON. All costs for any further stability studies requested by HORIZON shall be borne by HORIZON, unless such further stability studies are necessary due to BI's breach of this AGREEMENT, in which event BI shall bear the costs thereof. HORIZON will inform BI in due time which regulatory support is requested from BI. Further, all costs for any translation services that relate solely to such regulatory services support from BI shall be borne directly by HORIZON.

6.3.8 HORIZON shall bear the costs for HEALTH AUTHORITY regulatory inspections
that are solely related to PRODUCT as set forth in Section 6.3.2 and Exhibit 14. With respect to HEALTH AUTHORITY regulatory inspections that are substantially related to PRODUCT as well as other products, Horizon shall bear such costs proportionally to the amount of time such inspection is specifically directed to the PRODUCT relative to the entirety of the inspection, and solely to the extent that such costs are not incurred by BI in the ordinary course of its business. For clarity, any costs incurred in connection with inspections that relate to the manufacture, use, sale or other disposition of IMUKIN PRODUCT by or on behalf of BI prior to the Closing Date (as defined in the ASSET PURCHASE AGREEMENT) shall be borne by BI.

6.4 Environmental

BI shall ensure proper disposal of any and all hazardous waste materials involved with the manufacture of DRUG SUBSTANCE and PRODUCT that are generated or resulting from the activities performed hereunder, if any, in full compliance with all applicable laws and regulations at BI’s sole liability and expense.

6.5 Person-in-Plant

During the term of this AGREEMENT HORIZON may reasonably request that up to [*...***...] experienced technical or quality personnel of HORIZON, which may be employees or contractors, (each, a “PIP”) be present at the FACILITY during manufacture under this AGREEMENT, to the extent set forth below, for the purpose of observing manufacturing of PRODUCT or DRUG SUBSTANCE, participating in reviews, acting as liaison / single point of contact between HORIZON and BI with respect to MANUFACTURING PROCESS related issues and performing such other actions set forth in the QAA. Such PIP shall be entitled to make decisions on quality and/or technical matters related to the PRODUCT and DRUG SUBSTANCE. HORIZON shall provide BI with [...***...] notice of such visit by such PIP specifying the function of the PIP. The role, rights and obligations of the PIP when present at the FACILITY shall be as set forth below in this section, together with any additional responsibilities, authorities and obligations as may be set forth in the QAA.

The PIP’s presence at the FACILITY shall be limited to the active manufacturing operational hours of the PRODUCT and DRUG SUBSTANCE and the PIP’s access to the FACILITY shall be limited to MANUFACTURING PROCESS steps in accordance with a mutually agreed schedule.

BI shall ensure that the PIP at the FACILITY is kept reasonably informed of the relevant issues which may affect the PRODUCT and/or DRUG SUBSTANCE quality and will use the PIP to coordinate the performance of activities with respect thereto that are the responsibility of HORIZON.

The PIP at the FACILITY shall at all times:

• be accompanied by BI’s personnel for safety and confidentiality reasons; and
• observe BI’s house rules, regulations, confidentiality rules and requirements, standard procedures, safety requirements and security procedures, to the extent previously disclosed in writing by BI to HORIZON; and

• operate in a manner as not to adversely interfere with operations at the FACILITY or at the premises, and not give any instruction to BI or personnel; and

• respect any instructions provided by BI regarding presence in the FACILITY and overall use of BI’s premises and EQUIPMENT at the FACILITY.

With respect to any PIP present at the FACILITY during the term of this AGREEMENT, BI shall provide, at no cost to HORIZON, (i) space in an on-site office along with reasonable access to conference rooms (as necessary for meetings and telephone conferences of a proprietary nature), routine office supplies, parking, and cafeteria facilities; (ii) reasonable access to and use of high-speed internet (but not BI’s intranet) and photocopying services and (iii) such other reasonable and customary business accommodations as are necessary for such PIP to perform its activities as described above.

HORIZON shall comply with all responsibilities under applicable laws concerning the employment or engagement of the PIP. In addition, HORIZON shall ensure that the PIP will be fully insured while working at the FACILITY. HORIZON acknowledges that according to local immigration and/or employment laws, BI may need to obtain a deployment authorization for the PIP from the local authorities before any scheduled visit of the PIP to the FACILITY. HORIZON and the respective PIP shall timely provide BI with the necessary information requested by BI, and BI shall timely process such information, to request a deployment authorization for the PIP from the local authorities. HORIZON further acknowledges that notwithstanding BI’s diligent processing of such a request, the six-week notification period set forth above may not be sufficient to secure a deployment authorization, if necessary, before the scheduled visit to the FACILITY.

HORIZON shall bear its own costs with respect to the PIP’s presence at the FACILITY and BI shall not charge fees for any PIP’s presence.

7. CO-OPERATION AND CO-ORDINATION BETWEEN THE PARTIES

7.1 PROJECT LEADER

In order to implement the additional services for […]***…], and in any case the PARTIES agree to introduce other changes to the MANUFACTURING PROCESS and/or the DRUG SUBSTANCE or the PRODUCT, such changes shall be agreed upon and implemented in the format of a project. Upon commencement of a project, BI and HORIZON will each appoint a project leader (“PROJECT LEADER”), who will coordinate and supervise the project including communication of all instructions and information concerning the project to the other Party. The PROJECT LEADER will serve as contact person for the other Party. Each PROJECT LEADER

***Confidential Treatment Requested
will be available on an agreed (monthly) basis for consultation at prearranged times during the course of the Project. The PROJECT LEADERs shall be copied on all correspondence by other JOINT PROJECT TEAM members and all correspondence between the PARTIES. In the absence of the PROJECT LEADER, a substitute shall be appointed. Additional modes or methods of communication and decision making may be implemented with the mutual written consent of each PARTY. Each PARTY will use reasonable efforts to provide the other PARTY with […] prior written notice of any change in such Party’s PROJECT LEADER.

7.2 JOINT PROJECT TEAM

7.2.1 The PARTIES shall establish a JOINT PROJECT TEAM consisting of the necessary disciplines and their respective PROJECT LEADER to (i) ensure the progress of the project, (ii) coordinate the performance of the project, and (iii) facilitate communication among the PARTIES. Each JOINT PROJECT TEAM member shall have knowledge and ongoing familiarity with the project and will possess the authority to make decisions on matters likely to be raised in the JOINT PROJECT TEAM. Each PARTY shall have the right to substitute its members of the JOINT PROJECT TEAM as needed from time to time by giving written notice to the other PARTY due time in advance.

7.2.2 The JOINT PROJECT TEAM shall meet in person or by means of a video conference or teleconference on a periodic basis (i) as agreed by the PROJECT LEADERs after written request for such meeting by either PARTY, or (ii) as specified in the project plan, as amended from time to time.

7.2.3 The JOINT PROJECT TEAM shall oversee a project. Prior to each meeting of the JOINT PROJECT TEAM the PARTIES will distribute to each other written copies of all reasonably necessary materials, data and information arising out of the conduct of their activities hereunder.

7.2.4 Each PARTY shall bear its own costs associated with such meetings and communications. It is the right of each PARTY to call for a JOINT PROJECT TEAM meeting according to the covenants of this Section 7.2 in writing (e-mail sufficient) at any time. In such case the meeting will be held at the other PARTY’s offices (or by means of videoconference or teleconference upon suggestion of the requesting PARTY) at a time mutually agreed to by both PROJECT LEADERs.

7.2.5 In the event that the JOINT PROJECT TEAM is unable to reach agreement on any issue and is unable to make decisions arising out of operational and scientific issues within […*…], each PARTY may call in an expert of its own choice to render advice to the JOINT PROJECT TEAM. Based on the advice of such expert(s) and the team members’ know-how, the JOINT PROJECT TEAM will try to resolve such issue. In the event that the PROJECT TEAM fails to reach agreement on an issue within […*…] of first undertaking resolution of such issue, such issue shall then be referred to the STEERING COMMITTEE for immediate resolution.
7.2.6 The JOINT PROJECT TEAM shall have no authority to amend this Agreement, including any Appendix or CHANGE ORDER. The JOINT PROJECT TEAM shall recommend to the STEERING COMMITTEE for approval changes to any planned activities that are expected to result in increased costs to HORIZON, but shall have no authority itself to approve such activities.

7.3 PRODUCT Team

7.3.1 The day-to-day responsibilities of the Parties with respect to this AGREEMENT shall be overseen by the PRODUCT TEAM, which shall be responsible for deciding operational and scientific issues arising out of this AGREEMENT and unanimously agreeing in good faith with respect to the monitoring of the compliance with this AGREEMENT.

7.3.2 The PRODUCT TEAM shall consist of a team consisting of equal numbers of people, if feasible, each appointed by HORIZON and BI and notified to the other, which appointees may be changed from time to time by the appointing Party on written notice to the other Party. Each member of the PRODUCT TEAM shall be a person of appropriate skill and experience. Either Party may change its own designated PRODUCT TEAM members provided, however, that the total number of members of the PRODUCT TEAM may not be changed, if feasible, nor the number of members representing HORIZON decreased, without the Parties’ prior written agreement. HORIZON’s and BI’s respective functions of the PRODUCT TEAM as of the Effective Date are listed in Exhibit 8.

7.3.3 During the term of this AGREEMENT, the PRODUCT TEAM shall meet regularly to communicate updates and provide a forum for decision-making and rapid resolution of issues arising under this AGREEMENT. Meetings of the PRODUCT TEAM may be conducted by telephone conference, videoconference or face-to-face meetings as agreed by the PRODUCT TEAM.

7.3.4 Decisions of the PRODUCT TEAM shall be reflected in the approved minutes. Meeting minutes shall be prepared in alternate turns by the Parties by the respective PRODUCT MANAGERS of the relevant Party to record all issues discussed and decisions. The Party responsible for meeting minutes shall provide the other Party herewith no later than [...***...] after the relevant meeting has taken place. Minutes that have not been objected to in writing by a Party within said [...***...] of receipt thereof shall be deemed approved by such Party and followed by issuance of the minutes duly executed by the Parties’ PRODUCT MANAGER.

7.3.5 In the event that the PRODUCT TEAM is unable to reach agreement on any issue and is unable to make decisions arising out of operational and scientific issues within [...***...], each PARTY may call in an expert of its own choice to render advice to the PRODUCT TEAM. Based on the advice of such expert(s) and the team members’ know-how, the PRODUCT TEAM will try to resolve such issue. In the event that the PRODUCT TEAM fails to reach agreement on an issue within [...***...] of first undertaking

***Confidential Treatment Requested
resolution of such issue, such issue shall then be referred to the STEERING COMMITTEE for immediate resolution.

7.4 Steering Committee

7.4.1 The Parties shall create a STEERING COMMITTEE consisting of authorized representatives who shall be appointed by HORIZON and by BI in equal numbers, if feasible, and notified to the other Party. The STEERING COMMITTEE shall be responsible for unanimously agreeing in good faith all issues on which the JOINT PROJECT TEAM and/or the PRODUCT TEAM has been unable to reach agreement or that are otherwise delegated under this AGREEMENT to the STEERING COMMITTEE for resolution, and, where possible, make decisions arising out of such issues as well as carry out the specific functions, including but not limited to decisions with an impact on costs and timelines of any activities to be carried out under this AGREEMENT. Each Party may change its own designated STEERING COMMITTEE members by providing written notice thereof to the other Party; provided, however that the total number of members of the STEERING COMMITTEE may not be changed, if feasible, nor the number of members representing HORIZON decreased, without the Parties’ prior written agreement. The functions of the STEERING COMMITTEE are listed in Exhibit 8.

7.4.2 The STEERING COMMITTEE shall attempt in good faith to expeditiously and fairly resolve all issues before it. In the event that the STEERING COMMITTEE is unable to resolve any issue before it within [...***…] from the date that such issue is referred to it, such issue shall be referred to the Chief Executive Officer of HORIZON and BI’s Managing Director for prompt, good faith resolution. If such individuals do not reach agreement on such issue within [...***…] of such referral, then each Party shall be free to pursue all available legal and/or equitable remedies.

7.4.3 Notwithstanding Section 7.4.2, and solely with respect to the determination (a) pursuant to Section 4.9 of whether it is appropriate for HORIZON to engage a second source manufacturer for the manufacture of other PRODUCT formats not sourced from BI as described in Section 4.3.2 or (b) pursuant to Section 4.10.4 of whether it is necessary or desirable to establish a second source manufacturer to prevent such a MATERIAL SUPPLY BREACH from occurring, HORIZON shall in each case have the right to make the final decision on behalf of the STEERING COMMITTEE, without prejudice to Section 14.4.

7.4.4 Decisions of the STEERING COMMITTEE shall be reflected in approved minutes. Meeting minutes shall be prepared by the Parties in alternate turns to record all issues discussed and decisions and the responsible Party shall provide the other Party with a draft for review no later than [...***…] after the relevant meeting has taken place. Minutes that have not been objected to in writing by a Party within [...***…] of receipt thereof shall be deemed approved by such Party and followed by issuance of the minutes duly executed by the relevant members of the STEERING COMMITTEE.

7.5 Limitation of Powers

***Confidential Treatment Requested
The powers of the PROJECT TEAM, PRODUCT TEAM and/or the STEERING COMMITTEE are limited to those expressly set forth in this AGREEMENT. Without limiting the generality of the foregoing, neither the PROJECT TEAM, PRODUCT TEAM nor the STEERING COMMITTEE shall have the right to amend this AGREEMENT or waive compliance with any provision hereof. The actions of the PROJECT TEAM, the PRODUCT TEAM and/or the STEERING COMMITTEE shall not substitute for either Party’s ability to exercise any right, nor excuse the performance of any obligation, set forth herein.

8. INTELLECTUAL PROPERTY AND LICENSES

8.1 The ownership of HORIZON BACKGROUND IP and PRODUCT is and shall remain with HORIZON and shall not vest in BI.

8.2 The ownership of BI’S BACKGROUND IP is and shall remain with BI and shall not vest in HORIZON.

8.3 HORIZON shall have the exclusive ownership of all HORIZON IMPROVEMENTS. [...***...]. BI agrees to assign and hereby assigns to HORIZON all right title and interest it may have in any HORIZON IMPROVEMENTS. BI shall ensure that all entities and individuals that perform any work are subject to an obligation to assign (directly or through their employer) all rights in an HORIZON IMPROVEMENTS to BI, so that they may be further assigned to HORIZON as set forth above. BI shall provide reasonable assistance to HORIZON for any action which may be necessary to assign or otherwise transfer any rights to HORIZON IMPROVEMENTS contemplated by this Section 8.3. BI shall notify HORIZON in writing within [...***... of becoming aware of any HORIZON IMPROVEMENTS.

8.4 BI shall have the exclusive ownership of all BI IMPROVEMENTS. [...***...]. HORIZON agrees to assign and hereby assigns to BI (and/or any designated AFFILIATE) all right, title and interest it may have in any BI IMPROVEMENTS. HORIZON shall ensure that all entities and individuals that perform any work are subject to an obligation to assign (directly or through their employer) all rights in BI IMPROVEMENTS to HORIZON, so that they may be further assigned to BI (and/or any designated AFFILIATE) as set forth above. HORIZON shall provide reasonable assistance to BI (and/or any designated AFFILIATE) for any action which may be necessary to assign or otherwise transfer such rights to BI IMPROVEMENTS contemplated by this Section 8.4.

