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 March 31, 2019

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

Ireland
(State or other jurisdiction of incorporation or organization)

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)

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 every Interactive Data File required to be submitted 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 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 ☐ 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 ☒

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

<table>
<thead>
<tr>
<th>Title of each class</th>
<th>Trading Symbol</th>
<th>Name of each exchange on which registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordinary shares, nominal value $0.0001 per share</td>
<td>HZNP</td>
<td>The Nasdaq Global Select Market</td>
</tr>
</tbody>
</table>

Number of registrant’s ordinary shares, nominal value $0.0001, outstanding as of May 1, 2019: 184,883,881.
**PART I. FINANCIAL INFORMATION**

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</tr>
</thead>
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<td>2</td>
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<td>3</td>
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<tr>
<td></td>
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<td>4</td>
</tr>
<tr>
<td></td>
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ITEM 1. FINANCIAL STATEMENTS

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

<table>
<thead>
<tr>
<th></th>
<th>As of March 31, 2019</th>
<th>As of December 31, 2018</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>$1,032,808</td>
<td>$958,712</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>3,731</td>
<td>3,405</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>403,862</td>
<td>464,730</td>
</tr>
<tr>
<td>Inventories, net</td>
<td>51,598</td>
<td>50,751</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>67,741</td>
<td>68,218</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td>1,559,740</td>
<td>1,545,816</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>22,135</td>
<td>20,101</td>
</tr>
<tr>
<td>Developed technology, net</td>
<td>1,888,431</td>
<td>1,945,639</td>
</tr>
<tr>
<td>Other intangible assets, net</td>
<td>4,431</td>
<td>4,630</td>
</tr>
<tr>
<td>Goodwill</td>
<td>413,669</td>
<td>413,669</td>
</tr>
<tr>
<td>Deferred tax assets, net</td>
<td>2,546</td>
<td>3,148</td>
</tr>
<tr>
<td>Other assets</td>
<td>44,757</td>
<td>8,959</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>$3,935,709</td>
<td>$3,941,962</td>
</tr>
<tr>
<td><strong>LIABILITIES AND SHAREHOLDERS’ EQUITY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CURRENT LIABILITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term debt—current portion</td>
<td>$250,000</td>
<td>—</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>36,459</td>
<td>30,284</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>197,242</td>
<td>215,739</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td>406,868</td>
<td>457,763</td>
</tr>
<tr>
<td>Deferred revenues—current portion</td>
<td>4,834</td>
<td>4,901</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td>895,403</td>
<td>708,687</td>
</tr>
<tr>
<td><strong>LONG-TERM LIABILITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exchangeable notes, net</td>
<td>336,858</td>
<td>332,199</td>
</tr>
<tr>
<td>Long-term debt, net of current</td>
<td>1,021,263</td>
<td>1,564,485</td>
</tr>
<tr>
<td>Deferred tax liabilities, net</td>
<td>108,668</td>
<td>107,768</td>
</tr>
<tr>
<td>Other long-term liabilities</td>
<td>69,429</td>
<td>38,717</td>
</tr>
<tr>
<td><strong>Total long-term liabilities</strong></td>
<td>1,536,218</td>
<td>2,043,169</td>
</tr>
<tr>
<td><strong>COMMITMENTS AND CONTINGENCIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SHAREHOLDERS’ EQUITY:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ordinary shares, $0.0001 nominal value; 300,000,000 shares authorized;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>185,130,348 and 169,244,520 shares issued at March 31, 2019 and December 31, 2018, respectively, and 184,745,982 and 168,860,154 shares outstanding at March 31, 2019 and December 31, 2018, respectively</td>
<td>18</td>
<td>17</td>
</tr>
<tr>
<td>Treasury stock, 384,366 ordinary shares at March 31, 2019 and December 31, 2018</td>
<td>(4,585)</td>
<td>(4,585)</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>2,722,233</td>
<td>2,374,966</td>
</tr>
<tr>
<td>Accumulated other comprehensive loss</td>
<td>(2,010)</td>
<td>(1,523)</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(1,211,568)</td>
<td>(1,178,769)</td>
</tr>
<tr>
<td><strong>Total shareholders’ equity</strong></td>
<td>1,504,088</td>
<td>1,190,106</td>
</tr>
<tr>
<td><strong>Total liabilities and shareholders’ equity</strong></td>
<td>$3,935,709</td>
<td>$3,941,962</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these condensed consolidated financial statements.
<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>$280,371</td>
<td>$223,881</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>88,142</td>
<td>110,288</td>
</tr>
<tr>
<td><strong>Gross profit</strong></td>
<td><strong>192,229</strong></td>
<td><strong>113,593</strong></td>
</tr>
<tr>
<td><strong>OPERATING EXPENSES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>21,725</td>
<td>17,645</td>
</tr>
<tr>
<td>Selling, general and administrative</td>
<td>172,299</td>
<td>179,599</td>
</tr>
<tr>
<td>Impairment of long-lived assets</td>
<td>—</td>
<td>33,647</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td><strong>194,024</strong></td>
<td><strong>230,891</strong></td>
</tr>
<tr>
<td>Operating loss</td>
<td>(1,795)</td>
<td>(117,298)</td>
</tr>
<tr>
<td><strong>OTHER EXPENSE, NET:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(27,530)</td>
<td>(30,454)</td>
</tr>
<tr>
<td>Loss on debt extinguishment</td>
<td>(5,586)</td>
<td>—</td>
</tr>
<tr>
<td>Foreign exchange loss</td>
<td>(61)</td>
<td>(110)</td>
</tr>
<tr>
<td>Other income, net</td>
<td>189</td>
<td>151</td>
</tr>
<tr>
<td><strong>Total other expense, net</strong></td>
<td><strong>(32,988)</strong></td>
<td><strong>(30,413)</strong></td>
</tr>
<tr>
<td><strong>Loss before (benefit) expense for income taxes</strong></td>
<td><strong>(34,783)</strong></td>
<td><strong>(147,711)</strong></td>
</tr>
<tr>
<td><strong>Benefit) expense for income taxes</strong></td>
<td><strong>(1,920)</strong></td>
<td><strong>945</strong></td>
</tr>
<tr>
<td>Net loss</td>
<td>$32,863</td>
<td>$(148,656)</td>
</tr>
<tr>
<td>Net loss per ordinary share—basic and diluted</td>
<td>$(0.19)</td>
<td>$(0.90)</td>
</tr>
<tr>
<td>Weighted average ordinary shares outstanding—basic and diluted</td>
<td>172,789,209</td>
<td>164,549,502</td>
</tr>
<tr>
<td><strong>OTHER COMPREHENSIVE (LOSS) INCOME, NET OF TAX</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign currency translation adjustments</td>
<td>$(487)</td>
<td>$463</td>
</tr>
<tr>
<td>Other comprehensive (loss) income</td>
<td>(487)</td>
<td>463</td>
</tr>
<tr>
<td><strong>Comprehensive loss</strong></td>
<td>$(33,350)</td>
<td>$(148,193)</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these condensed consolidated financial statements.
HORIZON THERAPEUTICS PLC
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(UNAUDITED)
(In thousands, except share data)

<table>
<thead>
<tr>
<th></th>
<th>Ordinary Shares</th>
<th>Treasury Stock</th>
<th>Additional Paid-in</th>
<th>Other Comprehensive Loss</th>
<th>Accumulated Deficit</th>
<th>Total Shareholders' Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balances at December 31, 2018</td>
<td>169,244,520</td>
<td>384,366</td>
<td>(4,585)</td>
<td>2,374,966</td>
<td>(1,523)</td>
<td>1,190,106</td>
</tr>
<tr>
<td>Cumulative effect adjustments from adoption of ASU 2016-02</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>64</td>
</tr>
<tr>
<td>Issuance of ordinary shares - public offering</td>
<td>14,081,632</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>326,849</td>
</tr>
<tr>
<td>Issuance of ordinary shares in conjunction with vesting of restricted stock units and stock option exercises</td>
<td>1,804,196</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10,042</td>
</tr>
<tr>
<td>Ordinary shares withheld for payment of employees' withholding tax liability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share-based compensation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(17,171)</td>
</tr>
<tr>
<td>Currency translation adjustment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(487)</td>
</tr>
<tr>
<td>Net loss</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(32,863)</td>
</tr>
<tr>
<td>Balances at March 31, 2019</td>
<td>185,130,348</td>
<td>384,366</td>
<td>(4,585)</td>
<td>2,722,233</td>
<td>(2,010)</td>
<td>1,504,088</td>
</tr>
</tbody>
</table>

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

3
# HORIZON THERAPEUTICS PLC
## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
### (UNAUDITED)

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended March 31,</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2019</td>
<td>2018</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM OPERATING ACTIVITIES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td></td>
<td>$32,863</td>
<td>$148,656</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash provided by (used in) operating activities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization expense</td>
<td></td>
<td>58,891</td>
<td>62,435</td>
</tr>
<tr>
<td>Equity-settled share-based compensation</td>
<td></td>
<td>27,548</td>
<td>27,833</td>
</tr>
<tr>
<td>Amortization of debt discount and deferred financing costs</td>
<td></td>
<td>5,851</td>
<td>5,496</td>
</tr>
<tr>
<td>Loss on debt extinguishment</td>
<td></td>
<td>5,586</td>
<td>—</td>
</tr>
<tr>
<td>Deferred income taxes</td>
<td></td>
<td>1,502</td>
<td>1,680</td>
</tr>
<tr>
<td>Foreign exchange and other adjustments</td>
<td></td>
<td>404</td>
<td>(120)</td>
</tr>
<tr>
<td>Impairment of long-lived assets</td>
<td></td>
<td>—</td>
<td>33,647</td>
</tr>
<tr>
<td>Changes in operating assets and liabilities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts receivable</td>
<td></td>
<td>60,769</td>
<td>1,064</td>
</tr>
<tr>
<td>Inventories</td>
<td></td>
<td>(847)</td>
<td>14,290</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td></td>
<td>111</td>
<td>(9,805)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td></td>
<td>6,416</td>
<td>6,528</td>
</tr>
<tr>
<td>Accrued trade discounts and rebates</td>
<td></td>
<td>(50,904)</td>
<td>(72,120)</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td></td>
<td>(21,336)</td>
<td>19,028</td>
</tr>
<tr>
<td>Deferred revenues</td>
<td></td>
<td>(67)</td>
<td>1,484</td>
</tr>
<tr>
<td>Other non-current assets and liabilities</td>
<td></td>
<td>(4,893)</td>
<td>(627)</td>
</tr>
<tr>
<td><strong>Net cash provided by (used in) operating activities</strong></td>
<td></td>
<td>56,168</td>
<td>(60,811)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM INVESTING ACTIVITIES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payment related to license agreement</td>
<td></td>
<td>—</td>
<td>(12,000)</td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td></td>
<td>(1,849)</td>
<td>(665)</td>
</tr>
<tr>
<td><strong>Net cash used in investing activities</strong></td>
<td></td>
<td>(1,849)</td>
<td>(12,665)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM FINANCING ACTIVITIES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net proceeds from the issuance of ordinary shares</td>
<td></td>
<td>327,750</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from the issuance of ordinary shares in connection with stock option exercises</td>
<td></td>
<td>10,042</td>
<td>945</td>
</tr>
<tr>
<td>Proceeds from the issuance of ordinary shares through ESPP programs</td>
<td></td>
<td>—</td>
<td>14</td>
</tr>
<tr>
<td>Payment of employee withholding taxes relating to share-based awards</td>
<td></td>
<td>(17,171)</td>
<td>(3,517)</td>
</tr>
<tr>
<td>Repayment of term loans</td>
<td></td>
<td>(300,000)</td>
<td>(2,125)</td>
</tr>
<tr>
<td><strong>Net cash provided by (used in) financing activities</strong></td>
<td></td>
<td>20,621</td>
<td>(4,683)</td>
</tr>
<tr>
<td>Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash</td>
<td></td>
<td>(518)</td>
<td>982</td>
</tr>
<tr>
<td><strong>Net increase (decrease) in cash, cash equivalents and restricted cash</strong></td>
<td></td>
<td>74,422</td>
<td>(77,177)</td>
</tr>
<tr>
<td>Cash, cash equivalents and restricted cash, beginning of the period</td>
<td></td>
<td>962,117</td>
<td>757,897</td>
</tr>
<tr>
<td><strong>Cash, cash equivalents and restricted cash, end of the period</strong></td>
<td></td>
<td>$1,036,539</td>
<td>$680,720</td>
</tr>
</tbody>
</table>

## SUPPLEMENTAL CASH FLOW INFORMATION:

<table>
<thead>
<tr>
<th>Description</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash paid for interest</td>
<td>$15,842</td>
<td>$15,376</td>
</tr>
<tr>
<td>Net cash paid for income taxes</td>
<td>856</td>
<td>(914)</td>
</tr>
<tr>
<td>Cash paid for amounts included in the measurement of lease liabilities</td>
<td>1,611</td>
<td>—</td>
</tr>
</tbody>
</table>

## SUPPLEMENTAL NON-CASH FLOW INFORMATION:

<table>
<thead>
<tr>
<th>Description</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchases of property and equipment included in accounts payable and accrued expenses</td>
<td>2,759</td>
<td>8</td>
</tr>
<tr>
<td>Transaction costs related to issuance of ordinary shares included in accrued expenses</td>
<td>902</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 months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. The December 31, 2018 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 “Horizon”, the “Company”, “we”, “us” and “our” refer to Horizon Therapeutics plc (formerly known as 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 intra-company transactions and balances have been eliminated.

On May 2, 2019, the shareholders of the Company approved changing the name of the Company from “Horizon Pharma Public Limited Company” to “Horizon Therapeutics Public Limited Company” to better reflect the Company’s long-term strategy to develop and commercialize innovative new medicines to address rare diseases with very few effective options.

Business Overview

Horizon is focused on researching, developing and commercializing medicines that address critical needs for people impacted by rare and rheumatic diseases. The Company’s pipeline is purposeful: it applies scientific expertise and courage to bring clinically meaningful therapies to patients. Horizon believes science and compassion must work together to transform lives. The Company has two reportable segments, referred to as the “orphan and rheumatology segment” and the “primary care segment”, and currently markets eleven medicines in the areas of orphan diseases, rheumatology and primary care.

The Company’s currently marketed medicines are:

**Orphan and Rheumatology**
- KRYSTEXXA® (pegloticase injection), for intravenous infusion
- RAVICTI® (glycerol phenylbutyrate) oral liquid
- PROCYSBI® (cysteamine bitartrate) delayed-release capsules, for oral use
- ACTIMMUNE® (interferon gamma-1b) injection, for subcutaneous use
- RAYOS® (prednisone) delayed-release tablets
- BUPHENYL® (sodium phenylbutyrate) Tablets and Powder
- QUINSAIR™ (levofloxacin) solution for inhalation

**Primary Care**
- PENNSAID® (diclofenac sodium topical solution) 2% w/w (“PENNSAID 2%”), for topical use
- DUEXIS® (ibuprofen/famotidine) tablets, for oral use
- VIMOVO® (naproxen/esomeprazole magnesium) delayed-release tablets, for oral use
- MIGERGOT® (ergotamine tartrate & caffeine suppositories), for rectal use
Change in Accounting Method

When accounting for business combinations under ASC Topic 805, Business Combinations, the Company previously separately identified and recorded at fair value intangible assets acquired and their related third-party contingent royalties at the date of acquisition. Third-party contingent royalties are royalties payable to parties other than sellers of the businesses. Effective January 1, 2019, the Company retrospectively changed its accounting for business combinations and will record acquired intangible assets and their related third-party contingent royalties on a net basis (“New Method”). The Company changed its accounting principle on the basis that the use of the New Method is preferable primarily due to improved comparability with the Company’s peers. The Company has adjusted the accompanying condensed consolidated balance sheet as at December 31, 2018, and the condensed consolidated statement of comprehensive loss and of cash flows for the three months ended March 31, 2018 to reflect this change in accounting. Total shareholders’ equity at December 31, 2018 was adjusted by $135.9 million to reflect the cumulative impact of the change to the earliest year presented. The impact on the consolidated statement of cash flows consisted of adjustments to reconcile net loss to net cash provided by operating activities and changes in operating assets and liabilities for all periods presented. There was no impact on total operating, investing or financing cash flows for any prior period. The following are selected line items from the Company’s condensed consolidated financial statements illustrating the effect of the change in accounting method (in thousands, except per share data):

<table>
<thead>
<tr>
<th>Account</th>
<th>As Previously Reported</th>
<th>Impact of Accounting Change (1)</th>
<th>As Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>$70,828</td>
<td>$(2,610)</td>
<td>$68,218</td>
</tr>
<tr>
<td>Total current assets</td>
<td>$1,548,426</td>
<td></td>
<td>$1,545,816</td>
</tr>
<tr>
<td>Developed technology, net</td>
<td>$2,120,596</td>
<td>$(174,957)</td>
<td>$1,945,639</td>
</tr>
<tr>
<td>Goodwill</td>
<td>$426,441</td>
<td>$(12,772)</td>
<td>$413,669</td>
</tr>
<tr>
<td>Other assets</td>
<td>$23,029</td>
<td>$(14,070)</td>
<td>$8,959</td>
</tr>
<tr>
<td>Total assets</td>
<td>$4,146,371</td>
<td>$(204,409)</td>
<td>$3,941,962</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>$205,593</td>
<td>$10,146</td>
<td>$215,739</td>
</tr>
<tr>
<td>Accrued royalties - current portion</td>
<td>$63,363</td>
<td></td>
<td>$63,363</td>
</tr>
<tr>
<td>Total current liabilities</td>
<td>$761,904</td>
<td>$(53,217)</td>
<td>$708,687</td>
</tr>
<tr>
<td>Deferred tax liabilities, net</td>
<td>$93,630</td>
<td>$14,138</td>
<td>$107,768</td>
</tr>
<tr>
<td>Accrued royalties - net of current</td>
<td>$285,374</td>
<td></td>
<td>$285,374</td>
</tr>
<tr>
<td>Other long-term liabilities</td>
<td>$54,622</td>
<td>$(15,905)</td>
<td>$38,717</td>
</tr>
<tr>
<td>Total long-term liabilities</td>
<td>$2,330,310</td>
<td>$(287,141)</td>
<td>$2,043,169</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(1,314,718)</td>
<td>$135,949</td>
<td>(1,178,769)</td>
</tr>
<tr>
<td>Total shareholders’ equity</td>
<td>$1,054,157</td>
<td>$135,949</td>
<td>$1,190,106</td>
</tr>
<tr>
<td>Total liabilities and shareholders' equity</td>
<td>$4,146,371</td>
<td>$(204,409)</td>
<td>$3,941,962</td>
</tr>
</tbody>
</table>

(1) The change in accounting principle resulted in the Company re-performing its purchase price allocations as of the respective acquisition dates for prior business combinations. The adjustments to the purchase price allocations primarily resulted in a decrease in developed technology intangible assets and the elimination of liabilities for accrued contingent royalties due to recording these items on a net basis. The re-performance of purchase price allocations also impacted goodwill and deferred tax liabilities. In addition, the change in accounting principle resulted in the elimination of royalty reimbursement assets and accrued contingent royalty liabilities that were recorded in connection with divestitures, impacting prepaid expenses and other current assets, other assets, accrued expenses and other long-term liabilities captions as shown in the table above. In addition, under the New Method of accounting, the Company is presenting accrued royalties based on each periods’ net sales as part of the accrued expenses line item on its condensed consolidated balance sheets.
## Consolidated Statement of Comprehensive Loss

<table>
<thead>
<tr>
<th></th>
<th>As Previously Reported</th>
<th>Revision (1)</th>
<th>As Revised</th>
<th>Impact of Accounting Change (2)</th>
<th>As Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of goods sold</td>
<td>$ 116,092</td>
<td>$ (753)</td>
<td>$ 115,339</td>
<td>$ (5,051)</td>
<td>$ 110,288</td>
</tr>
<tr>
<td>Gross profit</td>
<td>107,789</td>
<td>753</td>
<td>108,542</td>
<td>5,051</td>
<td>113,593</td>
</tr>
<tr>
<td>Impairment of long-lived assets</td>
<td>37,853</td>
<td>—</td>
<td>37,853</td>
<td>(4,206)</td>
<td>33,647</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>235,097</td>
<td>—</td>
<td>235,097</td>
<td>(4,206)</td>
<td>230,891</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(127,308)</td>
<td>753</td>
<td>(126,555)</td>
<td>9,257</td>
<td>(117,298)</td>
</tr>
<tr>
<td>Other income, net</td>
<td>178</td>
<td>—</td>
<td>178</td>
<td>(27)</td>
<td>151</td>
</tr>
<tr>
<td>Total other expenses, net</td>
<td>(30,386)</td>
<td>—</td>
<td>(30,386)</td>
<td>(27)</td>
<td>(30,413)</td>
</tr>
<tr>
<td>Loss before (benefit) expense for income taxes</td>
<td>(157,694)</td>
<td>753</td>
<td>(156,941)</td>
<td>9,230</td>
<td>(147,711)</td>
</tr>
<tr>
<td>(Benefit) expense for income taxes</td>
<td>(367)</td>
<td>—</td>
<td>(367)</td>
<td>1,312</td>
<td>945</td>
</tr>
<tr>
<td>Net loss</td>
<td>(157,327)</td>
<td>753</td>
<td>(156,574)</td>
<td>7,918</td>
<td>(148,656)</td>
</tr>
<tr>
<td>Net loss per ordinary share - basic and diluted</td>
<td>(0.96)</td>
<td>0.01</td>
<td>(0.95)</td>
<td>0.05</td>
<td>(0.90)</td>
</tr>
<tr>
<td>Comprehensive loss</td>
<td>(156,864)</td>
<td>753</td>
<td>(156,111)</td>
<td>7,918</td>
<td>(148,193)</td>
</tr>
</tbody>
</table>

(1) During the course of preparing the Company’s consolidated financial statements for the year ended December 31, 2018, the Company identified an error in the measurement of the contingent royalty liability calculation pertaining to the royalty end date for one of its medicines. The amounts in this column reflect the revisions to the Company’s previously reported consolidated statement of comprehensive loss on Form 10-Q for the quarterly period ended March 31, 2018. The Company concluded that the amounts were not material to any of its previously issued consolidated financial statements. Refer to Note 1 and Note 23 of the Company’s Annual Report on Form 10-K for the year ended December 31, 2018 for further detail of this revision. The impact on the consolidated statements of cash flows consisted of adjustments to reconcile net (loss) income to net cash provided by operating activities and changes in operating assets and liabilities. There was no impact on total operating, investing or financing cash flows for the quarterly period ended March 31, 2018.

(2) The change in accounting principle resulted in the Company re-performing its purchase price allocations as of the respective acquisition dates for prior business combinations. The adjustments to the purchase price allocations primarily resulted in a net decrease in cost of goods sold reflecting lower intangible asset amortization and the elimination of royalty accretion and remeasurement expenses, partially offset by the royalty expense based on the periods’ net sales. The re-performance of purchase price allocations also directly impacted impairments of long-lived assets, benefit/expense for income taxes, as shown in the table above.

### NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### 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, 2019, the Company adopted Accounting Standards Updated (“ASU”) No. 2016-02, *Leases (Topic 842)* (“ASU No. 2016-02”). Under ASU No. 2016-02, an entity is required to recognize right-of-use lease assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. The Company adopted this standard on January 1, 2019, using a modified retrospective approach at the adoption date through a cumulative-effect adjustment to retained earnings. The Company elected the package of transition provisions available for expired or existing contracts, which allowed the Company to carry forward its historical assessments of (i) whether contracts are or contain leases, (ii) lease classification and (iii) initial direct costs. In addition, the Company elected the hindsight practical expedient to determine the lease term for existing leases. The Company applied the new guidance to all operating leases within the scope of the standard that were in effect on January 1, 2019, or entered into after, the adoption date. Comparative information for prior periods has not been restated and continues to be reported under the accounting standards in effect for those periods. The adoption did not have a material impact on the Company’s condensed consolidated statement of comprehensive loss. However, the new standard established $37.1 million of liabilities and corresponding right-of-use assets of $34.9 million on the Company’s condensed consolidated balance sheet for leases, primarily related to operating leases on rented office properties, that existed as of the January 1, 2019, adoption date.

Effective January 1, 2019, the Company adopted ASU No. 2018-08, Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made (“ASU No. 2018-08”). The new guidance applies to all entities that receive or make contributions, including business entities. The Company adopted the standard in the first quarter of 2019, using prospective application to any new agreements entered into after the effective date. The adoption of ASU No. 2018-08 did not have a material impact on the Company’s condensed consolidated financial statements and related disclosures.

Other recent authoritative guidance issued by the FASB (including technical corrections to the Accounting Standards Codification (“ASC”)), the American Institute of Certified Public Accountants and the Securities and Exchange Commission (“SEC”) did not, or are not expected to, have a material impact on the Company’s condensed consolidated financial statements and related disclosures.

Significant Accounting Policies

As described in Note 1, effective January 1, 2019, the Company modified its accounting policy related to intangible assets and contingent royalty liabilities acquired through business combinations following a change in accounting principle, and the Company’s updated policy in respect of all royalties is described below.

In addition, as described above, the Company adopted ASU No. 2016-02 effective January 1, 2019. The Company modified its accounting policy related to leases following the adoption of ASU No. 2016-02, and the Company’s updated policy is described below.

**Royalties**

The Company records royalty expense based on each periods’ net sales as part of cost of goods sold.

**Leases**

The Company’s leases primarily relate to operating leases of rented office properties. For contracts entered into on or after January 1, 2019, at the inception of a contract the Company assesses whether the contract is, or contains, a lease. The Company’s assessment is based on: (1) whether the contract involves the use of a distinct identified asset, (2) whether the Company obtains the right to substantially all the economic benefit from the use of the asset throughout the period, and (3) whether the Company has the right to direct the use of the asset. At inception of a lease, the Company allocates the consideration in the contract to each lease component based on its relative stand-alone price to determine the lease payments.

For leases with terms greater than 12 months, the Company records the related asset and obligation at the present value of lease payments over the term. The right-of-use lease asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease.

The right-of-use lease asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, plus any initial direct costs incurred. All right-of-use lease assets are reviewed for impairment. The lease liability is initially measured at the present value of the lease payments, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Company’s secured incremental borrowing rate for the same term as the underlying lease.

The Company has elected not to recognize right-of-use lease assets and lease liabilities for short-term leases that have a term of 12 months or less. The Company reports right-of-use lease assets within non-current “Other assets” in its condensed consolidated balance sheet. The Company reports the current portion of lease liabilities within “Accrued expenses” and long-term lease liabilities within “Other long-term liabilities” in its condensed consolidated balance sheet.
NOTE 3 – NET LOSS PER SHARE

The following table presents basic and diluted net loss per share for the three months ended March 31, 2019 and 2018 (in thousands, except share and per share data):

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended March 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td>Net loss</td>
<td>(32,863)</td>
</tr>
<tr>
<td>Weighted average ordinary shares outstanding</td>
<td>172,789,209</td>
</tr>
<tr>
<td>Basic and diluted net loss per share</td>
<td>(0.19)</td>
</tr>
</tbody>
</table>

Basic net loss per share is computed by dividing net loss by the weighted-average number of ordinary shares outstanding during the period. Diluted net loss per share reflects the potential dilution 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 per share excluded 8.2 million shares subject to equity awards for the three months ended March 31, 2019, and 12.0 million shares subject to equity awards for the three months ended March 31, 2018, respectively, because their inclusion would have had an anti-dilutive effect on diluted net loss 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 income (loss) 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 income (loss) 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 months ended March 31, 2019 and 2018.
NOTE 4 – ACQUISITIONS, DIVESTITURES AND OTHER ARRANGEMENTS

Sale of RAVICTI and AMMONAPS Rights outside of North America and Japan

On December 28, 2018, the Company sold its rights to RAVICTI and AMMONAPS (known as BUPHENYL in the United States) outside of North America and Japan to Medical Need Europe AB, part of the Immedica Group, for $35.0 million (the “Immedica transaction”). The Company previously distributed RAVICTI and AMMONAPS through a commercial partner in Europe and other non-U.S. markets. The Company has retained the rights to RAVICTI and BUPHENYL in North America and Japan.

Pursuant to ASC 805 (as amended by ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business (“ASU No. 2017-01”)), the Company accounted for the Immedica transaction as a sale of assets, specifically a sale of intellectual property rights.

The gain on sale of assets recorded to the consolidated statement of comprehensive loss during the year ended December 31, 2018, was determined as follows (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash proceeds</td>
<td>$35,000</td>
</tr>
<tr>
<td>Less net assets sold:</td>
<td></td>
</tr>
<tr>
<td>Developed technology</td>
<td>(4,146)</td>
</tr>
<tr>
<td>Transaction costs</td>
<td>(197)</td>
</tr>
<tr>
<td><strong>Gain on sale of assets</strong></td>
<td><strong>$30,657</strong></td>
</tr>
</tbody>
</table>

Acquisition and Subsequent Sale 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 GmbH (“Boehringer Ingelheim International”) in all territories outside of the United States, Canada and Japan and in connection therewith, paid Boehringer Ingelheim International €19.5 million ($22.3 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1406). Boehringer Ingelheim International commercialized interferon gamma-1b as IMUKIN in an estimated thirty countries, primarily in Europe and the Middle East. Upon closing, during the year ended December 31, 2017, the Company accounted for the payment as the acquisition of an asset which was immediately impaired as projections for future net sales of IMUKIN in these territories did not exceed the related costs, and included the payment in the “impairment of long-lived assets” line item in its condensed consolidated statement of comprehensive loss.

On July 24, 2018, the Company sold its rights to interferon gamma-1b in all territories outside the United States, Canada and Japan to Clinigen Group plc (“Clinigen”) for an upfront payment of €7.5 million ($8.8 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1683) and a potential additional contingent consideration payment of €3.0 million ($3.5 million when converted using a Euro-to-Dollar exchange rate of 1.1673) (the “IMUKIN sale”). The Company continues to market interferon gamma-1b as ACTIMMUNE in the United States.

Pursuant to ASC 805 (as amended by ASU No. 2017-01), the Company accounted for the IMUKIN sale as a sale of assets, specifically a sale of intellectual property rights, and a sale of inventory.

The gain on sale of assets recorded to the condensed consolidated statement of comprehensive loss during the year ended December 31, 2018, was determined as follows (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash proceeds including $715 for inventory</td>
<td>$9,477</td>
</tr>
<tr>
<td>Contingent consideration receivable</td>
<td>3,502</td>
</tr>
<tr>
<td>Less net assets sold:</td>
<td></td>
</tr>
<tr>
<td>Inventory</td>
<td>(623)</td>
</tr>
<tr>
<td>Transaction costs</td>
<td>(28)</td>
</tr>
<tr>
<td><strong>Gain on sale of assets</strong></td>
<td><strong>$12,328</strong></td>
</tr>
</tbody>
</table>
Other Arrangements

On January 3, 2019, the Company entered into a collaboration agreement with HemoShear Therapeutics, LLC (“HemoShear”), a biotechnology company, to discover and develop novel therapeutics for gout. The collaboration provides the Company with an opportunity to address unmet treatment needs for people with gout by evaluating new targets for the control of serum uric acid levels as well as new targets to address the inflammation associated with acute flares of gout. Under the terms of the agreement, the Company paid HemoShear an upfront cash payment of $2.0 million with additional potential future milestone payments upon commencement of new stages of development, contingent on the Company’s approval at each stage.

NOTE 5 – INVENTORIES

Inventories are stated at the lower of cost or net realizable 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 and 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 March 31, 2019 and December 31, 2018 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2019</th>
<th>December 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw materials</td>
<td>$6,709</td>
<td>$5,092</td>
</tr>
<tr>
<td>Work-in-process</td>
<td>25,722</td>
<td>27,068</td>
</tr>
<tr>
<td>Finished goods</td>
<td>19,167</td>
<td>18,591</td>
</tr>
<tr>
<td><strong>Inventories, net</strong></td>
<td><strong>$51,598</strong></td>
<td><strong>$50,751</strong></td>
</tr>
</tbody>
</table>

NOTE 6 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets as of March 31, 2019 and December 31, 2018 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2019</th>
<th>December 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferred charge for taxes on intra-company profit</td>
<td>$23,188</td>
<td>$21,734</td>
</tr>
<tr>
<td>Rabbi trust assets</td>
<td>10,738</td>
<td>8,203</td>
</tr>
<tr>
<td>Prepaid income taxes</td>
<td>6,080</td>
<td>5,899</td>
</tr>
<tr>
<td>Medicine samples inventory</td>
<td>2,515</td>
<td>4,539</td>
</tr>
<tr>
<td>Other prepaid expenses and other current assets</td>
<td>25,220</td>
<td>27,843</td>
</tr>
<tr>
<td><strong>Prepaid expenses and other current assets</strong></td>
<td><strong>$67,741</strong></td>
<td><strong>$68,218</strong></td>
</tr>
</tbody>
</table>

NOTE 7 – PROPERTY AND EQUIPMENT

Property and equipment as of March 31, 2019 and December 31, 2018 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2019</th>
<th>December 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software</td>
<td>$14,843</td>
<td>$14,843</td>
</tr>
<tr>
<td>Leasehold improvements</td>
<td>10,679</td>
<td>9,982</td>
</tr>
<tr>
<td>Machinery and equipment</td>
<td>4,800</td>
<td>4,800</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>2,561</td>
<td>2,485</td>
</tr>
<tr>
<td>Other</td>
<td>2,754</td>
<td>2,501</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>35,637</strong></td>
<td><strong>34,611</strong></td>
</tr>
<tr>
<td>Less accumulated depreciation</td>
<td>(20,670)</td>
<td>(19,197)</td>
</tr>
<tr>
<td>Construction in process</td>
<td>7,168</td>
<td>4,687</td>
</tr>
<tr>
<td><strong>Property and equipment, net</strong></td>
<td><strong>$22,135</strong></td>
<td><strong>$20,101</strong></td>
</tr>
</tbody>
</table>

Depreciation expense was $1.5 million and $1.6 million for the three months ended March 31, 2019 and 2018, respectively.
NOTE 8 – GOODWILL AND INTANGIBLE ASSETS

Effective January 1, 2019, the Company retrospectively changed its accounting for business combinations, which impacted the carrying amounts of its goodwill and intangible assets. Refer to Note 1 for further detail.

**Goodwill**

The gross carrying amount of goodwill as of March 31, 2019 and December 31, 2018 was $413.7 million.

The table below presents goodwill for the Company’s reportable segments as of March 31, 2019 (in thousands):

<table>
<thead>
<tr>
<th>Segment</th>
<th>Orphan and Rheumatology</th>
<th>Primary Care</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goodwill</td>
<td>$360,745</td>
<td>$52,924</td>
<td>$413,669</td>
</tr>
</tbody>
</table>

As of March 31, 2019, there were no accumulated goodwill impairment losses.

**Intangible Assets**

As of March 31, 2019, the Company’s finite-lived intangible assets consisted of developed technology related to ACTIMMUNE, BUPHENYL, KRYSTEXXA, MIGERGOT, PENNSAID 2%, PROCYSBI, RAVICTI and RAYOS, as well as customer relationships for ACTIMMUNE.

During the year ended December 31, 2018, in connection with the Immedica transaction, the Company recorded a reduction in the net book value of developed technology related to RAVICTI and AMMONAPS of $4.1 million. See Note 4 for further details.

The Company tests its intangible assets for impairment when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. During the year ended December 31, 2018, the Company recorded an impairment of $33.6 million to fully write off the book value of developed technology related to PROCYSBI in Canada and Latin America due primarily to lower anticipated future net sales based on a Patented Medicine Prices Review Board review. The fair value of developed technology was determined using an income approach.

The Company also recorded an impairment of $10.6 million during the year ended December 31, 2018, to fully write off the book value of developed technology related to LODOTRA as result of amendments to its license and supply agreements with Jagotec AG (“Jagotec”) and Skyepharma AG, which are affiliates of Vectura Group plc (“Vectura”). Under these amendments, effective January 1, 2019, the Company agreed to transfer all economic benefits of LODOTRA in Europe to Vectura during an initial transition period, with full rights transferring to Vectura when certain transfer activities have been completed. The Company no longer recorded LODOTRA revenue from January 1, 2019. The fair value of developed technology was determined using an income approach.

Intangible assets as of March 31, 2019 and December 31, 2018 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2019</th>
<th>December 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cost Basis</td>
<td>Accumulated Amortization</td>
</tr>
<tr>
<td>Developed technology</td>
<td>$2,784,403</td>
<td>$(895,972)</td>
</tr>
<tr>
<td>Customer relationships</td>
<td>8,100</td>
<td>(3,669)</td>
</tr>
<tr>
<td><strong>Total intangible assets</strong></td>
<td><strong>$2,792,503</strong></td>
<td><strong>$(899,641)</strong></td>
</tr>
</tbody>
</table>

Amortization expense for the three months ended March 31, 2019 and 2018 was $57.4 million and $60.9 million, respectively. As of March 31, 2019, estimated future amortization expense was as follows (in thousands):

<table>
<thead>
<tr>
<th>Year</th>
<th>Amortization Expense</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019 (April to December)</td>
<td>$174,316</td>
</tr>
<tr>
<td>2020</td>
<td>231,366</td>
</tr>
<tr>
<td>2021</td>
<td>225,861</td>
</tr>
<tr>
<td>2022</td>
<td>222,689</td>
</tr>
<tr>
<td>2023</td>
<td>222,069</td>
</tr>
<tr>
<td>Thereafter</td>
<td>818,561</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$1,892,862</strong></td>
</tr>
</tbody>
</table>
NOTE 9 – ACCRUED EXPENSES

Accrued expenses as of March 31, 2019 and December 31, 2018 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th>Account</th>
<th>March 31, 2019</th>
<th>December 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payroll-related expenses</td>
<td>$46,731</td>
<td>$78,555</td>
</tr>
<tr>
<td>Allowances for returns</td>
<td>37,076</td>
<td>39,041</td>
</tr>
<tr>
<td>Consulting and professional services</td>
<td>31,445</td>
<td>35,799</td>
</tr>
<tr>
<td>Accrued interest</td>
<td>24,810</td>
<td>13,196</td>
</tr>
<tr>
<td>Accrued royalties</td>
<td>15,350</td>
<td>15,746</td>
</tr>
<tr>
<td>Pricing review liability</td>
<td>12,966</td>
<td>9,091</td>
</tr>
<tr>
<td>Accrued other</td>
<td>28,864</td>
<td>24,311</td>
</tr>
<tr>
<td><strong>Accrued expenses</strong></td>
<td><strong>$197,242</strong></td>
<td><strong>$215,739</strong></td>
</tr>
</tbody>
</table>

NOTE 10 – ACCRUED TRADE DISCOUNTS AND REBATES

Accrued trade discounts and rebates as of March 31, 2019 and December 31, 2018 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th>Account</th>
<th>March 31, 2019</th>
<th>December 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accrued commercial rebates and wholesaler fees</td>
<td>$126,776</td>
<td>$153,083</td>
</tr>
<tr>
<td>Accrued co-pay and other patient assistance</td>
<td>138,586</td>
<td>179,463</td>
</tr>
<tr>
<td>Accrued government rebates and chargebacks</td>
<td>141,506</td>
<td>125,217</td>
</tr>
<tr>
<td><strong>Accrued trade discounts and rebates</strong></td>
<td><strong>$406,868</strong></td>
<td><strong>$457,763</strong></td>
</tr>
<tr>
<td>Invoiced commercial rebates and wholesaler fees, co-pay and other patient assistance, and government rebates and chargebacks in accounts payable</td>
<td>17,883</td>
<td>3,666</td>
</tr>
<tr>
<td><strong>Total customer-related accruals and allowances</strong></td>
<td><strong>$424,751</strong></td>
<td><strong>$461,429</strong></td>
</tr>
</tbody>
</table>

The following table summarizes changes in the Company’s customer-related accruals and allowances from December 31, 2018 to March 31, 2019 (in thousands):

<table>
<thead>
<tr>
<th>Description</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, 2018</td>
<td>$153,445</td>
<td>$179,462</td>
<td>$128,522</td>
<td>$461,429</td>
</tr>
<tr>
<td>Current provisions relating to sales during the three months ended March 31, 2019</td>
<td>113,962</td>
<td>417,739</td>
<td>116,710</td>
<td>648,411</td>
</tr>
<tr>
<td>Adjustments relating to prior-year sales</td>
<td>(4,379)</td>
<td>—</td>
<td>(2,132)</td>
<td>(6,511)</td>
</tr>
<tr>
<td>Payments relating to sales during the three months ended March 31, 2019</td>
<td>(14,937)</td>
<td>(275,410)</td>
<td>(28,287)</td>
<td>(318,634)</td>
</tr>
<tr>
<td>Payments relating to prior-year sales</td>
<td>(121,060)</td>
<td>(173,507)</td>
<td>(65,377)</td>
<td>(359,944)</td>
</tr>
<tr>
<td>Balance at March 31, 2019</td>
<td>$127,031</td>
<td>$148,284</td>
<td>$149,436</td>
<td>$424,751</td>
</tr>
</tbody>
</table>
Effective as of the second quarter of 2018, management realigned the Company’s reportable segments to reflect changes in the manner in which the Company’s chief operating decision maker (“CODM”) assesses financial information for decision-making purposes. This realignment resulted in the Company changing its reporting from one operating segment to two operating segments. All prior year amounts have been presented using the Company’s current reporting structure.

The Company has two reportable segments, the orphan and rheumatology segment and the primary care segment, and the Company reports net sales and segment operating income for each segment.

The orphan and rheumatology segment includes the marketed medicines ACTIMMUNE, BUPHENYL, KRYSTEXXA, PROCYSBI, QUINSAIR, RAVICTI and RAYOS/LODOTRA. The primary care segment consists of four marketed medicines, including DUEXIS, MIGERGOT, PENNSAID 2% and VIMOVO.

Management structured the business into two segments to improve operating and resource allocation decisions to align with the Company’s long-term strategic goal of transforming into a leading rare disease medicine company.

The Company’s CODM evaluates the financial performance of the Company’s segments based upon segment operating income. Segment operating income is defined as income (loss) before (benefit) expense for income taxes adjusted for the items set forth in the reconciliation below. Items below income from operations are not reported by segment, since they are excluded from the measure of segment profitability reviewed by the Company’s CODM. Additionally, certain expenses are not allocated to a segment. The Company does not report balance sheet information by segment as no balance sheet by segment is reviewed by the Company’s CODM.