8.5 BI hereby grants to HORIZON a non-exclusive, perpetual (subject to Horizon’s payment of all undisputed amounts under this AGREEMENT), sublicenseable (through multiple tiers), royalty free license under the BI IMPROVEMENTS and BI BACKGROUND IP (i) to the extent necessary to develop, use, import, offer for sale and sell products containing INTERFERON GAMMA 1b in the name and on the account of HORIZON (or its successor in interest) throughout the world, and (ii) in the event HORIZON is entitled to request a TECHNOLOGY TRANSFER in accordance with Section 14.4.1, to make and have made products containing INTERFERON GAMMA 1b in the name and on account of HORIZON (or
its successor in interest) throughout the world, whereby in each case HORIZON shall assume the costs to be paid by BI for awards to inventors of BI IMPROVEMENTS, as such awards are set forth in written agreements between BI and such inventor or in an applicable industry labor contract or mandatory by applicable laws, but solely to the extent that BI has given HORIZON written notice of such costs and inventors.

8.6 HORIZON hereby grants to BI a non-exclusive, nonsublicensable (except to BI’s AFFILIATES and PERMITTED SUBCONTRACTORS solely to perform the services under and in accordance with this Agreement, without the right to further sublicense) license to use HORIZON BACKGROUND IP and HORIZON IMPROVEMENTS solely for the purpose of manufacturing PRODUCT and DRUG SUBSTANCE for HORIZON, as provided in this AGREEMENT. The license granted under this Section 8.6 shall automatically terminate upon the expiration or effective termination of this AGREEMENT.

9. COMPLAINTS; ADVERSE EVENTS; RECALLS

9.1 Each Party shall inform the other Party of any complaints, adverse reaction reports, safety issues or toxicity issues relating to any PRODUCT in accordance with the SDEA (as defined in Section 3.1.2.2) and/or the QUALITY ASSURANCE AGREEMENT.

9.2 Recalls

9.2.1 HORIZON shall notify BI within [***] if any DELIVERED MATERIAL (including, without limitation, clinical trial material) manufactured by BI hereunder is the subject of a recall, withdrawal or correction, and HORIZON and/or its designee shall have the sole responsibility for the handling and disposition of such recall, market withdrawal or correction. In the event that a recall is required directly due to BI’s breach of any of its warranties set forth in Section 10.2 hereof, BI shall reimburse HORIZON for the purchase price of such DELIVERED MATERIAL and all other reasonable costs and expenses associated with such DELIVERED MATERIAL recall, market withdrawal or correction, but only to the extent that the foregoing costs and expenses are attributable to BI’s breach of its warranties hereunder. In all other events of a recall, all costs and expenses incurred in connection with such PRODUCT recall shall be borne by HORIZON, and BI shall be entitled to charge HORIZON for reasonable costs and expenses for BI’s support to HORIZON in handling a recall. Notwithstanding the foregoing, if each of BI and HORIZON contribute to the cause of a recall, the costs and expenses shall be shared in proportion to each Party’s responsibility, provided however that the limitation of liability according to Section 12 shall apply. HORIZON and/or its designee shall serve as the sole point of contact with the FDA or other applicable HEALTH AUTHORITY concerning any recall, market withdrawal or correction with respect to the DELIVERED MATERIAL.

9.3 Insurance

During the term of this AGREEMENT and following the term of this Agreement for the remainder of the shelf life of all DRUG SUBSTANCE and PRODUCT supplied to HORIZON hereunder, the Parties shall maintain product liability insurance in such amounts and with such

***Confidential Treatment Requested
scope of coverage as are adequate to cover the Parties’ obligations under this AGREEMENT and as appropriate for companies of like size, taking into account the scope of activities contemplated herein. Notwithstanding the foregoing the Parties shall maintain minimum limits of product liability of [...] US$ per occurrence and in the aggregate annually. The Parties shall provide to each other within [...] of execution of this AGREEMENT and thereafter, once a year upon the other Party’s request, a certificate of insurance evidencing the respective Party’s product liability insurance. In addition to the foregoing coverage, the Parties shall maintain Commercial General Liability Insurance for limits of not less than [...] US$ per occurrence and in the aggregate annually for bodily injury and property damage. Notwithstanding the foregoing, BI shall have the right to self-insure at any time that it can demonstrate it has the financial resources and capabilities to adequately self-insure against the potential liabilities at levels equivalent to or greater than those set forth above, provided that BI gives HORIZON written notice of such self-insurance. If BI self-insures as set forth above, then it shall provide HORIZON with current information reasonably requested by HORIZON as is necessary to verify BI’s ability to so self-insure.

10. REPRESENTATIONS AND WARRANTIES

10.1 Each Party hereby represents and warrants to the other Party that: (a) the person executing this AGREEMENT is authorized to execute this AGREEMENT; (b) this AGREEMENT is legal and valid and the obligations binding upon such Party are enforceable by their terms; and (c) the execution, delivery and performance of this AGREEMENT does not conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

10.2 BI Warranties

10.2.1 BI represents and warrants (gewährleistet):

10.2.1.1 All DRUG SUBSTANCE manufactured hereunder shall on the MANUFACTURER’S RELEASE date conform to DRUG SUBSTANCE SPECIFICATIONS;

10.2.1.2 All PRODUCT manufactured and supplied hereunder shall at the date of shipment conform to the PRODUCT SPECIFICATIONS;

10.2.1.3 All DRUG SUBSTANCE and PRODUCT manufactured and supplied hereunder shall be in accordance with the applicable MANUFACTURING PROCESS;

10.2.1.4 Subject to Section 10.4, all DRUG SUBSTANCE and PRODUCT manufactured hereunder shall be manufactured, handled, stored, labelled, packaged and transported (within the FACILITY and between the FACILITIES) in accordance with cGMP requirements, the QUALITY ASSURANCE AGREEMENT and all applicable laws, regulations and ordinances of the jurisdiction in which such manufacture occurs;

***Confidential Treatment Requested

Page 39 of 138
10.2.1.5 No DRUG SUBSTANCE or PRODUCT manufactured and supplied to HORIZON hereunder shall be (i) adulterated or misbranded by BI within the meaning of the FD&C Act, or (ii) an article that may not be introduced into interstate commerce under the provisions of Sections 404 or 505 of the FD&C Act;

10.2.1.6 BI shall not use in any capacity the services of any persons debarred under 21 U.S.C. sections 335 (a) and 335 (b) in connection with the manufacture of DRUG SUBSTANCE or PRODUCT under this AGREEMENT; and

10.2.1.7 BI shall comply with those terms of the […***…], that are applicable to BI as a sublicensee thereunder.

10.3 Except as expressly provided for herein, BI makes no further warranties of the merchantability or fitness of the DRUG SUBSTANCE or PRODUCT or any warranties of any other nature, express or implied.

10.4 Notwithstanding the foregoing, BI’s representations and warranties under Section 10.2.1.4 with respect to compliance with cGMP requirements shall not apply to DRUG SUBSTANCE or PRODUCT manufactured as contemplated in Exhibit 17 and/or in the event of a project performed under Sections 7.1 and 7.2, until BI manufactured DRUG SUBSTANCE and PRODUCT […***…], or in the event that an applicable purchase order expressly exempts DRUG SUBSTANCE and/or PRODUCT from compliance with cGMP.

10.5 For clarification purposes, all BI liability or indemnification obligations that might result from the representations and warranties under this Section 10 are always subject to the limitations set forth in Section 12 of this AGREEMENT.

10.6 In the event of a breach of a BI Warranty set forth in Section 10.2.1, HORIZON shall be entitled to the remedies set forth in Section 437 German Civil Code (Bürgerliches Gesetzbuch – BGB) in each case irrespective of BI acting culpable (verschuldsunabhängig).

10.7 HORIZON Warranties

10.7.1 HORIZON represents and warrants (gewährleistet):

10.7.1.1 Any excess non-GMP and/or expired DRUG SUBSTANCE supplied in accordance with Section 4.3.5 will in no event be used in humans.

10.7.2 Except as expressly provided for herein, HORIZON makes no further warranties of any other nature, express or implied.

Page 40 of 138
10.7.3 In the event of a breach of a HORIZON Warranty set forth in Section 10.7.1, BI shall be entitled to the remedies set forth in Section 437 German Civil Code (Bürgerliches Gesetzbuch – BGB) in each case irrespective of HORIZON acting culpable (verschuldnunabhängig).

10.7.4 For clarification purposes, all HORIZON liability or indemnification obligations that might result from the representations and warranties under this Section 10 are always subject to the limitations set forth in Section 12.1 of this AGREEMENT.

11. LIABILITY/INDEMNIFICATION

11.1 Unless this AGREEMENT stipulates otherwise, in the event that a Party violates its obligations under this AGREEMENT, the violating Party shall be liable in accordance with statutory German law, in particular, Sections 280, 281 German Civil Code (Bürgerliches Gesetzbuch – BGB), subject always to Section 12.

11.2 Subject to Section 11.4 and 12, BI shall indemnify, defend and hold harmless (freistellen) HORIZON and its AFFILIATES and their respective officers, directors, employees and agents from and against all Third Party costs, claims, (including death and bodily injury) suits, expenses (including reasonable attorneys’ fees), liabilities and damages (collectively, “LIABILITIES”) arising out of or resulting from (a) any willful or negligent act or omission by BI, its AFFILIATES and/or subcontractors relating to the subject matter of this AGREEMENT, (b) any failure to deliver DELIVERED MATERIAL in accordance with BI’s warranties, or (c) any breach of this AGREEMENT by BI for which BI is responsible in accordance with Section 276 BGB (except in each case to the extent such LIABILITIES arose or resulted from any negligent act or omission by HORIZON or breach of this AGREEMENT by Horizon for which HORIZON is responsible in accordance with Section 276 BGB). For clarity, any indemnification of HORIZON by BI according to this Section 11.2 shall not extend to any LIABILITIES if and to the extent HORIZON is required to indemnify BI according to Section 11.3 below, and shall not exceed BI’s aggregate liability as set forth in Section 12.2 (subject to the exceptions set forth therein).

11.3 Subject to Section 11.4 and 12, HORIZON shall indemnify, defend and hold harmless (freistellen) BI and its AFFILIATES and their respective officers, directors, employees and agents from and against all LIABILITIES arising out of or resulting from (a) any willful or negligent act or omission by HORIZON relating to the subject matter of this AGREEMENT, (b) the use by or administration to any person of DELIVERED MATERIAL manufactured by BI in performance of its obligations under this AGREEMENT or (c) any breach of this AGREEMENT by HORIZON for which HORIZON is responsible in accordance with Section 276 BGB (except in each case to the extent such LIABILITIES arose or resulted from any negligent act or omission by BI, its AFFILIATES or subcontractors, or any failure to deliver DELIVERED MATERIAL in accordance with BI’s warranties, or any breach of any other provision of this AGREEMENT for which BI is responsible in accordance with Section 276 BGB). For clarity, any indemnification of BI by HORIZON according to this Section 11.3 shall not extend to any LIABILITIES if and to the extent arising from any action or omission described in Section 11.2(a), (b) or (c) above.
11.4 A Party and its AFFILIATES and their respective directors, officers, employees and agents which intends to claim indemnification under this Section 11 (each, an “INDEMNITEE”) shall promptly notify the other Party (the “INDEMNITOR”) in writing of any action, claim or other matter in respect of which the INDEMNITEE intend to claim such indemnification; provided, however, that the failure to provide such notice within a reasonable period of time shall not relieve the INDEMNITOR of any of its obligations hereunder except to the extent that the INDEMNITOR is prejudiced by such failure. The INDEMNITEE shall permit the INDEMNITOR at its discretion to settle any such action, claim or other matter, and the INDEMNITEE agrees to the complete control of such defense or settlement by the INDEMNITOR. Notwithstanding the foregoing, the INDEMNITOR shall not enter into any settlement that would adversely affect the INDEMNITEE’s rights hereunder, or impose any obligations on the INDEMNITEE in addition to those set forth herein in order for it to exercise such rights, without INDEMNITEE’s prior written consent, which shall not be unreasonably withheld or delayed. No such action, claim or other matter shall be settled without the prior written consent of the INDEMNITOR, which shall not be unreasonably withheld or delayed. The INDEMNITOR shall not be responsible for any attorneys’ fees or other costs incurred other than as provided herein. The INDEMNITEE shall cooperate fully with the INDEMNITOR and its legal representatives in the investigation and defense of any action, claim or other matter covered by the indemnification obligations of this Section 11. The INDEMNITEE shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

12. LIMITATIONS ON LIABILITY

12.1 In no event shall either Party be liable to the other Party for any consequential, incidental, punitive, special or indirect damages, including, but not limited to, loss of profits, loss of revenue, loss of opportunity or loss of good will, arising in connection with this AGREEMENT except in the case of willful misconduct or willful omission by such Party. For clarity, this Section 12.1 will not apply with respect to claims for which a Party is required to provide indemnification pursuant to Article 11.

12.2 Except as set forth in Section 12.1, BI’s maximum aggregate liability (including its indemnification obligation) under this Agreement shall not exceed [***] or the amount of [***] Euros, except in the event of BI’s willful misconduct or omission.

13. CONFIDENTIALITY

13.1 Each Party shall treat confidentially all CONFIDENTIAL INFORMATION of the other Party, and shall not use or disclose such CONFIDENTIAL INFORMATION other than it is expressly permitted under this AGREEMENT. Each Party will take steps to protect the other Party’s CONFIDENTIAL INFORMATION that are at least as stringent as the steps such Party uses to protect its own CONFIDENTIAL INFORMATION, but in no event shall be less than reasonable. Each Party may disclose the other Party’s CONFIDENTIAL INFORMATION to employees (including those of its AFFILIATES), (sub)contractors, advisors, agents and potential ***Confidential Treatment Requested
or actual merger, acquisition or other business partners who reasonably need to know that CONFIDENTIAL INFORMATION provided that (i) they are bound by written obligations of confidentiality and non-use consistent with those set forth in this AGREEMENT or (ii) that they enter into a legally binding agreement with the disclosing PARTY pursuant to which they agree to observe confidentiality provisions which are substantially similar to those set out in this Section 13 or are bound by confidentiality obligations under applicable laws and/or rules of professional conduct. BI may disclose CONFIDENTIAL INFORMATION for corporate reporting purposes to its AFFILIATES.

13.2 Each Party may disclose CONFIDENTIAL INFORMATION of the other Party hereunder to the extent that such disclosure is reasonably necessary for prosecuting or defending litigation, complying with applicable government regulations, conducting preclinical or clinical trials or obtaining marketing approval for the PRODUCT, provided that if a Party is required by law or regulation to make any such disclosure of the other Party’s CONFIDENTIAL INFORMATION it will, except where impracticable for necessary disclosures, for example in the event of medical emergency, give reasonable advance notice to the other Party of such disclosure requirement and will use its best efforts assist such other Party to secure a protective order or confidential treatment of such CONFIDENTIAL INFORMATION required to be disclosed.

13.3 Neither Party shall disclose CONFIDENTIAL INFORMATION of the other Party in any patent filings without the prior written consent of such other Party.

13.4 The Parties agree that, except as may otherwise be required by applicable laws, regulations, rules, or orders, including without limitation the rules and regulations promulgated by the US Securities and Exchange Commission, and except as may be authorised in Section 13.2, no material information concerning this AGREEMENT and the transactions contemplated herein shall be made public by either Party without the prior written consent of the other. Each Party agrees that it shall cooperate fully and in a timely manner with the other with respect to all disclosures to the Securities and Exchange Commission and any other governmental and regulatory agencies, including requests for confidential treatment of CONFIDENTIAL INFORMATION of either Party included in any such disclosure.

13.5 The Parties expressly acknowledge and agree that any breach or threatened breach of Section 13 by either Party may cause immediate and irreparable harm to the other Party that may not be adequately compensated by damages. Each Party therefore agrees that in the event of such breach or threatened breach by the receiving Party, and in addition to any remedies available at law, the disclosing Party shall have the right to seek injunctive relief, without bond, in connection with such a breach or threatened breach.

13.6 This confidentiality obligations of this Section 13 shall survive the termination or expiration of this AGREEMENT for period of […] or, with respect to CONFIDENTIAL INFORMATION of a THIRD PARTY, for such longer period as is required by the applicable agreement pursuant to which both Parties are bound with regards to the
14. DURATION AND TERMINATION

14.1 Duration

The AGREEMENT shall be effective as of the EFFECTIVE DATE and, subject to Section 14.2, shall continue for an indefinite period or until such earlier date that the Agreement is earlier terminated for cause pursuant to Section 14.2. Each Party may terminate the AGREEMENT for convenience by giving written notice (Textform) with a three (3) year notice period per the end of a calendar month. Notwithstanding Section 14.2, the earliest a notice pursuant to this Section 14.1 may take effect is 30 June 2024.

14.2 Termination for Cause

14.2.1 In the event that a Party materially breaches its obligations under this AGREEMENT (including without limitation a MATERIAL SUPPLY BREACH or a late payment of more than thirty (30) days from its due date), the non-breaching Party may terminate this AGREEMENT for cause (aus wichtigem Grund) in writing (Textform) upon thirty (30) business days prior written notice (Textform) to the breaching Party, unless the breaching Party cures such breach to the non-breaching Party’s reasonable satisfaction during said 30 day period, or initiates remedial steps reasonably acceptable to the non-breaching Party to cure the breach within a reasonable time frame, if such a breach cannot be cured within 30 days. Notwithstanding the preceding sentence, in the event that a Party materially breaches its obligations under this AGREEMENT more than two (2) times in any consecutive twenty-four (24) month period, the non-breaching Party may terminate this AGREEMENT for cause (aus wichtigem Grund) with immediate effect without providing the breaching Party with an opportunity to cure such breach, by giving the breaching Party written notice thereof (Textform).

14.2.2 Each Party may terminate this AGREEMENT with immediate effect by notice in writing (Textform) to the other Party, for cause, if such other Party is adjudicated to be insolvent or files a petition in bankruptcy.

14.2.3 HORIZON may terminate this AGREEMENT with immediate effect by notice in writing (Textform) if HORIZON should be prevented by the HEALTH AUTHORITIES from distributing PRODUCT on the market for all indications. In such event, […] for the following: (A) HORIZON shall either (at HORIZON’s discretion) (i) […] in accordance with the then existing […] (in which case […] or (ii) […] of the unit price of the PRODUCT then in effect for the PRODUCT forecasted in the then existing […] for such […] and (B) […] any non-cancellable costs incurred by BI for COMPONENTS which were purchased by BI at HORIZON’s request to the extent that HORIZON has not yet paid for such COMPONENTS; and (C) […]

***Confidential Treatment Requested
[***]. Notwithstanding the foregoing, [***] under this section in the event that such HEALTH AUTHORITY action is solely due to any breach of BI’s warranties under this AGREEMENT or any negligence or willful misconduct by BI.

14.2.4 Either Party may terminate this AGREEMENT upon thirty (30) days written notice (Textform) to the other Party (or its successor) in the event of a CHANGE OF CONTROL of the other Party (or in the case of HORIZON, of its AFFILIATES who have or have had a direct or indirect connection to this AGREEMENT or the QUALITY ASSURANCE AGREEMENT, or, in the case of BI, of its AFFILIATES who are Permitted Subcontractors) which right of termination shall be exercised within five (5) months after the Party subject to a CHANGE OF CONTROL has informed the other Party of the CHANGE OF CONTROL event, provided that BIs’ rights of termination hereunder shall be limited to a CHANGE OF CONTROL of HORIZON or its Affiliates with the new controlling entity being a direct competitor to BI or its AFFILIATES in the field of contract manufacturing of biopharmaceuticals by means of [***]. Each Party shall inform the other Party in writing (Textform) of a CHANGE OF CONTROL event which gives rise to a right of termination of the other Party pursuant to this Section at the latest within ten (10) Business Days of the implementation of the CHANGE OF CONTROL event.

14.2.5 All payments in connection with early termination shall be due within [***] after receipt by BI of the notice of early termination from HORIZON and receipt by HORIZON of the respective invoice from BI.

14.3 Effect of Termination

14.3.1 In the event of any termination of this AGREEMENT (other than for BI’s material breach or negligence or willful misconduct by BI), HORIZON shall also do one of the following (at HORIZON’s option): (i) HORIZON shall purchase (in which case BI shall sell) PRODUCT [***] or (ii) HORIZON shall pay to BI an amount equal to [***] of the unit price of the PRODUCT then in effect for the PRODUCT [***]; provided, however, that with regard to any [***] by BI at the time of termination, [***] and (B) [***] for any non-cancellable costs incurred by BI for COMPONENTS which were purchased by BI at HORIZON’s request to the extent that HORIZON has not yet paid for such COMPONENTS; and (C) [***]. Notwithstanding the foregoing, in the event of termination by HORIZON under Section 14.2.3 (prevention by HEALTH AUTHORITIES), Section 14.2.3 shall govern and this Section 14.3.1 shall not apply.
14.3.2 In the event of any termination or expiration of this AGREEMENT, at the request of HORIZON, BI shall either (i) destroy all material, including but not limited to samples and all documentation received from HORIZON under this AGREEMENT, the CONSOLIDATED SUPPLY AGREEMENT, the ORIGINAL SUPPLY AGREEMENT or the RESTATED SUPPLY AGREEMENT, or (ii) deliver the same to HORIZON or a party nominated by HORIZON, at HORIZON’s cost (except in the case of termination by HORIZON for BI’s material breach, in which case such destruction or delivery shall be at BI’s cost).

14.3.3 BI shall promptly return all of HORIZON’s CONFIDENTIAL INFORMATION (as well as all CONFIDENTIAL INFORMATION of HORIZON provided to BI under the ORIGINAL SUPPLY AGREEMENT, the RESTATED SUPPLY AGREEMENT or the CONSOLIDATED SUPPLY AGREEMENT) to HORIZON, except for a single copy and/or sample of each item for documentation purposes and for the purpose of compliance with the legal obligations under applicable law only. BI’s responsibility to keep and store all other materials provided by HORIZON in the course of this AGREEMENT shall terminate […] after expiration or termination of this AGREEMENT (except as may be otherwise provided in the QUALITY ASSURANCE AGREEMENT with respect to storage of records and BATCH samples).

14.3.4 HORIZON shall promptly return all of BI’s CONFIDENTIAL INFORMATION (as well as all CONFIDENTIAL INFORMATION of BI provided to HORIZON under the ORIGINAL SUPPLY AGREEMENT, the RESTATED SUPPLY AGREEMENT or the CONSOLIDATED SUPPLY AGREEMENT) to BI, except for a single copy and/or sample for documentation purposes only.

14.3.5 The following provisions shall survive termination of this AGREEMENT: Sections 4.3.6 (2nd paragraph only), 4.4.4, 4.7.2, 6.3.8, 6.4, 8.1, 8.2, 8.3, 8.4, 8.5, 9, 10, 11, 12, 13, 14.2.3, 14.2.5, 14.3, 14.4 and 15. In addition, the applicable terms of the QUALITY ASSURANCE AGREEMENT with respect to the storage of records and BATCH samples for each BATCH of DRUG SUBSTANCE and PRODUCT, or otherwise specified to survive termination, shall also survive the termination of this AGREEMENT. Termination of this AGREEMENT shall not relieve either Party of any liability which accrued hereunder prior to the effective date of such termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this AGREEMENT, nor prejudice either Party’s right to obtain performance of any obligation.

14.4 Technology Transfer

14.4.1 In connection with (i) the establishment of a second source manufacturer pursuant to Section 4.9 or 4.10, or (ii) any expiration or termination of this AGREEMENT, HORIZON shall be entitled to request TRANSFER SUPPORT and/or PROCESS PACKAGE (as defined in Section 2 and below, respectively), as applicable, from BI. Upon receipt by BI of such written request from HORIZON, BI shall, as soon as practicable after such written request, and only to the extent necessary and for the sole purpose that an established manufacturer of biopharmaceuticals at large scale (whether HORIZON or a THIRD PARTY designated by

***Confidential Treatment Requested
HORIZON) may manufacture DRUG SUBSTANCE or PRODUCT (it being understood that there may be separate such manufacturers for DRUG SUBSTANCE and PRODUCT),

(i) Provide reasonable support and assistance to HORIZON with [...] of the then current MANUFACTURING PROCESS of the DRUG SUBSTANCE and/or PRODUCT from BI to HORIZON or such secondary source manufacturer during a period of [...] from HORIZON’s written notice of determination of such different second source manufacturer with a total capacity of [...] at an hourly rate of [...] for upstream, downstream, quality control, quality assurance and analytics (the “TRANSFER SUPPORT”),

and/or

(ii) deliver to HORIZON the PROCESS PACKAGE (as defined in Section 2) consisting of the most current version of the documentation and materials set forth below, always to the extent not already in HORIZON’s possession:

A. MASTER BATCH RECORD (including MASTER BATCH RECORDS for buffers, sampling plans);
B. MANUFACTURER’S RELEASE SPECIFICATIONS;
C. Analytical procedures for in-process control (IPC), release and stability, as applicable;
D. Bill of materials and raw materials specifications;
E. Storage specifications and instructions for DRUG SUBSTANCE and PRODUCT, as applicable, and other materials;
F. Executed BATCH records (i.e. the filled-in MASTER BATCH RECORD) from the most recent three (3) BATCHES;
G. Analytical records from the most recent three (3) BATCHES;
H. Stability protocols and reports, as applicable;
I. Process validation protocols and reports;
J. Method validation protocols and reports;
K. HORIZON material including but not limited to the reference standards, WCB, reagents, and retained DRUG SUBSTANCE and PRODUCT samples, as applicable, including in-process samples, and other than samples a or applicable laws and regulations in the jurisdictions in which such retention of material occurs; and
L. Any other documents, data or materials that the Parties mutually agree are necessary or reasonably required for HORIZON and/or its Affiliates or HORIZON’s designee(s) to manufacture DRUG SUBSTANCE and PRODUCT, as applicable, using the MANUFACTURING PROCESS and support APPROVALS for the PRODUCT, which documents, data and materials may be reflected in a list to be mutually agreed by the Parties, with such agreement not to be unreasonably withheld, delayed or conditioned.

(the TRANSFER SUPPORT under (i) and the PROCESS PACKAGE under (ii) shall collectively be referred to as “TECHNOLOGY TRANSFER”). In the event, the PARTIES agree to additional transfer support activities, such services shall be covered in an additional CHANGE ORDER.

HORIZON shall be solely responsible for any and all regulatory actions and other requirements, activities and actions required by HEALTH AUTHORITIES and any other regulatory authorities or under applicable laws and all related regulatory costs and expenses that arise in conjunction with any TECHNOLOGY TRANSFER.

14.4.2 Except in the event that HORIZON terminates this AGREEMENT for BI’s material breach as set forth in Section 14.2.1, HORIZON shall bear all costs and expenses for any and all TECHNOLOGY TRANSFER. If HORIZON terminates this AGREEMENT for BI’s material breach, then BI shall bear all TRANSFER SUPPORT costs (which, for clarity, include all BI FTE and out of pocket costs incurred in the delivery of the PROCESS PACKAGE).

15. MISCELLANEOUS

15.1 Performance by Affiliates

The Parties recognize that each Party may perform some or all of its obligations under this AGREEMENT through one or more of its AFFILIATES, provided, however, that each Party shall remain responsible for such performance by its AFFILIATES and shall cause its AFFILIATES to comply with the provisions of this AGREEMENT in connection with such performance. Each Party hereby expressly waives any requirement that the other Party exhausts any right, power or remedy, or proceeds against an AFFILIATE, for any obligation or performance hereunder prior to proceeding directly against such Party.

15.2 Force Majeure

Neither Party shall be liable for any failure or delay in performance or non-performance caused by circumstances beyond the reasonable control of such Party, including but not limited to explosion, fire, flood, labour strike or labour disturbances, sabotage, order or decree of any court or action of any governmental authority (except where such order, decree or action is a direct result of BI’s breach of its obligations hereunder), or other causes, whether similar or dissimilar to those specified which cannot reasonably be controlled by the Party who failed to perform
(each such event, a “FORCE MAJEURE EVENT”). A Party affected by a FORCE MAJEURE EVENT shall give notice of such to the other Party as soon as is reasonably possible, and shall resume performance hereunder as soon as is reasonably possible. Each Party shall have the right to terminate this AGREEMENT in the event that a FORCE MAJEURE EVENT continues for more than thirty (30) business days upon written notice thereof.

15.3 Assignment

This AGREEMENT shall be binding upon the successors and assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns. Except as expressly provided for herein, neither this AGREEMENT nor any rights or obligations hereunder may be assigned by either Party without the other Party’s prior written consent (not to be unreasonably withheld or delayed), except that either Party may (a) assign its rights and obligations under this Agreement to any of its AFFILIATES, or (b) assign this AGREEMENT in its entirety to its successor to all or substantially all of its business or assets to which this AGREEMENT relates, unless such successor does not have the financial resources to perform such Party’s obligations under this AGREEMENT in the reasonable judgment of the other Party by submitting pertinent financial information to such other Party. In the event of (b) above: (i) if HORIZON is the assignor, BI reserves the right to terminate this AGREEMENT upon one hundred eighty (180) days prior written notice in the event that such successor is a direct competitor to BI in the field of contract manufacturing of biopharmaceuticals by means of [...***...]; and (ii) HORIZON reserves the right to terminate this AGREEMENT upon one hundred eighty (180) days prior written notice in the event that such successor is a direct competitor to HORIZON in any indication for which PRODUCT is being marketed or sold. In case of an assignment, the assigning party shall immediately notify the other Party about the intended or executed assignment, as applicable, and the assignee. Any subsequent assignee or transferee shall be bound by the terms of this AGREEMENT. Any assignment of this AGREEMENT that is not in conformance with this Section 15.3 shall be null, void and of no legal effect.

15.4 Notices

Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be (i) delivered personally, (ii) sent by registered mail, return receipt requested, postage prepaid or (iii) delivered by facsimile and confirmed by certified or registered mail to the addresses or facsimile numbers set forth below:

**If to HORIZON:**
Horizon Pharma Ireland Limited
Connaught House
1 Burlington Road, Dublin 4
Ireland
Facsimile: +353 1 77 22 101
Attention: VP, Business Development
Copy to: Legal Department

***Confidential Treatment Requested***

Page 49 of 138
15.5 Dispute Resolution; Governing Law

15.5.1 In the event of any controversy or claim arising out of, relating to or in connection with any provision of this AGREEMENT, or the rights or obligations of the Parties hereunder, the Parties first shall try to settle their differences amicably between themselves by referring the disputed matter to the Chief Executive Officer of HORIZON and the board of management (Geschäftsführung) of BI for discussion and resolution. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within [...] of such notice the Chief Executive Officer of HORIZON and the board of management (Geschäftsführung) or one Managing Director (with proper authorization) of BI shall meet for attempted resolution by good faith negotiations. If such personnel are unable to resolve such dispute within [...] of initiating such negotiations, the controversy or claim will be referred to binding arbitration as set forth in Section 15.5.2.