The following table reflects net sales by medicine for the Company’s reportable segments for the three months ended March 31, 2019 and 2018 (in thousands):

<table>
<thead>
<tr>
<th>Medicine</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>KRYSTEXXA</td>
<td>$52,257</td>
<td>$46,718</td>
</tr>
<tr>
<td>RAVICTI</td>
<td>49,903</td>
<td>49,093</td>
</tr>
<tr>
<td>PROCYSBI</td>
<td>39,571</td>
<td>34,934</td>
</tr>
<tr>
<td>ACTIMMUNE</td>
<td>21,746</td>
<td>24,857</td>
</tr>
<tr>
<td>RAYOS</td>
<td>19,424</td>
<td>10,690</td>
</tr>
<tr>
<td>BUPHENYL</td>
<td>2,770</td>
<td>5,742</td>
</tr>
<tr>
<td>QUINSAIR</td>
<td>168</td>
<td>122</td>
</tr>
<tr>
<td>LODOTRA</td>
<td>—</td>
<td>115</td>
</tr>
<tr>
<td><strong>Orphan and Rheumatology segment net sales</strong></td>
<td><strong>$185,839</strong></td>
<td><strong>$172,271</strong></td>
</tr>
<tr>
<td>PENNSAID 2%</td>
<td>50,189</td>
<td>26,803</td>
</tr>
<tr>
<td>DUEXIS</td>
<td>29,457</td>
<td>15,677</td>
</tr>
<tr>
<td>VIMOVO</td>
<td>14,043</td>
<td>8,379</td>
</tr>
<tr>
<td>MIGERGOT</td>
<td>843</td>
<td>751</td>
</tr>
<tr>
<td><strong>Primary Care segment net sales</strong></td>
<td><strong>$94,532</strong></td>
<td><strong>$51,610</strong></td>
</tr>
<tr>
<td><strong>Total net sales</strong></td>
<td><strong>$280,371</strong></td>
<td><strong>$223,881</strong></td>
</tr>
</tbody>
</table>
The table below provides reconciliations of the Company’s segment operating income to the Company’s total income (loss) before (benefit) expense for income taxes for the three months ended March 31, 2019 and 2018 (in thousands):

<table>
<thead>
<tr>
<th>Segment operating income (loss):</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orphan and Rheumatology</td>
<td>$46,677</td>
<td>$43,104</td>
</tr>
<tr>
<td>Primary Care</td>
<td>41,446</td>
<td>(9,573)</td>
</tr>
</tbody>
</table>

Reconciling items:

- **Amortization and step-up:**
  - Intangible amortization expense: $(57,417) $(60,883)
  - Inventory step-up expense: $(115) $(17,076)
  - Share-based compensation: $(27,548) $(27,833)
  - Interest expense, net: $(27,530) $(30,454)
  - Loss on debt extinguishment: $(5,586) ---
  - Upfront and milestone payments related to license and collaboration agreements: $(2,000) $(90)
  - Depreciation: $(1,473) $(1,552)
  - Acquisition/divestiture-related costs: $(1,202) $(4,625)
  - Fees related to refinancing activities: $(142) $(27)
  - Drug substance harmonization costs: $(80) $(804)
  - Foreign exchange loss: $(61) $(3,342)
  - Restructuring and realignment costs: $(20) $(3,342)
  - Impairment of long-lived assets: --- $(33,647)
  - Charges relating to discontinuation of Friedreich’s ataxia program: 79 $(950)
  - Other income, net: 189 151

- **Loss before (benefit) expense for income taxes:** $(34,783) $(147,711)

The following table presents the amount and percentage of gross sales to customers that represented more than 10% of the Company’s gross sales included in its two reportable segments and all other customers as a group for the three months ended March 31, 2019 and 2018 (in thousands, except percentages):

<table>
<thead>
<tr>
<th>Customer</th>
<th>Amount</th>
<th>% of Gross Sales</th>
<th>Amount</th>
<th>% of Gross Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer A</td>
<td>$345,247</td>
<td>36%</td>
<td>$276,812</td>
<td>29%</td>
</tr>
<tr>
<td>Customer B</td>
<td>184,869</td>
<td>20%</td>
<td>217,857</td>
<td>23%</td>
</tr>
<tr>
<td>Customer C</td>
<td>122,057</td>
<td>13%</td>
<td>112,166</td>
<td>12%</td>
</tr>
<tr>
<td>Customer D</td>
<td>115,752</td>
<td>12%</td>
<td>55,419</td>
<td>6%</td>
</tr>
<tr>
<td>Other Customers</td>
<td>177,241</td>
<td>19%</td>
<td>292,185</td>
<td>30%</td>
</tr>
<tr>
<td><strong>Gross Sales</strong></td>
<td>$945,166</td>
<td>100%</td>
<td>$954,439</td>
<td>100%</td>
</tr>
</tbody>
</table>

Geographic revenues are determined based on the country in which the Company’s customers are located. The following table presents a summary of net sales attributed to geographic sources for the three months ended March 31, 2019 and 2018 (in thousands, except percentages):

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended March 31, 2019</th>
<th>Three Months Ended March 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>$279,209 (100%)</td>
<td>$219,371 (98%)</td>
</tr>
<tr>
<td>Rest of world</td>
<td>1,162</td>
<td>4,510</td>
</tr>
<tr>
<td><strong>Net sales</strong></td>
<td>$280,371 (100%)</td>
<td>$223,881 (100%)</td>
</tr>
</tbody>
</table>

* Less than 1%
NOTE 12 – 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.

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.

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 March 31, 2019 and December 31, 2018 (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>Money market funds</td>
<td>$1,010,625</td>
<td>$—</td>
<td>$—</td>
<td>$1,010,625</td>
</tr>
<tr>
<td>Other current assets</td>
<td>10,738</td>
<td>$—</td>
<td>$—</td>
<td>10,738</td>
</tr>
<tr>
<td><strong>Total assets at fair value</strong></td>
<td>$1,021,363</td>
<td>$—</td>
<td>$—</td>
<td>$1,021,363</td>
</tr>
<tr>
<td><strong>Liabilities:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other long-term liabilities</td>
<td>(10,738)</td>
<td>$—</td>
<td>$—</td>
<td>(10,738)</td>
</tr>
<tr>
<td><strong>Total liabilities at fair value</strong></td>
<td>$(10,738)</td>
<td>$—</td>
<td>$—</td>
<td>$(10,738)</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>$6,500</td>
<td>$—</td>
<td>$6,500</td>
</tr>
<tr>
<td>Money market funds</td>
<td>915,800</td>
<td>$—</td>
<td>$—</td>
<td>915,800</td>
</tr>
<tr>
<td>Other current assets</td>
<td>8,203</td>
<td>$—</td>
<td>$—</td>
<td>8,203</td>
</tr>
<tr>
<td><strong>Total assets at fair value</strong></td>
<td>$924,003</td>
<td>$6,500</td>
<td>$—</td>
<td>$930,503</td>
</tr>
<tr>
<td><strong>Liabilities:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other long-term liabilities</td>
<td>(8,203)</td>
<td>$—</td>
<td>$—</td>
<td>(8,203)</td>
</tr>
<tr>
<td><strong>Total liabilities at fair value</strong></td>
<td>$(8,203)</td>
<td>$—</td>
<td>$—</td>
<td>$(8,203)</td>
</tr>
</tbody>
</table>
NOTE 13 – DEBT AGREEMENTS

The Company’s outstanding debt balances as of March 31, 2019 and December 31, 2018 consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2019</th>
<th>December 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Term Loan Facility</td>
<td>$518,026</td>
<td>$818,026</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><strong>Total face value</strong></td>
<td><strong>1,693,026</strong></td>
<td><strong>1,993,026</strong></td>
</tr>
<tr>
<td>Debt discount</td>
<td>(78,465)</td>
<td>(87,038)</td>
</tr>
<tr>
<td>Deferred financing fees</td>
<td>(6,440)</td>
<td>(9,304)</td>
</tr>
<tr>
<td><strong>Total long-term debt</strong></td>
<td><strong>1,608,121</strong></td>
<td><strong>1,896,684</strong></td>
</tr>
<tr>
<td>Less: long-term debt—current portion</td>
<td>(250,000)</td>
<td>—</td>
</tr>
<tr>
<td><strong>Long-term debt, net of current portion</strong></td>
<td><strong>$1,358,121</strong></td>
<td><strong>$1,896,684</strong></td>
</tr>
</tbody>
</table>

**Term Loan Facility and Revolving Credit Facility**

On October 19, 2018, Horizon Pharma USA, Inc. (the “Borrower”), a wholly owned subsidiary of the Company, borrowed approximately $818.0 million aggregate principal amount of loans (the “October 2018 Refinancing Loans”) pursuant to an amendment (the “October 2018 Refinancing Amendment”) to the credit agreement, dated as of May 7, 2015, by and among the Borrower, 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, as amended by Amendment No. 1, dated as of October 25, 2016, Amendment No. 2, dated March 29, 2017 and Amendment No. 3, dated October 23, 2017 (the “2018 Term Loan Facility”). On March 11, 2019, the Borrower received $200.0 million aggregate principal amount of revolving commitments (the “New Incremental Revolving Commitments”) pursuant to an amendment (the “Revolving Facility Amendment”), dated as of March 11, 2019, to the October 2017 Credit Agreement as amended by the October 2018 Refinancing Amendment. The New Incremental Revolving Commitments were established pursuant to an incremental facility (the “Revolving Credit Facility”) and provide the Borrower with $200.0 million of additional borrowing capacity, which includes a $50.0 million letter of credit sub-facility. The New Incremental Revolving Commitments will terminate in March 2024, and borrowings under the Revolving Credit Facility are available for general corporate purposes. As of March 31, 2019, the Revolving Credit Facility was undrawn. As used herein, all references to the “Credit Agreement” are references to the October 2017 Credit Agreement, as amended by the October 2018 Refinancing Amendment, as further amended by the Revolving Facility Amendment.

The October 2018 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 October 23, 2017 under the October 2017 Credit Agreement (the “October 2017 Refinancing Loans”) to effectuate a repricing of the October 2017 Refinancing Loans. The Borrower used the proceeds of the October 2018 Refinancing Loans to repay the October 2017 Refinancing Loans, which totaled approximately $818.0 million. The October 2018 Refinancing Loans bear interest, at the Borrower’s option, at a rate equal to either the London Inter-Bank Offered Rate (“LIBOR”) plus an applicable margin of 3.00% per year (subject to a LIBOR floor of 1.00%), or the adjusted base rate plus 2.00% per year. The adjusted base rate is defined as the greatest of (a) LIBOR (using one-month interest period) plus 1.00%, (b) the prime rate, (c) the federal funds rate plus 0.50%, and (d) 2.00%. The interest rate applicable to loans under the Revolving Credit Facility is LIBOR plus 3.00%. As of March 31, 2019, there were no loans outstanding under the Revolving Credit Facility. Each of the foregoing applicable margins will be reduced by 0.25% if the Company’s ratio of consolidated total indebtedness to consolidated EBITDA, or leverage ratio, is less than or equal to 3.50 to 1.00. The Credit Agreement provides for (i) the October 2018 Refinancing Loans, (ii) the Revolving Credit Facility, (iii) one or more uncommitted additional incremental loan facilities subject to the satisfaction of certain financial and other conditions, and (iv) 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 additional borrowers under incremental or refinancing facilities.
The obligations under the Credit Agreement (including obligations in respect of the October 2018 Refinancing Loans and the Revolving Credit Facility) and any swap obligations and cash management obligations owing to a lender (or an affiliate of a lender) 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 October 2018 Refinancing Loans and the Revolving Credit Facility) and any related 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 Borrower and the guarantors, except for certain customary excluded assets, and (ii) all of the capital stock owned by the Borrower and guarantors thereunder (limited, in the case of the stock of certain non-U.S. subsidiaries of the Borrower, to 65% of the capital stock of such subsidiaries). The Borrower and the guarantors under the Credit Agreement are individually and collectively referred to herein as a “Loan Party” and the “Loan Parties,” as applicable.

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 Company’s sale of its rights to PROCYSBI and QUINSAIR in the Europe, Middle East and Africa regions to Chiesi Farmaceutici S.p.A. To the extent the Company had not applied 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 committed to so apply and then applied within 180 days after the end of such 365-day period), the Company was required to make a mandatory prepayment under the Credit Agreement in an amount equal to the unapplied net proceeds. In June 2018, the Company repaid $23.5 million under the mandatory prepayment provisions of the Credit Agreement.

On March 18, 2019, the Borrower completed the repayment of $300.0 million of the outstanding principal amount of term loans under the Credit Agreement following the closing of its underwritten public equity offering on March 11, 2019. Following this repayment, the outstanding principal balance of term loans under the Credit Agreement was $518.0 million and total aggregate outstanding principal amount of indebtedness was $1,693.0 million.

Additionally, 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 Immedica transaction. 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 of proceeds from the Immedica transaction (or commit to so apply and then apply within 180 days after the end of such 365-day period), the Borrower 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. Included in the repayment of term loans under the Credit Agreement of $300.0 million, as described above, was the repayment of $35.0 million of unapplied net proceeds under the mandatory prepayment provisions of the Credit Agreement.

The Borrower is permitted to make voluntary prepayments of the loans under the Credit Agreement at any time without payment of a premium. The Borrower is 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 October 2018 Refinancing Loans are amortized in equal quarterly installments that began on December 31, 2018, in an aggregate annual amount equal to 1.00% of the original principal amount of the October 2018 Refinancing Loans (i.e. $845.8 million), as the same may be reduced from time to time pursuant to the Credit Agreement (including by prepayments made prior to the date of the October 2018 Refinancing Amendment), with any remaining balance payable on March 29, 2024, the final maturity date of the October 2018 Refinancing Loans. Following the mandatory prepayment of $35.0 million in March 2019, as described above, the Company is not required to pay any further quarterly installments through the final maturity date of the October 2018 Refinancing Loans in March 2024.

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. The Credit Agreement also contains a springing financial maintenance covenant, which requires that the Company maintain a specified leverage ratio at the end of each fiscal quarter. The covenant is tested if both the outstanding loans and letters of credit under the Revolving Credit Facility, subject to certain exceptions, exceed 25% of the total commitments under the Revolving Credit Facility as of the last day of any fiscal quarter. If the Company fails to meet this covenant, the commitments under the Revolving Credit Facility could be terminated and any outstanding borrowings, together with accrued interest, under the Revolving Credit Facility could be declared immediately due and payable. As of March 31, 2019, the Revolving Credit Facility was undrawn.
Other events of default under the Credit Agreement include: (i) the failure 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 occur 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 interest on the Company’s 2018 Term Loan Facility is variable and as of March 31, 2019, the interest rate on the 2018 Term Loan Facility was 5.50% and the effective interest rate was 5.93%.

As of March 31, 2019, the fair value of the amounts outstanding under the 2018 Term Loan Facility was approximately $517.4 million, categorized as a Level 2 instrument, as defined in Note 12.

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 acquisition of Hyperion Therapeutics, Inc. (“Hyperion”) on May 7, 2015, Horizon Financing merged with and into Horizon Pharma, Inc. (“HPI”) and on October 31, 2018, HPI merged with and into Horizon Pharma USA, Inc. (“HPUSA”). As a result, the 2023 Senior Notes became the general unsecured senior obligations of HPUSA, which was previously a guarantor under the 2023 Senior Notes. 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.

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. 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, HPUSA 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, HPUSA 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, HPUSA will be required under certain circumstances to make an offer to purchase the 2023 Senior Notes at 100% of the principal amount thereof, plus accrued and unpaid interest to the repurchase date.

The indenture governing the 2023 Senior Notes contains covenants that limit the ability of the Company and its restricted subsidiaries to, among other things, pay dividends or distributions, repurchase equity, prepay junior debt and make certain investments, incur additional debt and issue certain preferred stock, incur liens on assets, engage in certain asset sales, merge, consolidate with or merge or sell all or substantially all of their assets, enter into transactions with affiliates, designate subsidiaries as unrestricted subsidiaries, and allow to exist certain restrictions on the ability of restricted subsidiaries to pay dividends or make other payments to the Company. Certain of the covenants will be suspended during any period in which the notes receive investment grade ratings. The indenture governing the 2023 Senior Notes also includes customary events of default.
As of March 31, 2019, the interest rate on the 2023 Senior Notes was 6.625% and the effective interest rate was 6.68%.

As of March 31, 2019, the fair value of the 2023 Senior Notes was approximately $490.4 million, categorized as a Level 2 instrument, as defined in Note 12.

Included in the current portion of long-term debt was $250.0 million related to the 2023 Senior Notes. As of March 31, 2019, the Company intended to redeem this amount of 2023 Senior Notes and the redemption subsequently occurred on May 1, 2019. In connection with this early redemption, the Company paid a premium of $8.3 million on May 1, 2019. Following this redemption, $225.0 million of the 2023 Senior Notes remain outstanding.

**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 8.750% Senior Notes due 2024 (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. On October 31, 2018, HPI merged with and into HPUSA, and as a result, HPI’s obligations as co-issuer under the 2024 Senior Notes became HPUSA’s general unsecured senior obligations.

The obligations under the 2024 Senior Notes are HPUSA’s 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 senior secured term loans under the Company’s term loan facility to fund a portion of the acquisition of Raptor Pharmaceutical Corp. (“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, HPUSA 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, HPUSA 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, HPUSA 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.

As of March 31, 2019, the interest rate on the 2024 Senior Notes was 8.75% and the effective interest rate was 9.20%.

As of March 31, 2019, the fair value of the 2024 Senior Notes was approximately $325.9 million, categorized as a Level 2 instrument, as defined in Note 12.
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 ended 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 March 31, 2019, none of the above conditions had been satisfied and no exchange of Exchangeable Senior Notes had been triggered.

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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 ASC Topic 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 March 31, 2019, the interest rate on the Exchangeable Senior Notes was 2.50% and the effective interest rate was 8.88%.

As of March 31, 2019, the fair value of the Exchangeable Senior Notes was approximately $452.0 million, categorized as a Level 2 instrument, as defined in Note 12.

NOTE 14 – LEASE OBLIGATIONS

As discussed in Note 2, the Company elected the Topic 842 transition provision that allows entities to continue to apply the legacy guidance in Topic 840, Leases, including its disclosure requirements, in the comparative periods presented in the year of adoption. Accordingly, the Topic 842 disclosures below are presented as of and for the three-month period ended March 31, 2019 only.

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

<table>
<thead>
<tr>
<th>Location</th>
<th>Approximate Square Feet</th>
<th>Lease Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dublin, Ireland</td>
<td>18,900</td>
<td>November 4, 2029</td>
</tr>
<tr>
<td>Lake Forest, Illinois</td>
<td>160,000</td>
<td>March 31, 2031</td>
</tr>
<tr>
<td>Novato, California</td>
<td>61,000</td>
<td>August 31, 2021</td>
</tr>
<tr>
<td>Brisbane, California (1)</td>
<td>20,100</td>
<td>November 19, 2019</td>
</tr>
<tr>
<td>South San Francisco, California (2)</td>
<td>20,000</td>
<td>January 31, 2030</td>
</tr>
<tr>
<td>Chicago, Illinois</td>
<td>9,200</td>
<td>December 31, 2028</td>
</tr>
<tr>
<td>Mannheim, Germany</td>
<td>4,800</td>
<td>December 31, 2020</td>
</tr>
<tr>
<td>Other</td>
<td>12,400</td>
<td>May 31, 2020 to September 15, 2022</td>
</tr>
</tbody>
</table>

(1) The remaining lease term on the Brisbane, California office space is less than twelve months as of the ASU No. 2016-02 adoption date of January 1, 2019. The Company elected not to recognize lease assets and liabilities for leases with a term of twelve months or less.

(2) In March 2019, the Company entered into an office lease agreement for approximately 20,000 square feet of office space in South San Francisco, California. The initial term of the lease will commence on November 1, 2019 and expire on January 31, 2030.

The Company recognizes rent expense on a monthly basis over the lease term based on a straight-line method. Rent expense was $1.6 million and $1.5 million for the three months ended March 31, 2019 and 2018, respectively.
The table below reconciles the undiscounted cash flows for each of the first five years and total of the remaining years to the operating lease liabilities recorded on the Company’s condensed consolidated balance sheet as of March 31, 2019 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>2019 (April to December)</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>Thereafter</th>
<th>Total lease payments</th>
<th>Imputed interest</th>
<th>Total operating lease liabilities</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$</td>
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<td></td>
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<tr>
<td>2019 (April to December)</td>
<td>$ -402</td>
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<td></td>
<td></td>
<td></td>
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<td></td>
<td>$ 37,077</td>
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<tr>
<td>2020</td>
<td>6,653</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2021</td>
<td>5,763</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2022</td>
<td>4,539</td>
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<tr>
<td>2023</td>
<td>4,417</td>
<td></td>
<td></td>
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<tr>
<td>Thereafter</td>
<td>36,263</td>
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<tr>
<td>Total lease payments</td>
<td>57,233</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Imputed interest</td>
<td>(20,156)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total operating lease liabilities</td>
<td>$ 37,077</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

The Company has certain leases that provide for lease incentives payable to the Company for construction of leasehold improvements. The cash inflows for these incentives are expected to be received in 2019 and are in excess of the Company’s expected lease payments resulting in a net cash inflow, as shown in the above table.

The weighted-average discount rate and remaining lease term for operating leases as of March 31, 2019 was 7.54% and 5.69 years, respectively.

NOTE 15 – COMMITMENTS AND CONTINGENCIES

Purchase Commitments

Patheon Pharmaceuticals Inc. (“Patheon”) is obligated to manufacture PROCYSBI for the Company through December 31, 2021. The Company must provide Patheon with rolling, non-binding forecasts of PROCYSBI, with a portion of the forecast being a firm written order. Cambrex Profarmaco Milano (“Cambrex”) is obligated to manufacture PROCYSBI active pharmaceutical ingredient (“API”) for the Company through November 2, 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 March 31, 2019, the Company had a binding purchase commitment with Patheon for PROCYSBI of $2.3 million, to be delivered through December 2019, and with Cambrex for PROCYSBI API of $1.6 million, to be delivered through December 2020.

Under an agreement with Boehringer Ingelheim Biopharmaceuticals GmbH (“Boehringer Ingelheim Biopharmaceuticals”), Boehringer Ingelheim Biopharmaceuticals is required to manufacture and supply ACTIMMUNE and IMUKIN to the Company. Following the IMUKIN sale, purchases by the Company of IMUKIN inventory are expected to be sold to Clinigen. The Company is required to purchase minimum quantities of finished medicine during the term of the agreement, which term extends to at least June 30, 2024. As of March 31, 2019, the minimum binding purchase commitment to Boehringer Ingelheim Biopharmaceuticals was $21.0 million (converted using a Dollar-to-Euro exchange rate of 1.1219) through July 2024. As of March 31, 2019, the Company also committed to incur an additional $1.0 million for the harmonization of the drug substance manufacturing process with Boehringer Ingelheim Biopharmaceuticals.

Under the Company’s agreement with Bio-Technology General (Israel) Ltd (“BTG Israel”), 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 for KRYSTEXXA 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 March 31, 2019, the Company had a binding purchase commitment with BTG Israel for KRYSTEXXA of $43.0 million, to be delivered through December 31, 2026. Additionally, purchase orders relating to the manufacture of KRYSTEXXA of $2.3 million were outstanding at March 31, 2019.
Jagotec or its affiliates are required to manufacture and supply RAYOS 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 March 31, 2019, the minimum purchase commitment based on tablet pricing in effect under the agreement was $4.2 million through December 2023. Additionally, purchase orders relating to the manufacture of RAYOS of $0.5 million were outstanding at March 31, 2019. Effective January 1, 2019, the Company amended its license and supply agreements with Jagotec AG and Skyepharma AG, which are affiliates of Vectura. Under these amendments, from the earlier of the completion of certain transfer activities related to the transfer of the Company’s rights to LODOTRA in Europe, or January 1, 2020, the Company will no longer be subject to a minimum purchase commitment in respect of the supply agreement with Jagotec AG.

Nuvo Pharmaceuticals Inc. (formerly known as Nuvo Research Inc.) (“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 March 31, 2019, the Company had a binding purchase commitment with Nuvo for PENNSAID 2% of $7.6 million, to be delivered through December 2019.

Sanofi-Aventis U.S. LLC (“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 2021 and automatically renews for successive two-year terms unless terminated by either party upon two years’ prior written notice. At March 31, 2019, the Company had a binding purchase commitment to Sanofi-Aventis U.S. for DUEXIS of $6.7 million, to be delivered through September 2019.

Excluding the above, additional purchase orders and other commitments relating to the manufacture of RAVICTI, BUPHENYL, QUINSAIR, VIMOVO and MIGERGOT of $10.5 million were outstanding at March 31, 2019. Additionally, at March 31, 2019, the Company had binding batch purchase commitments for teprotumumab of $5.4 million.

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 may 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.

On March 5, 2019, the Company received a civil investigative demand (“CID”) from the United States Department of Justice (“DOJ”) pursuant to the Federal False Claims Act regarding assertions that certain of the Company’s payments to pharmacy benefit managers (“PBMs”) were potentially in violation of the Anti-Kickback Statute. The CID requests certain documents and information related to the Company’s payments to PBMs, pricing and the Company’s patient assistance program regarding DUEXIS, VIMOVO and PENNSAID 2%. The Company is cooperating with the investigation. While the Company believes that its payments and programs are compliant with the Anti-Kickback Statute, no assurance can be given as to the timing or outcome of the DOJ’s investigation, or that it will not result in a material adverse effect on the Company’s business.
Under the agreement for the acquisition of River Vision Development Corp., the Company is required to pay up to $325.0 million upon the attainment of various milestones, composed of $100.0 million related to U.S. Food and Drug Administration (“FDA”) approval and $225.0 million related to net sales thresholds for teprotumumab. The agreement also includes a royalty payment of three percent of the portion of annual worldwide net sales exceeding $300.0 million (if any). Under a separate agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (together referred to as “Roche”), the Company is required to pay Roche up to CHF103.0 million ($103.4 million when converted using a CHF-to-Dollar exchange rate at March 31, 2019 of 1.0047) upon the attainment of various milestones related to approval, filing and net sales thresholds for teprotumumab. During the year ended December 31, 2017, CHF2.0 million ($2.0 million when converted using a CHF-to-Dollar exchange rate at the date of payment of 1.0169) was paid in relation to these milestones. The agreement with Roche also includes a royalty payment of between nine percent and twelve percent of annual worldwide net sales. Under a separate agreement with Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (“LA BioMed”), the Company is required to pay LA BioMed a royalty payment of less than one percent of net sales.

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. 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. The Company also has a director and officer insurance policy that enables it to recover a portion of any amounts paid for current and future potential claims. All of the Company’s officers and directors have also entered into separate indemnification agreements with HPUSA.

NOTE 16 - LEGAL PROCEEDINGS

RAVICTI

On March 17, 2014, Hyperion received notice from Par Pharmaceutical, Inc. (“Par Pharmaceutical”) that it had filed an Abbreviated New Drug Application (an “ANDA”) with the FDA seeking approval for a generic version of the Company’s medicine RAVICTI. On September 4, 2015 and November 6, 2015, the Company received notices from Lupin Limited of Lupin Limited’s Paragraph IV Patent Certification against the Company’s patents covering RAVICTI, advising that Lupin Limited had filed an ANDA with the FDA for a generic version of RAVICTI. The Company subsequently filed suits against Par Pharmaceutical and Lupin Limited, and engaged in ANDA litigation with both in multiple venues. All litigation with Par Pharmaceutical and Lupin Limited, relating to RAVICTI, is now settled.

The Company is still pursuing an appeal before the Federal Circuit Court of Appeals over U.S. Patent No. 9,095,559 against the United States Patent Office, seeking to overturn the Patent Trial and Appeal Board’s invalidity finding in an inter partes review (“IPR”) initiated by Lupin Limited.

PENNSAID 2%

On November 13, 2014, the Company received a Paragraph IV Patent Certification from Watson Laboratories, Inc., now known as Actavis Laboratories UT, Inc. (“Actavis UT”), advising that Actavis UT had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On December 23, 2014, June 30, 2015, August 11, 2015 and September 17, 2015, the Company filed four separate suits against Actavis UT and Actavis plc (collectively “Actavis”), in the United States District Court for the District of New Jersey, with each of the suits seeking an injunction to prevent approval of the ANDA. The lawsuits alleged that Actavis has infringed nine of the Company’s patents covering PENNSAID 2% 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 (the “Orange Book”). These four suits were consolidated into a single suit. On October 27, 2015 and on February 5, 2016, the Company filed two additional suits against Actavis, in the United States District Court for the District of New Jersey, for patent infringement of three additional Company patents covering PENNSAID 2%.
On August 17, 2016, the District Court issued a Markman opinion holding certain of the asserted claims of seven of the Company’s patents covering PENNSAID 2% invalid as indefinite. On March 16, 2017, the Court granted Actavis’ motion for summary judgment of non-infringement of the asserted claims of three of the Company’s patents covering PENNSAID 2%. In view of the Markman and summary judgment decisions, a bench trial was held from March 21, 2017 through March 30, 2017, regarding a claim of one of the Company’s patents covering PENNSAID 2%. On May 14, 2017, the Court issued its opinion upholding the validity of the 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 also filed its Notice of Appeal of the District Court’s rulings on certain claims of eleven of the Company’s patents covering PENNSAID 2%. The parties are awaiting the decision of the Federal Circuit Court of Appeals.

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 four of the Company’s newly issued patents covering PENNSAID 2%. All four of such patents are listed in the Orange Book. This litigation is currently stayed by agreement of the parties. The Company received from Actavis a Paragraph IV Patent Certification notice, dated September 27, 2016, against an additional newly issued patent covering PENNSAID 2%, advising that Actavis had filed an ANDA with the FDA for a generic version of PENNSAID 2%. The subject patent is listed in the Orange Book.

On March 29, 2019, the Company received notice from Aurolife Pharma, Inc. ("Aurolife") that it had filed an ANDA with the FDA seeking approval for a generic version of PENNSAID 2%. The ANDA contained a Paragraph IV Patent Certification alleging that the patents covering PENNSAID 2% are invalid and/or will not be infringed by Aurolife’s manufacture, use or sale of its generic version of PENNSAID 2%.

**DUEXIS**

On May 29, 2018, the Company received notice from Alkem Laboratories, Inc. ("Alkem") that it had filed an ANDA with the FDA seeking approval for a generic version of DUEXIS. The ANDA contained a Paragraph IV Patent Certification alleging that the patents covering DUEXIS are invalid and/or will not be infringed by Alkem’s manufacture, use or sale of the medicine for which the ANDA was submitted. The Company filed suit in the United States District Court of Delaware against Alkem on July 9, 2018, seeking an injunction to prevent the approval of Alkem’s ANDA and/or to prevent Alkem from selling a generic version of DUEXIS. The litigation is scheduled for a bench trial beginning on September 14, 2020.

On September 27, 2018, the Company received notice from Teva Pharmaceuticals USA, Inc. ("Teva") that it had filed an ANDA with the FDA seeking approval for a generic version of DUEXIS. The ANDA contained a Paragraph IV Patent Certification alleging that the patents covering DUEXIS are invalid and/or will not be infringed by Teva’s manufacture, use or sale of its generic version of DUEXIS.

**VIMOVO**

Currently, patent litigation is pending in the United States District Court for the District of New Jersey and the Court of Appeals for the Federal Circuit against three generic companies intending to market VIMOVO prior to the expiration of certain of the Company’s patents listed in the Orange Book. 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 Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"); and (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, "Mylan").

The Company understands that Dr. Reddy’s has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium® (esomeprazole) for the commercialization of VIMOVO. The settlement agreement, however, has no effect on the Nuvo 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 litigation that includes the Nuvo patents licensed to the Company under the amended and restated collaboration and license agreement for the United States with Nuvo.

The District Court consolidated all of the cases pending against the generic companies into two separate cases for purposes of discovery. The District Court entered final judgment for one of the consolidated cases on July 21, 2017, and both sides have appealed the District Court’s judgment to the Court of Appeals for the Federal Circuit. On November 19, 2018, the District Court granted Dr. Reddy’s and Mylan summary judgment ruling that U.S Patent Numbers 9,220,698 and 9,393,208 are invalid, and on January 21, 2019, it entered final judgment against the ‘698, ‘208, and U.S. Patent Number 8,945,621. On February 21, 2019, the Company initiated an appeal of the adverse judgments on the ‘208 and ‘698 patents with the Federal Circuit Court of Appeals. Proceedings on all remaining patents are currently stayed.

On August 24, 2017, Mylan filed a Petition for IPR against the ‘698 patent. The Company filed its Preliminary Patent Owner Response on December 12, 2017. On March 8, 2018, the Patent Trial and Appeals Board (the “PTAB”) instituted Mylan’s Petition for IPR. On March 27, 2019, the PTAB vacated its institution order and dismissed the ‘698 IPR.

On December 4, 2017, Mylan filed a Petition for IPR against the ‘208 patent. The PTAB instituted an IPR proceeding on Mylan’s Petition on June 14, 2018. On July 2, 2018, Dr. Reddy’s file a motion seeking to join Mylan’s ‘208 IPR. On April 1, 2019, the PTAB granted Dr. Reddy’s request to join the Mylan ‘208 IPR.

On April 29, 2019, the Company and Lupin entered into a Settlement and License Agreement (“Lupin Settlement Agreement”) under which they agreed to file stipulations of dismissal of the VIMOVO cases and pending appeals. The Lupin Settlement Agreement also provides for a full settlement and release by each party of all claims that relate to Lupin’s generic version of VIMOVO. Under the Lupin Settlement Agreement, the license entry date is January 1, 2025; however, Lupin may be able to enter the market earlier in certain circumstances.

NOTE 17 – SHAREHOLDERS’ EQUITY

On February 28, 2019, the Company entered into a Rights Agreement (the “Rights Agreement”), with Computershare Trust Company, N.A., as rights agent. The Board of Directors of the Company (the “Board”) has authorized the issuance of one ordinary share purchase right (a “Right”) for each outstanding ordinary share of the Company. Each Right represents the right to purchase one-fifth of an ordinary share of the Company, upon the terms and subject to the conditions of the Rights Agreement. The Rights were issued to the shareholders of record on March 11, 2019 and will expire on February 28, 2020.

The Board has adopted the Rights Agreement to enable all shareholders of the Company to realize the long-term value of their investment in the Company and to guard against attempts to acquire control of the Company at an inadequate price. In general terms, the Rights Agreement works by causing significant dilution to any person or group that acquires 10% (or 15% in the case of an existing “13G Investor” as defined in the Rights Agreement) or more of the outstanding ordinary shares of the Company without the prior approval of the Board. The Rights Agreement is not intended to prevent an acquisition of the Company on terms that the Board considers favorable to, and in the best interests of, all shareholders. Rather, the Rights Agreement aims to provide the Board with adequate time to fully assess any takeover proposal and therefore comply with its fiduciary duties and to encourage anyone seeking to acquire the Company to negotiate with the Board prior to attempting a takeover. The Rights Agreement was adopted in response to the takeover environment in general, particularly in light of the Company’s evolution into a biopharma company focused on rare diseases and rheumatology, the Phase 3 clinical trial results of its rare disease drug candidate teprotumumab announced on February 28, 2019 and the market opportunity for KRYSTEXXA and teprotumumab and was not in response to any specific approach to the Company or perceived imminent takeover proposal for the Company. The issuance of Rights is not taxable to the Company or to shareholders and does not affect reported earnings per share.

During the three months ended March 31, 2019, the Company issued an aggregate of 14.1 million of ordinary shares in connection with the closing of its underwritten public equity offering on March 11, 2019. The Company received a total of approximately $326.8 million after deducting underwriting discounts and other estimated offering expenses payable by the Company in connection with such offering.

During the three months ended March 31, 2019, the Company issued an aggregate of 1.8 million of ordinary shares in connection with stock option exercises and the vesting of restricted stock units. The Company received a total of $10.0 million in net proceeds in connection with such issuances.

During the three months ended March 31, 2019, the Company made payments of $17.2 million for employee withholding taxes relating to share-based awards.
On May 2, 2019, the shareholders of the Company approved an increase in the Company’s authorized share capital of an additional 300,000,000 ordinary shares of nominal value $0.0001 per share.

On May 2, 2019, the shareholders of the Company approved the renewal of the Board’s existing authority to allot and issue ordinary shares for cash and non-cash considerations under Irish law for a five-year period to expire on May 2, 2024. Additionally, on May 2, 2019, the shareholders of the Company approved the renewal of the Board’s existing authority to allot and issue ordinary shares for cash without first offering those ordinary shares to existing shareholders pursuant to the statutory pre-emption right that would otherwise apply under Irish law for a five-year period to expire on May 2, 2024.

NOTE 18 – SHARE-BASED AND LONG-TERM INCENTIVE PLANS

The Company’s equity incentive plans at March 31, 2019, include its 2005 Stock Plan, 2011 Equity Incentive Plan, as amended, 2014 Employee Share Purchase Plan, as amended (“2014 ESPP”), Amended and Restated 2014 Equity Incentive Plan (“2014 EIP”) and 2014 Non-Employee Equity Plan, as amended (“2014 Non-Employee Plan”). As of March 31, 2019, an aggregate of 2,084,665 ordinary shares were authorized and available for future issuance under the 2014 ESPP, an aggregate of 2,190,411 ordinary shares were authorized and available for future grants under the 2014 EIP (of which 495,665 shares are to be used exclusively for grants of awards to individuals who were not previously employees or non-employee directors of the Company (or following a bona fide period of non-employment with the Company)) and an aggregate of 116,163 ordinary shares were authorized and available for future grants under the 2014 Non-Employee Plan.

On February 20, 2019, the Compensation Committee of the Board (the “Compensation Committee”) approved, subject to shareholder approval, an amendment to the 2014 EIP, increasing the number of ordinary shares that may be issued under the 2014 EIP by 9,000,000 ordinary shares, subject to adjustment for certain changes in our capitalization. On May 2, 2019, the shareholders of the Company approved such amendment to the 2014 EIP.

On February 20, 2019, the Compensation Committee approved, subject to shareholder approval, an amendment to the 2014 Non-Employee Plan, increasing the number of ordinary shares that may be issued under the 2014 Non-Employee Equity Plan by 750,000 ordinary shares, subject to adjustment for certain changes in our capitalization. On May 2, 2019, the shareholders of the Company approved such amendment to the 2014 Non-Employee Plan.

Stock Options

The following table summarizes stock option activity during the three months ended March 31, 2019:

<table>
<thead>
<tr>
<th>Options</th>
<th>Weighted Average Exercise Price</th>
<th>Weighted Average Contractual Term Remaining (in years)</th>
<th>Aggregate Intrinsic Value (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2018 11,827,765</td>
<td>$19.06</td>
<td>6.24</td>
<td>$37,257</td>
</tr>
<tr>
<td>Exercised (618,324)</td>
<td></td>
<td>16.09</td>
<td></td>
</tr>
<tr>
<td>Forfeited (81,555)</td>
<td></td>
<td>24.52</td>
<td></td>
</tr>
<tr>
<td>Expired (91,138)</td>
<td></td>
<td>23.81</td>
<td></td>
</tr>
<tr>
<td>Outstanding as of March 31, 2019 11,036,748</td>
<td>$19.15</td>
<td>5.94</td>
<td>86,791</td>
</tr>
<tr>
<td>Exercisable as of March 31, 2019 9,925,625</td>
<td>$19.35</td>
<td>5.74</td>
<td>76,521</td>
</tr>
</tbody>
</table>

Stock options typically have a contractual term of ten years from grant date.

Restricted Stock Units

The following table summarizes restricted stock unit activity for the three months ended March 31, 2019:

<table>
<thead>
<tr>
<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, 2018 6,772,818</td>
<td>$15.56</td>
</tr>
<tr>
<td>Granted 2,809,817</td>
<td>20.46</td>
</tr>
<tr>
<td>Vested (1,451,576)</td>
<td>17.09</td>
</tr>
<tr>
<td>Forfeited (169,049)</td>
<td>16.34</td>
</tr>
<tr>
<td>Outstanding as of March 31, 2019 7,962,010</td>
<td>$16.99</td>
</tr>
</tbody>
</table>

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

The following table summarizes performance stock unit awards (“PSUs”) activity for the three months ended March 31, 2019:

<table>
<thead>
<tr>
<th></th>
<th>Number of Units</th>
<th>Weighted Average Grant-Date Fair Value Per Unit</th>
<th>Average Illiquidity Discount</th>
<th>Recorded Weighted Average Fair Value Per Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2018</td>
<td>1,393,943</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granted</td>
<td>689,057</td>
<td>$23.73</td>
<td>2.7%</td>
<td>$23.10</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(21,089)</td>
<td>16.00</td>
<td>2.7%</td>
<td>15.56</td>
</tr>
<tr>
<td>Vested</td>
<td>(515,629)</td>
<td>13.87</td>
<td>0.0%</td>
<td>13.87</td>
</tr>
<tr>
<td>Performance Based Adjustment (1)</td>
<td>560,746</td>
<td>13.87</td>
<td>0.0%</td>
<td>13.87</td>
</tr>
<tr>
<td>Outstanding as of March 31, 2019</td>
<td>2,107,028</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(1) Represents adjustment based on the net sales performance criteria meeting 157.4% of target as of December 31, 2018.

On January 5, 2018, the Company awarded PSUs to key executive participants (“2018 PSUs”). Vesting of the 2018 PSUs was contingent upon receiving shareholder approval of amendments to the 2014 EIP, which were approved on May 3, 2018. The 2018 PSUs utilize two performance metrics, a short-term component tied to business performance and a long-term component tied to total compounded annual shareholder rate of return (“TSR”), as follows:

- 30% of the 2018 PSUs that may vest (such portion of the PSU award, the “2018 Relative TSR PSUs”) are determined by reference to the level of the Company’s relative TSR over the three-year period ending December 31, 2020, as measured against the TSR of each company included in the Nasdaq Biotechnology Index (NBI) during such three-year period. Generally, in order to earn any portion of the 2018 Relative TSR PSUs, the participant must also remain in continuous service with the Company through the earlier of January 1, 2021 or the date immediately prior to a change in control. If a change in control occurs prior to December 31, 2020, the level of the Company’s relative TSR will be measured through the date of the change in control.

- 70% of the 2018 PSUs that may vest (such portion of the PSU award, the “2018 Net Sales PSUs”), are determined by reference to the Company’s net sales for its segments during 2018 (being the orphan and rheumatology segment and primary care segment), weighted with the orphan and rheumatology segment comprising the majority of the target sales (with respect to the total PSU award). During the year ended December 31, 2018, the net sales performance criteria was met at 157.4% of target. Accordingly, the first tranche of the 2018 Net Sales PSUs portion have vested and the remaining two tranches will vest in equal installments in January 2020 and January 2021, subject to the participant’s continued service with the Company through the applicable vesting dates.

On January 4, 2019, the Company awarded PSUs to key executive participants (“2019 PSUs”). The 2019 PSUs utilize two performance metrics, a short-term component tied to business performance and a long-term component tied to relative compounded annual TSR, as follows:

- 30% of the 2019 PSUs that may vest (such portion of the PSU award, the “2019 Relative TSR PSUs”) are determined by reference to the level of the Company’s relative TSR over the three-year period ending December 31, 2021, as measured against the TSR of each company included in the Nasdaq Biotechnology Index (NBI) during such three-year period. Generally, in order to earn any portion of the 2019 Relative TSR PSUs, the participant must also remain in continuous service with the Company through the earlier of January 1, 2022 or the date immediately prior to a change in control. If a change in control occurs prior to December 31, 2021, the level of the Company’s relative TSR will be measured through the date of the change in control.

- 70% of the 2019 PSUs that may vest (such portion of the PSU award, the “2019 Net Sales PSUs”), are determined by reference to the Company’s net sales for its orphan and rheumatology segment.
All PSUs outstanding at March 31, 2019, may vest in a range of between 0% and 200%, based on the performance metrics described above. The Company accounts for the 2018 PSUs and 2019 PSUs as equity-settled awards in accordance with ASC 718. Because the value of the 2018 Relative TSR PSUs and 2019 Relative TSR PSUs are 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 2018 Relative TSR PSUs and 2019 Relative TSR PSUs. As a result, the Monte Carlo model is applied and the most significant valuation assumptions used related to the 2019 PSUs during the three months ended March 31, 2019, include:

<table>
<thead>
<tr>
<th>Valuation date stock price</th>
<th>$20.39</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected volatility</td>
<td>38.9%</td>
</tr>
<tr>
<td>Risk free rate</td>
<td>2.6%</td>
</tr>
</tbody>
</table>

The value of the 2018 Net Sales PSUs and 2019 Net Sales PSUs is calculated at the end of each quarter based on the expected payout percentage based on estimated full period performance against targets, and the Company adjusts the expense quarterly.

On January 4, 2019, the Company awarded a company-wide grant of PSUs (the “Teprotumumab PSUs”). Vesting of the Teprotumumab PSUs was contingent upon receiving shareholder approval of amendments to the 2014 EIP, which approval was received on May 2, 2019. Additionally, the Teprotumumab PSUs are generally eligible to vest contingent upon receiving approval of teprotumumab from the FDA no later than September 30, 2020 and the employee’s continued service with the Company. At March 31, 2019, there were 1,583,006 Teprotumumab PSUs outstanding pending shareholder approval.

Share-Based Compensation Expense

The following table summarizes share-based compensation expense included in the Company’s condensed consolidated statements of operations for the three months ended March 31, 2019 and 2018 (in thousands):

<table>
<thead>
<tr>
<th>Share-based compensation expense</th>
<th>For the Three Months Ended March 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>$1,039</td>
</tr>
<tr>
<td>Research and development</td>
<td>2,636</td>
</tr>
<tr>
<td>Selling, general and administrative</td>
<td>23,873</td>
</tr>
<tr>
<td>Total share-based compensation expense</td>
<td>$27,548</td>
</tr>
</tbody>
</table>

During the three months ended March 31, 2019 and 2018, the Company recognized $2.5 million of tax benefit and $0.4 million of tax detriment, respectively, related to share-based compensation resulting from the current share prices in effect at the time of the exercise of stock options and vesting of restricted stock units. As of March 31, 2019, the Company estimates that pre-tax unrecognized compensation expense of $181.3 million for all unvested share-based awards, including stock options, restricted stock units and PSUs, will be recognized through the first quarter of 2022. 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.