15.5.2 Any controversy or claim arising out of, relating to or in connection with any provision of this AGREEMENT, or the rights or obligations of the Parties hereunder, and not resolved by executive mediation in accordance with Section 15.5.1 hereof, shall be referred to and finally settled by binding arbitration, in accordance with the Rules of Arbitration of the International Chamber of Commerce in force on the date the demand for arbitration is filed, which Rules are deemed to be incorporated by reference into this section. [...]
The language to be used in the arbitral proceedings shall be English. The place of arbitration shall be [...***...]. Any determination by such arbitration shall be final and conclusively binding. Judgment on the arbitral award may be entered in any court having jurisdiction thereof. [...***...].

This AGREEMENT shall be governed by and construed in accordance with the laws of Germany without reference to its conflict of law rules.

The Parties expressly exclude the application of the United Nations Convention on Contracts for the International Sale of Goods to this AGREEMENT.

This Section 15.5 shall also apply to quality disputes that cannot be resolved by the procedures set forth in the QAA.

Each of the Parties hereto is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners or joint venturers, or of principal and agent between the Parties hereto. Neither Party shall have the authority to bind the other Party.

Any delay in enforcing a Party’s rights under this AGREEMENT or any waiver as to a particular default or other matter shall not constitute a waiver of such Party’s rights to the future enforcement of its rights under this AGREEMENT, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

If any of the provisions of this AGREEMENT or parts thereof should be or become invalid, the remaining provisions will not be affected. The Parties shall undertake to replace the invalid provision or parts thereof by a new provision which will approximate as closely as possible the intent of the Parties.

This AGREEMENT, the QUALITY ASSURANCE AGREEMENT, the TERMINATION AGREEMENT and the Exhibits set forth the entire agreement between the Parties, and supersede all previous agreements (including but not limited to the RESTATED SUPPLY AGREEMENT), negotiation and understanding, written or oral, regarding the subject matter.
hereof, excluding, however the LYOPHILISATION DEVELOPMENT AGREEMENT. This AGREEMENT may be modified or amended only by an instrument in writing duly executed on behalf of the Parties. For the avoidance of doubt, this AGREEMENT does not supersede the TERMINATION AGREEMENT entered into by the Parties on June 6, 2007.

The Parties agree that the CONSOLIDATED SUPPLY AGREEMENT is hereby terminated as of the EFFECTIVE DATE and is superseded and replaced by this AGREEMENT. Such termination does not affect any liability, right, remedy or obligation accrued under the CONSOLIDATED SUPPLY AGREEMENT prior to the EFFECTIVE DATE except to the extent expressly set forth in this AGREEMENT.

15.10 Headings
The section headings appearing herein, including those of the exhibits, are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this AGREEMENT.

15.11 Interpretation
In this AGREEMENT, unless the context otherwise requires

(a) the singular includes the plural and vice versa and references to one gender shall include all genders;
(b) the words “includes”, “including” and “in particular” (or any similar term) are not to be construed as implying any limitation and shall be read and construed as if immediately followed by the words “without limitation”;
(c) the terms “Representation(s)”, “Warranty”, Warranties”, “represents” and “warrants” as set forth in this AGREEMENT shall have the meaning as set forth in Section 434 of the German Civil Code (BGB) and shall not be interpreted as a guarantee under Sections 311, 443 or 633 of the German Civil Code (BGB) or any other provision of German law;
(d) references to the recitals/preamble, Sections and Exhibits are to recitals/preamble, sections and exhibits of this AGREEMENT; and
(e) the word “or” means “and/or”.

15.12 Priority of Documents
In the event of a conflict or ambiguity between any term of the ASSET PURCHASE AGREEMENT, this AGREEMENT and its Exhibits and any purchase order or the like, the following order of precedence shall apply (1= highest priority) except where explicitly provided otherwise. The document with the higher priority shall prevail over the document with the lower priority.
1. The ASSET PURCHASE AGREEMENT, except for the event that a provision of this AGREEMENT expressly and specifically states the intent to supersede a specific provision of the ASSET PURCHASE AGREEMENT

2. This AGREEMENT and its Exhibits

4. The QAA and its Exhibits, except for the event that a provision of the QAA expressly and specifically states the intent to supersede a specific provision of this AGREEMENT

5. Any purchase order or the like

15.13 Ambiguities
Ambiguities, if any, in this AGREEMENT shall not be strictly construed against either Party, regardless of which Party is deemed to have drafted the provision at issue.

15.14 Counterparts
The AGREEMENT may be executed in two or more counterparts, each of which shall be an original and all of which shall constitute the same document.

15.15 English Language
The English language will govern any interpretation of or dispute in connection with this AGREEMENT.

[REMAINDER OF PAGE IS INTENTIONALLY BLANK.
THE SIGNATURE PAGE FOLLOWS.]
In Witness Whereof, the Parties hereto have caused this AGREEMENT to be executed by their duly authorized representatives as of the EFFECTIVE DATE.

Biberach an der Riss, Germany

BOEHRINGER INGELHEIM
BIOPHARMACEUTICALS GMBH

By: /s/ Alois Konrad
Name: Alois Konrad
Title: VP, Business & Contracts
Date: June 29, 2017

By: /s/ ppo. Andrea Stöckle
Name: Andrea Stöckle
Title: Head, Legal Biopharmaceuticals
Date: June 29, 2017

Dublin, Ireland

HORIZON PHARMA IRELAND LIMITED

By: /s/ David G. Kelly
Name: David G. Kelly
Title: Director
Date: June 29, 2017
List of Exhibits:
Exhibit 1: Product Specifications
Exhibit 2: Drug Substance Specifications
Exhibit 3: Certificate of Analysis (COA)
Exhibit 4: Certificate of Compliance (COC)
Exhibit 5: DNA sequence of Interferon Gamma lb
Exhibit 6: Product
Exhibit 7 a, b and c: Manufacturing Processes for DRUG SUBSTANCE of Imukin, Actimmune and harmonised process thereof
Exhibit 8: Governance: Product Manager, Product Team and Steering Committee
Exhibit 9: Billing plan for additional services
Exhibit 10: Price
Exhibit 11: Rolling Forecast for Product
Exhibit 12: Territory
Exhibit 13: Permitted Subcontractors
Exhibit 14: Costs of Regulatory Inspections for PRODUCT
Exhibit 15: BCP
Exhibit 16: Manufacturing Process for PRODUCT of Imukin, Actimmune and harmonised process thereof
Exhibit 17: Additional Scope of Services for Process Harmonisation
Exhibit 1: Product Specifications

[...***...]

***Confidential Treatment Requested

Page 56 of 138
[...***...]

Page 57 of 138
Exhibit 2: Drug Substance Specifications

[...***...]

***Confidential Treatment Requested
Exhibit 3: Certificate of Analysis (COA):

[...***...]

Page 64 of 138
Exhibit 4: Certificate of Compliance (COC)

[...***...]

***Confidential Treatment Requested

Page 65 of 138
Exhibit 5: DNA sequence of Interferon Gamma lb
[...***…]

Page 66 of 138
Exhibit 6: PRODUCT

[...***...]

Page 67 of 138

***Confidential Treatment Requested
Exhibit 7 a, b and c: MANUFACTURING PROCESSES

[...***...]

Page 68 of 138

***Confidential Treatment Requested
Exhibit 7 a: MANUFACTURING PROCESS for ACTIMMUNE:

[...***...]

***Confidential Treatment Requested

Page 69 of 138
[...***...]

Page 72 of 138
[...***...]

Page 73 of 138
Exhibit 7 b: MANUFACTURING PROCESS for IMUKIN PRODUCT:
[...***...]

***Confidential Treatment Requested

Page 74 of 138
Exhibit 7 c: Harmonised MANUFACTURING PROCESS for ACTIMMUNE and IMUKIN PRODUCT [...***…]:

[...***…]

***Confidential Treatment Requested
Exhibit 8: Governance

[...***...]

***Confidential Treatment Requested
Exhibit 10: Price

[...***...]

***Confidential Treatment Requested
Exhibit 11: Rolling Forecast for DP

[...***...]

***Confidential Treatment Requested
Exhibit 12: Territory

[...***...]

***Confidential Treatment Requested

Page 93 of 138
Exhibit 13: Permitted subcontractors

[...***...]

Page 94 of 138
Exhibit 14: Costs of Regulatory Inspections for Product

[...***...]

***Confidential Treatment Requested
Exhibit 15: Generic Business Continuity Plan (BCP)

[...***…]
Exhibit 16: Manufacturing Process for PRODUCT of Imukin, Actimmune and harmonised process thereof

[...***...]

***Confidential Treatment Requested
Exhibit 17: Additional Scope of Services for Process Harmonization

[...***...]

Page 105 of 138
[...***...]

Page 114 of 138
[...***...]

Page 122 of 138
[...]***...]

Page 127 of 138
[...***...]

Page 134 of 138
AMENDED AND RESTATED
LICENSE AGREEMENT
BETWEEN
HORIZON ORPHAN LLC
AND
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA
FOR
CASE NOS. SD2006-092, SD2017-110, SD2017-113 AND SD2017-236
<table>
<thead>
<tr>
<th>ARTICLE</th>
<th>TITLE</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>DEFINITIONS</td>
<td>2</td>
</tr>
<tr>
<td>2.</td>
<td>GRANTS</td>
<td>4</td>
</tr>
<tr>
<td>3.</td>
<td>CONSIDERATION</td>
<td>6</td>
</tr>
<tr>
<td>4.</td>
<td>REPORTS, RECORDS AND PAYMENTS</td>
<td>13</td>
</tr>
<tr>
<td>5.</td>
<td>PATENT MATTERS</td>
<td>16</td>
</tr>
<tr>
<td>6.</td>
<td>GOVERNMENTAL MATTERS</td>
<td>20</td>
</tr>
<tr>
<td>7.</td>
<td>TERMINATION OR EXPIRATION OF THE AGREEMENT</td>
<td>21</td>
</tr>
<tr>
<td>8.</td>
<td>LIMITED WARRANTY AND INDEMNIFICATION</td>
<td>23</td>
</tr>
<tr>
<td>9.</td>
<td>USE OF NAMES AND TRADEMARKS</td>
<td>25</td>
</tr>
<tr>
<td>10.</td>
<td>MISCELLANEOUS PROVISIONS</td>
<td>25</td>
</tr>
</tbody>
</table>
AMENDED AND RESTATED LICENSE AGREEMENT

This agreement ("Agreement") is made by and between Horizon Orphan LLC, as successor in interest to Raptor Pharmaceuticals, Inc. (f/k/a Encode Pharmaceuticals, Inc.), a Delaware limited liability company having an address at 150 South Saunders Road, Lake Forest, Illinois 60045 ("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, Office of Innovation and Commercialization, Mail Code 0910, 9500 Gilman Drive, La Jolla, California 92093-0910 ("UCSD"). This Agreement is being entered into as of the date of last signature below ("Execution Date") and is deemed effective as of October 31, 2007 ("Effective Date").

RECITALS

WHEREAS, as of the Execution Date hereof, UNIVERSITY and LICENSEE are parties to that certain License Agreement dated as of October 30, 2012 (entered into as an Amended and Restated License Agreement), as further amended effective as of March 1, 2013 and as of December 16, 2013 (as amended, the "Prior Agreement"), which agreement grants specific rights to the inventions disclosed in UCSD Disclosure Docket No. SD SD2006-092 and titled "Enterically Coated Cysteamine", made in the course of research at UCSD by Drs. Ranjan Dohil and Jerry Schneider; SD2017-110 "Methods of treating non-alcoholic steatohepatitis (NASH) using cysteamine compounds", made with Licensee in the course of research at UCSD by Dr. Dohil; SD2017-113 "Formulations of cysteamine and cystamine", made in the course of research at UCSD by Dr. Dohil; and SD2017-236 “Delayed release cysteamine bead formulation", made with Licensee in the course of research at UCSD by Dr. Dohil (hereinafter and collectively, the “Invention” and “Inventors”) and covered by Patent Rights (as defined herein) and Technology (as defined herein);

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 and UNIVERSITY now wish to restate and further amend the Prior Agreement in order to modify certain terms and conditions thereof in light of the development and commercialization activities that have occurred and are planned with respect to the Licensed Product(s) (as defined below); and

WHEREAS, as of the Execution Date hereof, UNIVERSITY and LICENSEE are parties to that certain License Agreement dated as of December 12, 2012, as amended, with regard to an invention titled “Intravenous cysteamine for rapid elevation of adiponectin levels during myocardial infarction and other situations of oxidative stress/ischemia” (the "CV License"), and the parties are terminating the CV License Agreement as of the Execution Date, and UNIVERSITY has requested, and LICENSEE is willing to accommodate, certain amendments to the Prior Agreement as a result of such termination, as set forth herein.

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 “Commercially Reasonable Efforts” means, [...].

1.3 “Cystinosis Indication” means the diagnosis, prevention or treatment of cystinosis, including nephropathic cystinosis.

1.4 “Field” means all modes of administration and uses whatsoever and, beginning on the Execution Date, specifically excluding intravenous administration for treatment of cardiovascular and ischemic injury or disease.

1.5 “Generic Product” means, with respect to a Licensed Product, any pharmaceutical or biological product that (i) is distributed by a third party under an application for approval approved by a regulatory authority in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of such Licensed Product, including any product authorized for sale (a) in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the Act (21 U.S.C. 355(b)(2) and 21 U.S.C. 355(j), respectively), (b) in the EU pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision) or (c) in any other country or jurisdiction pursuant to all equivalents of such provisions or (ii) is otherwise substitutable under applicable law for such Licensed Product when dispensed without the intervention of a physician or other health care provider with prescribing authority.

1.6 “HD Indication” means the diagnosis, prevention or treatment of Huntington’s Disease.
1.7 “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.

1.8 “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, 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 the Patent Rights.

1.9 “NASH Indication” means the diagnosis, prevention or treatment of nonalcoholic steatohepatitis.

1.10 “Net Sales” means [...***...].

1.11 “Patent Costs” means [...***...].

1.12 “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 Paragraph 1.12 as of the Execution Date.

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)).

***Confidential Treatment Requested
1.14 “Royalty Term” means, with respect to each Licensed Product, the period beginning on the date of the first commercial sale of such Licensed Product and ending on the last to occur of: (i) the expiration of the last-to-expire Patent Rights in the applicable country that covers the making, sale, offer for sale or import of such Licensed Product in such country; and (ii) the ........ of the first commercial sale of such Licensed Product.

1.15 “Sublicense” means an agreement with a third party that is not an Affiliate of LICENSEE 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 that is not an Affiliate which enters into a Sublicense.

1.16 “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.

1.17 “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.

1.18 “Term” means the period of time beginning on the Effective Date and, unless earlier terminated in accordance herewith, ending on the date of expiration of the last Royalty Term for the last Licensed Product in all countries in the Territory.

1.19 “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. The license granted herein is exclusive for Patent Rights and non-exclusive for Technology. Upon expiration of the Royalty Term and provided that all royalty

***Confidential Treatment Requested
payments due hereunder have been paid, LICENSEE shall retain the license granted herein on a continuing fully paid-up royalty-free basis.

2.2 Sublicense.

(a) The license granted in Paragraph 2.1 includes the right (i) to grant Sublicenses to third parties, through multiple tiers of Sublicensees, during the Term but only for as long the license is exclusive with respect to any Patent Rights and (ii) to grant sublicenses to Affiliates, through multiple tiers of Affiliates and Sublicensees.

(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 to the rights granted under a Sublicense, include all of the rights of and obligations due to UNIVERSITY and contained in this Agreement;

(iii) within […] 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 may terminate a Sublicensee but will allow any Sublicenses granted by LICENSEE or its Affiliates prior to such termination to survive as direct licenses from UNIVERSITY provided a) that the Sublicensee is in good standing upon termination of this Agreement with Licensee; and b) the Sublicensee is not currently involved in litigation as an adverse party to the UNIVERSITY. In no case, however, will UNIVERSITY be bound by duties and obligations contained in any Sublicense that extends beyond the duties and obligations of the UNIVERSITY set forth in this Agreement. If a Sublicense survives, the Sublicensee will promptly agree in writing to be bound by the applicable terms of this Agreement, including but not limited to, in lieu of the payment obligations under the applicable Sublicense agreement from the LICENSEE to said Sublicensee, payment to the UNIVERSITY of milestone, earned royalty, patent reimbursement, and Sublicense fees required under Article 3 applicable to such Sublicensee. If there is more than one Sublicense that survives the termination of this Agreement, the payment obligations for Patent Costs may be prorated among the Sublicensees of relevant Patent Rights.

2.3 Reservation of Rights. UNIVERSITY reserves the right to:

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

***Confidential Treatment Requested
(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 (it being understood that LICENSEE has fully performed this obligation as of the Execution 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 (it being understood that LICENSEE has fully performed this obligation as of the Execution Date);

(c) a license restatement fee of [...***...];

(d) 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>[...***...]</td>
<td>For each orphan indication, the following amounts will be paid:</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested 6
For clarity, it is agreed that as of the Execution Date LICENSEE has [...***...] under such clause with respect to such indication.

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

[...***...]

For clarity, it is agreed that as of the Execution Date LICENSEE [...***...] under such clause with respect to such indication.
(e) during the Royalty Term, an **earned royalty** of […***…].

(f) a percentage of all **Sublicense Fees** received by LICENSEE from its Sublicensees […***…]:

 […***…];

(g) during the Royalty Term, 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 applicable percentage, determined pursuant to Paragraph 3.1(f), of royalty amounts received by LICENSEE from such Sublicensee; and (ii) royalties based on the applicable royalty rate in Paragraph 3.1(e) as applied to Net Sales of such Sublicensee. For the sake of clarity, royalties due for Net Sales by Licensee and/or Affiliate(s), Paragraph 3.1(e) will apply and for Net Sales by Sublicensee, this Paragraph 3.1(g), will apply;

(h) 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(e) and (g) 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(e) and (g); 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(h) 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.

3.3 Patent Costs. LICENSEE shall reimburse UNIVERSITY all past (prior to the Execution Date) and future (on or after the Execution Date) Patent Costs within [...***...] 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 [...***...] 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 [...***...] 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 [...***...] following the date an itemized invoice is sent as set forth in Paragraph 4.3.

3.4 Due Diligence.

(a) Cystinosis Indication. LICENSEE shall use Commercially Reasonable Efforts to maintain existing regulatory approvals for a Licensed Product for the Cystinosis Indication and to continue to commercialize a Licensed Product for the Cystinosis Indication in the counties where such regulatory approvals have been obtained.

(b) HD Indication. LICENSEE shall use Commercially Reasonable Efforts to [...***...]

***Confidential Treatment Requested
(c) NASH Indication.

(i) Background. Raptor Pharmaceutical, Inc., executed an agreement with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health, whereby the NIDDK sponsored and conducted the CyNCh study that was designed to evaluate the safety and efficacy of a delayed-release formulation of cysteamine bitartrate in children with biopsy-confirmed NASH (the “CyNCh Study”). Although the CyNCh Study did not achieve its primary endpoints, following receipt and full analysis of data from the CyNCh Study, LICENSEE will consider whether to pursue further development of a delayed-release formulation of cysteamine bitartrate for NASH. [...***…].

(ii) Establishment of NASH Working Group. The parties shall form a joint working group to further evaluate the possible further development and clinical investigation of a cysteamine bitartrate delayed-release formulation for patients diagnosed with NASH. [...***…].

(iii) Responsibilities of the NASH Working Group. The NASH Working Group shall have the following responsibilities:

(A) [...***…]; and
(B) within […***…] of the first meeting of the NASH Working Group (or such longer period as agreed by the NASH Working Group), make recommendations (collectively the “NASH Recommendations”) with regard to […***…]

(iv) General Provisions Governing NASH Working Group. The following general provisions shall govern the conduct of the NASH Working Group, except as otherwise expressly provided in this Agreement or as agreed by the parties in writing:

(A) **Composition.** Each party shall appoint representatives to the NASH Working Group to engage in the NASH evaluation. The NASH Working Group shall consist of […***…] number of representatives from each of the parties, each with the requisite experience and seniority to enable him or her to contribute to evaluation to be conducted by the NASH Working Group. The NASH Working Group shall include, in the case of UNIVERSITY, […***…], and in the case of LICENSEE, its or its parent company’s […***…]. Other relevant thought leaders may be included as the parties agree. From time to time, each party may substitute one or more of its representatives on written notice to the other party. The NASH Working Group shall have co-chairpersons. UNIVERSITY and LICENSEE shall each select from their representatives a co-chairperson for the NASH Working Group, and each party may change its designated co-chairperson from time to time on written notice to the other party. […***…].

(B) **Recommendations.** The NASH Working Group shall have the right to adopt such standing rules as shall be necessary or useful for its work to the extent that such rules are not inconsistent with this Agreement. […***…].

(C) **Meetings.** The NASH Working Group shall establish a schedule of times for meetings to carry out the work of the NASH Working Group; provided, that the NASH Working Group shall meet at least […***…]. Such meetings may be in person or by telephone, video conference or similar means by which each participant can hear what is said by, and be heard by, the other participants. Subject to Horizon’s prior approval of any in-person NASH Working group meeting, including the location and
attendees, LICENSEE shall be responsible for […] of UNIVERSITY representatives incurred for participation in attending such meetings of the NASH Working Group, as arranged by LICENSEE or otherwise approved in advance by LICENSEE.

(D) Agendas and Minutes. The co-chairpersons shall agree in advance of each meeting on an agenda for such meeting. The co-chairpersons or their designees shall prepare and circulate, for review and approval of the parties, minutes of each meeting within […] after such meeting. The parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the NASH Working Group.

(v) Determination Regarding Conduct of a NASH Study. LICENSEE shall consider the NASH Working Group’s final NASH Recommendations and determine whether it will commit to fund and carry out a NASH Study, subject to obtaining any regulatory approvals or authorizations from the FDA required for the conduct of a NASH Study. […] No later than […] after LICENSEE’s receipt of the NASH Working Group’s final NASH Recommendations or such other date as the parties may agree (the “Determination Date”), LICENSEE shall notify UNIVERSITY in writing of LICENSEE’s determination.

(A) In the event that LICENSEE declines to proceed with a NASH Study, unless otherwise agreed by the parties, the parties shall cooperate to mutually terminate the NASH Indication pursuant to Paragraph 7.4 within […] of the Determination Date.

(B) In the event that LICENSEE elects to proceed with a NASH Study, LICENSEE shall commit to fund up to […] to plan and conduct, and shall use Commercially Reasonable Efforts to plan and conduct, a NASH Study, including to commence promptly customary preparatory activities and seek required regulatory approvals or authorizations from the FDA with the goal of achieving first dosing of an enrolled study subject within […] of the Determination Date. LICENSEE shall form a steering committee that includes representatives of LICENSEE and one or more thought leaders in relation to NASH, including […], to consult on the study design and endpoints and the conduct of the study and shall consider in good faith the recommendations of such advisory group with respect thereto. Notwithstanding the foregoing, unless otherwise agreed by LICENSEE in its sole discretion, in no event shall LICENSEE’s obligation pursuant to this Paragraph 3.4(c)(v) require LICENSEE (including its Affiliates and Sublicensees) to allocate or incur more than […] in the aggregate […] to conduct a NASH Study.

(vi) In the event that LICENSEE elects to proceed with a NASH Study as allowed by the Regulatory Authority, then pursuant to Sections 3.4(c)(v)(A) and (B) within […] of the conclusion of such NASH Study, LICENSEE must either:

***Confidential Treatment Requested
(x) notify UNIVERSITY in writing that it is declining to further pursue a Licensed Product for the NASH Indication, in which case the parties shall cooperate to mutually terminate the NASH Indication pursuant to Paragraph 7.4, or

(y) use Commercially Reasonable Efforts to [...***...].

3.5 No Other Diligence Obligations. The obligations of LICENSEE pursuant to this Paragraph 3.4 represent its only diligence obligations hereunder, recognizing that LICENSEE may elect to conduct additional activities with respect to one or more Licensed Products in the Field in its discretion to the extent consistent with the its license rights hereunder.

3.6 Requests for Support for Clinical Investigations. [...***...].

ARTICLE 4. REPORTS, RECORDS AND PAYMENTS

4.1 Reports and Periodic Meetings.

(a) Progress Reports and Periodic Meetings.

(i) Progress Reports. Beginning six (6) 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.
(ii) **Periodic Meetings.** The parties shall establish a joint team (the "**Project Team**") to meet on a periodic basis and provide a forum for discussing LICENSEE’s progress reports and other matters that relate to LICENSEE’s ongoing development and commercialization activities in relation to Licensed Products. Each Project Team shall try to meet at least twice each calendar year, or as otherwise agreed by the Project Team.

(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:

(i) the date of first commercial sale of a Licensed Product in each country;
(ii) the gross sales, deductions as provided in Paragraph 1.12 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.

(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.

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

***Confidential Treatment Requested***
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 underreporting 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) General. 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 to UNIVERSITY earned royalties within […***…] after the end of each previously stated […***…] noted in Paragraph 4.1(b). Each such payment shall be for earned royalties accrued within such preceding […***…].

(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 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

***Confidential Treatment Requested
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 pending 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 within the Patent Rights that is patentably 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 within the Patent Rights 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 (in each case with respect to the Net Sales for Licensed Products sold, and settlements entered into and recoveries received (as applicable) during the Term).

(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. For purposes of clarity, […***…]. 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).

(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.

***Confidential Treatment Requested

16
(c) LICENSEE may elect to terminate its reimbursement obligations with respect to any patent application or patent in Patent Rights upon [...] 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 any exclusive rights under Patent Rights licensed under this Agreement (including with respect to any indication in the Field), neither party will notify a third party (including the infringer) of infringement or put such third party on written notice of the infringement of any Patent Rights without first obtaining consent of the other party.

(b) Except in the case of any infringement or action covered by Paragraph 5.2(d), LICENSEE shall have the first right, but not the obligation, to institute suit for patent infringement with respect to any Patent Rights against the infringer, and to institute any defense or counterclaim in connection with any third party infringement claim concerning any Licensed Product, at LICENSEE’s sole cost and expense, using counsel of its own choice; provided that, except in the case of any infringement or action covered by Paragraph 5.2(d), LICENSEE shall not institute any such suit for patent infringement with respect to any Patent Rights without the UNIVERSITY’s prior written consent, not to be unreasonably withheld or delayed; provided, further, that LICENSEE shall not institute any such suit for patent infringement unless and until infringing activity by the infringer has not abated within [...] following the date the Infringement Notice takes effect. UNIVERSITY may voluntarily join (but not control) any such suit at its own expense using counsel of its own choice, 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, with such written consent subject to

***Confidential Treatment Requested
the approval of the UC Board of Regents and a response to the LICENSEE’s request for such consent to be provided as promptly as possible. 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. In the event that, in a given country in which a Licensed Product is sold, there is infringing activity of potential commercial significance in such country with respect to Patent Rights in such country that cover the Licensed Product in the Field, which has not been abated and UNIVERSITY does not agree to join as a party in a suit proposed by LICENSEE to enforce Patent Rights against such infringement in such country, then the parties will meet and discuss a modification to LICENSEE’s obligation to pay royalties with respect to such Licensed Product in such country under this Agreement.

(c) If within a [...***... ] 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 and is not otherwise engaged in reasonable efforts to cause such infringement to be abated, UNIVERSITY may institute suit for patent infringement against the infringer upon [...***... ] prior written notice to LICENSEE; provided that, at the request of LICENSEE, UNIVERSITY will first meet with LICENSEE and consider in good faith any reasons that LICENSEE believes that such a suit by UNIVERSITY may have an adverse effect. 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, and UNIVERSITY will control such patent infringement suit, and also will control any counterclaims and defenses in connection with such suit; provided however that, in the event LICENSEE did not bring suit against the infringer because of UNIVERSITY’s refusal to consent to be joined in a suit brought by LICENSEE, UNIVERSITY will not bring a suit against the infringer unless it allows LICENSEE, at LICENSEE’s expense, to join and share control of such suit (“UNIVERSITY Refusal Suit”).

(d) Notwithstanding the foregoing, if either party, for UNIVERSITY, to the extent of the actual knowledge of the licensing professional responsible for the administration of this Agreement, (i) reasonably believes that a third party may be filing or preparing or seeking to file a generic or abridged drug approval application that refers or relies on regulatory documentation submitted by LICENSEE to any Regulatory Authority, whether or not such filing may infringe the Patent Rights; (ii) receives any notice of certification regarding the Patent Rights pursuant to the U.S. “Drug Price Competition and Patent Term Restoration Act” of 1984 (21 United States Code §355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV)) (“ANDA Act”) claiming that any such Patent Rights are invalid or unenforceable or claiming that any such Patent Rights will not be infringed by the manufacture, use, marketing or sale of a product for which an application under the ANDA Act is filed; or (iii) receives any equivalent or similar certification or notice in any other jurisdiction, it shall (A) notify the other party in writing identifying the alleged applicant or potential applicant and furnishing the information upon which determination is based and (B) provide with a copy of any such notice of certification within [...***... ] of the date of receipt. LICENSEE shall have the first, right, but not the obligation, to institute suit with respect to any Patent Rights against any such third party, or its affiliate(s), including any parent entity(ies) or subsidiary(ies), or other entities working with such third party or its affiliate(s) in connection with such ANDA filing, at LICENSEE’s sole cost and expense, using counsel of its own choice

***Confidential Treatment Requested
and without any requirement of obtaining the consent of UNIVERSITY to the initiation of such suit. Notwithstanding any requirements set forth in Paragraph 5.2(b) with respect to initiation of any infringement action, LICENSEE shall be permitted to initiate such action at any earlier date in order to ensure compliance with any time limit, if any, set forth in appropriate laws and regulations for filing of such actions; provided, further, that if LICENSEE fails to confirm in writing to the UNIVERSITY that LICENSEE will bring suit against the third party providing notice of such certification within [...] of receipt of such notice, UNIVERSITY shall have the right, but shall not be obligated, to bring suit against such third party, in which event UNIVERSITY shall hold LICENSEE harmless from and against any and all costs and expenses of such litigation, including reasonable attorneys’ fees and expenses. To clarify, see Paragraph 5.4(b) regarding UNIVERSITY being joined in an action brought by LICENSEE.

(e) Any monetary recovery or settlement received in connection with any suit covered by this Paragraph 5.2 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 under Paragraphs 5.2(b) or (d), 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 in accordance with the terms of this Agreement, any recovery in excess of litigation costs will belong to UNIVERSITY, except that in any UNIVERSITY Refusal Suit as defined in Paragraph 5.2(c), any recovery in excess of litigation costs will be shared [...] by UNIVERSITY and [...] by LICENSEE.