Cash Incentive Program

On January 5, 2018, the Compensation Committee approved a performance cash incentive program for the Company’s executive leadership team, including its executive officers (the “Cash Incentive Program”). Participants receiving awards under the Cash Incentive Program are eligible to earn a cash bonus based upon the achievement of specified Company goals, which both performance criteria were met on or before December 31, 2018. The Company determined that the cash bonus award under the Cash Incentive Program is to be paid out at the maximum 150% target level of $14.1 million. The first installment was paid in January 2019, and the remaining installments will vest and become payable in January 2020 and 2021, subject to the participant’s continued services with the Company through the applicable vesting dates, the date of any earlier change in control, or a termination due to death or disability.

The Company accounted for the Cash Incentive Program as a deferred compensation plan under ASC 710 and is recognizing the payout expense using straight-line recognition through the end of the 36-month vesting period. During the three months ended March 31, 2019 and 2018, the Company recorded an expense of $1.2 million and $1.3 million, respectively, to the condensed consolidated statement of comprehensive loss related to the Cash Incentive Program.
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. 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. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the period in which the change is enacted.

The following table presents the (benefit) expense for income taxes for the three months ended March 31, 2019 and 2018 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended March 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td>Loss before (benefit) expense for income taxes</td>
<td>$(34,783)</td>
</tr>
<tr>
<td>(Benefit) expense for income taxes</td>
<td>$(1,920)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$(32,863)</td>
</tr>
</tbody>
</table>

During the three months ended March 31, 2019, the Company recorded a benefit for income taxes of $1.9 million. During the three months ended March 31, 2018, the Company recorded an expense for income taxes of $0.9 million. The benefit for income taxes recorded during the three months ended March 31, 2019 resulted primarily from the tax benefits recognized on share-based compensation and the mix of pre-tax income and losses incurred in various tax jurisdictions.
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.

Unless otherwise indicated or the context otherwise requires, references to “Horizon”, “we”, “us” and “our” refer to Horizon Therapeutics plc (formerly known as Horizon Pharma plc) and its consolidated subsidiaries.

When accounting for business combinations under ASC Topic 805, Business Combinations, we previously separately identified and recorded at fair value intangible assets acquired and their related third-party contingent royalties at the date of acquisition. Third-party contingent royalties are royalties payable to parties other than sellers of the businesses. Effective January 1, 2019, we retrospectively changed our accounting for business combinations and will record acquired intangible assets and their related third-party contingent royalties on a net basis, or the New Method. We changed our accounting principle on the basis that the use of the New Method is preferable primarily due to improved comparability with our peers. We adjusted the accompanying condensed consolidated balance sheet as at December 31, 2018, and the condensed consolidated statement of comprehensive loss and of cash flows for the three months ended March 31, 2018, and the adjusted amounts are presented herein.

OUR BUSINESS

Horizon is focused on researching, developing and commercializing medicines that address critical needs for people impacted by rare and rheumatic diseases. Our pipeline is purposeful: we apply scientific expertise and courage to bring clinically meaningful therapies to patients. We believe science and compassion must work together to transform lives.

We have two reportable segments, (i) the orphan and rheumatology segment, our strategic growth business, and (ii) the primary care segment, and we report net sales and segment operating income for each segment.

Our marketed medicines are:

**Orphan and Rheumatology**
- KRYSTEXXA® (pegloticase injection), for intravenous infusion
- RAVICTI® (glycerol phenylbutyrate) oral liquid
- PROCYSBI® (cysteamine bitartrate) delayed-release capsules, for oral use
- ACTIMMUNE® (interferon gamma-1b) injection, for subcutaneous use
- RAYOS® (prednisone) delayed-release tablets
- BUPHENYL® (sodium phenylbutyrate) Tablets and Powder
- QUINSAIR™ (levofloxacin) solution for inhalation

**Primary Care**
- PENNSAID® (diclofenac sodium topical solution) 2% w/w, or PENNSAID 2%, for topical use
- DUEXIS® (ibuprofen/famotidine) tablets, for oral use
- VIMOVO® (naproxen/esomeprazole magnesium) delayed-release tablets, for oral use
- MIGERGOT® (ergotamine tartrate & caffeine suppositories), for rectal use
Acquisitions and Divestitures

Since January 1, 2018, we completed the following acquisitions and divestitures:

- Effective January 1, 2019, we amended our license and supply agreements with Jagotec AG and Skyepharma AG, which are affiliates of Vectura Group plc, or Vectura. Under these amendments, we agreed to transfer all economic benefits of LODOTRA® in Europe to Vectura during an initial transition period, with full rights transferring to Vectura when certain transfer activities have been completed. We no longer recorded LODOTRA revenue from January 1, 2019.

- On December 28, 2018 we sold our rights to RAVICTI and AMMONAPS (known as BUPHENYL in the United States) outside of North America and Japan to Medical Need Europe AB, part of the Immedica Group, or the Immedica transaction. We previously distributed RAVICTI and AMMONAPS through a commercial partner in Europe and other non-U.S. markets. We have retained the rights to RAVICTI and BUPHENYL in North America and Japan.

- On July 24, 2018, we sold the rights to interferon gamma-1b (known as IMUKIN outside the United States) in all territories outside of the United States, Canada and Japan to Clinigen Group plc, or Clinigen, for an upfront payment and a potential additional contingent consideration payment, or the IMUKIN sale.

Strategy

We aspire to be a leading rare disease biopharma company that delivers innovative therapies to patients and generates high returns for our shareholders. Our strategy is to build a robust and differentiated pipeline and to maximize the growth of our marketed rare disease medicines, in particular, KRYSTEXXA, our medicine for uncontrolled gout. 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 patients have access to medicines and support services and to investing in the further development of medicines for patients with rare or underserved diseases.

On May 2, 2019, our shareholders approved changing our name from “Horizon Pharma Public Limited Company” to “Horizon Therapeutics Public Limited Company”. We believe that the name “Horizon Therapeutics Public Limited Company” better reflects our long-term strategy to develop and commercialize innovative new medicines to address rare diseases with very few effective options.

Orphan and Rheumatology

RAVICTI, PROCYSBI, ACTIMMUNE, BUPHENYL and QUINSAIR are our marketed orphan medicines – all for rare diseases. Our strategy for RAVICTI is to drive growth through increased awareness and diagnosis of urea cycle disorders; to drive conversion to RAVICTI from older-generation nitrogen scavengers, such as generic forms of sodium phenylbutyrate based on the medicine’s differentiated benefits; and to increase awareness of label expansion of RAVICTI to position the medicine as first line of therapy. With respect to PROCYSBI, our strategy is to drive conversion of patients to PROCYSBI from older-generation immediate-release capsules of cysteamine bitartrate; increase the uptake of diagnosed but untreated patients; identify previously undiagnosed patients who are suitable for treatment; and increase awareness of the expanded label to position PROCYSBI as a first line of therapy. Our strategy with respect to ACTIMMUNE includes increasing awareness and diagnosis of chronic granulomatous disease and increasing the persistence of and adherence to treatment.

With our May 2017 acquisition of River Vision Development Corp., or River Vision, we added the late-stage rare disease biologic medicine candidate teprotumumab to our pipeline. Teprotumumab targets the treatment of thyroid eye disease, or TED, a debilitating autoimmune condition for which there is no approved treatment. Our strategy for teprotumumab is to support its continued clinical development and pursue regulatory approval.

On February 28, 2019, we reported statistically significant topline results from our Phase 3 confirmatory trial evaluating teprotumumab for the treatment of active TED. The study met its primary endpoint of the percentage of study participants with a 2 mm or more reduction in proptosis, or bulging of the eye, which is the main cause of morbidity in TED, at 24 weeks of treatment. The percent of patients treated with teprotumumab who had a meaningful improvement in proptosis was 82.9 percent compared to 9.5 percent of placebo patients, demonstrating the potential for teprotumumab to be a disease-modifying treatment. In addition, all secondary endpoints were met, and the safety profile was consistent with the Phase 2 study of teprotumumab in TED, which also met its primary endpoint and secondary endpoints, with the results published in The New England Journal of Medicine. We expect to submit a biologics license application in mid-2019, with the potential for approval in 2020. 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.
The rare disease medicine KRYSTEXXA is our primary marketed rheumatology medicine, the only approved medicine indicated for the treatment of uncontrolled gout, or gout that is refractory (unresponsive) to conventional therapies. We are focused on optimizing and maximizing the peak sales potential of KRYSTEXXA by expanding our commercialization efforts as well as investing in education, patient and physician outreach that demonstrates the benefits KRYSTEXXA offers in treating uncontrolled gout. In addition, we are investing in clinical development programs to increase the number of patients who can benefit from KRYSTEXXA by evaluating ways to improve its response rate. We believe that KRYSTEXXA represents a significant opportunity as a growth driver within our orphan and rheumatology segment. We also market the rheumatology medicine RAYOS.

Primary Care

Our strategy with respect to our primary care medicines, which include PENNSAID 2%, DUEXIS, VIMOVO and MIGERGOT, 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 entered into business arrangements with pharmacy benefit managers, or PBMs, and other payers to secure formulary status and reimbursement of our primary care 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.

We market all of our medicines in the United States through our field sales force, which numbered approximately 415 representatives as of March 31, 2019.

RESULTS OF OPERATIONS

Comparison of Three Months Ended March 31, 2019 and 2018

Consolidated Results

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 March 31, 2019, compared to the three months ended March 31, 2018.

<table>
<thead>
<tr>
<th>For the Three Months Ended March 31,</th>
<th>2019 (in thousands)</th>
<th>2018 (in thousands)</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>$280,371</td>
<td>$223,881</td>
<td>$56,490</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>88,142</td>
<td>110,288</td>
<td>(22,146)</td>
</tr>
<tr>
<td>Gross profit</td>
<td>192,229</td>
<td>113,593</td>
<td>78,636</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>21,725</td>
<td>17,645</td>
<td>4,080</td>
</tr>
<tr>
<td>Selling, general and administrative</td>
<td>172,299</td>
<td>179,599</td>
<td>(7,300)</td>
</tr>
<tr>
<td>Impairment of long-lived assets</td>
<td>—</td>
<td>33,647</td>
<td>(33,647)</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>194,024</td>
<td>230,891</td>
<td>(36,867)</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(1,795)</td>
<td>(117,298)</td>
<td>115,503</td>
</tr>
<tr>
<td>Other expense, net:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(27,530)</td>
<td>(30,454)</td>
<td>2,924</td>
</tr>
<tr>
<td>Loss on debt extinguishment</td>
<td>(5,586)</td>
<td>(5,586)</td>
<td></td>
</tr>
<tr>
<td>Foreign exchange loss</td>
<td>(61)</td>
<td>(110)</td>
<td>49</td>
</tr>
<tr>
<td>Other income, net</td>
<td>189</td>
<td>151</td>
<td>38</td>
</tr>
<tr>
<td>Total other expense, net</td>
<td>(32,988)</td>
<td>(30,413)</td>
<td>(2,575)</td>
</tr>
<tr>
<td>Loss before (benefit) expense for income taxes</td>
<td>(34,783)</td>
<td>(147,711)</td>
<td>112,928</td>
</tr>
<tr>
<td>(Benefit) expense for income taxes</td>
<td>(1,920)</td>
<td>945</td>
<td>(2,865)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (32,863)</td>
<td>$ (148,656)</td>
<td>$115,793</td>
</tr>
</tbody>
</table>

Net sales. Net sales increased $56.5 million, or 25.2%, to $280.4 million during the three months ended March 31, 2019, from $223.9 million during the three months ended March 31, 2018. The increase in net sales during the three months ended March 31, 2019, was due to an increase in net sales in our primary care segment of $42.9 million and an increase in net sales in our orphan and rheumatology segment of $13.6 million.
The following table reflects net sales by medicine for the three months ended March 31, 2019 and 2018 (in thousands, except percentages):

<table>
<thead>
<tr>
<th>Medicine</th>
<th>2019</th>
<th>2018</th>
<th>Change $</th>
<th>Change %</th>
</tr>
</thead>
<tbody>
<tr>
<td>KRYSTEXXA</td>
<td>$52,257</td>
<td>$46,718</td>
<td>$5,539</td>
<td>12%</td>
</tr>
<tr>
<td>RAVICTI</td>
<td>49,903</td>
<td>49,093</td>
<td>810</td>
<td>2%</td>
</tr>
<tr>
<td>PROCYSBI</td>
<td>39,571</td>
<td>34,934</td>
<td>4,637</td>
<td>13%</td>
</tr>
<tr>
<td>ACTIMMUNE</td>
<td>21,746</td>
<td>24,857</td>
<td>(3,111)</td>
<td>(13)%</td>
</tr>
<tr>
<td>RAYOS</td>
<td>19,424</td>
<td>10,690</td>
<td>8,734</td>
<td>82%</td>
</tr>
<tr>
<td>BUPHENYL</td>
<td>2,770</td>
<td>5,742</td>
<td>(2,972)</td>
<td>(52)%</td>
</tr>
<tr>
<td>QUINSAIR</td>
<td>168</td>
<td>122</td>
<td>46</td>
<td>38%</td>
</tr>
<tr>
<td>LODOTRA</td>
<td>—</td>
<td>115</td>
<td>(115)</td>
<td>(100)%</td>
</tr>
<tr>
<td><strong>Orphan and Rheumatology net sales</strong></td>
<td><strong>$185,839</strong></td>
<td><strong>$172,271</strong></td>
<td><strong>$13,568</strong></td>
<td><strong>8%</strong></td>
</tr>
<tr>
<td>PENNSAID 2%</td>
<td>50,189</td>
<td>26,803</td>
<td>23,386</td>
<td>87%</td>
</tr>
<tr>
<td>DUEXIS</td>
<td>29,457</td>
<td>15,677</td>
<td>13,780</td>
<td>88%</td>
</tr>
<tr>
<td>VIMOVO</td>
<td>14,043</td>
<td>8,379</td>
<td>5,664</td>
<td>68%</td>
</tr>
<tr>
<td>MIGERGOT</td>
<td>843</td>
<td>751</td>
<td>92</td>
<td>12%</td>
</tr>
<tr>
<td><strong>Primary care net sales</strong></td>
<td><strong>$94,532</strong></td>
<td><strong>$51,610</strong></td>
<td><strong>$42,922</strong></td>
<td><strong>83%</strong></td>
</tr>
<tr>
<td><strong>Total net sales</strong></td>
<td><strong>$280,371</strong></td>
<td><strong>$223,881</strong></td>
<td><strong>$56,490</strong></td>
<td><strong>25%</strong></td>
</tr>
</tbody>
</table>

**Orphan and Rheumatology**

**KRYSTEXXA.** Net sales increased $5.5 million, or 12%, to $52.2 million during the three months ended March 31, 2019, from $46.7 million during the three months ended March 31, 2018. Net sales increased by approximately $16.0 million resulting from volume growth, partially offset by a decrease of approximately $10.5 million due to lower net pricing.

**RAVICTI.** Net sales increased $0.8 million, or 2%, to $49.9 million during the three months ended March 31, 2019, from $49.1 million during the three months ended March 31, 2018. Net sales in the United States increased by approximately $1.9 million, which was composed of an increase of approximately $7.7 million resulting from volume growth, partially offset by a decrease of approximately $5.8 million due to lower net pricing. Net sales outside the United States decreased by approximately $1.1 million primarily as a result of the Immedica transaction in December 2018.

**PROCYSBI.** Net sales increased $4.6 million, or 13%, to $39.5 million during the three months ended March 31, 2019, from $34.9 million during the three months ended March 31, 2018. Net sales increased by approximately $4.8 million resulting from volume growth, partially offset by a decrease of approximately $0.2 million due to lower net pricing.

**ACTIMMUNE.** Net sales decreased $3.1 million, or 13%, to $21.7 million during the three months ended March 31, 2019, from $24.8 million during the three months ended March 31, 2018. Net sales decreased by approximately $2.0 million resulting from lower volume and by approximately $1.1 million due to lower net pricing.

**RAYOS.** Net sales increased $8.7 million, or 82%, to $19.4 million during the three months ended March 31, 2019, from $10.7 million during the three months ended March 31, 2018. Net sales increased by approximately $10.1 million resulting from higher net pricing primarily due to lower utilization of our patient assistance programs, partially offset by a decrease of approximately $1.4 million due to lower volume.

**BUPHENYL.** Net sales decreased $3.0 million, or 52%, to $2.7 million during the three months ended March 31, 2019, from $5.7 million during the three months ended March 31, 2018. Net sales decreased by approximately $4.3 million resulting from lower volume, partially offset by an increase of approximately $1.3 million due to higher net pricing.

**LODOTRA.** Effective January 1, 2019, we amended our license and supply agreements with Jagotec AG and Skyepharma AG, which are affiliates of Vectura. Under these amendments, we agreed to transfer all economic benefits of LODOTRA in Europe to Vectura during an initial transition period, with full rights transferring to Vectura when certain transfer activities have been completed. Effective January 1, 2019, we no longer record LODOTRA revenue.
Primary Care

PENNSAID 2%. Net sales increased $23.4 million, or 87%, to $50.2 million during the three months ended March 31, 2019, from $26.8 million during the three months ended March 31, 2018. Net sales increased by approximately $27.6 million resulting from higher net pricing primarily due to lower utilization of our patient assistance programs, partially offset by a decrease of approximately $4.2 million due to lower volume.

DUEXIS. Net sales increased $13.8 million, or 88%, to $29.5 million during the three months ended March 31, 2019, from $15.7 million during the three months ended March 31, 2018. Net sales increased by approximately $14.3 million due to higher net pricing primarily due to lower utilization of our patient assistance programs, partially offset by a decrease of approximately $0.5 million resulting from lower volume.

VIMOVO. Net sales increased $5.7 million, or 68%, to $14.1 million during the three months ended March 31, 2019, from $8.4 million during the three months ended March 31, 2018. Net sales increased by approximately $7.0 million due to higher net pricing primarily due to lower utilization of our patient assistance programs, partially offset by a decrease of approximately $1.3 million resulting from lower volume.

MIGERGOT. Net sales were $0.8 million during each of the three months ended March 31, 2019 and 2018.

The table below reconciles our gross to net sales for the three months ended March 31, 2019 and 2018 (in millions, except percentages):

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended March 31, 2019</th>
<th>Three Months Ended March 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amount</td>
<td>% of Gross Sales</td>
</tr>
<tr>
<td>Gross sales</td>
<td>$ 945.2</td>
<td>100.0%</td>
</tr>
<tr>
<td>Adjustments to gross sales:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prompt pay discounts</td>
<td>(17.8)</td>
<td>(1.9)%</td>
</tr>
<tr>
<td>Medicine returns</td>
<td>(5.1)</td>
<td>(0.5)%</td>
</tr>
<tr>
<td>Co-pay and other patient assistance</td>
<td>(417.8)</td>
<td>(44.2)%</td>
</tr>
<tr>
<td>Commercial rebates and wholesaler fees</td>
<td>(110.4)</td>
<td>(11.7)%</td>
</tr>
<tr>
<td>Government rebates and chargebacks</td>
<td>(113.7)</td>
<td>(12.0)%</td>
</tr>
<tr>
<td>Total adjustments</td>
<td>(664.8)</td>
<td>(70.3)%</td>
</tr>
<tr>
<td>Net sales</td>
<td>$ 280.4</td>
<td>29.7%</td>
</tr>
</tbody>
</table>

During the three months ended March 31, 2019, co-pay and other patient assistance, as a percentage of gross sales, decreased to 44.2% from 51.0% during the three months ended March 31, 2018, primarily due to lower utilization of our patient assistance programs.

During the three months ended March 31, 2019, government rebates and chargebacks, as a percentage of gross sales, increased to 12.0% from 8.7% during the three months ended March 31, 2018, primarily as a result of a change in the mix of medicines sold.

Additionally, on January 1, 2019, the 340B ceiling price rule became effective. With respect to KRYSTEXXA, the “additional rebate” scheme of the 340B pricing program has resulted in a 340B ceiling price of one penny. A material portion of KRYSTEXXA infusions (approximately twenty to twenty-five percent) are performed at institutions that are eligible for 340B drug pricing and therefore the reduction in 340B pricing to a penny has negatively impacted our net sales from KRYSTEXXA.

Cost of Goods Sold. Cost of goods sold decreased $22.1 million to $88.2 million during the three months ended March 31, 2019, from $110.3 million during the three months ended March 31, 2018. As a percentage of net sales, cost of goods sold was 31.4% during the three months ended March 31, 2019, compared to 49.3% during the three months ended March 31, 2018. The decrease in cost of goods sold was primarily attributable to a $17.0 million decrease in inventory step-up expense.

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 decrease in inventory step-up expense of $17.0 million recorded to cost of goods sold during the three months ended March 31, 2019, compared to the prior year period was due to KRYSTEXXA inventory step-up being fully expensed by March 31, 2018, resulting in no material inventory step-up expense being recorded during the three months ended March 31, 2019, compared to KRYSTEXXA inventory step-up expense of $17.0 million recorded during the three months ended March 31, 2018.
Research and Development Expenses. Research and development expenses increased $4.1 million to $21.7 million during the three months ended March 31, 2019, from $17.6 million during the three months ended March 31, 2018. The increase was primarily attributable to an upfront payment of $2.0 million made under our collaboration agreement with HemoShear Therapeutics, LLC, or HemoShear.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $7.3 million to $172.3 million during the three months ended March 31, 2019, from $179.6 million during the three months ended March 31, 2018. The decrease was primarily attributable to a decrease in legal fees.

Impairment of Long-Lived Asset. During the three months ended March 31, 2018, we recorded an impairment of $33.6 million to fully write off the book value of developed technology related to PROCYSBI in Canada and Latin America due primarily to lower anticipated future net sales based on a Patented Medicine Prices Review Board review.

Interest Expense, Net. Interest expense, net, decreased $3.0 million to $27.5 million during the three months ended March 31, 2019, from $30.5 million during the three months ended March 31, 2018. The decrease in expense was primarily due to an increase in interest income of $3.6 million.

(Benefit) Expense for Income Taxes. During the three months ended March 31, 2019, we recorded a benefit for income taxes of $1.9 million compared to an expense for income taxes of $0.9 million during the three months ended March 31, 2018. The benefit for income taxes recorded during the three months ended March 31, 2019, resulted primarily from the tax benefits recognized on share-based compensation and the mix of pre-tax income and losses incurred in various tax jurisdictions.

Information by Segment

See Note 11, Segment and Other Information, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q for a reconciliation of our segment operating income to our total loss before (benefit) expense for income taxes for the three months ended March 31, 2019 and 2018.

Orphan and Rheumatology

The following table reflects our orphan and rheumatology net sales and segment operating income for the three months ended March 31, 2019 and 2018 (in thousands, except percentages).

<table>
<thead>
<tr>
<th>For the Three Months Ended March 31,</th>
<th>Change</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>$185,839</td>
<td>$172,271</td>
</tr>
<tr>
<td>Segment operating income</td>
<td>46,677</td>
<td>43,104</td>
</tr>
</tbody>
</table>

The increase in orphan and rheumatology net sales during the three months ended March 31, 2019 is described in the Consolidated Results section above.

Segment operating income. Orphan and rheumatology segment operating income increased $3.6 million to $46.7 million during the three months ended March 31, 2019, from $43.1 million during the three months ended March 31, 2018. The increase was primarily attributable to an increase in net sales of $13.6 million as described above, partially offset by an increase in selling, general and administrative expenses of $8.0 million primarily due to marketing program costs related to KRYSTEXXA.
Primary Care

The following table reflects our primary care net sales and segment operating income for the three months ended March 31, 2019 and 2018 (in thousands, except percentages).

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended March 31,</th>
<th>Change</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
<td>2018</td>
<td></td>
</tr>
<tr>
<td>Net sales</td>
<td>$94,532</td>
<td>$51,610</td>
<td>$42,922</td>
</tr>
<tr>
<td>Segment operating income</td>
<td>41,446</td>
<td>(9,573)</td>
<td>51,019</td>
</tr>
</tbody>
</table>

The increase in primary care net sales during the three months ended March 31, 2019 is described in the Consolidated Results section above.

Segment operating income (loss). Primary care segment operating income increased $51.0 million to $41.4 million during the three months ended March 31, 2019, from a $9.6 million operating loss during the three months ended March 31, 2018. The increase was primarily attributable to an increase in net sales of $42.9 million as described above and a decrease in sales and marketing costs of $6.0 million.

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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. These non-GAAP financial measures are intended to provide additional information on our performance, operations and profitability. Adjustments to our GAAP figures as well as EBITDA exclude acquisition/divestiture-related costs, upfront and milestone payments related to license and collaboration agreements, drug substance harmonization costs, fees related to refinancing activities, restructuring and realignment costs and charges related to discontinuation of the Friedreich’s ataxia program, as well as non-cash items such as share-based compensation, inventory step-up expense, depreciation and amortization, non-cash interest expense, long-lived assets impairment charges, loss on debt extinguishments 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 financial results and trends and to facilitate comparisons between periods. 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, were as follows (in thousands, except share and per share amounts):

<table>
<thead>
<tr>
<th>GAAP net loss</th>
<th>For the Three Months Ended March 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td>GAAP net loss</td>
<td>($32,863)</td>
</tr>
<tr>
<td>Depreciation (1)</td>
<td>1,473</td>
</tr>
<tr>
<td>Amortization and step-up:</td>
<td></td>
</tr>
<tr>
<td>Intangible amortization expense (2)</td>
<td>57,417</td>
</tr>
<tr>
<td>Inventory step-up expense (3)</td>
<td>115</td>
</tr>
<tr>
<td>Interest expense, net (including amortization of debt discount and deferred financing costs)</td>
<td>27,530</td>
</tr>
<tr>
<td>(Benefit) expense for income taxes</td>
<td>(1,920)</td>
</tr>
<tr>
<td>EBITDA</td>
<td>51,752</td>
</tr>
<tr>
<td>Other non-GAAP adjustments:</td>
<td></td>
</tr>
<tr>
<td>Acquisition/divestiture-related costs (4)</td>
<td>1,345</td>
</tr>
<tr>
<td>Restructuring and realignment costs (5)</td>
<td>20</td>
</tr>
<tr>
<td>Impairment of long-lived assets (6)</td>
<td>—</td>
</tr>
<tr>
<td>Share-based compensation (7)</td>
<td>27,548</td>
</tr>
<tr>
<td>Loss on debt extinguishment (8)</td>
<td>5,586</td>
</tr>
<tr>
<td>Charges related to discontinuation of Friedreich’s ataxia program (9)</td>
<td>(79)</td>
</tr>
<tr>
<td>Drug substance harmonization costs (10)</td>
<td>80</td>
</tr>
<tr>
<td>Upfront and milestones payments related to license and collaboration agreements (11)</td>
<td>2,000</td>
</tr>
<tr>
<td>Fees related to refinancing activities (12)</td>
<td>142</td>
</tr>
<tr>
<td>Total of other non-GAAP adjustments</td>
<td>36,642</td>
</tr>
<tr>
<td>Adjusted EBITDA</td>
<td>$88,394</td>
</tr>
</tbody>
</table>
## For the Three Months Ended March 31, 2019 and 2018

<table>
<thead>
<tr>
<th>Non-GAAP adjustments:</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquisition/divestiture-related costs (4)</td>
<td>$1,345</td>
<td>$4,653</td>
</tr>
<tr>
<td>Restructuring and realignment costs (5)</td>
<td>$20</td>
<td>$3,342</td>
</tr>
<tr>
<td><strong>Amortization and step-up:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intangible amortization expense (2)</td>
<td>$57,417</td>
<td>$60,883</td>
</tr>
<tr>
<td>Inventory step-up expense (3)</td>
<td>$115</td>
<td>$17,076</td>
</tr>
<tr>
<td>Amortization of debt discount and deferred financing costs (13)</td>
<td>$5,912</td>
<td>$5,496</td>
</tr>
<tr>
<td>Impairment of long-lived assets (6)</td>
<td>—</td>
<td>$33,647</td>
</tr>
<tr>
<td>Share-based compensation (7)</td>
<td>$27,548</td>
<td>$27,833</td>
</tr>
<tr>
<td>Loss on debt extinguishment (8)</td>
<td>$5,586</td>
<td>—</td>
</tr>
<tr>
<td>Upfront and milestone payments related to license and collaboration agreements (11)</td>
<td>$2,000</td>
<td>$90</td>
</tr>
<tr>
<td>Depreciation (1)</td>
<td>$1,473</td>
<td>$1,552</td>
</tr>
<tr>
<td>Fees related to refinancing activities (12)</td>
<td>$142</td>
<td>$27</td>
</tr>
<tr>
<td>Drug substance harmonization costs (10)</td>
<td>$80</td>
<td>$804</td>
</tr>
<tr>
<td>Charges relating to discontinuation of Friedreich's ataxia program (9)</td>
<td>—</td>
<td>$950</td>
</tr>
<tr>
<td><strong>Total of pre-tax non-GAAP adjustments</strong></td>
<td>$101,559</td>
<td>$156,353</td>
</tr>
<tr>
<td>Income tax effect of pre-tax non-GAAP adjustments (14)</td>
<td>$(14,751)</td>
<td>$32,995</td>
</tr>
<tr>
<td>Other non-GAAP income tax adjustments (15)</td>
<td>—</td>
<td>$(35,893)</td>
</tr>
<tr>
<td><strong>Total non-GAAP adjustments</strong></td>
<td>$86,808</td>
<td>$153,455</td>
</tr>
</tbody>
</table>

### Non-GAAP Net Income

<table>
<thead>
<tr>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>$53,945</td>
<td>$4,799</td>
</tr>
</tbody>
</table>

### Non-GAAP Earnings Per Share:

#### Weighted average ordinary shares – Basic

<table>
<thead>
<tr>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>172,789,209</td>
<td>164,549,502</td>
</tr>
</tbody>
</table>

### Non-GAAP Earnings Per Share – Basic

<table>
<thead>
<tr>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0.19</td>
<td>$(0.90)</td>
</tr>
<tr>
<td>0.50</td>
<td>0.93</td>
</tr>
<tr>
<td><strong>Non-GAAP earnings per share – Basic</strong></td>
<td>$0.31</td>
</tr>
</tbody>
</table>

#### Weighted average ordinary shares – Diluted

<table>
<thead>
<tr>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>172,789,209</td>
<td>164,549,502</td>
</tr>
<tr>
<td>7,496,024</td>
<td>3,201,430</td>
</tr>
<tr>
<td><strong>Weighted average ordinary shares – Diluted</strong></td>
<td>180,285,233</td>
</tr>
</tbody>
</table>

### Non-GAAP Earnings Per Share – Diluted

<table>
<thead>
<tr>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0.19</td>
<td>$(0.90)</td>
</tr>
<tr>
<td>0.50</td>
<td>0.93</td>
</tr>
<tr>
<td>Diluted earnings per share effect of ordinary share equivalents</td>
<td>$(0.01)</td>
</tr>
<tr>
<td><strong>Non-GAAP earnings per share – Diluted</strong></td>
<td>$0.30</td>
</tr>
</tbody>
</table>

---

1. Represents depreciation expense related to our property, equipment, software and leasehold improvements.

2. Intangible amortization expenses are associated with our intellectual property rights, developed technology and customer relationships related to ACTIMMUNE, BUPHENYL, KRYSXXA, LODOTRA, MIGERGOT, PENNSAID 2%, PROCYSBI, RAVICTI, VIMOVO and RAYOS.

3. During the three months ended March 31, 2018, we recognized in cost of goods sold $17.1 million for inventory step-up expense primarily related to KRYSXXA inventory sold.

4. Represents expenses, including legal and consulting fees, incurred in connection with our acquisitions and divestitures.

5. Represents expenses, including severance costs and consulting fees, related to restructuring and realignment activities.

6. Impairment of long-lived assets during the three months ended March 31, 2018, relates to the write-off of the book value of developed technology related to PROCYSBI in Canada and Latin America.

7. Represents share-based compensation expense associated with our stock option, restricted stock unit and performance stock unit grants to our employees and non-employees and our employee share purchase plan.
During the three months ended March 31, 2019, we recorded a loss on debt extinguishment of $5.6 million in the condensed consolidated statement of comprehensive loss, which reflects the write-off of the deferred financing and debt discount fees related to the $300.0 million term loan repayment.

Represents expenses incurred relating to discontinuation of Friedreich’s ataxia program and a reduction to previous charges recorded.

During the year ended December 31, 2016, we entered into a definitive agreement to acquire certain rights to interferon gamma-1b, marketed as IMUKIN in an estimated thirty countries primarily in Europe and the Middle East, or the IMUKIN purchase agreement. We already owned the rights to interferon gamma-1b marketed as ACTIMMUNE in the United States, Canada and Japan. In connection with the IMUKIN purchase agreement, we also committed to pay our contract manufacturer certain amounts related to the harmonization of the manufacturing processes for ACTIMMUNE and IMUKIN drug substance, or the harmonization program. At the time we entered into the IMUKIN purchase agreement and the harmonization program commitment was made, we had anticipated achieving certain benefits should the Phase 3 clinical trial evaluating ACTIMMUNE for the treatment of Friedreich’s ataxia, or FA, be successful. If the study had been successful and if U.S. marketing approval had subsequently been obtained, we had forecasted significant increases in demand for the medicine and the harmonization program would have resulted in significant benefits for us. Following our discontinuation of the FA program, we determined that certain assets, including an upfront payment related to the IMUKIN purchase agreement, were impaired, and the costs under the harmonization program would no longer have benefit to us and should be expensed as incurred.

During the three months ended March 31, 2019, we recorded an upfront cash payment of $2.0 million to the collaboration agreement with HemoShear.

Represents arrangement and other fees relating to our refinancing activities.

Represents amortization of debt discount and deferred financing costs associated with our debt.

Income tax adjustments on pre-tax non-GAAP adjustments represent the estimated income tax impact of each pre-tax non-GAAP adjustment based on the statutory income tax rate of the applicable jurisdictions for each non-GAAP adjustment.

Following Notice 2018-28, issued by the U.S. Treasury Department and the U.S. Internal Revenue Service on April 2, 2018 and in accordance with the measurement period provisions under Staff Accounting Bulletin No. 118, or SAB 118, during the three months ended March 31, 2019 we reinstated the deferred tax asset previously written off during the year ended December 31, 2018, related to our U.S. interest expense carry forwards under Section 163(j) of the Internal Revenue Code of 1986, as amended, based on the revised U.S. federal tax rate of 21 percent. The impact of the deferred tax asset reinstatement in accordance with SAB 118 was a $35.9 million increase to our benefit for income taxes and a corresponding decrease to the U.S. group net deferred tax liability position.

LIQUIDITY, FINANCIAL POSITION AND CAPITAL RESOURCES

We have incurred losses since our inception in June 2005 and, as of March 31, 2019, we had an accumulated deficit of $1,211.6 million. We expect that our sales and marketing expenses will continue to increase as a result of the commercialization of our medicines but we believe these cost increases will be more than offset by higher net sales and gross profits. Additionally, we expect that our research and development costs will increase as we acquire or license more development-stage medicine candidates and advance our candidates through the clinical development and regulatory approval processes.

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 years. As of March 31, 2019, we had $1,032.8 million in cash and cash equivalents and total debt with a book value of $1,608.1 million and face value of $1,693.0 million. We believe our existing cash and cash equivalents and our expected cash flows from our operations will be sufficient to fund our business needs for at least the next twelve months from the issuance of the financial statements in this Quarterly Report on Form 10-Q. Part of our strategy is to expand and leverage our commercial capabilities and to develop a pipeline of rare disease medicine candidates by researching, developing and commercializing innovative medicines that address unmet treatment needs for rare and rheumatic diseases. 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, or through the use of cash on hand.

Underwritten Public Equity Offering

On March 11, 2019, we closed an underwritten public equity offering of 14.1 million ordinary shares at a price to the public of $24.50 per share, resulting in net proceeds of approximately $326.8 million after deducting underwriting discounts and other estimated offering expenses payable by us. This included the exercise in full by the underwriters of their option to purchase up to 1.8 million additional ordinary shares.
On March 11, 2019, Horizon Pharma USA, Inc., our wholly owned subsidiary, or the Borrower, received $200.0 million aggregate principal amount of revolving commitments, or the New Incremental Revolving Commitments, pursuant to an amendment to our Credit Agreement. The New Incremental Revolving Commitments were established pursuant to an incremental facility, or the Revolving Credit Facility, and will provide the Borrower with $200.0 million of additional borrowing capacity, which includes a $50.0 million letter of credit sub-facility. The New Incremental Revolving Commitments will terminate in March 2024. Borrowings under the Revolving Credit Facility are available for general corporate purposes. As of March 31, 2019, the Revolving Credit Facility was undrawn.

On March 18, 2019, the Borrower completed the repayment of $300.0 million of the outstanding principal amount of term loans under our Credit Agreement. Following this repayment, the outstanding principal balance of term loans under our Credit Agreement was $518.0 million and total aggregate outstanding principal amount of indebtedness was $1,693.0 million.

On April 1, 2019, we delivered a notice of partial optional redemption of $250.0 million of the 6.625% Senior Notes due 2023, or the 2023 Senior Notes, to the trustee under the indenture governing the 2023 Senior Notes and the holders of the 2023 Senior Notes, which were redeemed on May 1, 2019. In connection with this early redemption, we paid a premium of $8.3 million on May 1, 2019. Following such redemption, the total aggregate outstanding principal amount of indebtedness was $1,443.0 million.

For a more detailed description of our debt agreements, see Note 13, Debt Agreements, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q.

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 our 8.750% Senior Notes due 2024 and 6.625% Senior Notes due 2023 and our 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 three months ended March 31, 2019, we issued an aggregate of 1.8 million of our ordinary shares in connection with stock option exercises and the vesting of restricted stock units. We received a total of $10.0 million in proceeds in connection with stock options exercised.

**Sources and Uses of Cash**

The following table provides a summary of our cash position and cash flows for the three months ended March 31, 2019 and 2018 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>For the Three Months Ended March 31,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash, cash equivalents and restricted cash</td>
<td>$ 1,036,539</td>
<td>$ 680,720</td>
</tr>
<tr>
<td>Cash provided by (used in):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating activities</td>
<td>56,168</td>
<td>(60,811)</td>
</tr>
<tr>
<td>Investing activities</td>
<td>(1,849)</td>
<td>(12,665)</td>
</tr>
<tr>
<td>Financing activities</td>
<td>20,621</td>
<td>(4,683)</td>
</tr>
</tbody>
</table>

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Operating Cash Flows

During the three months ended March 31, 2019, net cash provided by operating activities of $56.2 million was primarily attributable to cash collections from net sales, partially offset by payments made during the first quarter of 2019 related to patient assistance costs and commercial rebates for our primary care medicines.

During the three months ended March 31, 2018, net cash used in operating activities was $60.8 million. Our net cash outflow reflects payments made during the first quarter of 2018 related to patient assistance costs and commercial rebates for our primary care medicines.

Investing Cash Flows

During the three months ended March 31, 2019, net cash used in investing activities of $1.8 million was primarily attributable to the purchases of property and equipment.

During the three months ended March 31, 2018 net cash used in investing activities of $12.7 million was primarily associated with the $12.0 million upfront amount paid to MedImmune LLC to license HZN-003 (formerly MEDI4945).

Financing Cash Flows

During the three months ended March 31, 2019, net cash provided by financing activities of $20.6 million was primarily attributable to net proceeds from the issuance of ordinary shares of $327.8 million, partially offset by the repayment of term loans of $300.0 million.

During the three months ended March 31, 2018, net cash used in financing activities was primarily attributable to the payment of employee withholding taxes related to share-based awards of $3.5 million and repayment of term loans of $2.1 million.

Financial Condition as of March 31, 2019 compared to December 31, 2018

Accounts receivable, net. Accounts receivable, net, decreased $60.8 million, from $464.7 million as of December 31, 2018 to $403.9 million as of March 31, 2019. The decrease was due to lower gross sales of our medicines during the first quarter of 2019 when compared to the fourth quarter of 2018.

Developed technology, net. Developed technology, net, decreased $57.2 million, from $1,945.6 million as of December 31, 2018 to $1,888.4 million as of March 31, 2019. The decrease was due to the amortization of developed technology of $57.2 million during the three months ended March 31, 2019.

Other assets. Other assets increased $35.8 million, from $9.0 million as of December 31, 2018 to $44.8 million as of March 31, 2019. Upon adoption of Accounting Standards Update No. 2016-02, Leases (Topic 842), or ASU No. 2016-02, on January 1, 2019, we established $37.1 million of liabilities and corresponding lease assets of $34.9 million on the condensed consolidated balance sheet for leases, primarily related to operating leases on rented office properties, that existed as of the January 1, 2019, adoption date.

Long-term debt – current portion. Long-term debt – current portion increased $250.0 million, from zero as of December 31, 2018 to $250.0 million as of March 31, 2019. This was due to the reclassification from long-term debt, net of current, to long-term debt-current portion following the notice of partial optional redemption of $250.0 million of the 2023 Senior Notes to the trustee under the indenture governing the 2023 Senior Notes and the holders of the 2023 Senior Notes, which notes were subsequently redeemed on May 1, 2019. See Note 13, Debt Agreements, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q for further detail.

Accrued expenses. Accrued expenses decreased $18.5 million, from $215.7 million as of December 31, 2018 to $197.2 million as of March 31, 2019. This was primarily due to a decrease in payroll-related expenses of $31.8 million, partially offset by an increase of $11.6 million in accrued interest.

Accrued trade discounts and rebates. Accrued trade discounts and rebates decreased $50.9 million, from $457.8 million as of December 31, 2018 to $406.9 million as of March 31, 2019. This was primarily due to a $40.9 million decrease in accrued co-pay and other patient assistance costs and a $26.3 million decrease in accrued commercial rebates and wholesaler fees, partially offset by a $16.3 million increase in accrued government rebates and chargebacks.
Long-term debt, net of current. Long-term debt, net of current, decreased $543.2 million, from $1,564.5 million as of December 31, 2018 to $1,021.3 million as of March 31, 2019. The decrease was primarily related to the repayment of $300.0 million of the outstanding principal amount of term loans under our Credit Agreement on March 18, 2019 and a $250.0 million reclassification from long-term debt, net of current, to long-term debt-current portion relating to the 2023 Senior Notes, which were partially redeemed on May 1, 2019. See Note 13, Debt Agreements, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q for further detail.

Other long-term liabilities. Other long-term liabilities increased $30.7 million, from $38.7 million as of December 31, 2018 to $69.4 million as of March 31, 2019. This was primarily due to $32.9 million related to long-term lease liabilities as of March 31, 2019. Upon adoption of ASU No. 2016-02 on January 1, 2019, we established $37.1 million of liabilities and corresponding lease assets of $34.9 million on the condensed consolidated balance sheet for leases, primarily related to operating leases on rented office properties, that existed as of the January 1, 2019, adoption date.

Contractual Obligations
During the three months ended March 31, 2019, 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, 2018, except for our entry into the following commitments described below.

On March 18, 2019, the Borrower completed the repayment of $300.0 million of the outstanding principal amount of term loans under our Credit Agreement. Following this repayment, the outstanding principal balance of term loans under our Credit Agreement was $518.0 million and total aggregate outstanding principal amount of indebtedness was $1,693.0 million.

On May 1, 2019, we redeemed $250.0 million of the 2023 Senior Notes under the indenture governing the 2023 Senior Notes.

In addition, on April 16, 2019, we entered into a binding purchase commitment with CMC Biologics A/S for teprotumumab drug substance of $39.7 million (converted using a Dollar-to-Euro exchange rate of 1.1219), to be paid in staged payments from July 2019 through September 2020 and to be delivered through September 2020.

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, 2018.

Effective January 1, 2019 we adopted ASU No. 2016-02. See Note 2, Summary of Significant Accounting Policies, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q for details of the impact of this adoption. We modified our critical accounting policies related to leases following the adoption of ASU No. 2016-02, and our updated policies are described in Note 2, Summary of Significant Accounting Policies, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q.

Effective January 1, 2019, we retrospectively changed our accounting for business combinations under ASC Topic 805, Business Combinations and will record acquired intangible assets and their related third-party contingent royalties on a net basis. Refer to Note 2, Summary of Significant Accounting Policies, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q for our updated policy.

During the three months ended March 31, 2019, other than the adoption of ASU No. 2016-02 and the resulting changes to our lease critical accounting policy and the changes to our accounting policy for contingent royalties and intangible assets as a result of our change in accounting for business combinations under ASC Topic 805, Business Combinations, there have been no significant changes in our application of our critical accounting policies.

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 15, Commitments and Contingencies, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q.
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 London Inter-Bank Offered Rate, or LIBOR, plus an applicable margin of 3.00% per annum (subject to a 1.00% LIBOR floor), or the adjusted base rate plus 2.00%. The adjusted base rate is defined as the greatest of (a) LIBOR (using one-month interest period) plus 1.00%, (b) the prime rate, (c) the federal funds rate plus 0.50% and (d) 2.00%. Our approximately $518.0 million of October 2018 Refinancing Loans are based on LIBOR. As of March 31, 2019, the Revolving Credit Facility was undrawn. The one month LIBOR rate as of April 29, 2019, which was the most recent date the interest rate on the term loan was fixed, was 2.5%, and as a result, the interest rate on our borrowings is currently 5.5% per annum. Because the United Kingdom Financial Conduct Authority, which regulates LIBOR, intends to phase out the use of LIBOR by the end of 2021, future borrowings under our Credit Agreement could be subject to reference rates other than LIBOR.

An increase of 100 basis points (1.00%) in the interest rate on our outstanding loans at the date of filing of this Quarterly Report on Form 10-Q would increase our interest expense related to the Credit Agreement by $5.2 million per year.

The goals of our investment policy are to preserve capital, fulfill liquidity needs and maintain 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 costs of teprotumumab and ACTIMMUNE inventory is principally denominated in Euros and is subject to foreign currency risk. We have contracts relating to RAVICTI, QUINSAIR and PROCYSBI for sales in Canada which sales 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. Therefore, we are subject to volatility in cash flows due to fluctuations in foreign currency exchange rates, particularly changes in the Euro and the Canadian dollar.

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 March 31, 2019, and December 31, 2018, our top four customers accounted for approximately 85% 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 March 31, 2019, the end of the period covered by this report.

Changes in Internal Control Over Financial Reporting. During the quarter ended March 31, 2019, 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 16, 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, 2018, 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 RAVICTI, 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 urea cycle disorder, or UCD, patients from BUPHENYL or generic equivalents, which are comparatively much less expensive, to RAVICTI and to encourage patients and physicians to continue RAVICTI therapy once initiated. With respect to PROCYSBI, 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 patients from the first-generation immediate-release cysteamine therapy to PROCYSBI, to identify additional patients with nephropathic cystinosis and to encourage patients and physicians to continue therapy once initiated. 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 access a wider patient population and encourage patients and physicians to continue treatment once initiated. 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. With respect to KRYSTEXXA, our ability to grow sales will be affected by the success of our sales, marketing and clinical strategies, which could expand the patient population and usage of KRYSTEXXA. This includes our marketing efforts in nephrology and our studies designed to improve the response rate to KRYSTEXXA and to evaluate the use of KRYSTEXXA in kidney transplant patients. With respect to each of BUPHENYL, RAYOS, PENNSAID 2% w/w, or PENNSAID 2%, DUEXIS and VIMOVO, 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 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. If our current medicines or any other medicine that we may seek approval for, or acquire, fail to attain market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects (including, possibly, the value of our ordinary shares).

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

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

With respect to our rare disease medicines, RAVICTI, PROCYSBI, ACTIMMUNE, BUPHENYL, QUINSAIR and 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. With respect to RAVICTI and PROCYSBI, our strategy includes accelerating the transition of patients from first-generation therapies, and increasing the diagnosis of the associated rare conditions through patient and physician outreach. Our strategy with respect to KRYSTEXXA includes supporting three pillars of growth: existing rheumatology account growth, new rheumatology account growth and accelerating nephrology growth.

With respect to our primary care medicines, PENNSAID 2%, DUEXIS, and VIMOVO, our strategy has 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 and ensuring patient access to these drugs when prescribed through our HorizonCares program. However, we cannot guarantee that we will be able to secure additional rebate agreements on commercially reasonable terms, 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. In addition, as the terms of our existing agreements with PBMs expire, we may not be able to renew the agreements on commercially favorable terms, or at all. 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, reimbursement decisions by commercial payers, the expense we incur through our patient access program for fully bought down contracts and the rebates we pay to PBMs, as well as the impact of numerous efforts at federal, state and local levels to further reduce reimbursement and net pricing of primary care medicines.

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, to study the effect of RAYOS on the fatigue experienced by systemic lupus erythematosus, or SLE, patients.

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 to achieve 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 biopharma 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. As of March 31, 2019, we had approximately 415 sales representatives in the field, consisting of approximately 25 orphan disease sales representatives, 140 rheumatology sales specialists and 250 primary care sales representatives. We currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market our medicines and any additional medicines we may acquire will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

As of March 31, 2019, we had approximately 415 sales representatives in the field, consisting of approximately 25 orphan disease sales representatives, 140 rheumatology sales specialists and 250 primary care sales representatives. We currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market our medicines and any additional medicines we may acquire will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

As a result of the evolving role of various constituents in the prescription decision making process, we focus on hiring sales representatives for our primary care medicines and RAYOS 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, despite such substitution being off-label in the case of DUEXIS and VIMOVO. We have faced similar challenges for BUPHENYL, RAYOS 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 BUPHENYL, RAYOS, PENNSAID 2%, DUEXIS 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.
There continues to be immense pressure from healthcare payers, PBMs and others to use less expensive or generic medicines or over-the-counter brands instead of certain 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, including shipment of prescriptions to patients. We also have contracted with a third party prescription clearinghouse that offers physicians a single point of contact for processing prescriptions through these independent pharmacies, reducing physician administrative costs, increasing the fill rates for prescriptions and enabling physicians to monitor refill activity. 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 PENNSAID 2%, DUEXIS and VIMOVO prescriptions. 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 have business relationships with two of the largest PBMs, Express Scripts, Inc., or Express Scripts, and CVS Caremark, that have resulted in DUEXIS and VIMOVO being removed from the Express Scripts and CVS Caremark exclusion lists starting in 2017, 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. 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 medicines and/or reductions in net pricing for our primary care medicines due to increasing patient assistance costs. If we are unable to increase adoption of HorizonCares for filling prescriptions of our medicines and 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 medicines 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 these 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 federal and 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, 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 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 on 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 prescriptions and reductions in our costs to provide our patient access programs that are sufficient to offset the administrative fees and rebate payments to the PBMs and/or other payers, our financial results may 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.
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 government 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 European Union, or EU, and other significant or potentially significant markets for our medicines and medicine candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medicines and services, particularly for new and innovative medicines and therapies, which has resulted in lower average selling prices. Further, the increased scrutiny of prescription drug pricing practices and emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on medicine pricing, reimbursement and usage, which may adversely affect our medicine sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general. In January 2019, the Office of Inspector General of the U.S. Department of Health and Human Services, or HHS, published a proposed rule that would eliminate the current safe harbor protection under the Anti-Kickback Statute for pharmaceutical manufacturer rebates to Medicare Part D plans, Medicaid MCOs and the PBMs with which they contract. The proposal would also create two new safe harbors. The first would protect certain point-of-sale price reductions to certain Federal Health Care Program enrollees and the second would protect certain fixed fees paid by drug manufacturers directly to PBMs for services provided by PBMs. 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 exclusion lists starting in 2017, 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 and medicine candidates 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. We market RAVICTI, PROCYSBI and QUINSAIR in Canada. Further, we cannot be certain that existing reimbursement in Canada 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 twelve 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. 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively 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. As concerns continue to grow over the need for tighter oversight, there remains the possibility that the Health Resources and Services Administration or another agency under the HHS will propose a similar regulation or that Congress will explore changes to the 340B program through legislation. For example, a bill was introduced in 2018 that would require hospitals to report their low-income utilization of the program. Further, the Centers for Medicare & Medicaid Services issued a final rule that would revise the Medicare hospital outpatient prospective payment system for calendar year 2019, including a new reimbursement methodology for drugs purchased under the 340B program for Medicare patients at the hospital setting and recently announced the same change for physician-based practices under 340B in 2019. Pursuant to the final rule, after January 1, 2019, manufacturers must calculate 340B program ceiling prices on a quarterly basis. Moreover, manufacturers could be subject to a $5,000 penalty for each instance where they knowingly and intentionally overcharge a covered entity under the 340B program. With respect to KRYSTEXXA, the “additional rebate” scheme of the 340B pricing rules, as applied to the historical pricing of KRYSTEXXA both before and after we acquired the medicine, have resulted in a 340B ceiling price of one penny. A material portion of KRYSTEXXA prescriptions (approximately twenty to twenty-five percent) are written by healthcare providers that are eligible for 340B drug pricing and therefore the reduction in 340B pricing to a penny has negatively impacted our net sales from KRYSTEXXA.

There may be additional pressure by payers, healthcare providers, state governments, 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 as well as state and federal government authorities 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, including donations to patient assistance programs offered by charitable foundations. Certain state and federal enforcement authorities and members of Congress have initiated inquiries about co-pay assistance programs. Some state legislatures have been considering proposals that would restrict or ban co-pay coupons. For example, legislation was recently signed into law in California that would limit the use of co-pay coupons in cases where a lower cost generic drug is available and if individual ingredients in combination therapies are available over the counter at a lower cost. It is possible that similar legislation could be proposed and enacted in additional states. If we are unsuccessful with our HorizonCares program or any other co-pay initiatives or free medicine programs, or we are alternatively 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 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 an adverse effect on our business.

Innomar Strategies Inc., or Innomer, is our exclusive distributor for RAVICTI, PROCYSBI and QUINSAIR in Canada. We rely on Orphan Pacific, Inc., or Orphan Pacific, for commercialization of BUPHENYL in Japan 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 Innomer, Orphan Pacific or any other third party with any future commercialization rights to any of our medicines or medicine candidates fail to adequately commercialize these 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. In addition, our agreements with Innomer and Orphan Pacific, 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 RAVICTI, PROCYSBI, BUPHENYL or QUINSAIR, outside the United States would be 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 pre-clinical 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 pre-clinical 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 pre-clinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional pre-clinical 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 pre-clinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
• may interpret data from pre-clinical 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 pre-clinical 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. For example, our anticipated biologics license application for teprotumumab for the treatment of moderate to severe active thyroid eye disease, or TED, may not be approved by FDA. 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.

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.
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, good clinical practices, or GCPs, good pharmacovigilance practice, good distribution practices and good laboratory practices, or GLPs. If we, our medicines or medicine candidates, or the third-party manufacturing facilities for our medicines or medicine candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose injunctions or restrictions on the marketing, manufacturing or distribution of a 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.

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 European Economic Area, or 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, European Medicines Agency, or 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. 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, 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 through 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 regarding internet and social media promotion of regulated medical products. 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.
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 we may fail to 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 RAVICTI and AMMONAPS (known as BUPHENYL in the United States) outside of North America and Japan to Medical Need Europe AB, part of the Immedica Group, or Immedica, in December 2018, Immedica has marketing and distribution rights to RAVICTI and AMMONAPS in those regions. Following our sale of the rights to PROCYSBI and QUINSAIR in the 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 the EMEA regions. Nuvo Pharmaceuticals Inc. (formerly known as Nuvo Research Inc.), or Nuvo, has retained its rights to PENNSAID 2% in territories outside of the United States. 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, and in December 2017 Nuvo announced that it had entered into a license and distribution agreement with Gebro Pharma AG for the exclusive right to register, distribute, market and sell PENNSAID 2% in Switzerland and Liechtenstein. Grünenthal GmbH, or Grünenthal, acquired the rights to VIMOVO in territories outside of the United States, including the right to use the VIMOVO name and related trademark from AstraZeneca AB, or AstraZeneca, in October 2018. We have little or no control over Immedica’s activities with respect to RAVICTI and AMMONAPS outside of North America and Japan, over Clinigen’s activities with respect to IMUKIN outside the United States, Canada and Japan, over Chiesi’s activities with respect to PROCYSBI and QUINSAIR in the EMEA, over Nuvo’s or its existing and future commercial partners’ activities with respect to PENNSAID 2% outside of the United States, or over Grünenthal’s activities with respect to VIMOVO outside the United States even though those activities could impact our ability to successfully commercialize these medicines. For example, Immedica or its assignees, Clinigen or its assignees, Chiesi or its assignees, Nuvo or its assignees or Grünenthal or its assignees can make statements or use promotional materials with respect to RAVICTI and AMMONAPS, IMUKIN, PROCYSBI and QUINSAIR, PENNSAID 2% or VIMOVO, respectively, in foreign countries 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 Grünenthal 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 Immedica, Clinigen, Chiesi, Nuvo or Grünenthal 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 Grünenthal’s (formerly AstraZeneca) 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 Grünenthal 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 Grünenthal 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. 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 KRSTEXXXA. If NOF failed to supply such PEGylation agent, it may lead to KRSTEXXXA supply constraints. 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.

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, BASF Corporation, or BASF, our manufacturer of one of the APIs in DUEXIS, ibuprofen in a direct compression blend called DC85, previously notified us that it was not able to supply DC85 due to a technical issue at its manufacturing facility in Bishop, Texas. BASF subsequently informed us that the manufacturing facility recently recommenced limited operations and confirmed its intention to resume supply of DC85. While we consider our DUEXIS inventory on hand to be sufficient to meet current and future commercial requirements, we cannot guarantee that BASF’s manufacturing facility will return to full operations or that we will be able to enter into a new supply agreement with BASF for DC85. 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 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 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 medical candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

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We have experienced growth and expanded the size of our organization substantially in connection with our 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, 2013, we employed approximately 300 full-time employees as a consolidated entity. As of March 31, 2019, we employed approximately 1,000 full-time employees, including approximately 415 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 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. 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 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 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.

We may not be successful in growing our commercial operations outside the United States, and could encounter other challenges in growing our commercial presence, 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 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.

RAVICTI and BUPHENYL face competition from generic NaPBA tablets and powder in treating UCD. Lucane Pharma, or Lucane, is seeking approval via an Abbreviated New Drug Application, or ANDA, in the United States for taste-masked NaPBA. If this ANDA is approved, this formulation may also compete with RAVICTI and BUPHENYL in treating UCD in the United States. 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. While KRYSTEXXA faces limited direct competition, a number of competitors have drugs in Phase 1 or Phase 2 trials, including Selecta Biosciences Inc. which has presented clinical data from its Phase 2 study and initiated a six-month head-to-head trial comparing their candidate to KRYSTEXXA in March 2019. 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%. The generic version of Voltaren Gel 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. DUEXIS and VIMOVO face competition from other NSAIDs, including Celebrex®, marketed by Pfizer Inc., and celecoxib, a generic form of the medicine 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, despite such substitution being off-label in the case of DUEXIS and VIMOVO. Because pharmacists often have economic and other incentives to prescribe lower-cost generics, if physicians prescribe PENNSAID 2%, DUEXIS, 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 generic diclofenac sodium topical solutions as a substitute for PENNSAID 2%, the substitution of generic ibuprofen and famotidine separately as a substitution for DUEXIS or generic naproxen and branded Nexium® (esomeprazole) as a substitute for VIMOVO, sales of PENNSAID 2%, DUEXIS and VIMOVO may suffer despite any success we may have in promoting PENNSAID 2%, DUEXIS 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.
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 (i) 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 October 17, 2027, (ii) non-exclusive licenses to manufacture and commercialize generic versions of PENNSAID 2% in the United States after January 10, 2029, (iii) a non-exclusive license to manufacture and commercialize a generic version of RAYOS tablets in the United States after December 23, 2022, (iv) a non-exclusive license to manufacture and commercialize a generic version of VIMOVO in the United States after January 1, 2025, and (v) non-exclusive licenses to manufacture and commercialize generic versions of RAVICTI in the United States after July 1, 2025, or earlier under certain circumstances.

Patent litigation is currently pending in the United States District Court for the District of New Jersey against several companies intending to market a generic version of VIMOVO before the expiration of certain of our patents listed in the Orange Book. These cases are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy’s Laboratories Inc. and Dr. Reddy’s Laboratories Ltd., or collectively Dr. Reddy’s; (ii) Lupin Limited and Lupin Pharmaceuticals, Inc., or collectively Lupin; and (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc., or collectively Mylan. 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.

Patent litigation is currently pending in the United States District Court for the District of New Jersey and the Court of Appeals for the Federal Circuit against several companies intending to market a generic version of DUEXIS prior to the expiration of certain of our patents listed in the Orange Book. These cases are collectively known as the DUEXIS cases, and involve the following sets of defendants: (i) Watson Laboratories, Inc., Actavis, Inc. and Actavis plc, or collectively Actavis, who intend to market a generic version of PENNSAID 2% prior to the expiration of certain of our patents listed in the FDA’s Orange Book, or the Orange Book. These cases arise from Paragraph IV Patent Certification notice letters from Actavis advising it had filed an ANDA with the FDA seeking approval to market a generic version of PENNSAID 2% before the expiration of the patents-in-suit.

Patent litigation is currently pending in the United States District Court for the District of Delaware against Alkem Laboratories, Inc., or Alkem, who intends to market a generic version of DUEXIS prior to the expiration of certain of our patents listed in the Orange Book. This case arises from Paragraph IV Patent Certification notice letters from Alkem advising it had filed an ANDA with the FDA seeking approval to market a generic version of DUEXIS before the expiration of the patents-in-suit.

If we are unsuccessful in any of the VIMOVO cases, PENNSAID 2% cases or DUEXIS case, we will likely face generic competition with respect to VIMOVO, PENNSAID 2% and DUEXIS and sales of VIMOVO, PENNSAID 2% and/or DUEXIS will be substantially harmed.

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.

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In addition, established pharmaceutical companies may invest heavily to accelerate discovery and development of 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 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 and December 2020, respectively, with exclusivity for PROCYSBI extending to 2022 for patients ages one to six years. In addition, teprotumumab has been granted orphan drug designation for treatment of active (dynamic) phase Graves’ orbitopathy and, if approved by the FDA for that indication, would be eligible for seven years of marketing exclusivity in the United States following such approval. 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 the applicable medicine, we could be subject to generic competition and revenues from the medicine could decrease materially. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as our medicines despite orphan drug exclusivity, we may face increased competition and lose market share with respect to these medicines.
Our business operations may subject us to numerous commercial disputes, claims and/or lawsuits and such litigation may be costly and time-consuming and could materially and adversely impact our financial position and results of operations.

Operating in the pharmaceutical industry, particularly the commercialization of medicines, involves numerous commercial relationships, complex contractual arrangements, uncertain intellectual property rights, potential product liability and other aspects that create heightened risks of disputes, claims and lawsuits. In particular, we may face claims related to the safety of our medicines, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture-related matters. 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 DUEXIS, PENNSAID 2% and VIMOVO.

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.

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 adversely affect our business.

In addition to our U.S. operations, we have operations in Ireland, Bermuda, the Grand Duchy of Luxembourg, or Luxembourg, Switzerland, Germany, Canada and in Israel (through Andromeda Biotech Ltd). RAVICTI received marketing authorization from Health Canada, or HC, in March 2016 and we launched RAVICTI in Canada in November 2016. PROCYSBI received marketing authorization from HC in June 2017 and we launched PROCYSBI in Canada in October 2017. BUPHENYL is currently marketed in Japan by Orphan Pacific. QUINSAIR received marketing authorization from HC in June 2015 and we launched QUINSAIR in Canada in December 2016. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for our medicines;
- compliance with Irish laws and the maintenance of our Irish tax residency with respect to our overall corporate structure and administrative operations, including the need to generally hold meetings of our board of directors and make decisions in Ireland, which may make certain corporate actions more cumbersome, costly and time-consuming;
- difficulties in staffing and managing foreign operations;
- in certain circumstances, including with respect to the commercialization of DUEXIS in Mexico and Chile, increased dependence on the commercialization efforts and regulatory compliance of third-party distributors or strategic partners;
- 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, or DOJ, 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.

We are subject to tax audits around the world, and such jurisdictions may assess additional income tax against us. Although we believe our tax positions are reasonable, the final determination of tax audits could be materially different from our recorded income tax provisions and accruals. The ultimate results of an audit could have a material adverse effect on our operating results or cash flows in the period or periods for which that determination is made and could result in increases to our overall tax expense in subsequent periods.

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 clinical 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 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 prior 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 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, we assumed responsibility for the patent infringement litigation with respect to RAVICTI upon the closing of our acquisition of Hyperion Therapeutics, Inc., or Hyperion, and we have assumed responsibility for completing post-marketing clinical trials of RAVICTI that are required by the FDA, one of which is ongoing.

In connection with our acquisition of Raptor Pharmaceutical Corp., or 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, as amended, if we do not spend a specified amount on the development of QUINSAIR for non-cystic fibrosis indications between January 1, 2018 and December 31, 2021 and if regulatory approval by the FDA for QUINSAIR for the CF indication is obtained prior to December 31, 2021, we may be obligated to pre-pay a milestone payment related to commercial sales of QUINSAIR for non-CF indications. This obligation is subject to certain exceptions due to, for example, manufacturing delays not under our control, or clinical trial suspension or delay ordered by the FDA. In October 2017, we triggered a milestone payment under this agreement and we paid Tripex $20.0 million in November 2017. 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 and/or commercialization activities in the United States until submission of the new drug application, or 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. 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, as amended, with respect to PROCYSBI. To the extent that we fail to perform our 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. 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 Nuvo (formerly Aralez Pharmaceuticals Inc.) with respect to its continued involvement in such litigation.

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.
We may not be able to successfully maintain our 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 has subsidiaries maintained in multiple jurisdictions, including Ireland, the United States, Switzerland, Luxembourg, Germany, Canada, Bermuda and Israel (through Andromeda Biotech Ltd). Prior to our merger transaction in September 2014 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-company service and transfer pricing agreements, each on an arm’s length basis. We are continuing a substantially similar structure and arrangements. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, changes to the tax laws of jurisdictions that we operate in (including for example, the enactment of new tax treaties or changes to existing tax treaties), changes in the mix of our profitability from jurisdiction to jurisdiction, the implementation of the EU Anti-Tax Avoidance Directive (see further discussion below), the implementation of the Bermuda Economic Substance Act of 2018 (effective after December 31, 2018) and our inability to secure or sustain acceptable agreements with tax authorities (if applicable). Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations. 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 and/or the Irish tax authorities may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Resisting 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 general 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.

In July 2018, the IRS issued regulations under Section 7874 that finalized, with few changes, guidance that the IRS had previously issued in temporary form in 2016. We do not believe that our classification as a foreign corporation for U.S. federal income tax purposes is affected by Section 7874 or the regulations thereunder, though the IRS may disagree.

Recent and 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 or the taxation of transactions between members of our group, 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.

In January 2017, the U.S. Treasury and the IRS 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 regulations, the former stockholders of U.S. corporations acquired by a foreign corporation within thirty-six 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.
In addition, the Organization for Economic Co-operation and Development, or the OECD, 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 intra-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 OECD’s Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting, commonly referred to as the MLI. The MLI came into effect on July 1, 2018. In January 2019, Ireland deposited the instrument of ratification of Ireland’s MLI choices with the OECD. Ireland’s MLI is expected to come into force on May 1, 2019. Depending on whether jurisdictions have ratified the MLI, the MLI could already, or may soon modify affected tax treaties making it more difficult for us to obtain advantageous tax-treaty benefits. The number of affected tax treaties could eventually be in the thousands. 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.

On July 12, 2016, the Anti-Tax Avoidance Directive, or ATAD, was formally adopted by the Economic and Financial Affairs Council of the EU. The stated objective of the ATAD is to provide for the effective and swift coordinated implementation of anti-base erosion and profit shifting measures at EU level. Like all directives, the ATAD is binding as to the results it aims to achieve though EU Member States are free to choose the form and method of achieving those results. In addition, the ATAD contains a number of optional provisions that present an element of choice as to how it will be implemented into law. On December 22, 2017, the U.S. federal income tax legislation was signed into law (H.R. 1, “An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018”, informally titled the Tax Cuts and Jobs Act, or the Tax Act) that significantly revises the Code in the United States. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), implementation of a “base erosion anti-abuse tax” which requires U.S. corporations to make an alternative determination of taxable income without regard to tax deductions for certain payments to affiliates, taxation of certain non-U.S. corporations’ earnings considered to be “global intangible low taxed income”, or GILTI, repeal of the alternative minimum tax, or AMT, for corporations and changes to a taxpayer’s ability to either utilize or refund the AMT credits previously generated, changes to the limitation on deductions for certain executive compensation particularly with respect to the removal of the previously allowed performance based compensation exception, changes in the attribution rules relating to shareholders of certain “controlled foreign corporations”, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. For example, U.S. federal income tax law resulting in additional taxes owed by U.S. shareholders under the GILTI rules, together with the Tax Act’s change to the attribution rules related to “controlled foreign corporations” may discourage U.S. investors from owning or acquiring 10% or greater of our outstanding ordinary shares, which other shareholders may have viewed as beneficial or may otherwise negatively impact the trading price of our ordinary shares. We are unable to predict what federal tax law may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our effective tax rates in the future in countries where we have operations and have an adverse effect on our overall tax rate in the future, along with increasing the complexity, burden and cost of tax compliance. We urge our shareholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our ordinary shares.

On December 20, 2018, the U.S. Treasury issued Proposed Regulations under Section 267A of the Code, or Section 267A Proposed Regulations, to clarify certain aspects of Section 267A of the Code, or Section 267A (commonly referred to as the “Anti-Hybrid Rules”; rules enacted as part of the Tax Act). The Section 267A Proposed Regulations were the first administrative guidance on Section 267A and provided several rules which expanded the reach and scope of the Anti-Hybrid Rules particularly involving the payment of interest and royalties by certain branches, reverse hybrid entities, and other hybrid mismatch arrangements. While Section 267A, as enacted under the Tax Act, does not appear to apply to the Company, the guidance and scope of the Section 267A Proposed Regulations with respect to Anti-Hybrid Rules may apply to the Company. We are currently in the process of assessing the provisions set forth in the Section 267A Proposed Regulations and their potential impact on the Company. To the extent that the Anti-Hybrid Rules are applicable to the Company, absent certain actions taken by the Company to restructure its intercompany financing arrangements, such application would have a material impact on our effective tax rate if and when the Section 267A Proposed Regulations become final as currently drafted.
On March 4, 2019, the U.S. Treasury issued Proposed Regulations under Section 250 of the Code, or Section 250 Proposed Regulations, which provide guidance on both the computation of the deductions for GILTI and “foreign-derived intangible income”, or FDII, and the determination of FDII. We do not expect the Company to be subject to the GILTI inclusion nor is it expected that the potential FDII deduction would have a material impact on our effective tax rate.

If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a United States person is treated as owning (directly, indirectly, or constructively) at least 10% of the value or voting power of our ordinary shares, such person may be treated as a “United States shareholder” with respect to each “controlled foreign corporation” in our group (if any). Because our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations (regardless of whether or not we are treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income,” and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with these reporting and tax paying obligations may subject a United States shareholder to significant monetary penalties and may prevent the statute of limitations from starting with respect to such shareholder’s U.S. federal income tax return for the year for which reporting was due. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries is treated as a controlled foreign corporation or whether any investor is treated as a United States shareholder with respect to any such controlled foreign corporation or furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax paying obligations. A United States investor should consult its advisors regarding the potential application of these rules to an investment in our ordinary shares.

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 officers 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, Head of Research and Development and Chief Scientific Officer, Shao-Lee Lin, M.D., Ph.D; our Executive Vice President, Chief Commercial Officer, Vikram Karnani; our Executive Vice President, Chief Human Resources Officer, Irina P. Konstantinovsky; our Executive Vice President, General Counsel, Brian K. Beeler; our Executive Vice President, Technical Operations, Michael A. DesJardin and our Executive Vice President, Corporate Affairs, Chief Communications Officer, Geoffrey M. Curtis and Senior Vice President, Head of Medical Affairs and Outcomes Research, Jeffrey Kent, M.D., FACP, FACC. In order to retain valuable employees at our company, in addition to salary and annual cash incentives, we provide a mix of performance stock units, or PSUs, that vest subject to attainment of specified corporate performance goals and continued services, stock options and restricted stock units, or RSUs, that vest over time subject to continued services. The value to employees of PSUs, stock options and RSUs 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 EMA obligations and continued regulatory review, which may result in significant additional expense. Additionally, any other medicine candidate, if approved by the FDA or the EMA, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our medicines.

Any regulatory approvals that we obtain for our medicine candidates may also be subject to limitations on the approved indicated uses for which the medicine may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the medicine candidate. In addition, with respect to our current FDA-approved medicines (and with respect to our medicine candidates, if approved), the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the medicine are subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, GCPs, International Council for Harmonisation, or ICH, guidelines 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 included obligations to conduct studies in UCD patients during the first two months of life, including a study of the pharmacokinetics in that age group and a randomized study to determine the safety and efficacy in UCD patients who are treatment naïve to phenylbutyrate treatment. 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. In December 2018, we received FDA approval to expand the age range for the use of RAVICTI in the chronic management of UCDs in patients from birth to two months and as a result, we now have approval for patients of all ages. As part of these approvals to expand the age range for use of RAVICTI in the chronic management of UCDs in patients from birth to two months and as a result, we now have approval for patients of all ages. As part of these approvals to expand the age range for use of RAVICTI in the chronic management of UCDs in patients from birth to two months and as a result, we now have approval for patients of all ages. As part of these approvals to expand the age range for use of RAVICTI in the chronic management of UCDs in patients from birth, we have fulfilled, and subsequently received FDA confirmation of release from the requirement to conduct studies in UCD patients during the first two months of life. We are currently conducting a study to determine the effects of RAVICTI in patients with UCDs that are treatment naïve to phenylbutyrate.

In addition, the FDA closely regulates the marketing and promotion of drugs and biologics. The FDA does not regulate the behaviour 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. While Congress has recently considered legislation that would modify or eliminate restrictions for off-label promotion, we do not have sufficient information to anticipate if the current regulatory environment will change.

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;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of medicine license approvals;
- medicine seizure or detention, or refusal to permit the import or export of medicines; and
- injunctions, the imposition of civil or criminal penalties, or exclusion, debarment or suspension from government healthcare programs.

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.

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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.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress has considered legislation that would repeal or replace and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA’s individual mandate to carry health insurance, and delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

Likewise, in the countries in the EU, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment in the EU. Certain of these changes could impose limitations on the prices we will be able to charge for our products and any approved product candidates or the amounts of reimbursement available for these products from governmental agencies or third party payers, may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products.
In addition, drug pricing by pharmaceutical companies has come under increased scrutiny. Specifically, there have been several recent state and U.S. Congressional inquiries, proposed federal and state legislation and state laws enacted designed to, among other things, bring more transparency to drug pricing by requiring drug companies to notify insurers and government regulators of price increases and provide an explanation of the reasons for the increase, 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. For example, legislation was recently signed into law in California that requires drug manufacturers to provide advance notice and explanation to state regulators, health plans and insurers and PBMs for price increases of more than 16% over two years. Moreover, in May 2018, the Trump administration released its “Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs”, or Blueprint. The Blueprint contains several potential regulatory actions and legislative recommendations aimed at lowering prescription drug prices including measures to promote innovation and competition for biologies, changes to Medicare Part D to give plan sponsors more leverage when negotiating prices with manufacturers and updating the Medicare drug-pricing dashboard to make price increases and generic competition more transparent. In addition, HHS released a Request for Information, or RFI, soliciting public input on ways to lower drug pricing. Together, the recommendations in the Blueprint and RFI, if enacted by Congress and HHS, could lead to changes to Medicare Parts B and D. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. The majority of our medicines are purchased by private payers, and much of the focus of pending legislation is on government program reimbursement. Most recently, the Office of Inspector General of HHS published a Proposed Rule in January 2019 that would, among other items, eliminate the current safe harbor protection under the Antikick Back Statute for pharmaceutical manufacturer rebates to Medicare Part D plans, Medicaid MCOs and the PBMs with which such entities contract. 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 or regulation would affect us. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payers. The Trump administration’s budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the 2020 budget process, through regulation or other future legislation. 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, transparency laws and false claims laws. 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 or through our customers, to various state and federal fraud and abuse and transparency laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, civil monetary penalty statutes prohibiting beneficiary inducements, and similar state and local laws, federal and state privacy and security laws, sunshine laws, government price reporting laws, and other fraud laws. Some states, such as Massachusetts, make certain reported information public. In addition, there are state and local laws that require pharmaceutical representatives to be licensed and comply with codes of conduct, transparency reporting, and other obligations. Collectively, these laws may affect, 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. We are subject to similar laws in the EU/EEA, including the EU General Data Protection Regulation (2016/679), or GDPR, under which fines of up to €20.0 million or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance.

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. Moreover, state governmental agencies may propose or enact laws and regulations that extend or contradict federal requirements. 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, including pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations, 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.

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Undesirable side effects caused by any medicine candidate that we develop could 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.

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.

We are unable to predict whether we could be subject to other 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.

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;

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.

On March 5, 2019, we received a civil investigative demand, or CID, from the DOJ pursuant to the Federal False Claims Act regarding assertions that certain of our payments to PBMs were potentially in violation of the Anti-Kickback Statute. The CID requests certain documents and information related to our payments to PBMs, pricing and our patient assistance program regarding DUExis, VIMOVO and PENNSAID 2%. We are cooperating with the investigation. While we believe that our payments and programs are compliant with the Anti-Kickback Statute, no assurance can be given as to the timing or outcome of the DOJ’s investigation, or that it will not result in a material adverse effect on 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.
• 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 pre-clinical 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. We have an agreement in place with Syneos Health, Inc. in connection with our Phase 3 extension trial to evaluate teprotumumab for the treatment of TED. We also 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 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 pre-clinical 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 pre-clinical studies and initial clinical testing. For example, in December 2016, we announced that the Phase 3 trial, Safety, Tolerability and Efficacy of ACTIMMUNE Dose Escalation in Friedreich’s ataxia, evaluating ACTIMMUNE for the treatment of Friedreich’s ataxia did not meet its primary endpoint. Additionally, we previously made a decision to discontinue our ACTIMMUNE investigator-initiated trials in oncology to focus on our strategic pipeline where we see more promise and long-term intellectual property.
We may experience delays in clinical trials or investigator-initiated studies. We do not know whether any additional clinical trials will be initiated in the future, begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

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

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

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

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

Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our medicine candidates.
We are dependent upon our own or third-party information technology systems, infrastructure and data, which exposes us to data security risks.

We are subject to extensive laws and regulations governing data privacy, and our failure to comply with these laws and regulations could harm our business.
Additionally, California recently enacted legislation that has been dubbed the first “GDPR-like” law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA will likely impact our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information.

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 $125.0 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 Holdings LLC, or Crealta, Raptor and River Vision Development Corp., or River Vision. We have financed our operations primarily through equity and debt financings and have incurred significant operating losses in the past. We recorded an operating loss of $1.8 million for the three months ended March 31, 2019, operating income of $37.9 million for the year ended December 31, 2018, an operating loss of $339.4 million for the year ended December 31, 2017 and an operating loss of $119.0 million for the year ended December 31, 2016. We recorded a net loss of $32.9 million for the three months ended March 31, 2019, a net loss of $38.4 million for the year ended December 31, 2018, a net loss of $350.1 million for the year ended December 31, 2017 and a net loss of $147.1 million for the year ended December 31, 2016. As of March 31, 2019, we had an accumulated deficit of $1,211.6 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’ equity 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 achieve or 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 achieve and 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, 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 teprotumumab;
• 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 achieve or sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our ordinary shares and could impair our ability to raise capital, expand our business, diversify our medicine offerings or continue our operations.

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

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

• commercialize our existing medicines in the United States, including the substantial expansion of our sales force in recent years;
• 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.

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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 acquisitions. 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 March 31, 2019, we had $1,608.1 million book value, or $1,693.0 million aggregate principal amount, of indebtedness, including $518.0 million in secured indebtedness. In March 2019, we received $200.0 million of commitments under a new revolving credit facility under our credit agreement. In October 2018, we borrowed approximately $818.0 million aggregate principal amount of loans pursuant to an amendment to our credit agreement to refinance the then outstanding senior secured term loans incurred in October 2017 under our credit agreement, and repaid $300.0 million of such aggregate principal amount in March 2019. 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. We subsequently redeemed $250.0 million of the 2023 Senior Notes in May 2019. In connection with the acquisition of Raptor, we issued $300.0 million aggregate principal amount of 8.750% 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 prior 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 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, medicine candidate 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 and medicine candidates, to potentially fund share repurchases, and for working capital, milestone payments, 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.
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 $7.7 million for 2019 through 2028. We continue to carry forward the annual limitation related to Hyperion of $50.0 million resulting from the last ownership change date in 2014 and the annual limitation related to Raptor of $0.2 million resulting from the last ownership change date in 2009. In addition, we recognized $32.2 million of federal net operating losses, $2.2 million of state net operating losses and $9.5 million of federal tax credits following our acquisition of River Vision. These acquired federal net operating losses and tax credits are subject to an annual limitation of $2.6 million. The net operating loss carryforward and tax credit carryforward limitations are 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. Under the Tax Act, U.S. federal net operating losses incurred in taxable years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal net operating losses generated in taxable years beginning after December 31, 2017 is limited to 80 percent of the current year’s taxable income. It remains uncertain if and to what extent various U.S. states will conform to the Tax Act.

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 for approximately ten years following the Vidara Merger with respect to certain intra-company transactions. As a result, we or our other U.S. affiliates may not be able to utilize their U.S. tax attributes to offset their U.S. taxable income or U.S. tax liability respectively, if any, resulting from certain intra-company taxable transactions during such period. Notwithstanding this limitation, we expect that we will be able to fully use our U.S. net operating losses and tax credits prior to their expiration. As a result of this limitation, however, it may take Horizon Pharma USA, Inc. (as the successor to HPI) longer to use its net operating losses and tax credits. 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 or tax obligations.

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.

The United Kingdom’s referendum to leave the EU, or “Brexit,” has caused 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 United Kingdom’s relationship with the EU and there is the potential that the United Kingdom and the EU may not agree to a withdrawal arrangement before the date the United Kingdom leaves the EU. During this period of negotiation and afterwards, 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 political uncertainty. In the short and medium term, there is a risk of disrupted import and export processes due to a lack of administrative processing capacity by the respective United Kingdom and EU customs agencies that may delay time-sensitive shipments and may negatively impact our product supply chain. 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 March 31, 2019, we had $1,032.8 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 March 31, 2019, 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.

If the London Inter-Bank Offered Rate, or LIBOR, is discontinued, interest payments under our credit agreement may be calculated using another reference rate.

In July 2017, the Chief Executive of the United Kingdom Financial Conduct Authority, or FCA, which regulates LIBOR, announced that the FCA intends to phase out the use of LIBOR by the end of 2021. In addition, the U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U.S. financial institutions, is considering replacing U.S. dollar LIBOR with the Secured Overnight Financing Rate, or SOFR, a new index calculated by short-term repurchase agreements, backed by Treasury securities. Although there have been certain issuances utilizing SOFR, it is unknown whether this or any other alternative reference rate will attain market acceptance as a replacement for LIBOR. LIBOR is used as a benchmark rate throughout our credit agreement, and our credit agreement does not provide fallback language for all circumstances in which LIBOR ceases to be published. There remains uncertainty regarding the future utilization of LIBOR and the nature of any replacement rate, and any potential effects of the transition away from LIBOR on us are not known. The transition process may involve, among other things, increased volatility and illiquidity in markets for instruments that currently rely on LIBOR and may result in increased borrowing costs, the effectiveness of related transactions such as hedges, uncertainty under applicable documentation, including the credit agreement, or difficult and costly processes to amend such documentation. As a result, our ability to refinance our credit agreement or other indebtedness or to hedge our exposure to floating rate instruments may be impaired, which would adversely affect the operations of our business.

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 or revolving loans, the revolving commitments, 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. For example, during the year ended December 31, 2018, we recorded an impairment of $33.6 million to fully write off the book value of developed technology related to PROCYSBI in Canada and Latin America. Such impairment and any reduction or other 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 RAYOS, DUEXIS and VIMOVO 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 Actavis, who intend to market a generic version of PENNSAID 2% prior to the expiration of certain of our patents listed in the Orange Book. These cases arise from Paragraph IV Patent Certification notice letters from Actavis advising they had filed an ANDA with the FDA seeking approval to market a generic version of PENNSAID 2% before the expiration of the patents-in-suit. For a more detailed description of the PENNSAID 2% litigation, see Note 16, Legal Proceedings, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q.
Patent litigation is currently pending in the United States District Court for the District of New Jersey and the Court of Appeals for the Federal Circuit 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. 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. For a more detailed description of the VIMOVO litigation, see Note 16, Legal Proceedings, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q.

Patent litigation is currently pending in the United States District Court for the District of Delaware against Alkem, who intends to market a generic version of DUEXIS prior to the expiration of certain of our patents listed in the Orange Book. This case arises from Paragraph IV Patent Certification notice letters from Alkem advising it had filed an ANDA with the FDA seeking approval to market a generic version of DUEXIS before the expiration of the patents-in-suit. For a more detailed description of the DUEXIS litigation, see Note 16, Legal Proceedings, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 of this Quarterly Report on Form 10-Q.

We intend to vigorously defend our intellectual property rights relating to our medicines, but we cannot predict the outcome of the DUEXIS case, the PENNSAID 2% cases and the VIMOVO cases. 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.

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 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.

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 United States Patent and Trademark Office, or 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 rely on a license from Bausch with respect to technology developed by Bausch in connection with the manufacturing of RAVICTI. The purchase agreement under which Hyperion purchased the rights to RAVICTI contains obligations to pay Bausch 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 Bausch, Hyperion received a license to use some of the manufacturing technology developed by Bausch in connection with the manufacturing of BUPHENYL. The restated collaboration agreement also contains obligations to pay Bausch regulatory and sales milestone payments, as well as royalties on net sales of BUPHENYL. If we fail to make a required payment to Bausch and do not cure the failure within the required time period, Bausch may be able to terminate the license to use its manufacturing technology for RAVICTI and BUPHENYL. If we lose access to the Bausch 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 Bausch 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 license rights to patents, know-how and trademarks for ACTIMMUNE from Genentech Inc., or Genentech. 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.

In addition, we are subject to contractual obligations under our agreements with Tripex and PARI related to QUINSAIR. Under the agreement with Tripex, as amended, if we do not spend a specified amount on the development of QUINSAIR for non-CF indications between January 1, 2018 and December 31, 2021 and regulatory approval by the FDA for QUINSAIR for the CF indication is obtained prior to December 31, 2021, we may be obligated to pre-pay a milestone payment related to commercial sales of QUINSAIR for non-CF indications. This obligation is subject to certain exceptions due to, for example, manufacturing delays not under our control, or clinical trial suspension or delay ordered by the FDA. In October 2017, we triggered a milestone payment under this agreement and we paid Tripex $20.0 million in November 2017. 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 and/or commercialization 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. We are also subject to contractual obligations under our amended and restated license agreement with UCSD, as amended, with respect to PROCYSBI. 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 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.

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. 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.

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 inter partes review, 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 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 one or more transactions at prices and in a manner we determine from time to time, the market price of our ordinary shares could decline.

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.*

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 liability 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 United States 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 or necessarily be enforceable in Ireland.

As an Irish company, we are governed by the Irish Companies Act 2014 (as amended), which differs 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, shareholder rights agreement and Irish law 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 February 2019, we adopted a shareholder rights agreement, or rights agreement, with a 12-month term under which shareholders have certain ordinary share purchase rights if a person or group acquires 10% (or 15% in the case of an existing “13G Investor” as defined in the rights agreement) or more of our outstanding ordinary shares without the prior approval of our board of directors. Until its expiration, the rights agreement could make it more difficult for a person or group to acquire a majority of our outstanding ordinary shares, and could otherwise prevent or delay an acquisition of us. The rights agreement could also reduce the price that investors might be willing to pay for our ordinary shares and result in the market price of our ordinary shares being lower than it would be without the rights agreement. In addition, the existence of the rights agreement itself may deter a potential acquirer from pursuing any acquisition of us at all. As a result, either by operation of the rights agreement or by its potential deterrent effect, acquisitions of us that our shareholders may consider in their best interests may not occur.