5.3 Invalidity or Unenforceability Defenses or Actions. Each party (in the case of UNIVERSITY to the extent of the actual knowledge of the licensing professional responsible for the administration of this Agreement or, if applicable, the Patent Manager or Director of Commercialization) shall promptly notify the other party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Patent Rights by a third party of which such party becomes aware. As between the parties, LICENSEE shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Patent Rights, at LICENSEE’s sole cost and expense, using counsel of its own choice, when such invalidity or unenforceability is raised as a defense or counterclaim in connection with an infringement action initiated pursuant to Paragraph 5.2(b) or (d). UNIVERSITY may participate in any such suit or proceeding in the Territory at its own expense using counsel of its own choice; provided that LICENSEE shall retain control of the defense in such suit or proceeding. If LICENSEE or its designee elects not to defend or control the defense of the Patent Rights in a suit or proceeding brought in the Territory or otherwise fails to initiate and maintain the defense of any such suit or proceeding, then UNIVERSITY may conduct and control the defense of any such suit or proceeding at its own expense pursuant to Paragraph 5.2(c). For the avoidance of doubt, interferences, oppositions and other inter partes matters originating in a patent office are subject

***Confidential Treatment Requested
to Paragraphs 5.1(a), (b), (c) and (d); provided that UNIVERSITY and LICENSEE will discuss LICENSEE taking the lead, at LICENSEE’s expense, on inter partes reviews and similar post-grant matters before the Patent Trial and Appeal Board or similar administrative body that are based on the same subject matter as the claims or counterclaims in an infringement action being led by LICENSEE pursuant to Section 5.2(b) or (d).

5.4 Related Provisions.

(a) LICENSEE may exercise any rights afforded to it in this Article 5, and satisfy its obligations under this Article 5, directly or by and through any Affiliate or Sublicensee so designated by LICENSEE for such purpose. Any agreement made by LICENSEE or its designee for purposes of settling litigation or other dispute shall comply with the requirements of Paragraph 2.2 (Sublicenses) of this Agreement.

(b) Each party will cooperate with the other in litigation proceedings instituted or defended hereunder but at the expense of the party who initiated or is defending the suit (unless such suit is being jointly prosecuted by the parties) including providing reasonable access to relevant documents and other evidence and making its employees available at reasonable business hours.

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

5.5 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 Term and Termination by UNIVERSITY.

(a) This Agreement shall be deemed to have commenced on the Effective Date and shall continue in effect until the last to expire Royalty Term anywhere in the Territory unless earlier terminated pursuant to Paragraph 7.1 or 7.2.

(b) Subject to Paragraph 7.1(d), if LICENSEE breaches its material obligations under this Agreement, then UNIVERSITY may give written notice of default (“Notice of Default”) to LICENSEE. If LICENSEE fails to cure the material breach within ninety (90) days of the Notice of Default, then (i) in the case of any Notice of Default based on LICENSEE’s material breach of its diligence obligations specified in Paragraphs 3.4(a), (b) or (c) with respect to a Cystinosis Indication, NASH Indication or HD Indication, as applicable, UNIVERSITY shall have the right and option, solely with respect to the applicable indication, to either terminate the license granted herein to such indication (in which case, the Field will exclude that terminated indication) or convert LICENSEE’s exclusive license to such indication to a nonexclusive license, and (ii) in the case of any other such material breach, UNIVERSITY may terminate this Agreement and the license granted herein. UNIVERSITY may exercise any such right to terminate or convert the license (in the case of clause (i), solely with respect to the applicable indication) by providing to LICENSEE a second written notice (in the case of a termination, a “Notice of Termination” and in the case of a license conversion, a “Notice of License Conversion”) to LICENSEE. If either such notice is sent to LICENSEE, this Agreement (or in the case of clause (i), the license solely with respect to the applicable indication) shall automatically terminate or the license shall convert to a non-exclusive license with respect to the subject indication, as applicable, on the effective date of that notice. Termination of this Agreement in its entirety or termination of the license granted herein with respect to any indication 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 as provided in Paragraph 3.3, 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.

(c) This Agreement will terminate immediately, without the obligation to provide ninety (90) days’ notice as set forth in Paragraph 7.1(b), 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, upon a ninety (90) day written notice to UNIVERSITY, either to terminate this Agreement in its entirety or to terminate the licensed granted herein with respect to any one or more indication(s) (in which case, the Field will exclude that terminated indication(s)). Said notice shall state LICENSEE’s reason for terminating this Agreement.
(b) 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) Paragraph 2.2(c);
(b) Article 4 (Reports, Records and Payments);
(c) Paragraph 7.3 (Survival on Termination or Expiration);
(d) Paragraph 7.5 (Disposition of Licensed Products on Hand);
(e) Article 8 (Limited Warranty and Indemnification);
(f) Article 9 (Use Of Names and Trademarks);
(g) Paragraph 10.2 hereof (Secrecy);
(h) Paragraph 10.5 (Failure to Perform); and
(i) Paragraph 10.6 (Governing Law).

7.4 Termination of License Solely to a Specific Indication. If the license granted in this Agreement is terminated solely with respect to a given indication under the provisions of Paragraph 3.4(c)(v)(A) or Paragraph 3.4(c)(vi) with respect to the NASH Indication or under the provisions of Paragraph 7.1(b) or Paragraph 7.2(a) with respect to any specific indication, but this Agreement is not terminated in its entirety, then following such termination solely with respect to a given indication, the provisions of this Agreement identified in Paragraph 7.3 shall remain in effect with respect to the terminated indication, as applicable (to the extent they would survive and apply in the event the Agreement expires or is terminated in its entirety) and all provisions not surviving in accordance with the foregoing shall terminate with respect to the terminated indication upon the effective date of termination thereof. This Agreement shall continue in effect in accordance with its terms with regard to all indications other than any such terminated indication. If UNIVERSITY grants a license under the Patent Rights or Technology for such terminated indication to any third party, UNIVERSITY shall use reasonable efforts to cause such third party, on behalf of itself and its affiliates, to agree not to make, have made, sell, have sold, offer for sale or import (including for clinical or commercial purposes) any Licensed Product in the Field and such agreement shall provide that LICENSEE is a third party beneficiary with respect to such covenant, which shall be enforceable by LICENSEE.

7.5 Disposition of Licensed Products on Hand. Upon termination of this Agreement in its entirety or with respect to a particular indication, LICENSEE may dispose of all previously made or partially made Licensed Product within a period of [...***…] of

***Confidential Treatment Requested
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.

7.6 Availability of LICENSEE data and rights. In the event that the license granted in this Agreement is terminated with respect to the NASH Indication or the HD Indication and subject to Section 2.2(c), in the event that the UNIVERSITY grants or reasonably expects to grant a license under the Patent Rights to a third party to develop or commercialize a Licensed Product for such terminated indication, following UNIVERSITY’s reasonable request, UNIVERSITY and LICENSEE shall discuss in good faith whether LICENSEE would be willing grant any license or other rights to such third party with respect to clinical data or patent rights owned by LICENSEE that would be reasonably necessary or useful for the further development and commercialization of a Licensed Product for the such terminated indication, it being understood and agreed that the grant of such license or other rights is within the sole discretion of LICENSEE and would only be considered on commercially reasonable terms.

ARTICLE 8. LIMITED WARRANTY AND INDEMNIFICATION

8.1 Limited Warranty.

(a) UNIVERSITY warrants as of the Effective Date and the Execution Date 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, A BREACH OF CONFIDENTIALITY UNDER PARAGRAPH 10.2 OR, IN THE CASE OF LICENSEE, LICENSEE’S DUTIES FOR CLAIMS OF THIRD PARTIES UNDER PARAGRAPH 8.2, NEITHER PARTY WILL 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 THE OTHER PARTY, 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 SUCH PARTY 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) From and after […***…], 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) 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) the coverage and limits referred to above shall not in any way limit the liability of LICENSEE; and

(iii) If the above insurance is written on a claims-made form, it shall continue for […***…] following termination or expiration of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the Effective Date.

***Confidential Treatment Requested
(c) Upon request, LICENSEE shall furnish UNIVERSITY with certificates of insurance showing compliance with all requirements. Such certificates shall: (i) indicate that UNIVERSITY has been endorsed as an additional insured party under the coverage referred to above; and (ii) 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. LICENSEE shall provide [...] advance written notice to the UNIVERSITY of any policy modification with respect to the matters addressed in clause (i) or (ii) of this Paragraph 8.2(c).

(d) 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:
Horizon Orphan LLC

***Confidential Treatment Requested
10.2 Secrecy.

(a) “Confidential Information” shall mean (i) with respect to UNIVERSITY, information, including Technology, relating to the Invention and disclosed by UNIVERSITY to LICENSEE during the term of this Agreement, and (ii) with respect to LICENSEE, information disclosed by LICENSEE or any of its Affiliates to UNIVERSITY, or its employees or agents (including Drs. Dohil or Barshop) on or after the Execution Date that relates to (i) the business or operations of LICENSEE or any of its Affiliates, (ii) this Agreement or any activities of LICENSEE in relation to any Licensed Product, including any such information disclosed by or on behalf of LICENSEE in connection with the NASH Working Group or the Project Team, or (iii) actual or planned patent prosecution or enforcement activities of LICENSEE or any of its Affiliates. The disclosing party will endeavor to mark Confidential Information (or cause such information to be marked) as “confidential” and reduce orally disclosed Confidential Information to writing within thirty (30) days of disclosure, provided that if any Confidential Information is disclosed and not so marked or reduced to writing, the receiving party agrees to treat such Confidential Information (or cause such information to be treated) as confidential to the extent that a reasonable person would consider such Confidential Information as confidential given the content and the circumstance of the disclosure.

(b) Each party and its employees and agents 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 and agents, or, in the case of LICENSEE as the receiving party, to its consultants or actual or proposed Sublicensees or acquirers who are bound to LICENSEE by a like obligation of confidentiality) without the express written permission of UNIVERSITY, except that receiving party shall not be prevented from using or disclosing any of the Confidential Information that:

(A) the receiving party 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 the receiving party or its employees or agents;

(C) is lawfully obtained by the receiving party from sources independent of the disclosing party; or

(D) is required to be disclosed by law or a court of competent jurisdiction;

(E) is disclosed by the receiving party or its designee in connection with filings or submissions to Regulatory Authorities with respect to Licensed Products as permitted under the terms of this Agreement.

(c) The secrecy obligations provided in this Paragraph 10.2 with respect to Confidential Information of the disclosing party shall continue for a period ending [***…***…] from the expiration or 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 or is to an Affiliate of LICENSEE.

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

***Confidential Treatment Requested
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, including the Prior Agreement.

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.

HORIZON ORPHAN LLC:

By: /s/ Brian K. Beeler
Name: Brian K. Beeler
Title: Executive Vice President
       General Counsel
Date: 5/19/17

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA:

By: /s/ Ruben Flores
Name: Ruben Flores
Title: Director, Office of Innovation
       and Commercialization
Date: 5/31/17
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA:

By: /s/ Lisa Meredith
Name: Lisa Meredith
Title: Associate Director, Office of Contract and Grant Administration

Date: May 31, 2017
<table>
<thead>
<tr>
<th>Title</th>
<th>Territory</th>
<th>Date of Filing</th>
<th>Application No.</th>
<th>Publication No.</th>
<th>Patent No.</th>
<th>Status</th>
<th>Comment</th>
<th>Owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>[...***...</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested
[...***...]

A-4

***Confidential Treatment Requested
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 Vikram Karnani (hereinafter referred as to the “Executive”).

The terms of this Agreement shall be effective commencing February 1, 2017 (the “Effective Date”).

RECITALS

WHEREAS, the Executive previously entered into an employment offer letter with the Company dated August 7, 2014 (the “Prior Agreement”).

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

WHEREAS, Executive desires to be in the continued employ of the Company, and is willing to accept such continued employment on the terms and conditions set forth in this Agreement, which as of the Effective Date shall replace and supersede in its entirety the terms of the Prior Agreement.

AGREEMENT

1. Employment

1.1 Term. The Executive originally commenced employment with the Company on July 31, 2014. The Company hereby agrees to continue to employ the Executive, and the Executive hereby accepts continued 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 Senior Vice President, Rheumatology Business Unit (such position held by Executive during such period is hereinafter referred to as “SVP RBU”) and Executive shall continue to serve in such other capacity or capacities commensurate with his position as SVP RBU 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 SVP RBU including being responsible for the Company’s rheumatology 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 the headquarters office for the Company in Lake Forest Illinois. The Company may from time to time require the Executive to travel temporarily to other locations outside of the Lake Forest Illinois area in connection with the Company’s business.

2. Loyalty of Executive.

2.1 Loyalty. During the Executive’s employment by the Company, the Executive shall devote the Executive’s business energies, interest, abilities and productive time to the proper and efficient performance of Executive’s duties under this Agreement. Subject to the prior written consent of the President and 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. The Company specifically agrees that the Executive may engage in any civic and not-for-profit board membership or activities (including, but not limited to Executive role on the board of the Arthritis Foundation) 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 four hundred thousand dollars ($400,000.00) per year, subject to standard deductions and withholdings, or such higher rate as may be determined from time to time by the Board or the compensation committee thereof (hereinafter referred to as the “Base Salary”). Such Base Salary shall be paid in accordance with the Company’s standard payroll practice. Payments of salary installments shall be made no less frequently than once per month. Executive’s Base Salary will be reviewed annually and Executive shall be eligible to receive a salary increase (but not decrease) annually in an amount to be determined by the Board or the compensation committee thereof in its sole and exclusive discretion. Once increased, the new salary shall become the Base Salary for purposes of this Agreement and shall not be reduced without the Executive’s written consent. Any material reduction in the Base Salary of the Executive, without his written consent, may be deemed Good Reason as set forth in and subject to Section 4.5.2 of this Agreement.

3.2 Discretionary Bonus. Provided the Executive meets the conditions stated in this Section 3.2, the Executive shall be eligible for an annual discretionary bonus (hereinafter referred to as the “Bonus”) with a target amount of fifty percent (50%) of the Executive’s Base Salary, subject to standard deductions and withholdings, 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 Prior Equity Grants. All Company equity awards previously granted to Executive shall continue in effect from and following the Effective Date in accordance with their existing terms. Executive may be eligible to receive additional grants of Company equity awards in the sole discretion and subject to the approval of the Board.

3.4 Legal Review. Upon the Executive’s submission of appropriate 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.

3.8 Expense Reimbursement. The Company shall reimburse the Executive for all reasonable and necessary out-of-pocket expenses incurred by Executive in the performance of his executive duties and responsibilities hereunder, including without limitation expenses incurred for all of Executive’s travel and accommodations, subject to the Company’s normal policies and procedures, including without limitation, for expense verification and documentation (it being understood by the parties hereto that the Executive’s duties hereunder will differ in scope and intensity from Company’s non-executive employees).

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(s) 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), as well as any other compensation and benefits specified in this Agreement.

4.4.1 Death or Complete Disability. If the Executive’s employment shall be terminated by his 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 earned through the date of termination, 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 collectively referred to as the “Accrued Amounts”), less standard deductions and withholdings. The Executive shall also be eligible to receive a pro-rated discretionary Bonus for the year in which the date of termination occurs, as determined by the Board or the Compensation Committee of the Board based on Executive’s then-current target Bonus and 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 earned through the date of termination, his accrued but unpaid business expenses and his 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 (defined above) 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 any 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 such time-based vesting equity award shares granted to Executive prior to such termination shall be fully vested and immediately exercisable, if applicable, by the Executive. Treatment of the PSU Awards previously granted to Executive will in all cases be governed solely by the terms of the Company’s Equity Long Term Incentive Plan (the “Equity LTIP”), and are not eligible for vesting acceleration pursuant to the foregoing provision.