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.

Any attempts to take us over will be subject to Irish Takeover Rules and subject to review by the Irish Takeover Panel.

We are subject to the Irish Takeover Rules, under which our board of directors will not be permitted to take any action which might frustrate an offer for our ordinary shares once it has received an approach which may lead to an offer or has reason to believe an offer is imminent.

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 Irish Companies Act 2014 (as amended) 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.

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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 biopharma 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, which lawsuits were dismissed by the plaintiffs in June 2018. Even if we are successful in defending 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.
<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>Memorandum and Articles of Association of Horizon Therapeutics Public Limited Company, as amended.</td>
</tr>
<tr>
<td>4.2</td>
<td>Form of 2.50% Exchangeable Senior Note due 2022 (incorporated by reference to Exhibit 4.1 to Horizon Therapeutics Public Limited Company’s Current Report on Form 8-K, filed on March 13, 2015).</td>
</tr>
<tr>
<td>4.3</td>
<td>Indenture, dated April 29, 2015, by and between Horizon Pharma Financing Inc. and U.S. Bank National Association (incorporated by reference to Exhibit 4.1 to Horizon Therapeutics Public Limited Company’s Current Report on Form 8-K, filed on April 29, 2015).</td>
</tr>
<tr>
<td>4.4</td>
<td>Form of 6.625% Senior Note due 2023 (incorporated by reference to Exhibit 4.1 to Horizon Therapeutics Public Limited Company’s Current Report on Form 8-K, filed on April 29, 2015).</td>
</tr>
<tr>
<td>4.6</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 (incorporated by reference to Exhibit 4.1 to Horizon Therapeutics Public Limited Company’s Current Report on Form 8-K, filed on October 25, 2016).</td>
</tr>
<tr>
<td>4.7</td>
<td>Form of 8.750% Senior Note due 2024 (incorporated by reference to Exhibit 4.1 to Horizon Therapeutics Public Limited Company’s Current Report on Form 8-K, filed on October 25, 2016).</td>
</tr>
<tr>
<td>4.9</td>
<td>Second Supplemental Indenture, dated October 19, 2018, by and between Horizon Pharma Services LLC and U.S. Bank National Association (incorporated by reference to Exhibit 4.9 to Horizon Therapeutics Public Limited Company’s Quarterly Report on Form 10-Q, filed on November 7, 2018).</td>
</tr>
<tr>
<td>4.15</td>
<td>Third Supplemental Indenture, dated November 15, 2018, by and between Horizon Medicines LLC and U.S. Bank National Association (incorporated by reference to Exhibit 4.15 to Horizon Therapeutics Public Limited Company’s Annual Report on Form 10-K, filed on February 27, 2019).</td>
</tr>
<tr>
<td>4.16</td>
<td>Seventh Supplemental Indenture, dated November 15, 2018, by and between Horizon Medicines LLC and U.S. Bank National Association (incorporated by reference to Exhibit 4.16 to Horizon Therapeutics Public Limited Company’s Annual Report on Form 10-K, filed on February 27, 2019).</td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Document</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>10.1</td>
<td>Amendment No. 5, dated March 11, 2019, to Credit Agreement, dated May 7, 2015 (as amended by Amendment No. 1, dated October 25, 2016, Amendment No. 2, dated March 29, 2017, Amendment No. 3, dated October 23, 2017, and Amendment No. 4, dated October 19, 2018), by and among Horizon Pharma USA, Inc., as Borrower, Horizon Therapeutics 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 (incorporated by reference to Exhibit 99.1 to Horizon Therapeutics Public Limited Company's Current Report on Form 8-K, filed on March 11, 2019).</td>
</tr>
<tr>
<td>10.2+</td>
<td>Executive Employment Agreement, effective as of May 1, 2019, by and between Horizon Pharma USA, Inc. and Jeffery Kent, M.D., FACP, FACG.</td>
</tr>
<tr>
<td>10.3*</td>
<td>Commercial Supply Agreement, effective as of February 14, 2018, by and between CMC Biologics A/S, dba AGC Biologics and Horizon Pharma Ireland Limited.</td>
</tr>
<tr>
<td>10.4*</td>
<td>Commercial Supply Agreement, effective as of December 18, 2018, by and between Catalent Indiana, LLC and Horizon Pharma Ireland Limited.</td>
</tr>
<tr>
<td>10.5*</td>
<td>License Agreement, effective as of June 15, 2011, by and among F. Hoffmann-La Roche Ltd, Hoffman-La Roche Inc. and River Vision Development Corp., as amended through Amendment No. 9 to the License Agreement, effective as of October 21, 2016.</td>
</tr>
<tr>
<td>10.6*</td>
<td>Exclusive License Agreement, dated December 5, 2012, by and between Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center and River Vision Development Corp.</td>
</tr>
<tr>
<td>10.7+</td>
<td>Horizon Therapeutics Public Limited Company Amended and Restated 2014 Equity Incentive Plan, and Form of Option Agreement, Form of Stock Option Grant Notice, Forms of Restricted Stock Unit Agreement and Forms of Restricted Stock Unit Grant Notice thereunder.</td>
</tr>
<tr>
<td>10.8+</td>
<td>Horizon Therapeutics Public Limited Company 2014 Non-Employee Equity Plan, as amended, and Form of Option Agreement, Form of Stock Option Grant Notice, Forms of Restricted Stock Unit Agreement and Forms of Restricted Stock Unit Grant Notice thereunder.</td>
</tr>
<tr>
<td>18.1</td>
<td>Preferability letter from Independent Registered Public Accounting Firm.</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>Exhibit Number</td>
<td>Description of Document</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------------------------------------------</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.

* Certain portions of this exhibit (indicated by “[***]”) have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.
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 THERAPEUTICS PLC

Date: May 8, 2019

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

Date: May 8, 2019

By:  /s/ Paul W. Hoelscher
     Paul W. Hoelscher
     Executive Vice President, Chief Financial Officer
     (Principal Financial Officer)
COMPANIES ACT 2014
PUBLIC LIMITED COMPANY
MEMORANDUM
AND
ARTICLES OF ASSOCIATION
OF
HORIZON THERAPEUTICS PUBLIC LIMITED COMPANY
Effective as of 2 May 2019
1. The name of the Company is: Horizon Therapeutics public limited company.

2. The Company is a public limited company for the purposes of Part 17 of the Companies Act 2014 (the “Act”).

3. The objects for which the Company is established are:

   (a) To carry on all or any of the businesses of manufacturers, developers, buyers, sellers, and distributing agents of and dealers in all kinds of patent, pharmaceutical, medicinal, and medicated preparations, patent medicines, drugs, herbs, and of and in pharmaceutical, medicinal, proprietary and industrial preparations, compounds, and articles of all kinds; and to manufacture, make up, prepare, buy, sell, and deal in all articles, substances, and things commonly or conveniently used in or for making up, preparing, or packing any of the products in which the Company is authorised to deal, or which may be required by customers of or persons having dealings with the Company.

   (b) To invest in pharmaceutical and related assets, including, amongst other items, investments in pharmaceutical companies, products, businesses, divisions, technologies, devices, sales force and other marketing capabilities, development projects and related activities, licences, intellectual and similar property rights, premises and equipment, royalty rights and all other assets needed to operate a pharmaceuticals business.

   (c) To establish, maintain and operate laboratories for the purpose of carrying on chemical, physical and other research in medicine, chemistry, industry or other unrelated or related fields.

   (d) To invest (including long-term investments in, and acquisitions of, the shares of pharmaceutical companies) any monies of the Company in such investments and in such manner as may from time to time be determined, and to hold, sell or deal with such investments and generally to purchase, take on lease or in exchange or otherwise acquire any real and personal property and rights or privileges.

   (e) To develop and turn to account any land acquired by the Company or in which it is interested and in particular by laying out and preparing the same for building purposes, constructing, altering, pulling down, decorating, maintaining, fitting up and improving buildings and conveniences, and by planting, paving, draining, farming, cultivating, letting on building lease or building agreement and by advancing money to and entering into contracts and arrangements of all kinds with builders, tenants and others.

   (f) To acquire and hold shares and stocks of any class or description, debentures, debenture stock, bonds, bills, mortgages, obligations, investments and securities of all descriptions and of any kind issued or guaranteed by any company, corporation or
undertaking of whatever nature and wheresoever constituted or carrying on business or issued or guaranteed by any government, state, dominion, colony, sovereign ruler, commissioners, trust, public; municipal, local or other authority or body of whatsoever nature and wheresoever situated and investments, securities and property of all descriptions and of any kind, including real and chattel real estates, mortgages, reversions, assurance policies, contingencies and choses in action.

(g) To remunerate by cash payments or allotment of shares or securities of the Company credited as fully paid up or otherwise any person or company for services rendered or to be rendered to the Company or any parent or subsidiary body corporate whether in the conduct or management of its business, or in placing or assisting to place or guaranteeing the placing of any of the shares of the Company’s capital, or any debentures or other securities of the Company or in or about the formation or promotion of the Company.

(h) To purchase for investment property of any tenure and any interest therein, and to make advances upon the security of land or other similar property or any interest therein.

(i) To acquire by purchase, exchange, lease, fee farm grant or otherwise, either for an estate in fee simple or for any less estate or other estate or interest, whether immediate or reversionary and whether vested or contingent, any lands, tenements or hereditaments of any tenure, whether subject or not to any charges or encumbrances, and to hold, farm, work and manage and to let, sublet, mortgage or charge land and buildings of any kind, reversions, interests, annuities, life policies, and any other property real or personal, movable or immovable, either absolutely or conditionally, and either subject or not to any mortgage, charge, ground rent or other rents or encumbrances.

(j) To erect or secure the erection of buildings of any kind with a view to occupying or letting them and to enter into any contracts or leases and to grant any licences necessary to effect same.

(k) To maintain and improve any lands, tenements or hereditaments acquired by the Company or in which the Company is interested, in particular by decorating, maintaining, furnishing, fitting up and improving houses, shops, flats, maisonettes and other buildings and to enter into contracts and arrangements of all kinds with tenants and others.

(l) To sell, exchange, mortgage (with or without power of sale), assign, turn to account or otherwise dispose of and generally deal with the whole or any part of the property, shares, stocks, securities, estates, rights or undertakings of the Company, real, chattels real or personal, movable or immovable, either in whole or in part, upon whatever terms and whatever consideration the Company shall think fit.

(m) To take part in the management, supervision, or control of the business or operations of any company or undertaking, and for that purpose to appoint and remunerate any directors, accountants, or other experts or agents to act as consultants, supervisors and agents of other companies or undertakings and to provide managerial, advisory, technical, design, purchasing and selling services.

(n) To make, draw, accept, endorse, negotiate, issue, execute, discount and otherwise deal with bills of exchange, promissory notes, letters of credit, circular notes, and other negotiable or transferable instruments.
To redeem, purchase, or otherwise acquire in any manner permitted by law and on such terms and conditions as the Company may think fit any shares in the Company’s capital.

To guarantee, support or secure whether by personal covenant or by mortgaging or charging all or any part of the undertaking, property and assets (present and future) and uncalled capital of the Company or by both such methods the performance of the obligations of, and the repayment or payment of the principal amounts of and the premiums, interest and dividends on any security of any person, firm or company including (without prejudice to the generality of the foregoing) any company which is for the time being the Company’s holding company or subsidiary as defined by Part 1 of the Act or another subsidiary as defined by the said Part of the Company’s holding company or otherwise associated with the Company in business notwithstanding the fact that the Company may not receive any consideration, advantage or benefit, direct or indirect from entering into such guarantee or other arrangement or transaction contemplated herein.

To lend the funds of the Company with or without security and at interest or free of interest and on such terms and conditions as the directors shall from time to time determine.

To raise or borrow or secure the payment of money in such manner and on such terms as the directors may deem expedient whether or not by the issue of bonds, debentures or debenture stock, perpetual or redeemable, or by mortgage, charge, lien or pledge upon the whole or any part of the undertaking, property, assets and rights of the Company, present or future, including its uncalled capital and generally in any other manner as the directors shall from time to time determine and to enter into or issue interest and currency hedging and swap agreements, forward rate agreements, interest and currency futures or options and other forms of financial instruments, and to purchase, redeem or pay off any of the foregoing and to guarantee the liabilities of the Company or any other person, and any debentures, debenture stock or other securities may be issued at a discount, premium or otherwise, and with any special privileges as to redemption, surrender, transfer, drawings, allotments of shares; attending and voting at general meetings of the Company, appointment of directors and otherwise.

To accumulate capital for any of the purposes of the Company, and to appropriate any of the Company’s assets to specific purposes, either conditionally or unconditionally, and to admit any class or section of those who have any dealings with the Company to any share in the profits thereof or in the profits of any particular branch of the Company’s business or to any other special rights, privileges, advantages or benefits.

To reduce the share capital of the Company in any manner permitted by law.

To make gifts or grant bonuses to officers or other persons who are or have been in the employment of the Company and to allow any such persons to have the use and enjoyment of such property, chattels or other assets belonging to the Company upon such terms as the Company shall think fit.

To establish and maintain or procure the establishment and maintenance of any pension or superannuation fund (whether contributory or otherwise) for the benefit of and to give or procure the giving of donations, gratuities, pensions, annuities, allowances, emoluments or charitable aid to any persons who are or were at any time in the employment or service of the Company or any of its predecessors in business, or of any company which is a subsidiary of the Company or who may be or have
been directors or officers of the Company, or of any such other company as aforesaid, or any persons in whose welfare the Company or any such other company as aforesaid may be interested and the wives, widows, children, relatives and dependants of any such persons and to make payments towards insurance and assurance and to form and contribute to provident and benefit funds for the benefit of such persons and to remunerate any person, firm or company rendering services to the Company, whether by cash payment, gratuities, pensions, annuities, allowances, emoluments or by the allotment of shares or securities of the Company credited as paid up in full or in part or otherwise.

(w) To employ experts to investigate and examine into the conditions, prospects, value, character and circumstances of any business concerns, undertakings, assets, property or rights.

(x) To insure the life of any person who may, in the opinion of the Company, be of value to the Company, as having or holding for the Company interests, goodwill, or influence or otherwise and to pay the premiums on such insurance.

(y) To distribute either upon a distribution of assets or division of profits among the Members of the Company in bind any property of the Company, and in particular any shares, debentures or securities of other companies belonging to the Company or of which the Company may have the power of disposing.

(z) To give, whether directly or indirectly, and whether by means of a loan, guarantee, the provision of security or otherwise, any financial assistance for the purpose of or in connection with a purchase or subscription made or to be made by any person of or for any shares in the Company, or, where the Company is a subsidiary company, in its holding company.

(aa) To do and carry out all or any of the foregoing objects in any part of the world and either as principals, agents, contractors, trustees or otherwise, and either by or through agents, trustees or otherwise and either alone or in partnership or in conjunction with any other company, firm or person, provided that nothing herein contained shall empower the Company to carry on the businesses of insurance.

(bb) To apply for, purchase or otherwise acquire any patents, brevets d’invention, licences, trade marks, industrial designs, know-how, concessions and other forms of intellectual property rights and the like conferring any exclusive or non-exclusive or limited or contingent rights to use, or any secret or other information as to any invention or process of the Company, or the acquisition of which may seem calculated directly or indirectly to benefit the Company, and to use, exercise, develop, or grant licences in respect of, or otherwise turn to account the property, rights or information so acquired.

(cc) To enter into partnership or into any arrangement for sharing profits, union of interests, co-operation, joint venture, reciprocal concession or otherwise with any person or company carrying on or engaged in or about to carry on or engage in any business or transaction which the Company is authorised to carry on or engage in or any business or transaction capable of being conducted so as directly or indirectly to benefit the Company.

(dd) To acquire and undertake the whole or any part of the undertaking, business, property and liabilities of any person or company carrying on any business which the Company is authorised to carry on or which is capable of being conducted so as
to benefit the Company directly or indirectly or which is possessed of assets suitable for the purposes of the Company.

(ee) To adopt such means of making known the Company and its products and services as may seem expedient.

(ff) To acquire and carry on any business carried on by a subsidiary or a holding company of the Company or another subsidiary of a holding company of the Company.

(gg) To promote any company or companies for the purpose of acquiring all or any of the property and liabilities of this Company or for any other purpose which may seem directly or indirectly calculated to benefit this Company.

(hh) To amalgamate with, merge with or otherwise become part of or associated with any other company or association in any manner permitted by law.

(ii) To do and carry out all such other things, except the issuing of policies of insurance, as may be deemed by the Company capable of being conveniently carried on in connection with the above objects or any of them or calculated to enhance the value of or render profitable any of the Company’s properties or rights.

And it is hereby declared that the word “company” in this clause, except where used in reference to this Company, shall be deemed to include any person, partnership or other body of persons whether incorporated or not incorporated and whether domiciled in the State or elsewhere and that the objects of the Company as specified in each of the foregoing paragraphs of this clause shall be separate and distinct objects and shall not be in anywise limited or restricted by reference to or inference from the terms of any other paragraph or the name of the Company.

4. The liability of each Member is limited to the amount from time to time unpaid on such Member’s Shares.

5. The authorised share capital of the Company is € 40,000 and US$60,000 divided into 40,000 deferred shares of € 1.00 each and 600,000,000 ordinary shares of US$0.0001 each.

6. The shares forming the capital, increased or reduced, may be increased or reduced and be divided into such classes and issued with any special rights, privileges and conditions or with such qualifications as regards preference, dividend, capital, voting or other special incidents, and be held upon such terms as may be attached thereto or as may from time to time be provided by the original or any substituted or amended articles of association and regulations of the Company for the time being, but so that where shares are issued with any preferential or special rights attached thereto such rights shall not be alterable otherwise than pursuant to the provisions of the Company’s articles of association for the time being.

7. Capitalised terms that are not defined in this memorandum of association bear the same meaning as those given in the articles of association of the Company.
Cert. No. 507678

Companies Act 2014

PUBLIC LIMITED COMPANY

ARTICLES OF ASSOCIATION

of

Horizon Therapeutics Public Limited Company

(adopted by Special Resolution dated 3 May 2017)

PRELIMINARY

1. Disapplication of certain optional provisions of the Act:

Sections 43(2) and (3), 66(4), 77 to 81, 95(1)(a), 96(2) to (11), 124, 125, 126, 144(3), 144(4), 148(2), 158 to 165, 181(6), 182(2) and (5), 183(3) and (6), 187, 188, 193(1), 229, 230, 338(5), 338(6), 618(1)(b), 620(8), 1090, 1092 and 1113 of the Act shall not apply to the Company.

2. In these Articles:

"Act" means the Companies Act 2014 and every statutory modification and re-enactment thereof for the time being in force.

"Acts" means the Act and all statutory instruments which are to be read as one with, or construed or read together as one with the Act.

"Address" includes, without limitation, any number or address used for the purposes of communication by way of electronic mail or other electronic communication.

"Articles" or "Articles of Association" means these articles of association of the Company, as amended from time to time by Special Resolution.

"Assistant Secretary" means any person appointed by the Secretary from time to time to assist the Secretary.

"Auditors" means the statutory auditors for the time being of the Company.

"Board" means the board of directors for the time being of the Company.

"clear days" means, in relation to a period of notice, that period excluding the day when the notice is given or deemed to be given and the day for which it is given or on which it is to take effect.
“Company” means the above-named company.

“Court” means the Irish High Court.

“Directors” means the directors for the time being of the Company.

“dividend” includes interim dividends and bonus dividends.

“electronic communication” shall have the meaning given to those words in the Electronic Commerce Act 2000.

“electronic signature” shall have the meaning given to those words in the Electronic Commerce Act 2000.

“Exchange” means any securities exchange or other system on which the Shares of the Company may be listed or otherwise authorised for trading from time to time.


“Horizon Common Stock” means the shares of common stock of Horizon Pharma, Inc., of US$0.0001 par value per share.

“Member” means a person who has agreed to become a Member of the Company and whose name is entered in the Register of Members as a registered holder of Shares.

“Memorandum” means the memorandum of association of the Company as amended from time to time by Special Resolution.

“Merger” means the merger of Hamilton Merger Sub, Inc., with and into Horizon Pharma, Inc. consummated immediately prior to the Original Adoption Date and as a result of which Horizon Pharma, Inc. became the surviving entity and a wholly-owned subsidiary of the Company.

“month” means a calendar month.

“Ordinary Resolution” means an ordinary resolution of the Company’s Members within the meaning of Section 191 of the Act.

“Original Adoption Date” means 19 September 2014.

“paid-up” means paid-up as to the nominal value and any premium payable in respect of the issue of any Shares and includes credited as paid-up.

“Redeemable Shares” means redeemable shares in accordance with Section 64 of the Act.

“Register of Members” or “Register” means the register of Members of the Company maintained by or on behalf of the Company, in accordance with the Acts and includes (except where
otherwise stated) any duplicate Register of Members.

“registered office” means the registered office for the time being of the Company.

“Seal” means the common seal of the Company or (where relevant) the official securities seal kept by the Company pursuant to the Act.

“Secretary” means the person appointed by the Board to perform any or all of the duties of secretary of the Company and includes an Assistant Secretary and any person appointed by the Board to perform the duties of secretary of the Company.

“Share” and “Shares” means a share or shares in the capital of the Company.

“Special Resolution” means a special resolution of the Company’s Members within the meaning of Section 191 of the Act.

2.2 In the Articles:

(a) words importing the singular number include the plural number and vice-versa;

(b) words importing the feminine gender include the masculine gender;

(c) words importing persons include any company, partnership or other body of persons, whether corporate or not, any trust and any government, governmental body or agency or public authority, whether of Ireland or elsewhere;

(d) “written” and “in writing” include all modes of representing or reproducing words in visible form, including electronic communication;

(e) references to a company include any body corporate or other legal entity, whether incorporated or established in Ireland or elsewhere;

(f) references to provisions of any law or regulation shall be construed as references to those provisions as amended, modified, re-enacted or replaced from time to time;

(g) any phrase introduced by the terms “including”, “include”, “in particular” or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;

(h) reference to “officer” or “officers” in these Articles means any executive that has been designated by the Company as an “officer” and, for the avoidance of doubt, shall not have the meaning given to such term in the Act and any such officers shall not constitute officers of the Company within the meaning of Section 2(1) of the Act.

(i) headings are inserted for reference only and shall be ignored in construing these Articles; and
SHARE CAPITAL; ISSUE OF SHARES

3. The authorised share capital of the Company is € 40,000 and US$60,000 divided into 40,000 deferred shares of € 1.00 each and 600,000,000 ordinary shares of US$0.0001 each.

4. Subject to the provisions of these Articles relating to new Shares, the Shares shall be at the disposal of the Directors, and they may (subject to the provisions of the Acts) allot, grant options over or otherwise dispose of them to such persons, on such terms and conditions and at such times as they may consider to be in the best interests of the Company and its Members, but so that no Share shall be issued at a discount to its nominal value save in accordance with Sections 71(4) and 1026 of the Act, and so that, in the case of Shares offered to the public for subscription, the amount payable on application on each Share shall not be less than one-quarter of the nominal amount of the Share and the whole of any premium thereon.

5. Subject to any requirement to obtain the approval of Members under any laws, regulations or the rules of any Exchange, the Board is authorised, from time to time, in its discretion, to grant such persons, for such periods and upon such terms as the Board deems advisable, options to purchase or subscribe for any number of Shares of any class or classes or of any series of any class as the Board may deem advisable, and to cause warrants or other appropriate instruments evidencing such options to be issued.

6. The Directors are, for the purposes of Section 1021 of the Act, generally and unconditionally authorised to exercise all powers of the Company to allot and issue relevant securities (as defined by the said Section 1021) up to the amount of Company's authorised but unissued share capital as at the Original Adoption Date and to allot and issue any Shares purchased or redeemed by or on behalf of the Company pursuant to the provisions of the Act and held as treasury shares and this authority shall expire five years from the Original Adoption Date.

6.1 The Directors are hereby empowered pursuant and subject to Sections 1022 and 1023(3) of the Act to allot equity securities within the meaning of the said Section 1023 for cash pursuant to the authority conferred by Article 6.1 as if the said Section 1022 did not apply to any such allotment. The Company may before the expiry of such authority make an offer or agreement which would or might require equity securities to be allotted after such expiry and the Directors may allot equity securities in pursuance of such an offer or agreement as if the power conferred by Article 6.1 had not expired.

7. Without prejudice to any special rights previously conferred on the holders of any existing Shares or class of Shares, any Share in the Company may be issued with such preferred or deferred or other special rights or such restrictions, whether in regard to dividend, voting, return of capital or otherwise, as the Company may from time to time by Ordinary Resolution determine.

8. The Company may pay commission to any person in consideration of any person subscribing or agreeing to subscribe, whether absolutely or conditionally, for the shares in the Company or procuring or agreeing to procure subscriptions, whether absolute or conditional, for any shares in the Company on such terms and, subject to the provisions of the Act and to such conditions as the Directors may determine, including, without limitation, by paying cash or
allotting and issuing fully or partly paid shares or any combination of the two. The Company may also on any issue of Shares pay such brokerage as may be lawful.

ORDINARY SHARES

9. The holder of an ordinary share shall be:

9.1 entitled to dividends on a pro rata basis in accordance with the relevant provisions of these Articles;

9.2 entitled to participate pro rata in the total assets of the Company in the event of the Company’s winding up; and

9.3 entitled, subject to the right of the Company to set record dates for the purpose of determining the identity of Members entitled to notice of and/or vote at a general meeting, to attend general meetings of the Company and shall be entitled to one vote for each Ordinary Share registered in her name in the Register of Members, both in accordance with the relevant provisions of these Articles.

10. An ordinary share shall be deemed to be a Redeemable Share on, and from the time of, the existence or creation of an agreement, transaction or trade between the Company (including any agent or broker acting on behalf of the Company) and any third party pursuant to which the Company acquires or will acquire ordinary shares, or an interest in ordinary shares, from the relevant third party. In these circumstances, the acquisition of such shares by the Company shall constitute the redemption of a Redeemable Share in accordance with Part 3 of the Act.

11. All ordinary shares shall rank pari passu with each other in all respects.

THE MERGER

12. Pursuant to the terms of the Merger, ordinary shares in the share capital of the Company equal in number to the number of shares of common stock of Horizon Pharma, Inc. held immediately prior to the Merger becoming effective (the “Effective Time”), will be allotted and issued by the Company to an exchange agent (the “Exchange Agent”) who shall hold such ordinary shares in trust for the holders of shares of common stock of Horizon Pharma, Inc. (the “Merger Consideration”). As soon as reasonably practicable after the Effective Time, and in any event within ten (10) Business Days after the Effective Time, the Company shall cause the Exchange Agent to mail to each holder of record of a certificate or certificates which immediately prior to the Effective Time represented outstanding shares of Horizon Common Stock (the “Horizon Certificates”) and each holder of record of a non-certificated outstanding share of Horizon Common Stock represented by book entry (“Horizon Book Entry Shares”), which at the Effective Time were converted into the right to receive the Merger Consideration, (i) a letter of transmittal (which shall specify that delivery shall be effected, and that risk of loss and title to the Horizon Certificates and Horizon Book Entry Shares shall pass, only upon delivery of the Horizon Certificates or Horizon Book Entry Shares (as applicable) to the Exchange Agent and which shall be in form and substance reasonably satisfactory to Horizon Pharma, Inc.), and (ii) instructions for use in effecting the surrender of the Horizon Certificates and Horizon Book Entry Shares in exchange for ordinary shares in the capital of the Company. Upon surrender of Horizon Certificates or Horizon Book Entry Shares (as applicable) for cancellation to the Exchange Agent, together with such letter of transmittal, duly completed and validly executed in accordance with the instructions thereto, and such other documents as may reasonably be required by the Exchange Agent, the holder of such Horizon Certificates or Horizon Book Entry Shares (as applicable) shall be entitled to receive in exchange therefor that number of ordinary shares in the capital of the Company (after taking into account all Horizon Certificates or Horizon
Book Entry Shares (as applicable) surrendered by such holder) to which such holder is entitled (which may be in uncertificated form), and the Horizon Certificates or Horizon Book Entry Shares (as applicable) so surrendered shall forthwith be cancelled. In the event of a transfer of ownership of shares of Horizon Common Stock which is not registered in the transfer records of Buyer, the proper number of ordinary shares in the capital of the Company may be transferred to a person other than the person in whose name the Horizon Certificate or Horizon Book Entry Shares (as applicable) so surrendered is registered, if such Horizon Certificate or Horizon Book Entry Shares (as applicable) shall be properly endorsed or otherwise be in proper form for transfer and the person requesting such transfer shall pay any transfer or other taxes required by reason of the issuance of ordinary shares in the capital of the Company to a person other than the registered holder of such Horizon Certificate or Horizon Book Entry Shares (as applicable) or establish to the reasonable satisfaction of Horizon Pharma, Inc. that such tax has been paid or is not applicable. Any portion of the Merger Consideration which has not been transferred to the holders of Horizon Certificates or Horizon Book Entry Shares (as applicable) as of the one year anniversary of the Effective Time shall be delivered to the Company or its designee, upon demand, and the ordinary shares in the capital of the Company included therein shall be sold at the best price reasonably obtainable at that time. Any holder of Horizon Certificates or Horizon Book Entry Shares (as applicable) who has not complied with this Article 12 prior to the one year anniversary of the Effective Time shall thereafter look only to the Company for payment of such holder’s claim for the Merger Consideration (subject to abandoned property, escheat or other similar applicable laws).

DEFERRED SHARES

13. The holders of the deferred shares shall not be entitled to receive any dividend or distribution and shall not be entitled to receive notice of, nor to attend, speak or vote at any general meeting of the Company. On a return of assets, whether on liquidation or otherwise, the deferred shares shall entitle the holder thereof only to the repayment of the amounts paid up on such shares after repayment of the capital paid up on the ordinary shares plus the payment of $5,000,000 on each of the ordinary shares and the holders of the deferred shares (as such) shall not be entitled to any further participation in the assets or profits of the Company.

14. The special resolution passed on the Original Adoption Date adopting these Articles shall be deemed to confer irrevocable authority on the Company at any time after the Original Adoption Date:

14.1 to acquire all or any of the fully paid deferred shares otherwise than for valuable consideration in accordance with Section 102(1) of the Act and without obtaining the sanction of the holders thereof;

14.2 to appoint any person to execute on behalf of the holders of the deferred shares remaining in issue (if any) a transfer thereof and/or an agreement to transfer the same otherwise than for valuable consideration to the Company or to such other person as the Company may nominate;

14.3 to cancel any acquired deferred shares; and

14.4 pending such acquisition and/or transfer and/or cancellation to retain the certificate (if any) for such deferred shares.

15. In accordance with Section 1040(3) of the Act the Company shall, not later than three years after any acquisition by it of any deferred shares as aforesaid, cancel such shares (except those which, or any interest of the Company in which, it shall have previously disposed of) and reduce the amount of the share capital by the nominal value of the shares so cancelled and
the Directors may take such steps as are requisite to enable the Company to carry out its obligations under that subsection without complying with Sections 84 and 85 of the Act including passing resolutions in accordance with Section 1040(5) of the Act.

16. Neither the acquisition by the Company otherwise than for valuable consideration of all or any of the deferred shares nor the redemption thereof nor the cancellation thereof by the Company in accordance with this Article shall constitute a variation or abrogation of the rights or privileges attached to the deferred shares, and accordingly the deferred shares or any of them may be so acquired, redeemed and cancelled without any such consent or sanction on the part of the holders thereof. The rights conferred upon the holders of the deferred shares shall not be deemed to be varied or abrogated by the creation of further shares ranking in priority thereto or pari passu therewith.

**ISSUE OF WARRANTS**

17. The Board may issue warrants to subscribe for any class of Shares or other securities of the Company on such terms as it may from time to time determine.

**CERTIFICATES FOR SHARES**

18. Unless otherwise provided for by the Board or the rights attaching to or by the terms of issue of any particular Shares, or to the extent required by any Exchange, depository, or any operator of any clearance or settlement system, no person whose name is entered as a Member in the Register of Members shall be entitled to receive a share certificate for all or a portion of the Shares of each class held by her (nor on transferring a part of holding, to a certificate for the balance).

19. Any share certificate, if issued, shall specify the number of Shares in respect of which it is issued and the amount paid thereon or the fact that they are fully paid, as the case may be, and may otherwise be in such form as shall be determined by the Board. Such certificates may be under Seal. All certificates for Shares shall be consecutively numbered or otherwise identified and shall specify the Shares to which they relate. The name and address of the person to whom the Shares represented thereby are issued, with the number of Shares and date of issue, shall be entered in the Register of Members of the Company. All certificates surrendered to the Company for transfer shall be cancelled and no new certificate shall be issued until the former certificate for a like number of Shares shall have been surrendered and cancelled. The Board may authorise certificates to be issued with the Seal and authorised signature(s) affixed by some method or system of mechanical process. In respect of a Share or Shares held jointly by several persons, the Company shall not be bound to issue a certificate or certificates to each such person, and the issue and delivery of a certificate or certificates to one of several joint holders shall be sufficient delivery to all such holders.

20. If a share certificate is defaced, worn out, lost or destroyed, it may be renewed on such terms (if any) as to evidence and indemnity and on the payment of such expenses reasonably incurred by the Company in investigating such evidence, as the Board may prescribe, and, in the case of defacement or wearing out, upon delivery of the old certificate.

**REGISTER OF MEMBERS**

21. The Company shall maintain or cause to be maintained a Register of its Members in accordance with the Acts.

22. If the Board considers it necessary or appropriate, the Company may establish and maintain a duplicate Register or Registers of Members at such location or locations within or outside Ireland as the Board thinks fit. The original Register of Members shall be treated as the Register of Members for the purposes of these Articles and the Acts.

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23. The Company, or any agent(s) appointed by it to maintain the duplicate Register of Members in accordance with these Articles, shall as soon as practicable and on a regular basis record or procure the recording in the original Register of Members all transfers of Shares effected on any duplicate Register of Members and shall at all times maintain the original Register of Members in such manner as to show at all times the Members for the time being and the Shares respectively held by them, in all respects in accordance with the Acts.

24. The Company shall not be bound to register more than four persons as joint holders of any Share. If any Share shall stand in the names of two or more persons, the person first named in the Register of Members shall be deemed the sole holder thereof as regards service of notices and, subject to the provisions of these Articles, all or any other matters connected with the Company.

TRANSFER OF SHARES

25. All transfers of Shares shall be effected by an instrument of transfer in such form as the Board may approve. All instruments of transfer must be left at the registered office or at such other place as the Board may appoint and all such instruments of transfer shall be retained by the Company.

26.

26.1 The instrument of transfer shall be executed by or on behalf of the transferor. The instrument of transfer of any Share shall be in writing and shall be executed with a manual signature or facsimile signature (which may be machine imprinted or otherwise) by or on behalf of the transferor provided that in the case of execution by facsimile signature by or on behalf of a transferor, the Board shall have previously been provided with a list of specimen signatures of the authorised signatories of such transferor and the Board shall be reasonably satisfied that such facsimile signature corresponds to one of those specimen signatures. The instrument of transfer need not be signed by the transferee.

26.2 The instrument of transfer of any Share may be executed for and on behalf of the transferor by any Director, the Secretary or an Assistant Secretary on behalf of the Company, and the Company shall be deemed to have been irrevocably appointed agent for the transferor of such Share or Shares all such transfers of Shares held by the Members in the share capital of the Company. Any document which records the name of the transferor, the name of the transferee, the class and number of Shares agreed to be transferred, the date of the agreement to transfer Shares, shall, once executed by the transferor or any Director or the Secretary or Assistant Secretary on behalf of the Company as agent for the transferor, be deemed to be a proper instrument of transfer for the purposes of Sections 94(4) and 94(5) of the Act. The transferor shall be deemed to remain the holder of the Share until the name of the transferee is entered on the Register in respect thereof, and neither the title of the transferee nor the title of the transferor shall be affected by any irregularity or invalidity in the proceedings in reference to the sale should the Directors so determine.

26.3 The Company, at its absolute discretion and insofar as the Acts or any other applicable law permits, may, or may procure that a subsidiary of the Company shall, pay Irish stamp duty arising on a transfer of Shares on behalf of the transferee of such Shares of the Company. If stamp duty resulting from the transfer of Shares in the Company which would otherwise be payable by the transferee is paid by the Company or any subsidiary of the Company on behalf of the transferee, then in those circumstances, the Company shall, on its behalf or on behalf of its subsidiary (as the
26.4 Notwithstanding the provisions of these Articles and subject to any regulations made under Section 1086 of the Act, title to any Shares in the Company may also be evidenced and transferred without a written instrument in accordance with Section 1086 of the Act or any regulations made thereunder. The Directors shall have power to permit any class of Shares to be held in uncertificated form and to implement any arrangements they think fit for such evidencing and transfer which accord with such regulations and in particular shall, where appropriate, be entitled to disapply or modify all or part of the provisions in these Articles with respect to the requirement for written instruments of transfer and share certificates (if any), in order to give effect to such regulations.

27. The Board may in its absolute discretion and without assigning any reason for its decision, decline to register any transfer of any Share which is not a fully paid Share. The Board may also, in its absolute discretion, and without assigning any reason, refuse to register a transfer of any Share unless:

27.1 the instrument of transfer is fully and properly completed and lodged with the Company accompanied by the certificate for the Shares (if any) to which it relates (which shall upon registration of the transfer be cancelled) and such other evidence as the Board may reasonably require to show the right of the transferor to make the transfer;

27.2 the instrument of transfer is in respect of only one class of Shares;

27.3 a registration statement under the Securities Act of 1933 of the United States of America is in effect with respect to such transfer or such transfer is exempt from registration and, if requested by the Board, a written opinion from counsel reasonably acceptable to the Board is obtained to the effect that such transfer is exempt from registration;

27.4 the instrument of transfer is properly stamped (in circumstances where stamping is required). For the purposes of these Articles, the Company is entitled to assume that the instrument of transfer is chargeable with stamp duty unless the transferor or transferee can demonstrate that it is not chargeable;

27.5 in the case of a transfer to joint holders, the number of joint holders to which the Share is to be transferred does not exceed four;

27.6 it is satisfied, acting reasonably, that all applicable consents, authorisations, permissions or approvals of any governmental body or agency in Ireland or any other applicable jurisdiction required to be obtained under relevant law prior to such transfer have been obtained; and

27.7 it is satisfied, acting reasonably, that the transfer would not violate the terms of any agreement to which the Company (or any of its subsidiaries) and the transferor are party or subject.

28. If the Board shall refuse to register a transfer of any Share, it shall, within two (2) months after the date on which the transfer was lodged with the Company, send to each of the transferor and the transferee notice of such refusal.
29. The Company shall not be obligated to make any transfer to an infant or to a person in respect of whom an order has been made by a competent court or official on the grounds that she is or may be suffering from mental disorder or is otherwise incapable of managing her affairs or under other legal disability.

30. Upon every transfer of Shares the certificate (if any) held by the transferor shall be given up to be cancelled, and shall forthwith be cancelled accordingly, and subject to Article 18 a new certificate may be issued without charge to the transferee in respect of the Shares transferred to her, and if any of the Shares included in the certificate so given up shall be retained by the transferor, a new certificate in respect thereof may be issued to her without charge. The Company shall also retain the instrument(s) of transfer.

**REDEMPTION AND REPURCHASE OF SHARES**

31. Subject to the provisions of the Act and the other provisions of this Article 31, the Company may:

31.1 pursuant to Section 66(4) of the Act, issue any Shares of the Company which are to be redeemed or are liable to be redeemed at the option of the Company or the Member on such terms and in such manner as may be determined by the Company in general meeting (by Special Resolution) on the recommendation of the Directors;

31.2 redeem Shares of the Company on such terms as may be contained in, or be determined pursuant to the provisions of, these Articles. Subject as aforesaid, the Company may cancel any Shares so redeemed or may hold them as treasury shares and re-issue such treasury shares as Shares of any class or classes or cancel them;

31.3 subject to or in accordance with the provisions of the Acts and without prejudice to any relevant special rights attached to any class of shares, pursuant to Section 105 of the Act, purchase any of its own Shares (including any Redeemable Shares and without any obligation to purchase on any pro rata basis as between Members or Members of the same class) and may cancel any shares so purchased or hold them as treasury (as defined by Section 109 of the Act) and may reissue any such shares as shares of any class or classes or cancel them; or

31.4 pursuant to Section 83 of the Act, convert any of its Shares into Redeemable Shares.

32. The Company may make a payment in respect of the redemption or purchase of its own Shares in any manner permitted by the Acts.

33. The holder of the Shares being purchased shall be bound to deliver up to the Company at its registered office or such other place as the Board shall specify, the certificate(s) (if any) thereof for cancellation and thereupon the Company shall pay to her the purchase or redemption monies or consideration in respect thereof.

**VARIATION OF RIGHTS OF SHARES**

34. If at any time the share capital of the Company is divided into different classes of Shares, the rights attached to any class (unless otherwise provided by the terms of issue of the Shares of that class) may be varied or abrogated with the consent in writing of the holders of three-quarters of all the votes of the issued Shares of that class, or with the sanction of a Special Resolution passed at a general meeting of the holders of the Shares of that class.

35. The provisions of these Articles relating to general meetings of the Company shall apply mutatis mutandis to every such general meeting of the holders of one class of Shares except that the necessary quorum shall be one or more persons holding or representing by proxy at least one-half of the issued Shares of the class.
36. The rights conferred upon the holders of the Shares of any class issued with preferred or other rights shall not, unless otherwise expressly provided by the terms of issue of the Shares of that class, be deemed to be varied by (i) the creation or issue of further Shares ranking pari passu therewith; (ii) a purchase or redemption by the Company of its own Shares; or (iii) the creation or issue for value (as determined by the Board) of further Shares ranking as regards participation in the profits or assets of the Company or otherwise in priority to them.

LIEN ON SHARES

37. The Company shall have a first and paramount lien on every Share (not being a fully paid Share) for all monies (whether presently payable or not) payable at a fixed time or called in respect of that Share. The Directors, at any time, may declare any Share to be wholly or in part exempt from the provisions of this Article. The Company’s lien on a Share shall extend to all monies payable in respect of it.

38. The Company may sell in such manner as the Directors determine any Share on which the Company has a lien if a sum in respect of which the lien exists is presently payable and is not paid within fourteen clear days after notice demanding payment, and stating that if the notice is not complied with the Share may be sold, has been given to the holder of the Share or to the person entitled to it by reason of the death or bankruptcy of the holder.

39. To give effect to a sale, the Directors may authorise some person to execute an instrument of transfer of the Share sold to, or in accordance with the directions of, the transferee. The transferee shall be entered in the Register as the holder of the Share comprised in any such transfer and she shall not be bound to see to the application of the purchase monies nor shall her title to the Share be affected by any irregularity in or invalidity of the proceedings in reference to the sale, and after the name of the transferee has been entered in the Register, the remedy of any person aggrieved by the sale shall be in damages only and against the Company exclusively.

40. The net proceeds of the sale, after payment of the costs, shall be applied in payment of so much of the sum for which the lien exists as is presently payable and any residue (upon surrender to the Company for cancellation of the certificate for the Shares sold and subject to a like lien for any monies not presently payable as existed upon the Shares before the sale) shall be paid to the person entitled to the Shares at the date of the sale.

41. Whenever any law for the time being of any country, state or place imposes or purports to impose any immediate or future or possible liability upon the Company to make any payment or empowers any government or taxing authority or government official to require the Company to make any payment in respect of any Shares registered in the Register as held either jointly or solely by any Members or in respect of any dividends, bonuses or other monies due or payable or accruing due or which may become due or payable to such Member by the Company on or in respect of any Shares registered as mentioned above or for or on account or in respect of any Member and whether in consequence of:

41.1 the death of such Member;
41.2 the non-payment of any income tax or other tax by such Member;
41.3 the non-payment of any estate, probate, succession, death, stamp or other duty by the executor or administrator of such Member or by or out of her estate; or
41.4 any other act or thing;

in every such case (except to the extent that the rights conferred upon holders of any class of Shares render the Company liable to make additional payments in respect of sums withheld on account of the foregoing):
41.5 the Company shall be fully indemnified by such Member or her executor or administrator from all liability;

41.6 the Company shall have a lien upon all dividends and other monies payable in respect of the Shares registered in the Register as held either jointly or solely by such Member for all monies paid or payable by the Company as referred to above in respect of such Shares or in respect of any dividends or other monies thereon or for or on account or in respect of such Member under or in consequence of any such law, together with interest at the rate of 15% per annum (or such other rate as the Board may determine) thereon from the date of payment to date of repayment, and the Company may deduct or set off against such dividends or other monies so payable any monies paid or payable by the Company as referred to above together with interest at the same rate;

41.7 the Company may recover as a debt due from such Member or her executor or administrator (wherever constituted) any monies paid by the Company under or in consequence of any such law and interest thereon at the rate and for the period referred to above in excess of any dividends or other monies then due or payable by the Company; and

41.8 the Company may if any such money is paid or payable by it under any such law as referred to above refuse to register a transfer of any Shares by any such Member or her executor or administrator until such money and interest is set off or deducted as referred to above or in the case that it exceeds the amount of any such dividends or other monies then due or payable by the Company, until such excess is paid to the Company.