(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
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. The Executive has previously executed the Company’s Confidential Information and Invention Assignment Agreement the terms of which shall continue to govern the terms of Executive’s employment following the Effective Date, and 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.
6. **Notice.**

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:
Vikram Karnani
360 Linden Avenue
Lake Forest, IL 60045

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-1, Exhibit B-2, Exhibit C and the Equity LTIP 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.
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
6/28/2017
Date

EXECUTIVE:

/s/ Vikram Karnani
Vikram Karnani, individually
6/22/2017
Date
In consideration of the payments and other benefits set forth in Section ______ of the Executive Employment Agreement dated February 1, 2017, (the “Employment Agreement”), to which this form is attached, I, Vikram Karnani, 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 Illinois Human Rights Act, the Illinois Equal Pay Act, the Illinois Religious Freedom Restoration Act, and the Illinois Genetic Information Privacy Act. Notwithstanding the foregoing, this Release and Waiver, shall not release or waive my rights: to indemnification under the articles and bylaws of the Company, any and all indemnification agreements, 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

**EXHIBIT A**

RELEASE AND WAIVER OF CLAIMS
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 to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier); (d) I have seven (7) days following the execution of this Release and Waiver to revoke my consent to this Release and Waiver; and (e) this Release and Waiver shall not be effective until the seven (7) day revocation period has expired unexercised. If I am less than 40 years of age upon execution of this Release and Waiver, I acknowledge that I have the right to consult with an attorney prior to executing this Release and Waiver (although I may choose voluntarily not to do so); and (c) I have five (5) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier).

I acknowledge my continuing obligations under my Confidential Information and Inventions Agreement dated 7/31, 2014. 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 7/31, 2014, 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: Vikram Karnani
HORIZON PHARMA, INC.

SECOND AMENDMENT TO
AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This Second Amendment to Amended and Restated Executive Employment Agreement (this “Amendment”), amending that certain Amended and Restated Executive Employment Agreement dated July 27, 2010 as amended January 16, 2014 (the “Employment Agreement”), by and among Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation (hereinafter referred to together as the “Company”), and Jeffrey W. Sherman, M.D. (the “Executive”), is entered into as of May 4, 2017 by and among the Company and the Executive. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Employment Agreement.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Employment Agreement;

WHEREAS, Section 9 of the Employment Agreement provides that the Employment Agreement may be amended with the written agreement of the Company and the Executive; and

WHEREAS, the Company and the Executive desire to amend the Employment Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Employment Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. Section 4.4.3 of the Employment Agreement. Section 4.4.3 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

   “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

   1
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 the following benefits subject to the following terms and conditions:

(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 up to twelve (12) months following the date of termination (hereinafter referred to as the “Non Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Non Change in Control 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) 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 Non Change in Control 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 “Non Change in Control 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 Non Change in Control COBRA Payment Period; and

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

(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 three (3) months 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 the following benefits subject to the following terms and conditions:

(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 up to eighteen (18) months following the date of termination (hereinafter referred to as the "Change in Control Severance Period"), less standard deductions and withholdings, to be paid during the Change in Control 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) one and half (1.5) times Executive’s target Bonus in effect at the time of termination, or if none, one and half (1.5) times 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 Change in Control Severance 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 Change in Control Severance Period; and

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

(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).”

2. Section 4.4.4 of the Employment Agreement. Section 4.4.4 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“4.4.4 Equity Award Acceleration.

(i) Not in Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason and Section 4.4.4 (ii) below does not apply, the vesting of any equity awards granted to Executive that vest solely subject to Executive’s continued
services to the Company (the “Time-Based Vesting Equity Awards”) shall be deemed vested and immediately exercisable (if applicable) by the Executive with respect to such number of shares as determined in accordance with their applicable vesting schedules as if Executive had provided an additional twelve (12) months of services as of the date of termination. Treatment of any performance based vesting equity awards granted to Executive will in all cases be governed solely by the terms of the equity award plan or agreement under which they were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(ii) 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 three (3) months immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of any Time-Based Vesting Equity Awards granted to Executive shall be fully accelerated such that on the effective date of such termination one hundred percent (100%) of any Time-Based Vesting Equity Awards granted to Executive prior to such termination shall be fully vested and immediately exercisable (if applicable) by the Executive. Treatment of any performance based vesting equity awards granted to Executive will in all cases be governed solely by the terms of the equity award plan or agreement under which they were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(iii) Release and Waiver. Any equity vesting acceleration pursuant to this Section 4.4.4 shall be conditioned upon and subject to the Executive’s delivery to the Company of a fully effective Release in accordance with the terms specified by Section 4.4.3 hereof and such vesting acceleration benefit shall be in addition to the benefits provided by Section 4.4.3 hereof.”

3. Effect of Amendment. Except as expressly modified by this Amendment, the Employment Agreement shall remain unmodified and in full force and effect.

4. Governing Law. This Amendment 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.

5. Counterparts. This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[Remainder of Page Intentionally Left Blank]
IN WITNESS WHEREOF, the parties have executed this Second Amendment to Amended and Restated Executive Employment Agreement as of the date first written above.

COMPANY:

HORIZON PHARMA, INC.
HORIZON PHARMA USA, INC.

By: /s/ Timothy P. Walbert

TIMOTHY P. WALTBERG, CHAIRMAN, PRESIDENT AND
CHIEF EXECUTIVE OFFICER

EXECUTIVE:

/s/ Jeffrey W. Sherman

JEFFREY W. SHERMAN, M.D.
HORIZON PHARMA, INC.

FIRST AMENDMENT TO
EXECUTIVE EMPLOYMENT AGREEMENT

This First Amendment to Executive Employment Agreement (this “Amendment”), amending that certain Executive Employment Agreement dated June 17, 2014 (the “Employment Agreement”), by and among Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation (hereinafter referred to together as the “Company”), and Paul W. Hoelscher (the “Executive”), is entered into as of May 4, 2017 by and among the Company and the Executive. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Employment Agreement.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Employment Agreement;

WHEREAS, Section 9 of the Employment Agreement provides that the Employment Agreement may be amended with the written agreement of the Company and the Executive; and

WHEREAS, the Company and the Executive desire to amend the Employment Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Employment Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. Section 4.4.3 of the Employment Agreement. Section 4.4.3 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“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 “Non Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Non Change in Control 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 Non Change in Control 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 “Non Change in Control 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 Non Change in Control COBRA Payment Period.

(iii) 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 three (3) months 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 for a period of eighteen (18) months following the date of termination (hereinafter referred to as the “Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Change in Control 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) one and half (1.5) times Executive’s target Bonus in effect at the time of termination, or if none, one and half (1.5) times 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 Change in Control Severance 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 Change in Control Severance 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).”

2. Section 4.4.4 of the Employment Agreement. Section 4.4.4 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“4.4.4 Equity Award Acceleration.

(i) Not in Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason and Section 4.4.4 (ii) below does not apply, the vesting of any equity awards granted to Executive that vest solely subject to Executive’s continued services to the Company (the “Time-Based Vesting Equity Awards”) shall be deemed vested and immediately exercisable (if applicable) by the Executive with respect to such number of shares as determined in accordance with their applicable vesting schedules as if Executive had provided an additional twelve (12) months of services as of the date of termination. Treatment of any performance based vesting equity awards will be governed solely by the terms of the agreements under which such awards were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(ii) 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 three (3) months immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of any Time-Based Vesting 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 any Time-Based Vesting Equity Awards granted to Executive prior to such termination shall be fully vested and immediately exercisable. In no event shall the time-based vesting Equity Awards be deemed vested and exercisable earlier than their scheduled vesting dates. The terms of any performance-based vesting equity awards will be governed solely by the terms of the agreements under which such awards were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.”
exercisable, if applicable, by the Executive. Treatment of any performance based vesting equity awards will be governed solely by the terms of the agreements under which such awards were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(iii) Release and Waiver. Any equity vesting acceleration pursuant to this Section 4.4.4 shall be conditioned upon and subject to the Executive’s delivery to the Company of a fully effective Release in accordance with the terms specified by Section 4.4.3 hereof and such vesting acceleration benefit shall be in addition to the benefits provided by Section 4.4.3 hereof.”

3. Effect of Amendment. Except as expressly modified by this Amendment, the Employment Agreement shall remain unmodified and in full force and effect.

4. Governing Law. This Amendment 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.

5. Counterparts. This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[Remainder of Page Intentionally Left Blank]
IN WITNESS WHEREOF, the parties have executed this First Amendment to Executive Employment Agreement as of the date first written above.

COMPANY:

HORIZON PHARMA, INC.
HORIZON PHARMA USA, INC.

By: /s/ Timothy P. Walbert
TIMOTHY P. WALBERT, CHAIRMAN, PRESIDENT AND
CHIEF EXECUTIVE OFFICER

EXECUTIVE:

/s/ Paul W. Hoelscher
PAUL W. HOELSCHER
HORIZON PHARMA, INC.

FIRST AMENDMENT TO
EXECUTIVE EMPLOYMENT AGREEMENT

This First Amendment to Executive Employment Agreement (this “Amendment”), amending that certain Executive Employment Agreement dated February 25, 2015 (the “Employment Agreement”), by and among Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation (hereinafter referred to together as the “Company”), and Barry Moze (the “Executive”), is entered into as of May 4, 2017 by and among the Company and the Executive. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Employment Agreement.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Employment Agreement;

WHEREAS, Section 9 of the Employment Agreement provides that the Employment Agreement may be amended with the written agreement of the Company and the Executive; and

WHEREAS, the Company and the Executive desire to amend the Employment Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Employment Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. **Section 1.2 of the Employment Agreement.** Section 1.2 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

   “1.2 Title. From and after the Effective Date the Executive will have the title of Executive Vice President, Chief Administrative Officer (such position held by Executive during such period is hereinafter referred to as “EVP AO”) and Executive shall continue to serve in such other capacity or capacities commensurate with his position as EVP AO as the President and CEO of the Company may from time to time prescribe.”

2. **Section 4.4.3 of the Employment Agreement.** Section 4.4.3 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

   1
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 “Non Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Non Change in Control 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 Non Change in Control 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 “Non Change in Control 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 Non Change in Control 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 three (3) months 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 for a period of eighteen (18) months following the date of termination (hereinafter referred to as the “Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Change in Control 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) one and half (1.5) times Executive’s target Bonus in effect at the time of termination, or if none, one and half (1.5) times 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 Change in Control Severance 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 Change in Control Severance 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).”

3. **Section 4.4.4 of the Employment Agreement.** Section 4.4.4 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“4.4.4 Equity Award Acceleration.

(i) Not in Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason and Section 4.4.4 (ii) below does not apply, the vesting of any equity awards granted to Executive that vest solely subject to Executive’s continued services to the Company (the “Time-Based Vesting Equity Awards”) shall be deemed vested and immediately exercisable (if applicable) by the Executive with respect to such number of shares as determined in accordance with their applicable vesting schedules as if Executive had provided an additional twelve (12) months of services as of the date of termination. Treatment of any performance based vesting equity awards will be governed solely by the terms of the agreements under which such awards were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.
(ii) **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 three (3) months immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of any Time-Based Vesting 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 any Time-Based Vesting Equity Awards granted to Executive prior to such termination shall be fully vested and immediately exercisable, if applicable, by the Executive. Treatment of any performance based vesting equity awards will be governed solely by the terms of the agreements under which such awards were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(iii) **Release and Waiver.** Any equity vesting acceleration pursuant to this Section 4.4.4 shall be conditioned upon and subject to the Executive’s delivery to the Company of a fully effective Release in accordance with the terms specified by Section 4.4.3 hereof and such vesting acceleration benefit shall be in addition to the benefits provided by Section 4.4.3 hereof.”

4. **Effect of Amendment.** Except as expressly modified by this Amendment, the Employment Agreement shall remain unmodified and in full force and effect.

5. **Governing Law.** This Amendment 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.

6. **Counterparts.** This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.
IN WITNESS WHEREOF, the parties have executed this First Amendment to Executive Employment Agreement as of the date first written above.

COMPANY:

HORIZON PHARMA, INC.
HORIZON PHARMA USA, INC.

By: /s/ Timothy P. Walbert
TIMOTHY P. WALBERT, CHAIRMAN, PRESIDENT AND
CHIEF EXECUTIVE OFFICER

EXECUTIVE:

/s/ Barry Moze
BARRY MOZE
HORIZON PHARMA, INC.

FIRST AMENDMENT TO
EXECUTIVE EMPLOYMENT AGREEMENT

This First Amendment to Executive Employment Agreement (this “Amendment”), amending that certain Executive Employment Agreement dated May 7, 2015 (the “Employment Agreement”), by and among Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation (hereinafter referred to together as the “Company”), and Brian Beeler (the “Executive”), is entered into as of May 4, 2017 by and among the Company and the Executive. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Employment Agreement.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Employment Agreement;

WHEREAS, Section 9 of the Employment Agreement provides that the Employment Agreement may be amended with the written agreement of the Company and the Executive; and

WHEREAS, the Company and the Executive desire to amend the Employment Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Employment Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. Section 4.4.3 of the Employment Agreement. Section 4.4.3 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

   “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 "Non Change in Control Severance Period"), less standard deductions and withholdings, to be paid during the Non Change in Control 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 Non Change in Control 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 “Non Change in Control 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 Non Change in Control 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 three (3) months 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 for a period of eighteen (18) months following the date of termination (hereinafter referred to as the “Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Change in Control 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) one and half (1.5) times Executive’s target Bonus in effect at the time of termination, or if none, one and half (1.5) times 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 Change in Control Severance 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 Change in Control Severance 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).”

2. Section 4.4.4 of the Employment Agreement. Section 4.4.4 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“4.4.4 Equity Award Acceleration.

(i) Not in Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason and Section 4.4.4 (ii) below does not apply, the vesting of any equity awards granted to Executive that vest solely subject to Executive’s continued services to the Company (the “Time-Based Vesting Equity Awards”) shall be deemed vested and immediately exercisable (if applicable) by the Executive with respect to such number of shares as determined in accordance with their applicable vesting schedules as if Executive had provided an additional twelve (12) months of services as of the date of termination. Treatment of the Original PSU Award and Additional PSU Award will in all cases be governed solely by the terms of the Equity LTIP. Treatment of any other performance based vesting equity awards granted to Executive will in all cases be governed solely by the terms of the equity award plan or agreement under which they were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(ii) 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 three (3) months immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of any Time-Based Vesting 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 any Time-Based Vesting Equity Awards granted to Executive prior to such termination shall be fully vested and immediately exercisable, if applicable, by the Executive. Treatment of the Original PSU Award and Additional PSU Award will in all cases be governed solely by the terms of the Equity LTIP. Treatment of any other performance based vesting equity awards granted to Executive will in all cases be governed solely by the terms of the equity award plan or agreement under which they were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(iii) Release and Waiver. Any equity vesting acceleration pursuant to this Section 4.4.4 shall be conditioned upon and subject to the Executive’s delivery to the Company of a fully effective Release in accordance with the terms specified by Section 4.4.3 hereof and such vesting acceleration benefit shall be in addition to the benefits provided by Section 4.4.3 hereof.”