Subject to the rights conferred upon the holders of any class of Shares, nothing in this Article 41 will prejudice or affect any right or remedy which any law may confer or purport to confer on the Company. As between the Company and every such Member as referred to above (and, her executor, administrator and estate, wherever constituted), any right or remedy which such law shall confer or purport to confer on the Company shall be enforceable by the Company.

CALLS ON SHARES

42. Subject to the terms of allotment, the Directors may make calls upon the Members in respect of any monies unpaid on their Shares and each Member (subject to receiving at least fourteen clear days’ notice specifying when and where payment is to be made) shall pay to the Company as required by the notice the amount called on her Shares. A call may be required to be paid by instalments. A call may be revoked before receipt by the Company of a sum due thereunder, in whole or in part and payment of a call may be postponed in whole or in part.

43. A call shall be deemed to have been made at the time when the resolution of the Directors authorising the call was passed.

44. A person on whom a call is made shall (in addition to a transferee) remain liable notwithstanding the subsequent transfer of the Share in respect of which the call is made.

45. The joint holders of a Share shall be jointly and severally liable to pay all calls in respect thereof.

46. If a call remains unpaid after it has become due and payable, the person from whom it is due and payable shall pay interest on the amount unpaid from the day it became due until it is paid at the rate fixed by the terms of allotment of the Share or in the notice of the call or, if no
rate is fixed, at the appropriate rate (as defined by the Acts) but the Directors may waive payment of the interest wholly or in part.

47. An amount payable in respect of a Share on allotment or at any fixed date, whether in respect of nominal value by way of premium, shall be deemed to be a call and if it is not paid the provisions of these Articles shall apply as if that amount had become due and payable by virtue of a call.

48. Subject to the terms of allotment, the Directors may make arrangements on the issue of Shares for a difference between the holders in the amounts and times of payment of calls on their Shares.

49. The Directors may, if they think fit, receive from any Member willing to advance the same all or any part of the monies uncalled and unpaid upon any Shares held by her, and upon all or any of the monies so advanced may pay (until the same would, but for such advance, become payable) interest at such rate as may be agreed upon between the Directors and the Member paying such sum in advance.

FORFEITURE

50. If a Member fails to pay any call or instalment of a call on the day appointed for payment thereof, the Directors, at any time thereafter during such times as any part of the call or instalment remains unpaid, may serve a notice on her requiring payment of so much of the call or instalment as is unpaid together with any interest which may have accrued.

51. The notice shall state a further day (not earlier than the expiration of fourteen clear days from the date of service of the notice) on or before which the payment required by the notice is to be made, and shall state that in the event of non-payment at or before the time appointed the Shares in respect of which the call was made will be liable to be forfeited.

52. If the requirements of any such notice as aforesaid are not complied with then, at any time thereafter before the payment required by the notice has been made, any Shares in respect of which the notice has been given may be forfeited by a resolution of the Directors to that effect. The forfeiture shall include all dividends or other monies payable in respect of the forfeited Shares and not paid before forfeiture. The Directors may accept a surrender of any Share liable to be forfeited hereunder.

53. On the trial or hearing of any action for the recovery of any money due for any call it shall be sufficient to prove that the name of the Member sued is entered in the Register as the holder, or one of the holders, of the Shares in respect of which such debt accrued, that the resolution making the call is duly recorded in the minute book and that notice of such call was duly given to the Member sued, in pursuance of these Articles, and it shall not be necessary to prove the appointment of the Directors who made such call nor any other matters whatsoever, but the proof of the matters aforesaid shall be conclusive evidence of the debt.

54. A forfeited Share may be sold or otherwise disposed of on such terms and in such manner as the Directors think fit and at any time before a sale or disposition the forfeiture may be cancelled on such terms as the Directors think fit. Where for the purposes of its disposal such a Share is to be transferred to any person, the Directors may authorise some person to execute an instrument of transfer of the Share to that person. The Company may receive the consideration, if any, given for the Share on any sale or disposition thereof and may execute a transfer of the Share in favour of the person to whom the Share is sold or disposed of and thereupon she shall be registered as the holder of the Share and shall not be bound to see to the application of the purchase money, if any, nor shall her title to the Share be affected by any irregularity or invalidity in the proceedings in reference to the forfeiture, sale or disposal of the Share.
55. A person whose Shares have been forfeited shall cease to be a Member in respect of the forfeited Shares, but nevertheless shall remain liable to pay to the Company all monies which, at the date of forfeiture, were payable by her to the Company in respect of the Shares, without any deduction or allowance for the value of the Shares at the time of forfeiture but her liability shall cease if and when the Company shall have received payment in full of all such monies in respect of the Shares.

56. A statutory declaration or affidavit that the declarant is a Director or the Secretary of the Company, and that a Share in the Company has been duly forfeited on the date stated in the declaration, shall be conclusive evidence of the facts therein stated as against all persons claiming to be entitled to the Share.

57. The provisions of these Articles as to forfeiture shall apply in the case of non-payment of any sum which, by the terms of issue of a Share, becomes payable at a fixed time, whether on account of the nominal value of the Share or by way of premium, as if the same had been payable by virtue of a call duly made and notified.

58. The Directors may accept the surrender of any Share which the Directors have resolved to have been forfeited upon such terms and conditions as may be agreed and, subject to any such terms and conditions, a surrendered Share shall be treated as if it has been forfeited.

NON-RECOGNITION OF TRUSTS

59. The Company shall not be obligated to recognise any person as holding any Share upon any trust (except as is otherwise provided in these Articles or to the extent required by law) and the Company shall not be bound by or be compelled in any way to recognise (even when having notice thereof) any equitable, contingent, future, or partial interest in any Share, or any interest in any fractional part of a Share, or (except only as is otherwise provided by these Articles or the Acts) any other rights in respect of any Share except an absolute right to the entirety thereof in the registered holder. This shall not preclude the Company from requiring the Members or a transferee of Shares to furnish to the Company with information as to the beneficial ownership of any Share when such information is reasonably required by the Company.

TRANSMISSION OF SHARES

60. In case of the death of a Member, the survivor or survivors where the deceased was a joint holder, and the legal personal representatives of the deceased where she was a sole holder, shall be the only persons recognised by the Company as having any title to her interest in the Shares, but nothing herein contained shall release the estate of any such deceased holder from any liability in respect of any Shares which had been held by her solely or jointly with other persons.

61. Any person becoming entitled to a Share in consequence of the death or bankruptcy or liquidation or dissolution of a Member (or in any other way than by transfer) may, upon such evidence being produced as may from time to time be required by the Board and subject as hereinafter provided, elect either to be registered herself as holder of the Share or to make such transfer of the Share to such other person nominated by her and to have such person registered as the transferee thereof, but the Board shall, in either case, have the same right to decline or suspend registration as they would have had in the case of a transfer of the Share by that Member before her death or bankruptcy as the case may be.

62. If the person so becoming entitled shall elect to be registered herself as holder, she shall deliver or send to the Company a notice in writing signed by her stating that she so elects.
Subject to Article 64, a person becoming entitled to a Share by reason of the death or bankruptcy or liquidation or dissolution of the holder (or in any other case than by transfer) shall be entitled to the same dividends and other advantages to which she would be entitled if she were the registered holder of the Share, except that she shall not, before being registered as a Member in respect of the Share, be entitled in respect of it to exercise any right conferred by Membership in relation to meetings of the Company provided however that the Board may at any time give notice requiring any such person to elect either to be registered herself or to transfer the Share and if the notice is not complied with within ninety days the Board may thereafter withhold payment of all dividends, bonuses or other monies payable in respect of the Share until the requirements of the notice have been complied with.

The Board may at any time give notice requiring a person entitled by transmission to a Share to elect either to be registered herself or to transfer the Share and if the notice is not complied with within 60 days the Board may withhold payment of all dividends and other monies payable in respect of the Share until the requirements of the notice have been complied with.

AMENDMENT OF MEMORANDUM OF ASSOCIATION; CHANGE OF LOCATION OF REGISTERED OFFICE; AND ALTERATION OF CAPITAL

The Company may by Ordinary Resolution:

65.1 divide its share capital into several classes and attach to them respectively any preferential, deferred, qualified or special rights, privileges or conditions;

65.2 increase the authorised share capital by such sum to be divided into Shares of such nominal value, as such Ordinary Resolution shall prescribe;

65.3 consolidate and divide all or any of its share capital into Shares of larger amount than its existing Shares;

65.4 by subdivision of its existing Shares or any of them divide the whole or any part of its share capital into Shares of smaller nominal value than is fixed by the Memorandum subject to Section 83(1)(b) of the Act, so, however, that in the sub-division the proportion between the amount paid and the amount, if any, unpaid on each reduced Share shall be the same as it was in the case of the Share from which the reduced Share is derived;

65.5 cancel any Shares that at the date of the passing of the relevant Ordinary Resolution have not been taken or agreed to be taken by any person;

65.6 subject to applicable law, change the currency denomination of its share capital.

Subject to the provisions of the Acts, the Company may:

66.1 by Special Resolution change its name, alter or add to the Memorandum with respect to any objects, powers or other matters specified therein or alter or add to these Articles;

66.2 by Special Resolution reduce its share capital or any undenominated capital. In relation to such reductions, the Company may by Special Resolution determine the terms upon which the reduction is to be effected, including in the case of a reduction of part only of any class of Shares, those Shares to be affected; and

66.3 by resolution of the Directors change the location of its registered office.
Whenever as a result of an alteration or reorganisation of the share capital of the Company any Members would become entitled to fractions of a Share, the Directors may, on behalf of those Members, sell the Shares representing the fractions for the best price reasonably obtainable to any person and distribute the proceeds of sale in due proportion among those Members, and the Directors may authorise any person to execute an instrument of transfer of the Shares to, or in accordance with the directions of, the purchaser. The transferee shall not be bound to see to the application of the purchase money nor shall her title to the Shares be affected by any irregularity in or invalidity of the proceedings in reference to the sale.

CLOSED REGISTER OF MEMBERS OR FIXING RECORD DATE

For the purpose of determining Members entitled to notice of or to vote at any meeting of Members or any adjournment thereof, or Members entitled to receive payment of any dividend, or in order to make a determination of Members for any other proper purpose, the Board may provide, subject to the requirements of Section 174 of the Act, that the Register of Members shall be closed for transfers at such times and for such periods, not exceeding in the whole 30 days in each year. If the Register of Members shall be so closed for the purpose of determining Members entitled to notice of or to vote at a meeting of Members such Register of Members shall be so closed for at least five (5) days immediately preceding such meeting and the record date for such determination shall be the date of the closure of the Register of Members.

In lieu of, or apart from, closing the Register of Members, the Board may fix in advance a date as the record date (a) for any such determination of Members entitled to notice of or to vote at a meeting of the Members, which record date shall not be more than ninety (90) days nor less than ten (10) days before the date of such meeting, and (b) for the purpose of determining the Members entitled to receive payment of any dividend, or in order to make a determination of Members for any other proper purpose, which record date shall not be more than ninety (90) days prior to the date of payment of such dividend or the taking of any action to which such determination of Members is relevant. The record date shall not precede the date upon which the resolution fixing the record date is adopted by the Directors.

If the Register of Members is not so closed and no record date is fixed for the determination of Members entitled to notice of or to vote at a meeting of Members or Members entitled to receive payment of a dividend, the date immediately preceding the date on which notice of the meeting is deemed given under these Articles or the date on which the resolution of the Directors declaring such dividend is adopted, as the case may be, shall be the record date for such determination of Members. When a determination of Members entitled to vote at any meeting of Members has been made as provided in these Articles, such determination shall apply to any adjournment thereof; provided, however, that the Directors may fix a new record date of the adjourned meeting, if they think fit.

GENERAL MEETINGS

The Board shall convene and the Company shall hold annual general meetings in accordance with the requirements of the Acts.

The Board may, whenever it thinks fit, and shall, on the requisition in writing of Members holding such number of Shares as is prescribed by, and made in accordance with, Section 178 of the Act, convene a general meeting in the manner required by the Acts. All general meetings other than annual general meetings shall be called extraordinary general meetings.

The Company shall in each year hold a general meeting as its annual general meeting in addition to any other meeting in that year, and shall specify the meeting as such in the notices calling it. Not more than fifteen months shall elapse between the date of one annual general
meeting of the Company and that of the next. Subject to Section 176 of the Act, all general meetings may be held outside of Ireland.

74. Each general meeting shall be held at such time and place as specified in the notice of meeting.

75. The Board may, in its absolute discretion, authorise the Secretary to postpone any general meeting called in accordance with the provisions of these Articles (other than a meeting requisitioned under Article 72 of these Articles or the postponement of which would be contrary to the Acts, law or a court order pursuant to the Acts) if the Board considers that, for any reason, it is impractical or unreasonable to hold the general meeting, provided that notice of postponement is given to each Member before the time for such meeting. Fresh notice of the date, time and place for the postponed meeting shall be given to each Member in accordance with the provisions of these Articles.

NOTICE OF GENERAL MEETINGS

76. Subject to the provisions of the Acts allowing a general meeting to be called by shorter notice, an annual general meeting, and an extraordinary general meeting called for the passing of a Special Resolution, shall be called by at least twenty-one (21) clear days’ notice and all other extraordinary general meetings shall be called by at least fourteen (14) clear days’ notice. Such notice shall state the date, time and place of the meeting and the general nature of the business to be considered at the meeting. Every notice shall be exclusive of the day on which it is given or deemed to be given and of the day for which it is given and shall specify such other details as are required by applicable law or the relevant code, rules and regulations applicable to the listing of the Shares on the Exchange.

77. A general meeting of the Company shall, whether or not the notice specified in this Article has been given and whether or not the provisions of the Articles regarding general meetings have been complied with, be deemed to have been duly convened if applicable law so permits and it is so agreed by the Auditors and by all the Members entitled to attend and vote thereat or by their proxies.

78. The notice convening an annual general meeting shall specify the meeting as such, and the notice convening a meeting to pass a Special Resolution shall specify the intention to propose the resolution as a Special Resolution. Notice of every general meeting shall be given in any manner permitted by these Articles to:

78.1 every Member;
78.2 the personal representative of a deceased member of the Company;
78.3 the assignee in bankruptcy of a bankrupt member of the company (being a bankrupt member who is entitled to vote at the meeting);
78.4 the Directors and secretary of the Company; and
78.5 the Auditors.

79. There shall appear with reasonable prominence in every notice of general meetings of the Company a statement that a Member entitled to attend and vote is entitled to appoint one or more proxies, using the form set out in Section 184 of the Act, to attend, speak and vote instead of her, that a proxy need not be a Member of the Company and the time by which the proxy must be received at the Company’s registered office or some other place within the State as is specified in the statement for that purpose.
80. The accidental omission to give notice of a general meeting to, or the non-receipt of notice of a meeting by, any person entitled to receive notice shall not invalidate the proceedings of that meeting.

81. In cases where instruments of proxy are sent out with notices, the accidental omission to send such instrument of proxy, or the non-receipt of such instrument of proxy by, any person entitled to receive notice shall not invalidate any resolution passed or any proceeding at any such meeting. A Member present, either in person or by proxy, at any general meeting of the Company or of the holders of any class of Shares in the Company, will be deemed to have received notice of that meeting and, where required, of the purpose for which it was called.

PROCEEDINGS AT GENERAL MEETINGS

82. All business shall be deemed special that is transacted at an extraordinary general meeting, and also all that is transacted at an annual general meeting, with the exception of declaring a dividend, the consideration of the Company’s statutory financial statements and the reports of the Directors and Auditors, the election of Directors, the re-appointment of the retiring Auditors (subject to Sections 380 and 382 to 385 of the Act) and the fixing of the remuneration of the Auditors.

83. No business shall be transacted at any general meeting unless a quorum is present. One or more Members present in person or by proxy holding not less than a majority of the issued and outstanding ordinary shares of the Company entitled to vote at the meeting in question shall be a quorum.

84. If within one hour from the time appointed for the meeting a quorum is not present, the meeting, if convened upon the requisition of Members, shall be dissolved and in any other case it shall stand adjourned to the same day in the next week at the same time and place or to such other time or such other place as the Board may determine and if at the adjourned meeting a quorum is not present within one hour from the time appointed for the meeting the Members present shall be a quorum.

85. If the Board wishes to make this facility available to Members for a specific or all general meetings of the Company, a Member may participate in any general meeting of the Company, by means of a telephone, video, electronic or similar communication equipment by way of which all persons participating in such meeting can communicate with each other simultaneously and instantaneously and such participation shall be deemed to constitute presence in person at the meeting.

86. Each Director and the Auditors shall be entitled to attend and speak at any general meeting of the Company.

87. The Chairman, if any, of the Board shall preside as Chairman at every general meeting of the Company, or if there is no such Chairman, or if she shall not be present within one hour after the time appointed for the holding of the meeting, or is unwilling to act, the Directors present shall elect one of their number to be Chairman of the meeting or if all of the Directors present decline to take the chair, then the Members present shall choose one of their own number to be Chairman of the meeting.

88. The Chairman may, with the consent of any general meeting duly constituted hereunder, and shall if so directed by the meeting, adjourn the meeting from time to time and from place to place, but no business shall be transacted at any adjourned meeting other than the business left unfinished, or which might have been transacted, at the meeting from which the adjournment took place. When a general meeting is adjourned for thirty days or more, notice of the adjourned meeting shall be given as in the case of an original meeting; save as aforesaid
it shall not be necessary to give any notice of an adjournment or of the business to be transacted at an adjourned general meeting.

89.

89.1 Subject to the Acts, a resolution may only be put to a vote at a general meeting of the Company or of any class of Members if:

(a) it is proposed by or at the direction of the Board; or

(b) it is proposed at the direction of the Court; or

(c) it is proposed on the requisition in writing of such number of Members as is prescribed by, and is made in accordance with, Section 178 of the Act;

(d) it is proposed pursuant to, and in accordance with the procedures and requirements of, Articles 97 or 98; or

(e) the Chairman of the meeting in her absolute discretion decides that the resolution may properly be regarded as within the scope of the meeting.

89.2 No amendment may be made to a resolution, at or before the time when it is put to a vote, unless the Chairman of the meeting in her absolute discretion decides that the amendment or the amended resolution may properly be put to a vote at that meeting.

89.3 If the Chairman of the meeting rules a resolution or an amendment to a resolution admissible or out of order (as the case may be), the proceedings of the meeting or on the resolution in question shall not be invalidated by any error in her ruling. Any ruling by the Chairman of the meeting in relation to a resolution or an amendment to a resolution shall be final and conclusive.

90. Subject to Article 152, except where a greater majority is required by the Acts or these Articles, any question proposed for a decision of the Members at any general meeting of the Company or a decision of any class of Members at a separate meeting of any class of Shares shall be decided by an Ordinary Resolution.

91. At any general meeting a resolution put to the vote of the meeting shall be decided on a poll. The Board or the Chairman may determine the manner in which the poll is to be taken and the manner in which the votes are to be counted.

92. A poll demanded on the election of the Chairman or on a question of adjournment shall be taken forthwith. A poll demanded on any other question shall be taken at such time, not being more than ten days from the date of the meeting or adjourned meeting at which the vote was taken, as the Chairman of the meeting directs, and any business other than that on which a poll has been demanded may be proceeded with pending the taking of the poll.

93. No notice need be given of a poll not taken immediately. The result of the poll shall be deemed to be the resolution of the general meeting at which the poll was demanded. On a poll a Member entitled to more than one vote need not use all her votes or cast all the votes she uses in the same way.

94. If authorised by the Board, any vote taken by written ballot may be satisfied by a ballot submitted by electronic or telephonic transmission, provided that any such electronic or telephonic submission must either set forth or be submitted with information from which it can be determined that the electronic submission has been authorised by the Member or proxy.
95. The Board may, and at any general meeting, the chairman of such meeting may make such arrangement and impose any requirement or restriction it or she considers appropriate to ensure the security of a general meeting including, without limitation, requirements for evidence of identity to be produced by those attending the meeting, the searching of personal property and the restriction of items that may be taken into the meeting place. The Board and, at any general meeting, the chairman of such meeting are entitled to refuse entry to a person who refuses to comply with such arrangements, requirements or restrictions.

96. A resolution in writing signed by all of the Members for the time being entitled to attend and vote on such resolution at a general meeting (or being bodies corporate by their duly authorised representatives) shall be as valid and effective for all purposes as if the resolution had been passed at a general meeting of the Company duly convened and held, and may consist of several documents in like form each signed by one or more persons, and if described as a special resolution shall be deemed to be a special resolution within the meaning of the Act. Any such resolution shall be served on the Company.

ADVANCE NOTICE OF MEMBER BUSINESS AND NOMINATIONS OF DIRECTORS

97. Nominations of persons for election to the Board (other than Directors to be nominated by any series of preferred shares, voting separately as a class) and the proposal of other business to be considered by the Members at a general meeting may only be made (a) pursuant to the Company’s notice of meeting pursuant to Article 71 at the recommendation of the Board, (b) by or at the direction of the Board or any authorised committee thereof or (c) by any Member who (i) complies with the notice procedures set forth in Articles 98 or 99, as applicable, (ii) was a Member at the time such notice is delivered to the Secretary and on the record date for the determination of Members entitled to vote at such general meeting and (iii) is present at the relevant general meeting, either in person or by proxy, to present her nomination or proposal of other business, provided, however, that Members shall only be entitled to nominate persons for election to the Board at annual general meetings or at general meetings called specifically for the purpose of electing Directors. For the avoidance of doubt, clause (c) above shall be the exclusive means for a Member to make nominations and submit other business before an annual general meeting or other general meeting.

98. For nominations of persons for election to the Board (other than Directors to be nominated by any series of preferred shares, voting separately as a class) or other business to be properly brought before an annual general meeting by a Member, such Member must have given timely notice thereof in writing to the Secretary. To be timely, a Member’s notice shall be delivered to the Secretary at the registered office of the Company, or such other address as the Secretary may designate, not less than 90 days nor more than 150 days prior to the first anniversary of the date the Company’s proxy statement was first released to Members in connection with the prior year’s annual general meeting; provided, however, that in the event the date of the annual general meeting is changed by more than 30 days from the first anniversary date of the prior year’s annual general meeting, notice by the Member to be timely must be so delivered not earlier than the 150th day prior to such annual general meeting and not later than the later of the 90th day prior to such annual general meeting or the 10th day following the day on which public announcement of the date of such meeting is first made. To be in proper form, such Member’s notice shall set forth:

98.1 as to each person whom the Member proposes to nominate for election or re-election as a Director:

(a) the name, age, business address and residence address of such nominee;

(b) the principal occupation or employment of such nominee;
the class and number of Shares which are owned of record and beneficially by such nominee;

d) the date or dates on which such Shares were acquired and the investment intent of such acquisition;

e) completed and signed questionnaire, representation and agreement required by Article 98.4;

(f) such other information concerning such nominee as would be required to be disclosed in a proxy statement soliciting proxies for
the election of such nominee as a director in an election contest (even if an election contest is not involved), or that is otherwise
required pursuant to Regulation 14A under the Exchange Act and the rules and regulations promulgated thereunder (including
such proposed nominee’s written consent to being named as a nominee and to serving as a director if elected); and

g) the information required by Article 98.3,

and the Company may require any proposed nominee to furnish such other information as it may reasonably require to determine the
eligibility of such proposed nominee to serve as an independent director of the Company or that could be material to a reasonable
Member’s understanding of the independence, or lack thereof, of such proposed nominee, and the impact that such service would have on
the ability of the Company to satisfy the requirements of laws, rules, regulations and listing standards applicable to the Company or its
Directors;

98.2 as to any other business that the Member proposes to bring before the meeting:

(a) a brief description of the business desired to be brought before the meeting;

(b) the text of the proposal or business (including the text of any resolutions proposed for consideration and if such business
includes a proposal to amend these Articles, the text of the proposed amendment);

(c) the reasons for conducting such business at the meeting;

(d) any material interest (including any anticipated benefit of such business to any Proponent (as defined below) other than solely as
a result of its ownership of Shares, that is material to any Proponent individually, or to the Proponents in the aggregate) in such
business of any Proponent; and

(e) the information required by Article 98.3;

98.3 as to the Member giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (each, a
“Proponent” and collectively, the “Proponents”):

(a) the name and address of each Proponent (including, if applicable, the name and address that appear in the Register of
Members);

(b) the class or series and number of Shares that are owned beneficially and of record by each Proponent;

(c) a description of any agreement, arrangement or understanding (whether oral or in writing) with respect to the nomination or
proposal between or among any Proponent and any of its affiliates or associates, and any others
(including their names) acting in concert, or otherwise under the agreement, arrangement or understanding, with any of the foregoing;

(d) a representation that the Proponents are holders of record or beneficial owners, as the case may be, of Shares entitled to vote at the meeting and intend to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice;

(e) a representation as to whether the Proponents intend to deliver a proxy statement and form of proxy to holders of a sufficient number of the Company’s voting Shares to elect such nominee or nominees or to carry such proposal;

(f) to the extent known by any Proponent, the name and address of any other stockholder supporting the proposal on the date of such stockholder’s notice; and

(g) a description of all Derivative Transactions (as defined below) by each Proponent during the previous twelve (12) month period, including the date of any such Derivative Transaction and the class, series and number of securities involved in, and the material economic terms of, any such Derivative Transaction.

For purposes of this Article 98, a “Derivative Transaction” means any agreement, arrangement, interest or understanding entered into by, or on behalf or for the benefit of, any Proponent or any of its affiliates or associates, whether record or beneficial:

(h) the value of which is derived in whole or in part from the value of any class or series of shares or other securities of the Company;

(i) which otherwise provides any direct or indirect opportunity to gain or share in any gain derived from a change in the value of securities of the Company;

(j) the effect or intent of which is to mitigate loss, manage risk or benefit of security value or price changes, or

(k) which provides the right to vote or increase or decrease the voting power of, such Proponent, or any of its affiliates or associates, with respect to any securities of the Company, which agreement, arrangement, interest or understanding may include, without limitation, any option, warrant, debt position, note, bond, convertible security, swap, stock appreciation right, short position (for purposes hereof, a person or entity shall be deemed to have a short position in a security of the Company if such person or entity, directly or indirectly, through any contract, arrangement, relationship, understanding or otherwise, has the opportunity to profit or share in any profit derived from any decrease in the value of such security), profit interest, hedge, right to dividends, voting agreement, performance-related fee or arrangement to borrow or lend shares (whether or not subject to payment, settlement, exercise or conversion in any such class or series), and any proportionate interest of such Proponent in the securities of the Company held, directly or indirectly, by any general or limited partnership, or any limited liability company, of which such Proponent is a general partner or managing member or, directly or indirectly, beneficially owns an interest in such general partner or managing member.
To be eligible to be a nominee for election as a director of the Company, such nominee or a person on his or her behalf must deliver (in the case of a nomination under clause (c) of Article 97, in accordance with the time periods prescribed for delivery of notice under this Article 98) to the Secretary at the registered office a written questionnaire with respect to the background and qualification of such nominee (and in the case of a nomination under clause (c) of Article 97, the background of any other person or entity on whose behalf the nomination is being made), which questionnaire shall be provided by the Secretary promptly upon written request, and a written representation and agreement, in the form provided by the Secretary promptly upon written request, that such person (A) is not and will not become a party to (i) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such person, if elected as a director of the Company, will act or vote on any issue or question (a “Voting Commitment”) that has not been disclosed to the Company in the questionnaire or (ii) any Voting Commitment that could limit or interfere with such person’s ability to comply, if elected as a director of the Company, with such person’s fiduciary duties under applicable law; (B) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the Company with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director of the Company that has not been disclosed therein; and (C) except as otherwise disclosed in the questionnaire, would be in compliance, if elected as a director of the Company, and will comply with, all applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the Company.

A stockholder providing the written notice required by this Article 98 shall update and supplement such notice in writing, if necessary, so that the information provided or required to be provided in such notice is true and correct in all material respects as of (A) the record date for the meeting and (B) as of the date that is five (5) business days prior to the date of the meeting and, in the event of any adjournment or postponement thereof, five (5) business days prior to the date to which such meeting is adjourned or postponed (or such lesser number of days prior to the date of such adjourned or postponed meeting as is reasonably practicable under the circumstances). In the case of an update and supplement pursuant to clause (A) of this Article 98.5, such update and supplement shall be received by the Secretary at the principal executive offices of the Company not later than five (5) business days after the record date for the meeting. In the case of an update and supplement pursuant to clause (B) of this Article 98.5, such update and supplement shall be delivered to, or mailed and received by, the Secretary at the registered office not later than two (2) business days prior to the date of the meeting, and, in the event of any adjournment or postponement thereof, two (2) business days prior to the date to which such meeting is adjourned or postponed (or such lesser number of days prior to the date of such adjourned or postponed meeting as is reasonably practicable under the circumstances).

For nominations of persons for election to the Board (other than directors to be nominated by any series of preferred shares, voting separately as a class) or other business to be properly brought before a general meeting other than an annual general meeting by a Member, such Member must have given timely notice thereof in writing to the Secretary. To be timely, a Member’s notice shall be delivered to the Secretary at the registered office of the Company or such other address as the Secretary may designate, not earlier than the 150th day prior to such general meeting and not later of the 90th day prior to such general meeting or the 10th day following the day on which public announcement is first made of the date of the general meeting. Such Member’s notice shall set forth the same information as is required by Article 98.
Unless otherwise provided by the terms of any series of preferred shares or any agreement among Members or other agreement approved by the Board, only persons who are nominated in accordance with the procedures set forth in Articles 98 and 99 shall be eligible to serve as Directors of the Company. If the Chairman of a general meeting determines that a proposed nomination was not made in compliance with Articles 98 and 99, she shall declare to the meeting that nomination is defective and such defective nomination shall be disregarded. Notwithstanding the foregoing provisions of these Articles, if the Member (or a qualified representative of the Member) does not appear at the general meeting to present her nomination, such nomination shall be disregarded.

VOTES OF MEMBERS

101. Subject to any rights or restrictions for the time being attached to any class or classes of Shares, every Member of record present in person or by proxy shall have one vote for each Share registered in her name in the Register of Members.

102. In the case of joint holders of record the vote of the senior holder who tenders a vote, whether in person or by proxy, shall be accepted to the exclusion of the votes of the other joint holders, and for this purpose seniority shall be determined by the order in which the names stand in the Register of Members.

103. A Member of unsound mind, or in respect of whom an order has been made by any court, having jurisdiction in lunacy, may vote by her committee, receiver, curator bonis, or other person in the nature of a committee, receiver or curator bonis appointed by that court, and any such committee, receiver, curator bonis or other persons may vote by proxy.

104. No Member shall be entitled to vote at any general meeting unless she is registered as a Member on the record date for such meeting.

105. No objection shall be raised to the qualification of any voter except at the general meeting or adjourned general meeting at which the vote objected to is given or tendered and every vote not disallowed at such general meeting shall be valid for all purposes. Any such objection made in due time shall be referred to the Chairman of the general meeting whose decision shall be final and conclusive.

106. Votes may be given either personally or by proxy. A Member may appoint more than one proxy or the same proxy under one or more instruments to attend and vote at a meeting and may appoint a proxy to vote both in favour of and against the same resolution in such proportion as specified in the instrument appointing the proxy.

PROXIES AND CORPORATE REPRESENTATIVES

107.1 Every Member entitled to attend and vote at a general meeting may appoint a proxy to attend, speak and vote on her behalf and may appoint more than one proxy to attend, speak and vote at the same meeting. The appointment of a proxy or corporate representative shall be in the form as set out in Section 184 of the Act and may be accepted by the Company at such place and at such time as the Board or the Secretary shall from time to time determine, subject to applicable requirements of the Act, the United States Securities and Exchange Commission and the Exchange on which the Shares are listed. No such instrument appointing a proxy or corporate representative shall be voted or acted upon after 2 years from its date.

107.2 Without limiting the foregoing, the Directors may from time to time permit appointments of a proxy to be made by means of an electronic or internet communication or facility and may in a similar manner permit supplements to, or
amendments or revocations of, any such electronic or internet communication or facility to be made. The Directors may in addition prescribe the method of determining the time at which any such electronic or internet communication or facility is to be treated as received by the Company. The Directors may treat any such electronic or internet communication or facility which purports to be or is expressed to be sent on behalf of a Member as sufficient evidence of the authority of the person sending that instruction to send it on behalf of that Member.

108. Any body corporate which is a Member of the Company may authorise such person as it thinks fit to act as its representative at any meeting of the Company or of any class of Members of the Company and the person so authorised shall be entitled to exercise the same powers on behalf of the body corporate which she represents as that body corporate could exercise if it were an individual Member of the Company. The Company may require evidence from the body corporate of the due authorisation of such person to act as the representative of the relevant body corporate.

109. An appointment of proxy relating to more than one meeting (including any adjournment thereof) having once been received by the Company for the purposes of any meeting shall not require to be delivered, deposited or received again by the Company for the purposes of any subsequent meeting to which it relates.

110. Receipt by the Company of an appointment of proxy in respect of a meeting shall not preclude a Member from attending and voting at the meeting or at any adjournment thereof at which attendance and voting will automatically cancel any proxy previously submitted.

111. An appointment proxy shall be valid, unless the contrary is stated therein, as well for any adjournment of the meeting as for the meeting to which it relates.

112. 112.1 A vote given in accordance with the terms of an appointment of proxy or a resolution authorising a representative to act on behalf of a body corporate shall be valid notwithstanding the death or insanity of the principal, or the revocation of the appointment of proxy or of the authority under which the proxy was appointed or of the resolution authorising the representative to act or transfer of the Share in respect of which the proxy was appointed or the authorisation of the representative to act was given, provided that no direction in writing (whether in electronic form or otherwise) of such death, insanity, revocation or transfer shall have been received by the Company at the Office, at least one hour before the commencement of the meeting or adjourned meeting at which the appointment of proxy is used or at which the representative acts; provided, however, that where such direction is given in electronic form it shall have been received by the Company at least 24 hours (or such lesser time as the Directors may specify) before the commencement of the meeting.

112.2 The Directors may send, at the expense of the Company, by post, electronic mail or otherwise, to the Members forms for the appointment of a proxy (with or without stamped envelopes for their return) for use at any general meeting or at any class meeting, either in blank or nominating any one or more of the Directors or any other persons in the alternative.

DIRECTORS

113. Subject to the Acts, the Board may determine the size of the Board from time to time at its absolute discretion.
114. The remuneration to be paid to the Directors shall be such remuneration as the Directors shall determine. The Directors shall also be entitled to be paid their travelling, hotel and other expenses properly incurred by them in going to, attending and returning from meetings of the Directors, or any committee of the Directors, or general meetings of the Company, or otherwise in connection with the business of the Company, or to receive a fixed allowance in respect thereof as may be determined by the Board from time to time, or a combination partly of one such method and partly the other.

115. The Board may approve additional remuneration to any Director undertaking any special work or services for, or undertaking any special mission on behalf of, the Company other than her ordinary routine work as a Director. Any fees paid to a Director who is also counsel or solicitor to the Company, or otherwise serves it in a professional capacity shall be in addition to her remuneration as a Director.

DIRECTORS' INTERESTS

116. A Director who is in any way, whether directly or indirectly, interested in a contract, transaction or arrangement or proposed contract, transaction or arrangement with the Company shall, in accordance with Section 231 of the Act, declare the nature of her interest at the first opportunity either (a) at a meeting of the Board at which the question of entering into the contract, transaction or arrangement is first taken into consideration, if the Director or officer of the Company knows this interest then exists, or in any other case, at the first meeting of the Board after learning that she is or has become so interested or (b) by providing a general notice to the Directors declaring that she is a director or an officer of, or has an interest in, a person and is to be regarded as interested in any transaction or arrangement made with that person, and after giving such general notice it shall not be necessary to give special notice relating to any particular transaction.

117. A Director may hold any other office or place of profit under the Company (other than the office of its Auditors) in conjunction with her office of Director for such period and on such terms as to remuneration and otherwise as the Board may determine.

118. A Director may act by herself or her firm in a professional capacity for the Company (other than as its Auditors) and she or her firm shall be entitled to remuneration for professional services as if she were not a Director.

119. A Director may be or become a director, managing director, joint managing director, deputy managing director, executive director, manager or other officer or Member of any other company or otherwise interested in any company promoted by the Company or in which the Company may be interested as shareholder or otherwise, and no such Director shall be accountable to the Company for any remuneration or other benefits received by her as a director, managing director, joint managing director, deputy managing director, executive director, manager or other officer or Member of such other company; provided that she has declared the nature of her position with, or interest in, such company to the Board in accordance with Article 116.

120. No person shall be disqualified from the office of Director or from being an officer of the Company or prevented by such office from contracting with the Company, either as vendor, purchaser or otherwise, nor shall any such contract or any contract or transaction entered into by or on behalf of the Company in which any Director or officer of the Company shall be in any way interested be or be liable to be avoided, nor shall any Director or officer of the Company so contracting or being so interested be liable to account to the Company for any profit realised by any such contract or transaction by reason of such Director or officer of the Company holding office or of the fiduciary relation thereby established; provided that:
A Director may be counted in determining the presence of a quorum at a meeting of the Board which authorises or approves the contract, transaction or arrangement in which she is interested, provided that the nature of the interest of any Director in any such contract or transaction shall be disclosed by her in accordance with Article 116, at or prior to its consideration and any vote thereon.

For the purposes of Article 116:

122.1 a general notice given to the Directors that a Director is to be regarded as having an interest of the nature and extent specified in the notice in any transaction or arrangement in which a specified person or class of persons is interested shall be deemed to be a disclosure that the Director has an interest in any such transaction of the nature and extent so specified;

122.2 an interest of which a Director has no knowledge and of which it is unreasonable to expect her to have knowledge shall not be treated as an interest of her; and

122.3 a copy of every declaration made and notice given under Article 116 shall be entered within three days after the making or giving thereof in a book kept for this purpose. Such book shall be open for inspection without charge by any Director, Secretary, the Auditors or Member of the Company at the Registered Office and shall be produced at every general meeting of the Company and at any meeting of the Directors if any Director so requests in sufficient time to enable the book to be available at the meeting.

POWERS AND DUTIES OF DIRECTORS

123. The business of the Company shall be managed by the Directors, who may pay all expenses incurred in promoting and registering the Company and may exercise all such powers of the Company as are not, by the Acts or by these Articles, required to be exercised by the Company in general meeting, subject, nevertheless, to any of these Articles and to the provisions of the Acts. No resolution made by the Company in general meeting shall invalidate any prior act of the Directors that would have been valid if that resolution had not been made.

124. The Board shall have the power to appoint and remove executives in such terms as the Board sees fit and to give such titles and responsibilities to those executives as it sees fit.

125. The Company may exercise the powers conferred by Section 44 of the Act with regard to having an official seal for use abroad and such powers shall be vested in the Directors.

126. Subject as otherwise provided with these Articles, the Directors may exercise the voting powers conferred by shares of any other company held or owned by the Company in such manner in all respects as they think fit and in particular they may exercise their voting powers in favour of any resolution appointing the Directors or any of them as directors or officers of such other company or providing for the payment of remuneration or pensions to the directors or officers of such other company.
127. All cheques, promissory notes, drafts, bills of exchange and other negotiable instruments and all receipts for money paid to the Company shall be signed, drawn, accepted, endorsed or otherwise executed, as the case may be, by such person or persons and in such manner as the Directors shall from time to time by resolution determine.

128. A Director is expressly permitted (for the purposes of Section 228(1)(d) of the Act) to use the Company’s property subject to such conditions as may have been approved pursuant to such authority as may be delegated by the Board in accordance with these Articles.

129. Nothing in Section 228(1)(e) of the Act shall restrict a director from entering into any commitment which has been approved by the Board or has been approved pursuant to such authority as may be delegated by the Board in accordance with these Articles.

130. The Directors may from time to time authorise such person or persons as they see fit to perform all acts, including without prejudice to the foregoing, to effect a transfer of any shares, bonds, or other evidences of indebtedness or obligations, subscription rights, warrants, and other securities in another body corporate in which the Company holds an interest and to issue the necessary powers of attorney for the same; and each such person is authorised on behalf of the Company to vote such securities, to appoint proxies with respect thereto, and to execute consents, waivers and releases with respect thereto, or to cause any such action to be taken.

131. The Board may exercise all powers of the Company to borrow money and to mortgage or charge its undertaking, property and uncalled capital or any part thereof and to issue debentures, debenture stock, mortgages, bonds or such other securities whether outright or as security for any debt, liability or obligation of the Company or of any third party.

132. The Directors may procure the establishment and maintenance of or participate in, or contribute to any non-contributory or contributory pension or superannuation fund, scheme or arrangement or life assurance scheme or arrangement or for the benefit of, and pay, provide for or procure the grant of donations, gratuities, pensions, allowances, benefits or emoluments to any persons (including Directors or other officers) who are or shall have been at any time in the employment or service of the Company or of any company which is or was a subsidiary of the Company or of the predecessor in business of the Company or any such subsidiary or holding Company and the wives, widows, families, relatives or dependants of any such persons. The Directors may also procure the establishment and subsidy of or subscription to and support of any institutions, associations, clubs, funds or trusts calculated to be for the benefit of any such persons as aforesaid or otherwise to advance the interests and well being of the Company or of any such other company as aforesaid or its Members, and payments for or towards the issuance of any such persons as aforesaid and subscriptions or guarantees of money for charitable or benevolent objects or for any exhibition or for any public, general or useful object. Provided that any Director shall be entitled to retain any benefit received by her under this Article, subject only, where the Acts require, to disclosure to the Members and the approval of the Company in general meeting.

133. The Board may from time to time provide for the management of the affairs of the Company in such manner as it shall think fit and the specific delegation provisions contained in the Articles shall not limit the general powers conferred by these Articles.

MINUTES

134. The Board shall cause minutes to be made in books kept for the purpose of all appointments of officers made by the Board, all resolutions and proceedings at meetings of the Company or the holders of any class of Shares, of the Directors and of committees of Directors, including the names of the Directors present at each meeting.

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135. The Board may delegate any of its powers (with power to sub-delegate) to any committee consisting of one or more Directors. The Board may also delegate to any Director such of its powers as it considers desirable to be exercised by her. Any such delegation may be made subject to any conditions the Board may impose, and either collaterally with or to the exclusion of its own powers and may be revoked or altered. Subject to any such conditions, the proceedings of a committee of the Board shall be governed by the Articles regulating the proceedings of Directors, so far as they are capable of applying.

136. The Board may by power of attorney or otherwise appoint any person to be the agent of the Company on such conditions as the Board may determine, provided that the delegation is not to the exclusion of its own powers and may be revoked by the Board at any time.

137. The Board may by power of attorney or otherwise appoint any company, firm, person or body of persons, whether nominated directly or indirectly by the Board, to be the attorney or authorised signatory of the Company for such purpose and with such powers, authorities and discretions (not exceeding those vested in or exercisable by the Board under these Articles) and for such period and subject to such conditions as they may think fit, and any such powers of attorney or other appointment may contain such provisions for the protection and convenience of persons dealing with any such attorneys or authorised signatories as the Board may think fit and may also authorise any such attorney or authorised signatory to delegate all or any of the powers, authorities and discretions vested in her.

EXECUTIVE OFFICERS

138. The Company shall have a chairman, who shall be a Director and shall be elected by the Board. In addition to the chairman, the Directors and the Secretary, the Company may have such officers as the Board may from time to time determine.

PROCEEDINGS OF DIRECTORS

139. Except as otherwise provided by these Articles, the Directors shall meet together for the despatch of business, convening, adjourning and otherwise regulating their meetings and procedures as they think fit. Questions arising at any meeting shall be decided by a majority of votes of the Directors present at a meeting at which there is a quorum. Each Director shall have one vote.

140. Regular meetings of the Board may be held at such times and places as may be provided for in resolutions adopted by the Board. No additional notice of a regularly scheduled meeting of the Board shall be required.

141. The chairman, the chief executive officer of the Company or the majority of the Board may, and the Secretary on the requisition of any such person(s) shall, at any time summon a meeting of the Directors by at least 24 hours’ notice in writing to every Director which notice shall set forth the general nature of the business to be considered unless notice is waived by all the Directors either at, before or after the meeting is held and provided further if notice is given in person, by telephone, cable, telex, telecopy or email the same shall be deemed to have been given on the day it is delivered to the Directors or transmitting organisation as the case may be. The accidental omission to give notice of a meeting of the Directors to, or the non-receipt of notice of a meeting by any person entitled to receive notice shall not invalidate the proceedings of that meeting.

142. The quorum necessary for the transaction of the business of the Board may be fixed by the Board and unless so fixed shall be a majority of the Directors in office.
143. The continuing Directors may act notwithstanding any vacancy in their body, but if and so long as their number is reduced below the number fixed by or pursuant to these Articles as the necessary quorum of Directors, the continuing Directors or Director may act for the purpose of increasing the number of Directors to that number, or of summoning a general meeting of the Company, but for no other purpose.

144. The Directors may elect a Chairman of their Board and determine the period for which she is to hold office; but if no such Chairman is elected, or if at any meeting the Chairman is not present within five (5) minutes after the time appointed for holding the same, the Directors present may choose one of their number to be a Chairman of the meeting.

145. All acts done by any meeting of the Directors or of a committee of Directors shall, notwithstanding that it be afterwards discovered that there was some defect in the appointment of any Director, or that they or any of them were disqualified, be as valid as if every such person had been duly appointed and qualified to be a Director.

146. Members of the Board or of any committee thereof may participate in a meeting of the Board or of such committee by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other and participation in a meeting pursuant to this provision shall constitute presence in person at such meeting. Unless otherwise determined by the Directors the meeting shall be deemed to be held at the place where the Chairman is at the start of the meeting.

147. A resolution in writing (in one or more counterparts), signed by all the Directors for the time being or all the members of a committee of Directors shall be as valid and effectual as if it had been passed at a meeting of the Directors or committee as the case may be duly convened and held.

RESIGNATION AND DISQUALIFICATION OF DIRECTORS

148. The office of a Director shall be vacated:

148.1 if she resigns her office, on the date on which notice of her resignation is delivered to the Registered Office or tendered at a meeting of the Board or on such later date as may be specified in such notice; or

148.2 on her being prohibited by law from being a Director; or

148.3 on her ceasing to be a Director by virtue of any provision of the Acts.

149. The Company may, by Ordinary Resolution, of which notice has been given in accordance with Section 146 of the Act, remove any Director before the expiration of her period of office notwithstanding anything in these Articles or in any agreement between the Company and such Director. Such removal shall be without prejudice to any claim such Director may have for damages for breach of any contract of service between her and the Company.

APPOINTMENT OF DIRECTORS

150. The Directors shall be divided into three classes, designated Class I, Class II and Class III. The initial division of the Board into classes shall be made by the decision of the affirmative vote of a majority of the Directors in office and each class need not be of equal size or number. The term of the initial Class I directors shall terminate on the date of the 2015 annual general meeting; the term of the initial Class II directors shall terminate on the date of the 2016 annual general meeting; and the term of the initial Class III directors shall terminate on the date of the 2017 annual general meeting. At each annual general meeting of Members beginning in 2015, successors to the class of directors whose term expires at that annual general meeting shall be elected for a three-year term. Save as otherwise permitted in or prescribed by these
Articles, Directors will be elected by way of Ordinary Resolution of the Company in general meeting. If the number of Directors is changed, any increase or decrease shall be apportioned among the classes so as to maintain the number of Directors in each class as nearly equal as possible or as the Chairman of the Board may otherwise direct. In no case will a decrease in the number of Directors shorten the term of any incumbent Director. A Director shall hold office until the annual general meeting for the year in which her term expires and until her successor shall be elected and shall qualify, subject, however, to prior death, resignation, retirement, disqualification or removal from office. Any vacancy on the Board, including a vacancy that results from an increase in the number of directors or from the death, resignation, retirement, disqualification or removal of a Director, shall be deemed a casual vacancy. Subject to the terms of any one or more classes or series of preferred shares, any casual vacancy shall only be filled by decision of a majority of the Board then in office, provided that a quorum is present. Any Director of any class elected to fill a vacancy resulting from an increase in the number of Directors of such class shall hold office for a term that shall coincide with the remaining term of that class. Any Director elected to fill a vacancy not resulting from an increase in the number of Directors shall have the same remaining term as that of her predecessor. A Director retiring at a meeting shall retain office until the close or adjournment of the meeting.

151. During any vacancy in the Board, the remaining Directors shall have full power to act as the Board.

152. If, at any general meeting, the number of the persons who are validly nominated for election or re-election in accordance with these Articles (the “Director Nominees”), exceeds the maximum number of persons who may be appointed as Directors at that general meeting on the basis of:

152.1 the size of the Board determined in accordance with Article 113; and

152.2 the number of existing Directors who are to remain on the Board without seeking re-election,

(such maximum number being the “Available Director Positions”) then each of the Director Nominees shall be voted upon as a separate resolution and the Director Nominees who shall be elected as Directors shall be only those Director Nominees (in number equal to the Available Director Positions) who receive the highest number of votes of all Director Nominees in favour of their election or re-election.

153. Article 152 shall not limit the rights of holders of any class or series of shares then in issue having special rights to nominate or appoint Directors in accordance with the terms of issue of such class or series and nothing in Article 152 will require or result in the removal of a Director whose election or re-election to the Board was not voted on at the relevant general meeting.

154. Alternate Directors:

154.1 Any Director may appoint by writing under her hand any person (including another Director) to be her alternate provided always that no such appointment of a person other than a Director as an alternate shall be operative unless and until such appointment shall have been approved by resolution of the Directors.

154.2 An alternate Director shall be entitled, subject to her giving to the Company an address, to receive notices of all meetings of the Directors and of all meetings of committees of Directors of which her appointor is a member, to attend and vote at any such meeting at which the Director appointing her is not personally present and in the absence of her appointor to exercise all the powers, rights, duties and
authorities of her appointor as a Director (other than the right to appoint an alternate hereunder).

154.3 Save as otherwise provided in these Articles, an alternate Director shall be deemed for all purposes to be a Director and shall alone be responsible for her own acts and defaults and she shall not be deemed to be the agent of the Director appointing her. The remuneration of any such alternate Director shall be payable out of the remuneration paid to the Director appointing her and shall consist of such portion of the last mentioned remuneration as shall be agreed between the alternate and the Director appointing her.

154.4 A Director may revoke at any time the appointment of any alternate appointed by her. If a Director shall die or cease to hold the office of Director the appointment of her alternate shall thereupon cease and determine but if a Director retires by rotation or otherwise but is reappointed or deemed to have been reappointed at the meeting at which she retires, any appointment of an alternate Director made by her which was in force immediately prior to her retirement shall continue after her re-appointment.

154.5 Any appointment or revocation pursuant to this Article 154 may be sent by delivery, post, cable, telegram, telex, telefax, electronic mail or any other means of communication approved by the Directors and may bear a printed or facsimile signature of the Director making such appointment or revocation or in any other manner approved by the Directors.

SECRETARY

155. The Secretary shall be appointed by the Board at such remuneration (if any) and on such terms as it may think fit and any Secretary so appointed may be removed by the Board.

156. The duties of the Secretary shall be those prescribed by the Acts, together with such other duties as shall from time to time be prescribed by the Board, and in any case, shall include the making and keeping of records of the votes, doings and proceedings of all meetings of the Members and the Board of the Company, and committees, and the authentication of records of the Company.

157. A provision of the Acts or these Articles requiring or authorising a thing to be done by or to a Director and the Secretary shall not be satisfied by its being done by or to the same person acting both as Director and as, or in the place of, the Secretary.

SEAL

158. The Company shall have a common seal which shall only be used by the authority of the Board or of a committee of the Board authorised by the Board in that regard and every instrument to which the Seal has been affixed shall be signed by any person who shall be either a Director or the Secretary or Assistant Secretary or some other person authorised by the Board, either generally or specifically, for the purpose.

159. The Company may have for use in any place or places outside Ireland, a duplicate Seal or Seals each of which shall be a duplicate of the Seal of the Company except, in the case of a Seal for use in sealing documents creating or evidencing securities issued by the Company, for the addition on its face of the word “Securities” and if the Board so determines, with the addition on its face of the name of every place where it is to be used.
160. The Company in general meeting may declare dividends, but no dividends shall exceed the amount recommended by the Directors.

161. Subject to the Acts, the Board may from time to time declare dividends (including interim dividends) and distributions on Shares of the Company outstanding and authorise payment of the same out of the funds of the Company lawfully available therefore and in any currency chosen at its discretion.

162. The Board may, before declaring any dividends or distributions, set aside such sums as they think proper as a reserve or reserves which shall at the discretion of the Directors, be applicable for any purpose of the Company and pending such application may, at the like discretion, be employed in the business of the Company. The Directors may also, without placing the same to reserve, carry forward any profits which they may think it prudent not to divide.

163. No dividend, interim dividend or distribution shall be paid otherwise than in accordance with the provisions of the Act.

164. Subject to the rights of persons, if any, entitled to Shares with special rights as to dividends or distributions, if dividends or distributions are to be declared on a class of Shares they shall be declared and paid according to the amounts paid or credited as paid on the Shares of such class outstanding on the record date for such dividend or distribution as determined in accordance with these Articles.

165. The Directors may deduct from any dividend payable to any Member all sums of money (if any) immediately payable by her to the Company in relation to the Shares of the Company.

166. The Board or any general meeting declaring a dividend (upon the recommendation of the Board), may direct that any dividend or distribution be paid wholly or partly by the distribution of specific assets and in particular of paid up Shares, debentures, or debenture stock of any other company or in any one or more of such ways and where any difficulty arises in regard to such distribution, the Board may settle the same as they think expedient and in particular may issue fractional certificates and fix the value for distribution of such specific assets or any part thereof and may determine that cash payments shall be made to any Members upon the footing of the value so fixed in order to adjust the rights of all Members and may vest any such specific assets in trustees as may seem expedient to the Board.

167. Any dividend, distribution, interest or other monies payable in cash in respect of Shares may be paid by cheque or warrant sent through the post, or sent by any electronic or other means of payment, directed to the registered address of the holder or, in the case of joint holders, to the holder who is first named on the Register of Members or to such person and to such address as such holder or joint holders may in writing direct. Every such cheque or warrant, electronic or other payment shall be made payable to the order of the person to whom it is sent and payment of the cheque or warrant shall be a good discharge to the Company. Any one of two or more joint holders may give effectual receipts for any dividends, bonuses, or other monies payable in respect of the Share held by them as joint holders. Any such dividend or other distribution may also be paid by any other method (including payment in a currency other than US$, electronic funds transfer, direct debit, bank transfer or by means of a relevant system) which the Directors consider appropriate and any Member who elects for such method of payment shall be deemed to have accepted all of the risks inherent therein. The debiting of the Company’s account in respect of the relevant amount shall be evidence of good discharge of the Company’s obligations in respect of any payment made by any such methods.
168. No dividend or distribution shall bear interest against the Company.

169. If the Directors so resolve, any dividend which has remained unclaimed for six years from the date of its declaration shall be forfeited and cease to remain owing by the Company. The payment by the Directors of any unclaimed dividend or other monies payable in respect of a Share into a separate account shall not constitute the Company a trustee in respect thereof.

**CAPITALISATION**

170. Without prejudice to any powers conferred on the Directors as aforesaid, and subject to the Directors’ authority to issue and allot Shares under Article 6, the Directors may:

170.1 resolve to capitalise an amount standing to the credit of reserves (including any undenominated capital, profit and loss account and any sum representing unrealised revaluation reserves), whether or not available for distribution;

170.2 appropriate the sum resolved to be capitalised to the Members in proportion to the nominal amount of Shares held by them respectively and apply that sum on their behalf in or towards paying up in full unissued Shares or debentures of a nominal amount equal to that sum, and allot the Shares or debentures, credited as fully paid, to the Members (or as the Board of may direct) in those proportions, or partly in one way and partly in the other, but the profits, undenominated capital and any sum representing unrealised revaluation reserves that are not available for distribution may, for the purposes of this Article 169, only be applied in paying up unissued Shares to be allotted to Members credited as fully paid;

170.3 make any arrangements it thinks fit to resolve a difficulty arising in the distribution of a capitalised reserve and in particular, without limitation, where Shares or debentures become distributable in fractions the Board may deal with the fractions as it thinks fit;

170.4 authorise a person to enter (on behalf of all the Members concerned) into an agreement with the Company providing for the allotment to the Members respectively, credited as fully paid, of Shares or debentures to which they may be entitled on the capitalisation and any such agreement made under this authority being effective and binding on all those Members; and

170.5 generally do all acts and things required to give effect to the resolution.

**ACCOUNTS**

171. The Directors shall cause to be kept adequate accounting records, whether in the form of documents, electronic form or otherwise, that:

171.1 correctly record and explain the transactions of the Company;

171.2 will at any time enable the financial position of the Company to be determined with reasonable accuracy;

171.3 will enable the Directors to ensure that any balance sheet, profit and loss account or income and expenditure account of the Company complies with the requirements of the Acts;

171.4 will record all sums of money received and expended by the Company and the matters in respect of which the receipt or expenditure takes place, all sales and purchases of goods by the Company and the assets and liabilities of the Company; and
171.5 will enable the accounts of the Company to be readily and properly audited.

172. The accounting records shall be kept on a continuous and consistent basis and entries therein shall be made in a timely manner and be consistent from year to year. The Company may send by post, electronic mail or any other means of electronic communication a summary financial statement to its Members or persons nominated by any Member. The Company may meet, but shall be under no obligation to meet, any request from any of its Members to be sent additional copies of its full report and accounts or summary financial statement or other communications with its Members.

173. The accounting records shall be kept at the registered office of the Company or, subject to the provisions of the Acts, at such other place as the Directors think fit and shall be open at all reasonable times to the inspection of the Directors.

174. Adequate accounting records shall not be deemed to be kept as required by Articles 171 to 173, if there are not kept such accounting records as are necessary to give a true and fair view of the state of the Company’s affairs and to explain its transactions.

175. In accordance with the provisions of the Acts, the Board may from time to time cause to be prepared and to be laid before the Company in general meeting statutory financial statements, group accounts (if any) and such other reports and accounts as may be required by law.

176. A copy of the statutory financial statements of the Company (including every document required by law to be annexed thereto) which is to be laid before the annual general meeting of the Company together with a copy of the Directors’ report and Auditors’ report or summary financial statements prepared in accordance with Section 1119 of the Act shall be sent by post, electronic mail or any other means of communication (electronic or otherwise), not less than twenty-one clear days before the date of the annual general meeting, to every person entitled under the provisions of the Acts to receive them; provided that in the case of those documents sent by electronic mail or any other means of electronic communication, such documents shall be sent with the consent of the recipient, to the address of the recipient notified to the Company by the recipient for such purposes, and provided further that where the Directors elect to send a summary financial statements to the members, any member may request that he be sent a copy of the statutory financial statements of the Company.

AUDIT

177. Auditors shall be appointed and their duties regulated in accordance with the Acts, any other applicable law and such requirements not inconsistent with the Acts as the Board may from time to time determine.

NOTICES

178. Any notice to be given, served, sent or delivered pursuant to these Articles shall be in writing (whether in electronic form or otherwise).

178.1 A notice or document to be given, served, sent or delivered in pursuance of these Articles may be given to, served on or delivered to any Member by the Company:

(a) by handing same to her or her authorised agent;

(b) by leaving the same at her registered address;

(c) by sending the same by the post in a pre-paid cover addressed to her at her registered address; or
(d) by sending, with the consent of the Member to the extent required by law, the same by means of electronic mail or other means of electronic communication approved by the Directors, to the Address of the Member notified to the Company by the Member for such purpose (or if not so notified, then to the Address of the Member last known to the Company).

178.2 For the purposes of these Articles and the Act, a document shall be deemed to have been sent to a Member if a notice is given, served, sent or delivered to the Member and the notice specifies the website or hotlink or other electronic link at or through which the Member may obtain a copy of the relevant document.

178.3 Where a notice or document is given, served or delivered pursuant to sub-paragraph 178.1(a) or 178.1(b) of this Article, the giving, service or delivery thereof shall be deemed to have been effected at the time the same was handed to the Member or her authorised agent, or left at her registered address (as the case may be).

178.4 Where a notice or document is given, served or delivered pursuant to sub-paragraph 178.1(c) of this Article, the giving, service or delivery thereof shall be deemed to have been effected at the expiration of twenty-four hours after the cover containing it was posted. In proving service or delivery it shall be sufficient to prove that such cover was properly addressed, stamped and posted.

178.5 Where a notice or document is given, served or delivered pursuant to sub-paragraph 178.1(d) of this Article, the giving, service or delivery thereof shall be deemed to have been effected at the expiration of 48 hours after despatch.

178.6 Every legal personal representative, committee, receiver, curator bonis or other legal curator, assignee in bankruptcy, examiner or liquidator of a Member shall be bound by a notice given as aforesaid if sent to the last registered address of such Member, or, in the event of notice given or delivered pursuant to sub-paragraph 178.1(d), if sent to the address notified by the Company by the Member for such purpose notwithstanding that the Company may have notice of the death, lunacy, bankruptcy, liquidation or disability of such Member.

178.7 Notwithstanding anything contained in this Article, the Company shall not be obliged to take account of or make any investigations as to the existence of any suspension or curtailment of postal services within or in relation to all or any part of any jurisdiction.

178.8 Any requirement in these Articles for the consent of a Member in regard to the receipt by such Member of electronic mail or other means of electronic communications approved by the Directors, including the receipt of the Company’s statutory financial statements and the directors’ and auditor’s reports thereon, shall be deemed to have been satisfied where the Company has written to the Member informing him/her of its intention to use electronic communications for such purposes and the Member has not, within four weeks of the issue of such notice, served an objection in writing on the Company to such proposal. Where a Member has given, or is deemed to have given, her/his consent to the receipt by such Member of electronic mail or other means of electronic communications approved by the Directors, she/he may revoke such consent at any time by requesting the Company to communicate with her/him in documented form; provided, however, that such revocation shall not take effect until five days after written notice of the revocation is received by the Company.

178.9 Without prejudice to the provisions of sub-paragraphs 178.1(a) and 178.1(b) of this Article, if at any time by reason of the suspension or curtailment of postal services in...
any territory, the Company is unable effectively to convene a general meeting by notices sent through the post, a general meeting may be
convened by a public announcement (as defined below) and such notice shall be deemed to have been duly served on all Members
entitled thereto at noon (New York time) on the day on which the said public announcement is made. In any such case the Company shall
put a full copy of the notice of the general meeting on its website. A “public announcement” shall mean disclosure in a press release
reported by a financial news service or in a document publicly filed by the Company with the U.S. Securities and Exchange Commission
pursuant to Sections 13, 14 or 15(d) of the Exchange Act and the rules and regulations promulgated thereunder.

179. Notice may be given by the Company to the joint Members of a Share by giving the notice to the joint Member whose name stands first in the
Register in respect of the Share and notice so given shall be sufficient notice to all the joint Holders.

180. Every person who becomes entitled to a Share shall before her name is entered in the Register in respect of the Share, be bound by any
notice in respect of that Share which has been duly given to a person from whom she derives her title.

180.1 A notice may be given by the Company to the persons entitled to a Share in consequence of the death or bankruptcy of a Member by
sending or delivering it, in any manner authorised by these Articles for the giving of notice to a Member, addressed to them at the
address, if any, supplied by them for that purpose. Until such an address has been supplied, a notice may be given in any manner in which
it might have been given if the death or bankruptcy had not occurred.

181. The signature (whether electronic signature, an advanced electronic signature or otherwise) to any notice to be given by the Company may be
written (in electronic form or otherwise) or printed.

182. A Member present, either in person or by proxy, at any meeting of the Company or the Holders of any class of Shares in the Company shall be
deemed to have received notice of the meeting and, where requisite, of the purposes for which it was called.

UNTRACED HOLDERS

183. The Company shall be entitled to sell at the best price reasonably obtainable any Share or stock of a Member or any Share or stock to
which a person is entitled by transmission if and provided that:

(a) for a period of six years (not less than three dividends having been declared and paid) no cheque or warrant sent by the
Company through the post in a prepaid letter addressed to the Member or to the person entitled by transmission to the Share or
stock at her address on the Register or other the last known address given by the Member or the person entitled by transmission
to which cheques and warrants are to be sent has been cashed and no communication has been received by the Company from
the Member or the person entitled by transmission; and

(b) at the expiration of the said period of six years the Company has given notice by advertisement in a leading Dublin newspaper
and a newspaper circulating in the area in which the address referred to in paragraph (a) of this Article is located of its intention
to sell such Share or stock; and

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the Company has not during the further period of three months after the date of the advertisement and prior to the exercise of the power of sale received any communication from the Member or person entitled by transmission.

184. To give effect to any such sale the Company may appoint any person to execute as transferor an instrument of transfer of such Share or stock and such instrument of transfer shall be as effective as if it had been executed by the Member or person entitled by transmission to such Share or stock. The Company shall account to the Member or other person entitled to such Share or stock for the net proceeds of such sale by carrying all monies in respect thereof to a separate account which shall be a permanent debt of the Company and the Company shall be deemed to be a debtor and not a trustee in respect thereof in such Member or other person. Monies carried to such separate account may either be employed in the business of the Company or invested in such investments (other than shares of the Company or its holding company if any) as the Directors may from time to time think fit.

DESTRUCTION OF DOCUMENTS

185. The Company may destroy:

185.1 any dividend mandate or any variation or cancellation thereof or any notification of change of name or address, at any time after the expiry of two years from the date such mandate variation, cancellation or notification was recorded by the Company;

185.2 any instrument of transfer of Shares which has been registered, at any time after the expiry of six years from the date of registration; and

185.3 any other document on the basis of which any entry in the Register was made, at any time after the expiry of six years from the date an entry in the Register was first made in respect of it;

185.4 and it shall be presumed conclusively in favour of the Company that every share certificate (if any) so destroyed was a valid certificate duly and properly sealed and that every instrument of transfer so destroyed was a valid and effective instrument duly and properly registered and that every other document destroyed hereunder was a valid and effective document in accordance with the recorded particulars thereof in the books or records of the Company provided always that:

(a) the foregoing provisions of this Article shall apply only to the destruction of a document in good faith and without express notice to the Company that the preservation of such document was relevant to a claim;

(b) nothing contained in this Article shall be construed as imposing upon the Company any liability in respect of the destruction of any such document earlier than as aforesaid or in any case where the conditions of proviso (a) above are not fulfilled; and

(c) references in this Article to the destruction of any document include references to its disposal in any manner.

WINDING UP

186. If the Company shall be wound up and the assets available for distribution among the Members as such shall be insufficient to repay the whole of the paid up or credited as paid up share capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the Members in proportion to the capital paid up or credited as paid up at the commencement of the winding up on the Shares held by them respectively. And if in a
winding up the assets available for distribution among the Members shall be more than sufficient to repay the whole of the share capital paid up or credited as paid up at the commencement of the winding up, the excess shall be distributed among the Members in proportion to the capital at the commencement of the winding up paid up or credited as paid up on the said Shares held by them respectively. Provided that this Article shall not affect the rights of the Members holding Shares issued upon special terms and conditions.

186.1 In case of a sale by the liquidator under Section 601 of the Act, the liquidator may by the contract of sale agree so as to bind all the Members for the allotment to the Members directly of the proceeds of sale in proportion to their respective interests in the Company and may further by the contract limit a time at the expiration of which obligations or Shares not accepted or required to be sold shall be deemed to have been irrevocably refused and be at the disposal of the Company, but so that nothing herein contained shall be taken to diminish, prejudice or affect the rights of dissenting Members conferred by the said Section.

186.2 The power of sale of the liquidator shall include a power to sell wholly or partially for debentures, debenture stock, or other obligations of another company, either then already constituted or about to be constituted for the purpose of carrying out the sale.

187. If the Company is wound up, the liquidator, with the sanction of a Special Resolution and any other sanction required by the Acts, may divide among the Members in specie or kind the whole or any part of the property of the Company (whether they shall consist of property of the same kind or not), and, for such purpose, may value any property and determine how the division shall be carried out as between the Members or different classes of Members. The liquidator, with the like sanction, may vest the whole or any part of such property in trustees upon such trusts for the benefit of the contributories as, with the like sanction, she determines, but so that no Member shall be compelled to accept any property upon which there is a liability.

INDEMNITY

188.

188.1 Subject to the provisions of and so far as may be admitted by the Acts, every Director and Secretary shall be entitled to be indemnified by the Company against all costs, charges, losses, expenses and liabilities incurred by him in the execution and discharge of her duties or in relation thereto including any liability incurred by him in defending any proceedings, civil or criminal, which relate to anything done or omitted or alleged to have been done or omitted by him as an officer or employee of the Company and in which judgement is given in her favour (or the proceedings are otherwise disposed of without any finding or admission of any material breach of duty on her part) or in which she is acquitted or in connection with any application under any statute for relief from liability in respect of any such act or omission in which relief is granted to him by the Court.

188.2 As far as permissible under the Acts, the Company shall indemnify any current or former executive of the Company (excluding any Directors or Secretary) or any person who is serving or has served at the request of the Company as a director, executive or trustee of another company, joint venture, trust or other enterprise against expenses, including attorneys’ fees, judgments, fines, and amounts paid in settlement actually and reasonably incurred by him or her in connection with any threatened, pending, or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the Company, to which she or he was, is, or is threatened to be made a party by reason of the fact that she or he is or was such a director, executive or trustee, provided always
that the indemnity contained in this Article 188.2 shall not extend to any matter which would render it void pursuant to the Acts.

188.3 In the case of any threatened, pending or completed action, suit or proceeding by or in the right of the Company, the Company shall indemnify each person indicated in Article 188.2 of this Article against expenses, including attorneys' fees, actually and reasonably incurred in connection with the defence or the settlement thereof, except no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged by the Court or the court in which such action or suit was brought to be liable for fraud or dishonesty in the performance of her or her duty to the Company unless and only to the extent that the Court or the court in which such action or suit was brought shall determine upon application that despite the adjudication of liability, but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses as the court shall deem proper.

188.4 As far as permissible under the Acts, expenses, including attorneys' fees, incurred in defending any action, suit or proceeding referred to in Articles 188.2 and 188.3 of this Article may be paid by the Company in advance of the final disposition of such action, suit or proceeding as authorised by the Board in the specific case upon receipt of an undertaking by or on behalf of the director, executive or trustee, or other indemnitee to repay such amount, unless it shall ultimately be determined that she or he is entitled to be indemnified by the Company as authorised by these Articles.

188.5 It being the policy of the Company that indemnification of the persons specified in this Article shall be made to the fullest extent permitted by law, the indemnification provided by this Article shall not be deemed exclusive (a) of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the Constitution, any agreement, any insurance purchased by the Company, any vote of Members or disinterested directors, or pursuant to the direction (however embodied) of any court of competent jurisdiction, or otherwise, both as to action in her or his official capacity and as to action in another capacity while holding such office, or (b) of the power of the Company to indemnify any person who is or was an employee or agent of the Company or of another company, joint venture, trust or other enterprise which she or he is serving or has served at the request of the Company, to the same extent and in the same situations and subject to the same determinations as are hereinabove set forth with respect to a director, executive or trustee. As used in this Article 188.5, references to the "Company" include all constituent companies in a consolidation or merger in which the Company or a predecessor to the Company by consolidation or merger was involved. The indemnification provided by this Article shall continue as to a person who has ceased to be a director, executive or trustee and shall inure to the benefit of the heirs, executors, and administrators of such a person.

188.6 The Directors shall have power to purchase and maintain for any Director, the Secretary or other officers or employees of the Company insurance against any such liability as referred to in Section 235 of the Act.

188.7 The Company may additionally indemnify any employee or agent of the Company or any director, executive, employee or agent of any of its subsidiaries to the fullest extent permitted by law.

FINANCIAL YEAR

189. The financial year of the Company shall be as prescribed by the Board from time to time.
190. The Board is hereby expressly authorised to adopt any shareholder rights plan, upon such terms and conditions as the Board deems expedient and in the best interests of the Company, subject to applicable law.
EXECUTIVE EMPLOYMENT
AGREEMENT BY AND BETWEEN
HORIZON PHARMA USA, INC. AND
DR. JEFFERY KENT

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 Dr. Jeffery Kent (hereinafter referred to as the “Executive”). The terms of this Agreement shall be effective commencing May 1, 2019 (the “Effective Date”).

RECITALS

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 May 14, 2012. 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, head of medical affairs and outcomes research (such position held by Executive during such period is hereinafter referred to as “SVP”) and Executive shall continue to serve in such other capacity or capacities commensurate with his position as SVP 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 including being responsible for the Company’s business units. 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 at the Company’s U.S. Headquarters in Lake Forest Illinois. The Company may from time to time require the Executive to travel temporarily to other locations outside of 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 Twenty Six Thousand Thirty Seven Dollars ($426,037.00) 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. Without limitation, Executive shall be entitled to participate in the Company sponsored 401k and Deferred Compensation plans and other compensation/benefit plans in which Executive now participates.

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 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 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; 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
(e) 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).

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 and/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 and/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.

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 inccurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance Benefit payments shall be delayed until the earlier to occur of: (i) the date that is six months and one day after Executive’s Separation From Service, or (ii) the date of Executive’s death (such applicable date, the “Specified Employee Initial Payment Date”), the Company (or the successor entity thereto, as applicable) shall (A) pay to Executive a lump sum amount equal to the sum of the Severance Benefit payments that Executive would otherwise have received through the Specified Employee Initial Payment Date if the commencement of the payment of the Severance Benefits had not been so delayed pursuant to this Section and (B) commence paying the balance of the Severance Benefits in accordance with the applicable payment schedules set forth in this Agreement.
Notwithstanding anything to the contrary set forth herein, Executive shall receive the Severance Benefits described above, if and only if Executive duly executes and returns to the Company within the applicable time period set forth therein, but in no event more than forty-five days following Separation From Service, the Company’s standard form of release of claims in favor of the Company (attached to this Agreement as Exhibit A) (the “Release”) and permits the release of claims contained therein to become effective in accordance with its terms (such latest permitted date, the “Release Deadline”). If the severance benefits are not covered by one or more exemptions from the application of Section 409A and the Release could become effective in the calendar year following the calendar year in which Executive separates from service, the Release will not be deemed effective any earlier than the Release Deadline. Notwithstanding any other payment schedule set forth in this Agreement, none of the Severance Benefits will be paid or otherwise delivered prior to the effective date (or deemed effective date) of the Release. Except to the extent that payments may be delayed until the Specified Employee Initial Payment Date pursuant to the preceding paragraph, on the first regular payroll pay day following the effective date of the Release, the Company will pay Executive the Severance Benefits Executive would otherwise have received under the Agreement on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the Severance Benefits being paid as originally scheduled.

The severance benefits are intended to qualify for an exemption from application of Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences under Section 409A, and any ambiguities herein shall be interpreted accordingly.

4.7 Application of Internal Revenue Code Section 280G. If any payment or benefit Executive would receive pursuant to a Change in Control from the Company or otherwise (“Payment”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then such Payment shall be equal to the Reduced Amount. The “Reduced Amount” shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive’s receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting “parachute payments” is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.
In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, Executive agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, Executive will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

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

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

4.8 Indemnification Agreements. The Company and the Executive have previously entered 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.


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:

Dr. Jeffery Kent
1573 Stratford Road
Deerfield, IL 60015

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 and Exhibit C 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 USA, INC.

By:
Title: Chairman, President & CEO
Print Name: Timothy P. Walbert

/s/ Timothy P. Walbert
Signature
As authorized agent of the Company

Date

EXECUTIVE:

/s/ Dr. Jeffery Kent
Dr. Jeffery Kent, individually

5/1/19
Date
EXHIBIT A

RELEASE AND WAIVER OF CLAIMS

In consideration of the payments and other benefits set forth in Section 4.4 of the Executive Employment Agreement dated May 1, 2019, (the “Employment Agreement”), to which this form is attached, I, Dr. Jeffery Kent, 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
and waiver granted herein does not relate to claims under the ADEA which may arise after this Release and Waiver is executed; (b) I should consult with an attorney prior to executing this Release and Waiver; and (c) I have twenty-one (21) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier); (d) I have seven (7) days following the execution of this Release and Waiver to revoke my consent to this Release and Waiver; and (e) this Release and Waiver shall not be effective until the seven (7) day revocation period has expired unexercised. If I am less than 40 years of age upon execution of this Release and Waiver, I acknowledge that I have the right to consult with an attorney prior to executing this Release and Waiver (although I may choose voluntarily to do so); and (c) I have five (5) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier).

I acknowledge my continuing obligations under my Confidential Information and Inventions Assignment Agreement dated May 14, 2012. Pursuant to the Confidential Information and Inventions Assignment 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 Assignment Agreement.

This Release and Waiver, including my Confidential Information and Inventions Agreement dated May 14, 2012, 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: _______________________________

Dr. Jeffery Kent
CONFIDENTIAL
EXECUTION COPY

COMMERCIAL SUPPLY AGREEMENT

BETWEEN

CMC BIOLOGICS A/S, dba AGC Biologics

and

HORIZON PHARMA IRELAND LIMITED

DISCLAIMER

THIS DOCUMENT IS FOR DISCUSSION PURPOSES ONLY. IT IS NOT INTENDED TO CONSTITUTE ANY OFFER OR CREATE ANY LEGAL RELATIONS.

THE SUPPLY OF THIS DOCUMENT IN ELECTRONIC FORM IS STRICTLY ON THE UNDERSTANDING THAT NO AMENDMENTS WILL BE MADE TO IT WHICH ARE NOT EXPLICITLY DRAWN TO THE OTHER PARTY’S ATTENTION EITHER BY MARKING THE CHANGES IN THE TEXT ITSELF OR OTHERWISE.
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## APPENDIX ONE

## APPENDIX TWO

### COMMERCIAL SUPPLY AGREEMENT
THIS COMMERCIAL SUPPLY AGREEMENT is made and effective as of February 14, 2018 (the “Effective Date”).

BETWEEN

(1) CMC BIOLOGICS A/S, dba AGC Biologics, duly formed under the laws of Denmark and having its principal place of business at Vandtaarnsvej 83B DK-2860 Soeborg, Copenhagen, Denmark (hereinafter referred to as “AGC”); and,

(2) HORIZON PHARMA IRELAND LIMITED, duly incorporated under the laws of Ireland and having its principal place of business at Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, Ireland (hereinafter referred to as “Customer”).

AGC and Customer may each be referred to herein as a “Party” and collectively as the “Parties.”

RECITALS

(A) Customer is engaged in the research, development, manufacture and sale of new biologic products, including the product designated by Customer as teprotumumab (“Product”);

(B) In addition to development and scale-up activities, AGC also provides commercial manufacturing activities for biological products to pharmaceutical and biotechnology companies; and

(C) Customer wishes to contract with AGC to provide the Services (as defined below) for the commercial supply of Product; and

(D) AGC is willing to provide the Services to the Customer on the terms and conditions set out in this Agreement in exchange for the Batch Price which the Customer agrees to pay.
NOW THEREFORE, THE PARTIES AGREE as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 For the purposes of this Agreement, the terms defined in this clause shall have the respective meanings set forth below:

“Affiliate” any company, partnership or other entity which directly or indirectly through one or more intermediaries controls or is controlled by, or is under common control with a Party. Solely for the purpose of this definition, “control” and its correlates means the direct or indirect beneficial ownership of more than 50% of the voting share capital in such company, partnership or entity or the legal power to control the general management and policies of such company, partnership or entity;

“AGC Confidential Information” AGC’s SOPs and non-public information relating to AGC Intellectual Property Rights;

“AGC Facility” AGC’s manufacturing facility in Copenhagen, Denmark or another AGC facility agreed on in writing by the Parties;

“AGC Materials” [***];

“AGC Intellectual Property Rights” All AGC Know-How and all Intellectual Property owned or Controlled by AGC or its Affiliates during the Term, in each case that is used in the Services or is otherwise reasonably useful or necessary for the further processing, use, handling or sale of the Product;

“AGC Know-How” all Information owned or Controlled by AGC or its Affiliates during the Term which is not of general public knowledge;

“Agreement” this Agreement including all Appendices attached hereto and any amendments to the foregoing made in accordance with this Agreement;

“Appendix” or “Appendices” one or more of the appendices to this Agreement;
“Batch”
a specific quantity of BDS that is intended to be of uniform character and quality and is produced during a single fermentation run (as defined by the applicable batch records) using the Cell Line at a specified fermenter scale;

“Batch Price”
the price payable for each Batch (including the purification, analytical and further processing steps applicable thereto) as initially described in the Appendix Two and as may be amended by written agreement between the Parties or by operation of Clause 7.2;

“Binding Order”
has the meaning set forth in Clause 5.8;

“Bulk Drug Substance” or “BDS”
means the Product in bulk, as expressed by the Cell Line and harvested and purified in bulk from a fermentation run pursuant to the applicable Process;

“Business Day”
any day which is not a Saturday, a Sunday or a U.S. public holiday;

“Calendar Day”
any day;

“Calendar Quarter”
a 3-month period beginning on January 1, April 1, July 1, or October 1 of each year;

“Campaign”
a series of Batches manufactured consecutively in accordance with the Process;

“Cell Line”
the mammalian cell line designated [***] which is owned by Customer and provided to AGC or derived from a master cell bank of the same strain as that provided by Customer to AGC and any progeny clone of the foregoing cell line(s);

“Certificate of Analysis” or “CoA”
a certificate of analysis in the form attached as Exhibit A confirming that Product to which the certificate relates meets the Specification and such other criteria as identified on the certificate;

“Certificate of Compliance” or “CoC”
a certificate of compliance in the form attached as Exhibit B confirming that the Product to which the certificate relates was manufactured and supplied in compliance with cGMP and such other criteria as identified on the certificate;

[***] = Certain Confidential Information Omitted
“cGMP” Current Good Manufacturing Practices as promulgated under each of the following as in effect on the Effective Date and as amended or revised after the Effective Date: (a) the U.S. Food, Drug & Cosmetics Act (21 U.S.C. § 301 et seq.) and related U.S. regulations, including 21 Code of Federal Regulations (Chapters 210 and 211) and other FDA regulations, policies, or guidelines in effect at a particular time for the manufacture, testing and quality control of investigational drugs; (b) EudraLex Volume 4; (c) the ICH guide Q7 “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients;” and (d) any other laws, regulations and statutes set forth by a Regulatory Authority applicable to the manufacture and supply of Product and other Services provided by AGC under this Agreement.

“Change of Control” in relation to a body corporate, the occurrence of an event or circumstance where a Person who is not presently able to do any of the following things becomes able to do one of the following things (whether directly or indirectly or through one or more intervening Persons):

(a) control the composition of more than one half of the body’s board of directors;

(b) be in a position to cast, or control the casting of, more than one half of the maximum number of votes that might be cast at a general meeting of the members of the body;

(c) hold or have a beneficial interest in more than one half of the issued share capital of the body;

“Commercial Quality Agreement” the agreement between the Parties defining the quality responsibilities, including cGMP standards, regarding the performance of the Services, as further described in Clause 2.3;

“[***]” [***] of an experienced contract manufacturing organization engaged in the cGMP manufacture of biological products that are similar to the Product;

“Confidential Information” means all Information owned or controlled by the Disclosing Party or its Affiliates that is disclosed to or made available to Recipient Party relating to this Agreement and includes:

(I) Information disclosed in writing, orally or by any other means;

(II) Information disclosed before, after or on the date of this Agreement;

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
(iii) Information relating to the Disclosing Party’s operations, products, processes, plans, intentions, market opportunities and business affairs, and any new and novel combinations thereof and any marketing and business plans, any financial (including pricing information) and personnel information relating to a Party or its present or future products, sales, suppliers, customers, employees, investors or business; and

(iv) the terms of this Agreement, which shall be deemed to be the Confidential Information of both Parties.

the use of which is governed according to the provisions of Clause 10;

“Conforming Product” BDS produced under cGMP that meets the Specifications;

“Controlled” with respect to any material, Information or Intellectual Property of a Party, the possession or the ability by such Party to grant access, a license, or a sublicense to such material, Information or Intellectual Property as provided for herein without violating an agreement with a Third Party;

“Customer Intellectual Property Rights” All Customer Know-How and all Intellectual Property owned or Controlled by Customer or its Affiliates during the Term, in each case covering any aspect of the Services, Cell Line, BDS or materials, techniques or processes used in the Services;

“Customer Know-How” all Information owned or Controlled by Customer or its Affiliates during the Term which is not of general public knowledge;

“Customer Materials” (a) Customer-Provided Materials, and (b) [***];

“Customer-Provided Materials” the Cell Line, BI media and any other materials described in Appendix 2 that will be supplied to AGC by or on behalf of Customer, subject to Clause 3.4;

“Defect” and “Defective” have the meaning set forth in Clause 6.12;

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
“Defect Notice” has the meaning set forth in Clause 6.12;

“Deliverables” the data, results and materials generated from the performance of the Services including Batch records, CoA, CoC, electronic files of IPC (in-process control) and IPM (in-process monitoring) data, Drug History Records and Product. All Deliverables will be deemed to be Customer’s Confidential Information, excluding AGC Confidential Information;

“Delivery” or “Delivered” has the meaning set forth in Clause 6.3;

“Delivery Date” the month determined in accordance with Clause 5.6 for Delivery for the Product manufactured under a Purchase Order. Where a Timeline has been amended in accordance with Clause 4.2 or 4.3, the corresponding Delivery Date shall be commensurately amended;

“Drug History Record” all lot disposition documentation relevant to a cGMP Batch to be provided to Customer with the Product from that cGMP Batch, including but not limited to manufacturing Batch records, Certificates of Compliance and Certificates of Analysis;

“Effective Date” as set forth in the first paragraph of this Agreement;

“EMA” European Medicines Agency;

“Exceptional Batches” has the meaning in Clause 5.7;

“FDA” means the United States Food and Drug Administration, or its successor agency;

“Firm Order” has the meaning set out in Clause 5.3.1;

“Forecast” has the meaning set out in Clause 5.1;

“Fundamental Change” means a Change of Control, merger, acquisition or change of management of AGC;

“Group” in respect of the relevant Party, its Affiliates and holding companies and the Affiliates of those holding companies;

COMMERCIAL SUPPLY AGREEMENT 8
“Information” techniques, data, discoveries, inventions, practices, methods, information, knowledge, know-how, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, regulatory submissions and approvals, production information, expertise, methodologies, drawings, specifications, designs and trade secrets;

“Initial Commitment Term” The term commencing on the Effective Date and ending on the seventh (7th) anniversary thereof;

“Intellectual Property” all intellectual property rights, including, without limitation, patents, supplementary protection certificates, petty patents, utility models, trademarks, database rights, rights in designs, copyrights (whether or not any of these are registered or capable of being registered) and including all applications and the right to apply for registered protection of the foregoing and all rights in Information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world, in each case for their full term and together with any renewals or extensions;

“Joint Steering Committee” has the meaning set forth in Clause 4.7;

“Minimum Volumes” the minimum number of Batches that must be ordered per Calendar Year by Customer as stipulated in Clause 5.3.5;

“Non-Fault Delays” has the meaning set forth in Clause 4.1;

“Person(s)” any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein;

“Process” the method for manufacture, harvesting and purification of the Product as defined in Customer approved manufacture batch records;

“Product” Customer’s biologic product which is a recombinant human anti-human insulin-like growth factor-I receptor monoclonal antibody, known as teprotumumab;

“Project Manager” has the meaning set forth in Clause 4.7;
“Project Team” has the meaning set forth in Clause 4.8;

“Raw Materials” media, resins, catalysts, solvents, filters, membranes, disposable analytical test kits, disposable bags, and other items consumed for the manufacture of Products in accordance with this Agreement;

“Recall” any action to withdraw from supply or distribution or to recover title to or possession of quantities of Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market or correction) or the detention or destruction of any Product by any Regulatory Authorities;

“Regulatory Authority” any regulatory authority involved in regulating any aspect of the conduct, development, manufacture, market approval, sale, distribution, packaging or use of the Services or the Deliverables, including, without limitation, the FDA and the EMA. “Regulatory Authority” also includes any non-governmental group licensed by an entity described in the preceding sentence to perform inspections, audits and/or reviews.