3. Effect of Amendment. Except as expressly modified by this Amendment, the Employment Agreement shall remain unmodified and in full force and effect.

4. Governing Law. This Amendment 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.

5. Counterparts. This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.
IN WITNESS WHEREOF, the parties have executed this First Amendment to Executive Employment Agreement as of the date first written above.

COMPANY:

HORIZON PHARMA, INC.
HORIZON PHARMA USA, INC.

By: /s/ Timothy P. Walbert

TIMOTHY P. WALBERT, CHAIRMAN, PRESIDENT AND
CHIEF EXECUTIVE OFFICER

EXECUTIVE:

/s/ Brian Beeler

BRIAN BEELER
HORIZON PHARMA, INC.

FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

This First Amendment to Executive Employment Agreement (this “Amendment”), amending that certain Executive Employment Agreement dated October 25, 2016 (the “Employment Agreement”), by and among Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation (hereinafter referred to together as the “Company”), and David A. Happel (the “Executive”), is entered into as of May 4, 2017 by and among the Company and the Executive. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Employment Agreement.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Employment Agreement;

WHEREAS, Section 9 of the Employment Agreement provides that the Employment Agreement may be amended with the written agreement of the Company and the Executive; and

WHEREAS, the Company and the Executive desire to amend the Employment Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Employment Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. Section 4.4.3 of the Employment Agreement. Section 4.4.3 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“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 “Non Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Non Change in Control 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 Non Change in Control 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 “Non Change in Control 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 Non Change in Control COBRA Payment Period.
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 three (3) months 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-compete 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 for a period of eighteen
(18) months following the date of termination (hereinafter referred to as the “Change in Control Severance Period”), less standard deductions and
withholdings, to be paid during the Change in Control 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) one and half (1.5) times Executive’s target Bonus in effect at the time of termination, or if none, one and half (1.5) times 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 Change in Control Severance 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 Change in Control Severance 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).”

2. Section 4.4.4 of the Employment Agreement. Section 4.4.4 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“4.4.4 Equity Award Acceleration.

(i) Not in Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason and Section 4.4.4 (ii) below does not apply, the vesting of any equity awards granted to Executive that vest solely subject to Executive’s continued services to the Company (the “Time-Based Vesting Equity Awards”) shall be deemed vested and immediately exercisable (if applicable) by the Executive with respect to such number of shares as determined in accordance with their applicable vesting schedules as if Executive had provided an additional twelve (12) months of services as of the date of termination. Treatment of any performance based vesting equity awards granted to Executive will in all cases be governed solely by the terms of the equity award plan or agreement under which they were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(ii) 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 three (3) months immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of any Time-Based Vesting 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 any Time-Based Vesting Equity Awards granted to Executive prior to such termination shall be fully vested and immediately exercisable, if applicable, by the Executive. Treatment of any performance based vesting equity awards granted to Executive will in all cases be governed solely by the terms of the equity award plan or agreement under which they were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(iii) Release and Waiver. Any equity vesting acceleration pursuant to this Section 4.4.4 shall be conditioned upon and subject to the Executive’s delivery to the Company of a fully effective Release in accordance with the terms specified by Section 4.4.3 hereof and such vesting acceleration benefit shall be in addition to the benefits provided by Section 4.4.3 hereof.”

3. Effect of Amendment. Except as expressly modified by this Amendment, the Employment Agreement shall remain unmodified and in full force and effect.

4. Governing Law. This Amendment 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.

5. Counterparts. This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[Remainder of Page Intentionally Left Blank]
IN WITNESS WHEREOF, the parties have executed this First Amendment to Executive Employment Agreement as of the date first written above.

COMPANY:

HORIZON PHARMA, INC.
HORIZON PHARMA USA, INC.

By: /s/ Timothy P. Walbert
TIMOTHY P. WALBERT, CHAIRMAN, PRESIDENT AND
CHIEF EXECUTIVE OFFICER

EXECUTIVE:

/s/ David A. Happel
DAVID A. HAPPEL
HORIZON PHARMA, INC.

FIRST AMENDMENT TO
EXECUTIVE EMPLOYMENT AGREEMENT

This First Amendment to Executive Employment Agreement (this “Amendment”), amending that certain Executive Employment Agreement dated August 6, 2015 (the “Employment Agreement”), by and among Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation (hereinafter referred to together as the “Company”), and George P. Hampton (the “Executive”), is entered into as of May 4, 2017 by and among the Company and the Executive. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Employment Agreement.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Employment Agreement;

WHEREAS, Section 9 of the Employment Agreement provides that the Employment Agreement may be amended with the written agreement of the Company and the Executive; and

WHEREAS, the Company and the Executive desire to amend the Employment Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Employment Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

Section

1. Section 1.2 of the Employment Agreement. Section 1.2 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“1.2 Title. From and after the Effective Date the Executive will have the title of Executive Vice President, Primary Care Business Unit (such position held by Executive during such period is hereinafter referred to as “EVP Primary Care”) and Executive shall continue to serve in such other capacity or capacities commensurate with his position as EVP Primary Care as the President and CEO of the Company may from time to time prescribe.”

2. Section 4.4.3 of the Employment Agreement. Section 4.4.3 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

1
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 “Non Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Non Change in Control 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 Non Change in Control 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 “Non Change in Control 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 Non Change in Control 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 three (3) months 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 for a period of eighteen (18) months following the date of termination (hereinafter referred to as the “Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Change in Control 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) one and half (1.5) times Executive’s target Bonus in effect at the time of termination, or if none, one and half (1.5) times 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 Change in Control Severance 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 Change in Control Severance 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).”

3. Section 4.4.4 of the Employment Agreement. Section 4.4.4 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“4.4.4 Equity Award Acceleration.

(i) Not in Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason and Section 4.4.4 (ii) below does not apply, the vesting of any equity awards granted to Executive that vest solely subject to Executive’s continued services to the Company (the “Time-Based Vesting Equity Awards”) shall be deemed vested and immediately exercisable (if applicable) by the Executive with respect to such number of shares as determined in accordance with their applicable vesting schedules as if Executive had provided an additional twelve (12) months of services as of the date of termination. Treatment of any performance based vesting equity awards will be governed solely by the terms of the agreements under which such awards were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

4
(ii) 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 three (3) months immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of any Time-Based Vesting 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 any Time-Based Vesting Equity Awards granted to Executive prior to such termination shall be fully vested and immediately exercisable, if applicable, by the Executive. Treatment of any performance based vesting equity awards will be governed solely by the terms of the agreements under which such awards were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(iii) Release and Waiver. Any equity vesting acceleration pursuant to this Section 4.4.4 shall be conditioned upon and subject to the Executive’s delivery to the Company of a fully effective Release in accordance with the terms specified by Section 4.4.3 hereof and such vesting acceleration benefit shall be in addition to the benefits provided by Section 4.4.3 hereof.”

4. Effect of Amendment. Except as expressly modified by this Amendment, the Employment Agreement shall remain unmodified and in full force and effect.

5. Governing Law. This Amendment 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.

6. Counterparts. This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.
IN WITNESS WHEREOF, the parties have executed this First Amendment to Executive Employment Agreement as of the date first written above.

COMPANY:

HORIZON PHARMA, INC.
HORIZON PHARMA USA, INC.

By:  /s/ Timothy P. Walbert

TIMOTHY P. WALBERT, CHAIRMAN, PRESIDENT AND CHIEF EXECUTIVE OFFICER

EXECUTIVE:

/s/ George P. Hampton

GEORGE P. HAMPTON
HORIZON PHARMA, INC.

FIRST AMENDMENT TO
EXECUTIVE EMPLOYMENT AGREEMENT

This First Amendment to Executive Employment Agreement (this “Amendment”), amending that certain Executive Employment Agreement dated March 5, 2014 (the “Employment Agreement”), by and among Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation (hereinafter referred to together as the “Company”), and Robert F. Carey (the “Executive”), is entered into as of May 4, 2017 by and among the Company and the Executive. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Employment Agreement.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Employment Agreement;

WHEREAS, Section 9 of the Employment Agreement provides that the Employment Agreement may be amended with the written agreement of the Company and the Executive; and

WHEREAS, the Company and the Executive desire to amend the Employment Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Employment Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. Section 4.4.3 of the Employment Agreement. Section 4.4.3 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

   “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

1
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 “Non Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Non Change in Control 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 Non Change in Control 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 “Non Change in Control 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 Non Change in Control 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 three (3) months 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 for a period of eighteen (18) months following the date of termination (hereinafter referred to as the “Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Change in Control 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) one and half (1.5) times Executive’s target Bonus in effect at the time of termination, or if none, one and half (1.5) times 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 Change in Control Severance 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 Change in Control Severance 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).”

2. Section 4.4.4 of the Employment Agreement. Section 4.4.4 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“4.4.4 Equity Award Acceleration.

(i) Not in Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason and Section 4.4.4 (ii) below does not apply, the vesting of any equity awards granted to Executive that vest solely subject to Executive’s continued services to the Company (the “Time-Based Vesting Equity Awards”) shall be deemed vested and immediately exercisable (if applicable) by the Executive with respect to such number of shares as determined in accordance with their applicable vesting schedules as if Executive had provided an additional twelve (12) months of services as of the date of termination. Treatment of other performance based vesting equity awards granted to Executive will in all cases be governed solely by the terms of the equity award plan or agreement under which they were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(ii) 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 three (3) months immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of any Time-Based Vesting 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 any Time-Based Vesting Equity Awards granted to Executive prior to such termination shall be fully vested and immediately exercisable, if applicable, by the Executive. Treatment of any performance based vesting equity awards granted to Executive will in all cases be governed solely by the terms of the equity award plan or agreement under which they were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(iii) Release and Waiver. Any equity vesting acceleration pursuant to this Section 4.4.4 shall be conditioned upon and subject to the Executive’s delivery to the Company of a fully effective Release in accordance with the terms specified by Section 4.4.3 hereof and such vesting acceleration benefit shall be in addition to the benefits provided by Section 4.4.3 hereof.”

3. Effect of Amendment. Except as expressly modified by this Amendment, the Employment Agreement shall remain unmodified and in full force and effect.

4. Governing Law. This Amendment 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.

5. Counterparts. This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[Remainder of Page Intentionally Left Blank]
IN WITNESS WHEREOF, the parties have executed this First Amendment to Executive Employment Agreement as of the date first written above.

COMPANY:
Horizon Pharma, Inc.
Horizon Pharma USA, Inc.

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

EXECUTIVE:
/s/ Robert F. Carey
Robert F. Carey
HORIZON PHARMA, INC.

SECOND AMENDMENT TO
AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This Second Amendment to Amended and Restated Executive Employment Agreement (this “Amendment”) amends that certain Amended and Restated Executive Employment Agreement dated July 27, 2010 as amended on January 16, 2014 (together, the “Employment Agreement”) by and among Horizon Pharma, Inc., a Delaware corporation, and its wholly owned subsidiary, Horizon Pharma USA, Inc., a Delaware corporation (hereinafter referred to together as the “Company”), and Timothy P. Walbert (the “Executive”), is entered into as of May 4, 2017 by and among the Company and the Executive. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Employment Agreement.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Employment Agreement;

WHEREAS, Section 9 of the Employment Agreement provides that the Employment Agreement may be amended with the written agreement of the Company and the Executive; and

WHEREAS, the Company and the Executive desire to amend the Employment Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Employment Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. Section 4.4.3 of the Employment Agreement. Section 4.4.3 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“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 Non Change in Control Severance Period (as defined below), substantially similar to Section 2.3, and continuing to abide by its terms during the Non Change in Control 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 twenty-four (24) months following the date of termination (hereinafter referred to as the “Non Change in Control Severance Period”), less standard deductions and withholdings, to be paid during the Non Change in Control 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) two (2) times Executive’s target Bonus in effect at the time of termination, or if none, two (2) times the last target Bonus in effect for Executive, less standard deductions and withholdings, to be paid in a lump sum no later than ten (10) days after the Release Effective Date; 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 up until the earlier of either (i) the last day of the Non Change in Control 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 “Non Change in Control 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 Non Change in Control 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 three (3) months 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 Change in Control Severance Period (as defined below), substantially similar to Section 2.3, and continuing to abide by its terms during the Change in Control 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 for a period of thirty-six (36) months following the date of termination (hereinafter referred to as the “**Change in Control Severance Period**”), less standard deductions and withholdings, to be paid during the Change in Control 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)** three (3) times Executive’s target Bonus in effect at the time of termination, or if none, three (3) times 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 up until the earlier of either (i) the date thirty-six (36) months following the date of termination 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 “Change in Control 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 Change in Control 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).”

2. Section 4.4.4 of the Employment Agreement. Section 4.4.4 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“4.4.4. Equity Award Acceleration.

(i) Not in Connection With a Change in Control. In the event that the Executive’s employment is terminated without Cause or for Good Reason and Section 4.4.4 (ii) below does not apply, the vesting of any equity awards granted to Executive that vest solely subject to Executive’s continued services to the Company (the “Time-Based Vesting Equity Awards”) shall be deemed vested and immediately exercisable (if applicable) by the Executive with respect to such number of shares as determined in accordance with their applicable vesting schedules as if Executive had provided an additional eighteen (18) months of services as of the date of termination. Treatment of any performance based vesting stock unit awards or other performance based vesting equity awards granted to Executive will in all cases be governed solely by the terms of the
(ii) 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 three (3) months immediately preceding or during the eighteen (18) months immediately following a Change in Control of the Company (as defined in Section 4.5.4 of this Agreement), the vesting of any Time-Based Vesting Equity Awards granted to Executive shall be fully accelerated such that on the effective date of such termination one hundred percent (100%) of any Time-Based Vesting Equity Awards granted to Executive prior to such termination shall be fully vested and immediately exercisable (if applicable) by the Executive. Treatment of any performance based vesting stock unit awards or other performance based vesting equity awards granted to Executive will in all cases be governed solely by the terms of the equity award plan or agreement under which they were granted and will not be eligible to accelerate vesting pursuant to the foregoing provision.

(iii) Release and waiver. Any equity vesting acceleration pursuant to this Section 4.4.4 shall be conditioned upon and subject to the Executive’s delivery to the Company of a fully effective Release in accordance with the terms specified by Section 4.4.3 hereof, and such vesting acceleration benefit shall be in addition to the benefits provided by Section 4.4.3 hereof.”

3. **Effect of Amendment.** Except as expressly modified by this Amendment, the Employment Agreement shall remain unmodified and in full force and effect.

4. **Governing Law.** This Amendment 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.

5. **Counterparts.** This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[Remainder of Page Intentionally Left Blank]
IN WITNESS WHEREOF, the parties have executed this Second Amendment to Amended and Restated Executive Employment Agreement as of the date first written above.

COMPANY:

HORIZON PHARMA, INC.
HORIZON PHARMA USA, INC.

By: /s/ Jeff Himawan  
    Jeff Himawan, Ph.D., Chairman of the Compensation Committee

EXECUTIVE:

/s/ Timothy P. Walbert  
TIMOTHY P. WALBERT
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: August 7, 2017

/s/ Timothy P. Walbert
Timothy P. Walbert
Chairman, President and Chief Executive Officer
(Principal Executive Officer)
Certification of Chief Financial 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: August 7, 2017

/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 June 30, 2017 (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: August 7, 2017

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

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and 18 U.S.C. Section 1350, I, 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 June 30, 2017 (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: August 7, 2017

/s/ Paul W. Hoelscher
Paul W. Hoelscher
Executive Vice President, Chief Financial Officer
(Principal Financial Officer)

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.