“Regulatory Obligations” those laws and regulatory requirements in [***] and any other jurisdiction agreed in writing by the Parties in accordance with Section 2.1.3, in each case applicable to the manufacture of cGMP Product for human use;

“Second Source” any Third Party that is able to supply or procure the supply of Product or a product that is similar or equivalent to the Product;

“Semi-Binding Order” has the meaning set forth in Clause 5.3.3;

“Services” the manufacturing services to be conducted by AGC as described in this Agreement and the Commercial Quality Agreement;

“Shipping Guidelines” the storage and transport guidelines for the Product that are determined by mutual written agreement of the Parties;

“Slot” the period of time AGC’s cGMP manufacturing suite is reserved in preparation for and the manufacture of a Batch;

[***] = Certain Confidential Information Omitted
“Specification” the specification for the Product as defined in Appendix One or as may otherwise be agreed between the Parties in writing or modified in accordance with Clause 4.5. The Specification includes (i) specifications for BDS and Raw Materials, (ii) manufacturing, testing and packaging instructions and specifications for Product in accordance with the Process, (iii) storage and shipping requirements, and (iv) any other technical information necessary to manufacture a Batch;

“Standard Operating Procedures” or “SOPs” the standard operating procedures of AGC which define AGC’s methods of performing activities applicable to the Services;

“Storage Cost” has the meaning set forth in Clause 7.7;

“Supply Failure” AGC’s failure, during any consecutive [***] month period, to Deliver at least the percentage set forth below (the “Designated Percentage”) of the quantities of Conforming Product specified in Purchase Orders that have been submitted by Customer in accordance with its firm Forecast in accordance with the Delivery Date. Notwithstanding the foregoing, [***].

The Designated Percentage shall be: (a) where the Firm Order is [***], and (b) where the Firm Order is [***].

“Term” has the meaning set forth in Clause 14.1;

“Testing Laboratories” any Third Party approved in writing by Customer and instructed by AGC to carry out tests on the Cell Line, Customer Materials, BDS or Product pursuant to the performance or conformance of the Services with a Specification;

“Timeline” collectively and individually, the timeline for AGC’s manufacture and Delivery of Product in accordance with the Forecast and each Delivery Date, and as may be amended in accordance with Clause 4.2 and 4.3; and

“Third Party” means a Person other than the Parties and their respective Affiliates.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

COMMERCIAL SUPPLY AGREEMENT

11
1.2 Additional Definitions. Each of the following definitions is set forth in the clause of this Agreement indicated below:

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1.3 In this Agreement (except where the context otherwise requires):

1.3.1 any reference to a recital, clause or appendix is to the relevant recital, clause or appendix of or to this Agreement and any reference to a sub-clause or paragraph is to the relevant sub-clause or paragraph of the clause or appendix in which it appears;

1.3.2 the table of contents and clause headings are included for convenience only and shall not affect the interpretation of this Agreement;
1.3.3 use of the singular includes the plural and vice versa and use of any gender includes the other genders;
1.3.4 a reference to a “Party” is a reference to a party to this Agreement and a reference to a “Party” includes a reference to that Party’s successors in title, permitted assignees and transferees (if any);
1.3.5 “will”, “shall” and “must” are synonyms;
1.3.6 “or” is used in the conjunctive (i.e., as “and/or”);
1.3.7 “days”, if not otherwise specified, means Calendar Days;
1.3.8 a reference to “writing” does not include email; and
1.3.9 any phrase introduced by the terms “including”, “include”, “in particular” or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

1.4 The Appendices form an integral part of this Agreement and shall have effect as if set out in full in the body of this Agreement and any reference to this Agreement includes the Appendices hereto.

1.5 Where there is any inconsistency between the Appendices and the main body of this Agreement, the conflicting terms of the main body of this Agreement shall, unless expressly specified to the contrary, prevail.

2. MANUFACTURING SUPPLY AND APPLICABLE STANDARDS

2.1 During the Term:

2.1.1 AGC shall use [***] to manufacture Product in the quantity of Batches that are the subject of a Firm Order pursuant to the forecast mechanism set out in Clause 5 and in accordance with the terms and requirements set out in this Agreement.

Customer shall purchase from AGC the Product in the quantity of Batches in accordance with the terms of this Agreement.

2.1.2 Notwithstanding the foregoing, and without reference to [***], AGC will manufacture and supply the Product hereunder in accordance with the Specification, cGMP and the Regulatory Obligations.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
2.1.3 If Customer wishes to extend the scope of the Regulatory Obligations to cover jurisdictions beyond [***], the Parties will discuss in good faith an amendment to this Agreement to do so. If the Parties do not execute such an amendment on mutually agreeable terms within [***] days of Customer’s written request to do so, then Customer will have the right to have its requirements of BDS and Product solely for such jurisdiction manufactured by a Third Party, or to do so itself or through an Affiliate, notwithstanding any other provision of this Agreement.

2.2 Where applicable, AGC will comply with the obligatory requirements stipulated in the International Conference on Harmonisation guidelines on quality.

2.3 AGC and Customer’s Affiliate Horizon Pharma Tepro, Inc. ("Horizon Tepro") have entered into that certain quality agreement dated October 10, 2017. Promptly following the Effective Date, but in any event within [***] days following the Effective Date unless mutually extended by the Parties, AGC and Horizon Tepro shall execute an amendment to such quality agreement in order to assign such quality agreement from Horizon Tepro to Customer and to address the manufacture of Product under this Agreement. Upon the execution of such amendment, such quality agreement shall be deemed to be the Commercial Quality Agreement. AGC will comply with quality standards as agreed to in the Commercial Quality Agreement. Any material breach of the Commercial Quality Agreement related to a quality matter will be deemed to be a material breach of this Agreement.

2.4 AGC shall retain and store samples of all gGMP Product released by AGC’s quality department with a Certificate of Analysis under this Agreement for such period as may be required by applicable Regulatory Obligations, which in the absence of a definitive time period shall be [***] years from the date of release or Delivery. If the Parties agree, AGC shall retain such samples for a longer period at the Customer’s cost. AGC will notify Customer in writing before disposing of any such samples and Customer will have the right to have such samples delivered to Customer or its designee at Customer’s expense.

Third Party Testing Laboratories

2.5 AGC may subcontract

2.5.1 to its Affiliates, any part of the Services (provided that the Affiliates may not further subcontract those parts of the Services), with the prior written consent of Customer (such consent not to be unreasonably withheld, delayed or conditioned);

2.5.2 to Testing Laboratories which the Customer has approved in writing, Services identified in the applicable Appendix as Services which AGC may subcontract to such Testing Laboratory(ies);

2.5.3 to any other Third Party, any part(s) of the Services with the prior written consent of Customer (such consent not to be unreasonably withheld, delayed or conditioned).

AGC shall remain directly and fully responsible to Customer for the activities of the Person to which it subcontracts any of the Services.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
Totality of Services

2.6 The Services described in this Agreement, subject to any written agreement or amendment to the contrary, are the only services to be performed by AGC hereunder. Due to the nature of the Services, changes to the Services may be necessary. Customer acknowledges this potential necessity and recognizes that any changes to Services may change the price for such Services.

2.7 If additional Services or a change to the Services is necessary, then the Parties shall promptly meet in good faith to negotiate with respect to any such changes as may be necessary. Any such changes do not become effective until set forth in an amendment to this Agreement or other written agreement signed by an authorized representative of each Party.

3. CUSTOMER MATERIALS; AGC MATERIALS

3.1 All Raw Materials purchased by AGC for the Services will be the property of the Customer and deemed Customer Materials. Customer hereby grants to AGC a security interest in all Raw Materials to secure the payment of any and all amounts due to AGC therefor.

3.2 AGC will test, use, handle, store, transport, package and dispose of all Customer Materials in accordance with all applicable laws and regulations, the applicable Materials Safety Data Sheet, the Commercial Quality Agreement, master Batch record and other applicable documentation, its applicable standard operating procedures (including, without limitation those relating to cleaning and sterilization) and industry standards applicable to the contract manufacture of biologics. AGC shall qualify, oversee and audit its suppliers of the Customer Materials and the AGC Materials in accordance with applicable cGMP requirements. The Parties agree to jointly work together to perform risk management analyses of vendors of the Customer Materials and Raw Materials, which shall include an assessment of the risks of interruption of supply from each such vendor over the [***] year period covered by the Binding Orders. If either Party determines that there is a reasonable likelihood that there may be an interruption in supply from any such vendor or with respect to any Customer Material or Raw Material it shall notify the Customer in writing and the Parties shall discuss in good faith risk mitigation strategies, which may include the payment by Customer of a reasonable stocking fee for the materials at issue.

3.3 As between the Parties, AGC shall be solely responsible for the procurement and performance of the AGC Materials.

3.4 If, following the Effective Date, the Parties through the change control procedures set forth in the Commercial Quality Agreement agree to changes in the Customer Materials (whether initiated by Customer or required by a Regulatory Authority), and [***].

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
4. TIMELINE, SPECIFICATION AND PROJECT MANAGEMENT

Timeline
4.1 AGC shall use its [***] to maintain the Timeline for each Batch. Notwithstanding that obligation, the Parties acknowledge and agree that the Timeline for a Batch may be varied as agreed by AGC and Customer in writing in order to accommodate delays or changes caused by or contributed to by (i) actions or omissions of the Customer (or its agents); and/or (ii) additional activities added to the Services; and/or (iii) force majeure events or other circumstances beyond AGC’s reasonable control (“Non-Fault Delays”).

4.2 In the event of any Non-Fault Delays described in Clause 4.1(i) or (ii), AGC shall update the Timeline for the applicable Batches as agreed in writing with the Customer and shall endeavor in good faith to keep the revised Timeline as close as possible to the Timeline in its form as it existed immediately prior to the Non-Fault Delays.

4.3 Notwithstanding Clause 18.4, the Timeline (for one or more Batches, or prospectively for all future Batches) may be amended by agreement between AGC and Customer provided that the revised Timeline is set out and agreed in writing by the Project Team.

4.4 Where the Timeline has been amended in accordance with this Clause 4, it shall be automatically binding upon the Parties. AGC shall keep Customer updated as to its conformance with the Timeline for Batches then in production on a reasonable frequency. Customer may at any time on a reasonable basis request an update on performance of the Services against the current Timeline.

Specification & Quantities
4.5 The Parties agree that the Specification may be modified and updated by the Parties if agreed to by the Project Team in writing and signed by an authorized representative of each Party. Each Party shall consider any proposed modifications to the Specification, including those that may be requested by a Regulatory Authority, in good faith. For the avoidance of doubt, where the Parties cannot agree to modify, amend or update the Specification, the previous Specification as agreed to by the Parties shall apply.

4.6 For clarity the Parties acknowledge that all quantities of BDS derived from a Batch [***]. Notwithstanding the foregoing, [***]

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4.7 Each Party shall, within [***] days of the Effective Date, appoint an individual as a project leader ("Project Manager") who shall be responsible for leading and coordinating the day to day operation of the Services. In addition, within [***] days of the Effective Date, each Party shall select two of their senior technical staff, one of whom (for each Party) may be a Project Manager, to form the steering committee who shall have responsibility for providing leadership and strategic oversight of the Services governed by this Agreement ("Joint Steering Committee").

4.8 Separate from the Joint Steering Committee, the Parties shall form the “Project Team” that will be responsible for the day to day performance of the Services including planning, executing and discussing issues regarding the Forecasts, the Timeline, the Services and communicating between the Parties. Any disputes or issues that cannot be readily resolved by the Project Team shall be referred to the Joint Steering Committee for resolution. Each Party shall notify the other in writing of its representatives to the Project Team ("Representatives"), as may be changed from time to time.

4.9 Each Party’s Project Manager shall, subject to the oversight of the Joint Steering Committee, (i) manage the relationship between the Parties, (ii) oversee the performance of the Services and the activities of the Project Team, (iii) undertake actions delegated to them by the Joint Steering Committee and (iv) be the principal point of contact for the Services. The Project Managers shall meet upon reasonable request either in person or by telephone or video conference and each Party shall bear its own costs for attending such meetings.

4.10 The Joint Steering Committee shall be responsible for (i) making decisions regarding issues outside the scope of the Project Team or Project Managers directly relating to the manufacture and supply of Product hereunder, (ii) reviewing the decisions of the Project Team and/or Project Managers, (iii) providing a forum for the Parties to exchange information and coordinate their respective activities regarding the Services, (iv) providing a forum to discuss any technical difficulties or changes to Services or Batch Price triggered by a change to the Services or in accordance with Clause 7.3 as well as attempting in good faith to resolve any disputes or disagreements within the scope of its authority before escalation to the dispute resolution provided for in Clause 17, and (v) ensure that intent of this Agreement is maintained throughout the Term. The Joint Steering Committee shall meet on a reasonably regular basis during the Term.

[***] = Certain Confidential Information Omitted
At regular intervals the Representatives shall schedule Project Team meetings for the purpose of overcoming any issues with Forecasts, delivery of Product or the performance of all other aspects of the Services and providing an initial forum for discussing and resolving any difficulties or hurdles encountered in the performance of the Services. Such meetings shall be conducted by telephone conference or, if necessary, by face-to-face meetings at an agreed frequency unless particular difficulties arise which dictate the need for more frequent meetings. Each Party shall be responsible for their own costs in attending and conducting the Project Team meetings.

Should either Party become aware or conclude that it is reasonably likely that AGC will be unable to meet the Timeline or Delivery Dates for one or more Batches of Product in accordance with Firm Orders resulting in a halting or delay in the manufacture of the Product, then it shall promptly notify the other Party. AGC shall as soon as reasonably practicable notify Customer of the circumstances of such delay and explain what efforts AGC is taking to address such delay, and the Parties shall discuss in good faith through the Project Team what steps may be taken to mitigate such delay.

Any decision by the Project Team, the Project Managers or Joint Steering Committee which has the effect of amending the Services in any way must, before it becomes binding, be recorded in writing and signed by both Parties in accordance with Clause 18.4.

In any decision to be made by the Project Team, the Project Managers or the Joint Steering Committee, each Party shall have one vote, irrespective of the number of its representatives participating.

The Project Team, Project Managers and Joint Steering Committee shall have no authority to amend this Agreement, determine compliance with any provision of this Agreement, or waive any right or obligation under this Agreement.

FORECASTS, ORDERS, MANUFACTURING CAPACITY AND FAILURE TO SUPPLY

Commencing on the Effective Date, and thereafter at the beginning of each subsequent Calendar Quarter, Customer shall, subject to the provisions of this clause, deliver to AGC a rolling [***] month forecast of Customer’s requirements for Product for the following [***] months ("Forecast"), subject to Clause 2.1.3.

Each Forecast shall set out the number of Batches of Product required by Customer during each Calendar Quarter covered by the Forecast together with the requested delivery dates for Product in each Calendar Quarter covered by the Forecast. In preparing a Forecast Customer shall:

Attempt to aggregate the number of Batches required throughout the period covered by the Forecast into contiguous Campaigns; and

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
shall use reasonable efforts to provide a Forecast that accurately reflects its good faith anticipated requirements for the period covered by the Forecast, subject to Clause 2.1.3.

5.3 In respect of each Forecast:

5.3.1 the first [***] Calendar Quarter periods covered by the Forecast shall be a definitive and binding order on Customer (a “Firm Order”);

5.3.2 the [***] Calendar Quarter periods covered by the Forecast shall be [***]% binding on Customer;

5.3.3 the [***] Calendar Quarter periods covered by the Forecast shall be [***]% binding on Customer (the order referred to in Clause 5.3.2 and this Clause 5.3.3, a “Semi Binding Order”);

5.3.4 the [***] Calendar Quarter periods covered by the Forecast shall not be binding on Customer; and serves only as information to AGC for capacity planning purposes.

5.3.5 Until the [***], Customer shall order at a minimum [***] Batches per Calendar Year. Thereafter, Customer shall order a minimum of [***] Batches per Calendar Year. Such batches may be ordered as a campaigns or as single Batches. This minimum may be increased or decreased (but never below [***] Batches following the [***]) from time to time by written agreement of the Parties. Once a [***] Batch has been [***], the Parties shall engage in good faith discussions and agree upon a reasonable new minimum. The Parties understand and agree that Customer is liable for the Minimum Volume of Batches required to be ordered for each Calendar Year during the Term of this Agreement at the then-current Batch Price, subject to Clauses 5.8 and 6.16. Notwithstanding the foregoing, the Parties agree that the Minimum Volume for [***] shall be satisfied by the [***] Batches that Customer ordered for Delivery during [***] under the Development and Manufacturing Services Agreement dated as of June 10, 2015 (the “MSA”). Such [***] Batches shall be paid for in accordance with the MSA and the applicable Work Statement(s) (as defined therein), notwithstanding Appendix Two.

AGC shall reserve a minimum of [***] Slots per Calendar Year for Customer, but Customer shall be entitled to reserve additional slots that AGC may have available or upon [***] months’ written notice. The Parties shall discuss in good faith increasing such minimum reservation as needed.

[***] = Certain Confidential Information Omitted
5.4 The Forecasts are intended to provide AGC with clarity as to the Customer’s requirements for Product. Forecasts shall be provided by Customer on a rolling quarterly basis as provided above and each subsequent Forecast shall reflect the previous relevant Forecasts provided by Customer such that:

5.4.1 the quantity of Product set out in the [***] Calendar Quarter of the immediately preceding Forecast shall, in the next Forecast, become the [***] Calendar Quarters of the Firm Order without any variation (other than with AGC’s prior written consent);

5.4.2 the quantity of Product set out in the [***] Calendar Quarter of the immediately preceding Forecast shall, in the next Forecast, become the [***] Calendar Quarter in the next Forecast and a Firm Order but may be varied by Customer by a maximum of [***]% in whole Batches or [***] Batch, whichever is the greater;

5.4.3 the quantity of Product set out in the [***] Calendar Quarter of the immediately preceding Forecast shall, in the next Forecast, become the [***] Calendar Quarters and Semi Binding Orders and may be varied by a maximum of [***]% in whole Batches or [***] Batches whichever is the greater; and

5.4.4 Customer shall provide a new projection for the [***] Calendar Quarters in accordance with the principles set out in Clause 5.3.

5.5 If Customer fails to submit a Forecast in accordance with the preceding provisions of this Clause 5, then a Forecast shall automatically be deemed to be served under this clause by Customer where:

5.5.1 the first [***] Calendar Quarters of such new Forecast shall be identical to the [***] Calendar Quarters of the immediately preceding Forecast; and

5.5.2 the [***] Calendar Quarter of the new Forecast shall be identical in terms of the quantity of Batches identified in the [***] Calendar Quarter of the immediately preceding Forecast; and

5.5.3 the preferred delivery dates for the [***] Calendar Quarter of the new deemed Forecast shall be the preferred delivery dates set out for the [***] Calendar Quarter of the immediately preceding Forecast, with each extended by a [***] month period.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
Customer shall provide a written or electronic purchase orders (each, a “Purchase Order”) for each Firm Order in conformance with the relevant Forecast within [***] days of the updated Forecast. Each Purchase Order shall include a requested [***], which may be changed by AGC +/- by [***] days. AGC shall provide written confirmation of each [***] within [***] days of receipt of the Purchase Order, and such confirmed [***] days shall thereafter be the Delivery Date. Each Purchase Order shall be in a form reasonably acceptable to AGC and Customer. No terms contained in any Purchase Order, order acknowledgment or similar document shall be construed to amend or modify the terms of this Agreement and in the event of any conflict, this Agreement shall prevail and control, unless the Parties otherwise expressly agree in writing by making reference to both this Agreement and the alternative terms.

Notwithstanding the limits on ordering under a Forecast, AGC may, in response to Customer’s written request, elect to manufacture additional Batches of Product in a Calendar Quarter beyond the quantity allocated in a Firm Order for that same Calendar Quarter (“Exceptional Batches”). AGC’s obligation to manufacture Exceptional Batches shall only arise upon AGC’s written acceptance whereby the Exceptional Batches accepted by AGC shall be deemed part of the Firm Order(s) for the relevant Calendar Quarter(s). AGC shall use [***] to accept Customer’s orders for Exceptional Batches.

All quantities of Batches that are the subject of a Firm Order or the binding portion of a Semi-Binding Order (collectively, a “Binding Order”) shall be binding upon Customer and may not be delayed or cancelled by Customer, except pursuant to Clause 5.12.

Should Customer [***], then Customer shall [***], provided that commencing as of [***]. AGC shall be entitled to invoice in [***], and Customer shall pay such invoice in accordance with the provisions of Clause 7.

Should Customer [***], then Customer shall [***], provided that commencing as of [***]. AGC shall be entitled to invoice [***], and Customer shall pay such invoice in accordance with the provisions of Clause 7.

Customer’s payments under this Section 5.8 shall be AGC’s sole remedy for any cancellation of any portion of a Binding Order.

AGC shall be obliged to manufacture the quantity of Batches identified in a Binding Order and shall use its [***] to meet the Timeline for Delivery of those Batches in accordance with Clause 2.1.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
AGC shall use the Forecasts to plan for, and, as appropriate, reserve Slots in its cGMP manufacturing suite for those Batches to be manufactured under a Binding Order to meet the applicable Delivery Dates according to the then-current Timeline. Upon the reasonable request of AGC, the Parties shall cooperate to seek an agreement in good faith to vary or amend any part of a Forecast (including the Firm Orders, Semi Binding Orders, Timeline and Delivery Date) to accommodate lead times.

Where the Timeline for one or more Batches is amended and such amendment effects the scheduled Slot(s) for those Batches which are the subject of a Binding Order, AGC shall update its manufacturing schedule and reserve a new Slot for each affected Batch which, subject to reserved slots under AGC’s existing manufacturing schedule for its whole facility, shall be reserved as near in time to the existing vacated Slots as AGC’s then current schedule will permit.

Supply Failure

If a Supply Failure occurs, the following shall apply, without limiting Customer’s other rights under this Agreement:

5.12.1 provided that such Supply Failure is not due to AGC’s negligence, willful misconduct or breach of this Agreement, AGC and Customer shall work collaboratively to discuss and find ways to promptly overcome the Supply Failure and re-establish supply of Product as soon as practicable;

5.12.2 Customer shall have the right to cancel any unfilled Purchase Orders and to engage another manufacturer for its BDS and Product requirements. Customer will be entitled to a technology transfer to a Second Source in accordance with Clause 15.

5.12.3 Customer shall have the right to use its Second Source to manufacture all or part of its requirements, and will not be subject to the limit set forth in Clause 5.14 while a Supply Failure is ongoing. The number of Batches manufactured by such Second Source shall commensurately reduce the Minimum Volume for the current and subsequent Calendar Years. A Supply Failure shall be deemed to be ongoing until such time as AGC can demonstrate to Customer’s reasonable satisfaction that AGC will be able to manufacture and Deliver Conforming Product in accordance with the then-current Timeline.

5.12.4 If a Supply Failure results from AGC’s negligence, intentional misconduct or breach of this Agreement or the Commercial Quality Agreement [***], then Customer shall not be liable for any portion of any Binding Order which AGC could not deliver, the Minimum Volume commitment shall not apply and AGC shall promptly reimburse Customer for any advance amounts paid by Customer in connection with such Batches. If a Supply Failure results from Customer’s negligence, intentional misconduct or breach of this Agreement or the Commercial

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
Quality Agreement [***] (and is not attributable to any failure to comply with cGMP by AGC), then Customer shall be liable for any portion of any Binding Order which AGC could not deliver due to such Supply Failure (provided that any cancelled Batches shall be subject to Clause 5.8) and the Minimum Volume commitment shall continue to apply. If a Supply Failure does not result from either Party’s negligence, intentional misconduct or breach of this Agreement or the Commercial Quality Agreement, and [***], or either Party disputes in good faith the cause of the Supply Failure, then the Parties shall negotiate in good faith an equitable allocation of costs for the Batches affected by such Supply Failure, including any Purchase Orders cancelled by Customer in accordance with Section 5.12.2.

5.12.5 AGC shall use reasonable efforts to sell to another customer capacity not previously reserved by that other customer at the time of the Supply Failure, filling any Slot that would have been used by Customer had the Supply Failure not occurred. If AGC fills such Slot, then AGC shall reduce Customer’s liability for such Slot by a sum equal to the fee paid or owed by the other customer.

5.12.6 If and when AGC is able to demonstrate to Customer’s reasonable satisfaction that it can resume supply after a Supply Failure, Customer shall resume manufacturing with AGC and cease its own or third party manufacturing of Product to meet Minimum Volumes, subject to Customer’s rights under Clause 5.14.

5.13 AGC will not be deemed to be in breach of the Agreement solely because of the occurrence of a Supply Failure, provided that AGC is not in material breach of any other provision of the Agreement and is continuing to use [***] to remedy the Supply Failure. Notwithstanding the foregoing, if AGC is unable to remedy a Supply Failure within [***] months following the commencement of such Supply Failure despite using [***], then either Party shall have the right to terminate this Agreement upon [***] days prior notice.

Second Source

5.14 Customer shall have the right, at any time during the Term, to establish a Second Source in order to ensure consistency of Product supply, provided that in no event shall AGC supply less than [***]% of Customer’s requirements for BDS except as provided in Clauses 2.1.3 and 5.12. AGC shall provide a technology transfer to such Second Source and Customer will be entitled to a technology transfer to a Second Source in accordance with Clause 15.
6. PACKAGING, DELIVERY, STORAGE AND EXAMINATION

Packaging

6.1 All Cell Lines, Product and perishable Deliverables to be Delivered shall be packaged by AGC in accordance with its applicable packaging SOPs and Regulatory Obligations. AGC will accommodate reasonable Customer specific packaging requests.

Delivery

6.2 AGC shall provide Customer with advance notice of each anticipated date of Delivery and, in any event, shall provide at least [***] Business Days advance notice of each date AGC is to Deliver Product to Customer or Customer’s shipping company.

6.3 Except as set out in Clause 6.5 or in the Specifications, the Product that AGC manufactures pursuant to this Agreement shall be [***]. The Product will be deemed to have been delivered upon the date Product is [***] (“Deliver”, “Delivery” or “Delivered”). Collection may be arranged at any time during normal business hours on Business Days or such other time as may be agreed by the Parties.

6.4 [***] shall not be responsible for or have an obligation to [***] pursuant to this Agreement.

6.5 AGC shall deliver data, results, Batch records, CoA, CoC, IPC (in-process control) and IPM (in-process monitoring) data in form of electronic files (e.g. excel files), and Drug History Records to Customer or its designee by mail or electronic mail.

Release For Further Processing

6.6 Subject to Regulatory Obligations and cGMP, Customer may, by written notice, request that AGC Deliver Product to Customer prior to AGC issuing a Certificate of Analysis for such Product (“Release For Further Processing”). Any Product that is the subject of Release For Further Processing shall, until the applicable Certificate of Analysis is issued by AGC:

6.6.1 not be administered to any human;

6.6.2 be handled by Customer with reasonable care and attention and treated with caution as if it were an unknown substance;

6.6.3 be accepted at Customer’s sole risk and liability and AGC shall not be liable for any loss or damage caused by Product which is the subject of Release For Further Processing other than for death or personal injury caused by AGC’s negligence, gross negligence or intentional misconduct.

Title and Risk

6.7 Title and risk in the Deliverables shall pass to Customer on Delivery.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
6.8 Where Customer elects to have a shipping company or other agent (“Shipping Company”) collect and transport the Product upon Delivery, Customer shall, prior to the collection of the Product, inform AGC of its designated Shipping Company. Customer shall coordinate with such Shipping Company for the shipment of the Product and AGC shall not be responsible for any shipping costs of the Shipping Company.

6.9 If Customer or Customer’s Shipping Company is unable to collect a Product scheduled to be picked up at the time of Delivery, AGC shall, upon the Customer’s request, store at its facility any such Product for a period of [***] Business Days after Delivery on behalf of Customer (the “Initial Storage Period”). Storage of Product at AGC’s premises after the Initial Storage Period shall be at Customer’s sole risk and liability except that AGC shall be responsible for damage to such Product to the extent any damage is caused during such storage by an act of AGC’s [***]. If Product has not been collected by Customer or Customer’s Shipping Company by the end of the Initial Storage Period, AGC shall notify Customer in writing of the outstanding collection. AGC shall be entitled, commencing [***] Business Days after Customer’s receipt of such notice, to charge Customer $[***] per week per Batch for the continued storage of such Deliverable, unless the Parties have previously negotiated for longer term storage.

6.10 Customer may, prior to Delivery, request that AGC arranges for storage of Product prior to the Product being transported to a location specified by Customer (“Alternative Site”) subsequent to its Delivery. Where AGC agrees to such a request:

6.10.1 Customer shall provide AGC with [***] the Alternative Site;

6.10.2 storage organized by AGC shall be at AGC’s sole cost, risk and liability; and

6.10.3 AGC shall, in the Customer’s name and at the Customer’s cost, insure the Product until such time as they are transported to the Alternative Site.

6.11 If Customer shall or intends to examine or test the Product and wishes to reserve its right to make a claim against AGC under this Article 6 in respect of a Defect in such Product, Customer undertakes to ensure that such Product since collection from AGC’s Facility or transport to the Alternative Site has been stored and transported in accordance with the applicable Shipping Guidelines. Failure by Customer to comply with such Shipping Guidelines in a manner that could reasonably cause or contribute the occurrence of such Defect before or after serving a Defect Notice (as defined below) will invalidate Customer’s right to make any claim under this Agreement in respect of such Product.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
Examination of Deliverables for Defects etc.

6.12 Following their Delivery, Customer shall promptly examine and test the Deliverables for any defect or non-conformity, including in the case of Product or BDS non-conformity with the Specifications and cGMP standards which Deliverables are specified to meet (a “Defect”, with such Product or BDS being “Defective”). Where any alleged Defect is identified, Customer shall notify AGC by written notice (“Defect Notice”) (a) within [***] Business Days of Customer’s or its agent’s receipt of the Deliverables, other than for Latent Defects, and (b) within [***] Business Days of becoming aware of a Latent Defect. A “Latent Defect” means a Defect that cannot be reasonably detected by the testing procedures used by Customer. AGC will have no liability for a Latent Defect unless [***].

6.13 A Defect Notice must identify (i) the Deliverable and, in the case of Product, the Batch from which the Product was derived, (ii) the date(s) of Delivery and collection (or where the Deliverables are transported to the Alternative Site, the date received at the Alternative Site), (iii) reasonable detail, including test results, of the Defect, (iv) where applicable, disclosure of the methodology of all analytical tests performed on the Deliverables and the results of those tests, (v) confirmation that the Deliverables have been stored and transported in accordance with the applicable Shipping Guidelines and (vi) where the Customer asserts that the Defect is due to AGC, the reasons why the Customer makes that assertion. If a Defect in any Deliverable is not notified to AGC in accordance with the provisions and time limits stipulated in Clauses 6.12, the Deliverable shall be deemed accepted and free of Defects and, Customer shall have no further remedy against AGC in respect of that Deliverable under this Clause 6. For clarity, nothing in this Clause 6.13 shall affect AGC’s indemnification obligations under Clause 12.

6.14 Upon receipt of the Defect Notice, AGC shall promptly investigate whether or not the Defect is due to AGC’s negligence or failure to comply with its obligations hereunder and shall report to Customer within [***] Calendar Days of receipt of the Deliverables whether it accepts responsibility for the Defect in full, in part or not.

6.15 If there is a dispute regarding whether or not a Deliverable is Defective (“Disputed Deliverable”), then (a) personnel from both Parties will directly communicate to determine the Parties’ respective methods of analysis are the same and are being executed in the same manner, and to attempt to determine whether any non-compliance may have been caused during the shipment of the Deliverable from AGC’s Facility, and (b) carefully controlled and split samples as agreed should be sent from one site to another for testing in an attempt to reach agreement (which may involve Customer sending a representative and a sample of the Disputed Deliverable to AGC, and the Parties conducting jointly agreed upon tests on the Customer sample of the Disputed Deliverable and a sample of the Disputed Deliverable retained by AGC). The Parties will use good faith efforts for a period of [***] days after completing such tests to resolve whether the Disputed Deliverable is Defective due to AGC’s failure to manufacture in accordance with this Agreement. In the event the Parties cannot resolve their dispute in the manner described, a mutually agreed-upon independent laboratory shall be engaged to test the Disputed Deliverable. The costs of such independent laboratory

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
shall initially be borne by the Parties equally; provided, however, the Party that is determined by such laboratory to be incorrect in the dispute shall be responsible for all such reasonable out of pocket costs in engaging such laboratory and shall reimburse the correct Party for its share of such reasonable costs incurred. The decision of such independent laboratory shall be in writing and shall be binding on both AGC and Customer. With respect to all Product that Customer properly rejects, Customer shall destroy all remaining unused Product as soon as possible after AGC’s request. In no event may Customer use any of the rejected Product for any human clinical testing or trials after it becomes aware of the basis for such rejection (and Customer shall indemnify AGC for all liabilities, costs and damages incurred by AGC resulting from Customer’s breach of this limitation on use in accordance with Clause 12).

Consequences of Defective Product

6.16 If Customer can demonstrate or if the independent laboratory pursuant to Clause 6.15 determines that the Defect is not the result of any wrongful action or inaction by Customer or a Customer-Provided Materials (or, if attributable to the Customer-Provided Materials, is the result of any failure to comply with cGMP by AGC) or any Third Party (other than a contractor or agent of AGC performing Services), then AGC shall replace the Defective Deliverables. AGC shall use its [***] to commence the manufacture of such Defective Deliverables within [***] days after AGC accepts fault or is determined to be at fault pursuant to Clause 6.15, [***]. In the event AGC cannot commence the manufacture of a replacement single Batch within such [***] days period or within [***] days after the end of a campaign if the Defective Batch was part of a campaign, [***]. Any amounts paid by Customer hereunder for such Defective Deliverables shall be credited to future amounts due to AGC hereunder, and any residual amounts existing at the time of termination of this Agreement shall be subject to Clause 14.4.

6.17 The remedies and obligations under Clause 6.16 shall be Customer’s sole remedy for Defective Deliverables, subject to Clause 12.2 (Indemnity of Customer).

7. BATCH PRICE, PAYMENT TERMS AND MILESTONE PAYMENTS

7.1 Customer shall make an initial payment of [***] Euros [***] and a further payment of [***] Euros [***] (collectively, the “Reserve Payment”). Following approval of the BLA for the Product, AGC shall, at Customer’s election, reimburse the Reserve Payment or offset the Reserve Payment against future Batches. Additional payment for Batches will be due as described in Appendix Two. The Batch Price in

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Appendix Two is stated in Euros and is exclusive of all taxes, duties, or other fees of whatever nature imposed by or under the authority of any state, government or public authority (other than taxes on AGC’s income), or any external costs, Raw Materials or shipping and associated costs that AGC incurs to provide the Services, which Customer agrees to pay in addition to the Batch Price.

7.2 The Batch Price stated in Appendix Two may increase on an annual basis on the anniversary of the Effective Date, commencing in [***], in accordance with the Producer Price Index that is applicable on the date of such anniversary of the Effective Date. The “Producer Price Index” means the Producer Price Index published by the Bureau of Labor Statistics (or if such index is discontinued, the successor index or, if none, such other similar index mutually agreed upon by the Parties).

7.3 If there are any material and unforeseen changes in cGMP or manufacturing regulations promulgated pursuant to enabling legislation under a statute that:

7.3.1 are specific to the Product and not of general requirement for biologics contract manufacturing services; or
7.3.2 which result in the financial returns under this Agreement being substantially affected to AGC’s detriment other than by the acts or omissions of AGC,

then the Parties shall negotiate in good faith a way to continue the Services to comply with such changes and/or address the financial detriment.

Invoicing & Payment Terms

7.4 All invoices will be in Euros and Customer agrees to pay all sums due hereunder in Euros.

7.5 AGC will issue invoices in accordance with the provisions of Appendix Two.

7.6 All invoices shall be paid by wire transfer to the following account:

ACCOUNT DETAILS:

[***]

SWIFT:

[***]

Bank accounts details:

[***]

[***] = Certain Confidential Information Omitted
Unless expressly stated on an invoice to the contrary, all invoices are issued net and if not disputed in good faith in writing before the due date, will be paid in full without any deductions, deferment or set off (except as expressly permitted herein) by Customer within [***] or such other address as Horizon may provide in writing pursuant to Clause 18.11. If Customer disputes an invoice, Customer shall notify AGC in writing of the dispute before the due date of the invoice, which notice must include a detailed description of the dispute and, if applicable, the relevant contract provisions. The Parties shall use reasonable efforts to resolve the dispute as quickly as possible. If the dispute is not resolved within [***] days after the date of Customer’s notice, the CEOs or designated persons of at least vice president level of the Parties shall meet and attempt in good faith to resolve the dispute. If the dispute remains unresolved [***] days after such individuals undertake to resolve such dispute, then Customer shall, on written request of AGC, pay the disputed portion to a mutually acceptable escrow agent to be held pending resolution of the dispute.

7.7 Customer shall pay to AGC, in addition to the Batch Price and the charges for the Raw Materials, a sum in respect of AGC’s storage of Raw Materials purchased by AGC for the Services as set forth in Appendix Two ("Storage Cost"). AGC shall invoice Customer on a [***] basis for the Storage Cost incurred during the Services.

7.8 Raw Materials and shipping costs for all Services will be invoiced to Customer as set forth in Appendix Two.

Late Payments

7.9 If the portion of an undisputed invoice is not settled by Customer in full in accordance with this Agreement and after providing the Customer with [***] days prior written notice to settle such undisputed portion of an invoice following the due date therefor, AGC may, at its discretion:

7.9.1 charge Customer, which Customer will pay, interest at a rate of [***]% per month on the sums overdue on a compounded basis until payment is received in full and/or;

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
7.9.2 until the portion of the invoice is received in full, suspend the performance of the Services, provided that AGC has provided Customer with [***] days prior written notice of its intent to suspend the Services. Where performance is suspended, AGC shall have no liability to Customer for such suspension or delay in the Timeline and the Batch Price for any Batches that are the subject of a Binding Order which are delayed or cancelled as a result of the suspension shall become due and payable by Customer.

Payments due to Customer

7.10 Where any payment, credit or refund is properly due to the Customer under this Agreement, the Customer can elect to:

7.10.1 have that amount refunded to it by AGC on [***] days’ notice; or

7.10.2 have that amount set-off against any further amount payable by the Customer under this Agreement or any future agreement the Parties enter into.

7.11 Where Customer elects to have an amount set-off against any further amount payable by the Customer under this Agreement and, subsequent to that credit, the Customer remains entitled to a payment, credit or refund, AGC shall refund that amount to the Customer within [***] days of the Customer requesting AGC refund that amount.

8. CUSTOMER AUDITS, REGULATORY INSPECTIONS & MATTERS

Audits

8.1 Customer’s audit rights are as set forth in the Commercial Quality Agreement.

Regulatory Inspections

8.2 Regulatory inspections are addressed in the Commercial Quality Agreement. AGC shall upon reasonable notice and during reasonable times make available facilities, documents, information and/or personnel as are reasonably necessary or useful pursuant to and during regulatory inspections by Regulatory Authorities as further set forth in the Commercial Quality Agreement.

Regulatory Filings and Standards

8.3 During the preparation for filing with any Regulatory Authority of any documentation which is or is equivalent to the Regulatory Authority’s Chemistry and Manufacturing Controls (“Authority Submission”) portion of applicable approval application, including any New Drug Application, Abbreviated New Drug Application (ANDA), Marketing Approval Application (MAA) or other approval, as the case may be, Customer shall provide AGC with a copy of the relevant Authority Submission portion as well as all material supporting documents which have been relied upon to prepare the Authority Submission portion so as to permit AGC to verify that the Authority Submission portion accurately describes the work that AGC has performed and the manufacturing processes that AGC will perform pursuant to this Agreement. AGC shall provide Customer with its comments within [***] Business Days from receipt of the documents.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

COMMERCIAL SUPPLY AGREEMENT

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

COMMERCIAL SUPPLY AGREEMENT

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8.4 For clarity, the Parties agree that in reviewing the documents referred to in Clause 8.3 above, AGC’s role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by AGC. As such, AGC shall not assume responsibility or liability for the accuracy of the filings with Regulatory Authorities other than for information provided by AGC in writing and intended for inclusion in regulatory filings. The sole responsibility of the preparation and filing of all regulatory documents with the Regulatory Authorities shall be borne by Customer.

8.5 Customer shall provide to AGC:

8.5.1 all documents reasonably necessary or reasonably requested by AGC relating to any Regulatory Authority’s pre-approval inspection of AGC’s Facility, including but not limited to, development reports, Chemistry and Manufacturing Controls documentation and stability data, subject to Customer being able to legally provide such documents to AGC; and

8.5.2 to the extent reasonably practicable, at least [***] days prior to [***] by AGC, Customer shall [***].

8.6 AGC will provide Customer with information and data regarding the manufacture of Product to the extent reasonably requested by Customer or necessary for Customer to prepare and defend any inquiries from the FDA or other Regulatory Authorities to satisfy regulatory requirements with respect to Product. Without limiting the foregoing,

8.6.1 AGC shall provide regulatory support to Customer for a Regulatory Authority’s pre-approval inspection, or PAI, of the AGC Facility and during review of any Regulatory Authority submission at a cost specified in Appendix Two. AGC shall allocate the costs of any post-approval inspection equally among its commercial customers.

8.6.2 Customer will inform AGC of requests for information from Regulatory Authorities during review of a Regulatory Authority submission for which AGC support is needed. AGC will use [***] to adhere with the turn-around times requested by Customer to support such regulatory responses.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
8.7 On reasonable advance notice to AGC, Customer’s employees or representatives may be present at the AGC’s facilities to observe Product and BDS manufacture, subject to AGC’s reasonable site rules, regulations and room capacity constraints.

9. **WARRANTIES**

Customer Warranties

9.1 Customer warrants and represents to AGC that:

9.1.1 it has the right to supply and deliver to AGC the Customer Materials (including the Cell Line provided by or on behalf of Customer where applicable) and the Customer Intellectual Property Rights and AGC has the right to use the same for the Services and the manufacture of Product, in each case in accordance with this Agreement;

9.1.2 to the best of its knowledge as of the Effective Date, the Materials Safety Data Sheets for the Customer-Provided Materials are accurate and the Customer-Provided Materials are free from all contaminants including, without limitation, virus, bacteria or other vectors. Customer will advise AGC immediately of any safety or toxicity issues of which it becomes aware regarding the Customer-Provided Materials that are not included in the applicable Materials Safety Data Sheet;

9.1.3 to the best of its knowledge as of the Effective Date, AGC’s use of any of the Cell Line, Customer Materials, Customer Intellectual Property Rights and the Process, and AGC’s manufacture of Product, in each case in accordance with this Agreement, will not infringe any Intellectual Property of Third Parties;

9.1.4 the license of or other access to Customer Intellectual Property Rights to AGC for the Services is lawfully granted; and

9.1.5 to the best of its knowledge as of the Effective Date, the Cell Line and Process provided by or on behalf of the Customer and Customer-Provided Materials are viable, adequate and suitable for the effective performance of the Services and manufacture of Product according to Specification.

AGC Warranties

9.2 AGC warrants and represents to Customer that:

9.2.1 its permits and regulatory licenses applicable for the Services and the manufacture of the Product are valid;

9.2.2 to the best of AGC’s knowledge as of the Effective Date, it has the necessary facilities, Third Party contractors and skilled personnel that may be reasonably anticipated to be necessary of a biologics contract manufacturer for the regular provision of manufacturing and development services of biologic material and required for performance of the Services in accordance with this Agreement;
9.2.3 all Deliverables shall be Delivered free of encumbrances or liens but for the avoidance of doubt no warranty is given in this Clause 9.2.3 in respect of non-infringement of Third Party Intellectual Property or freedom to use;

9.2.4 to the best of its knowledge as of the Effective Date, AGC’s use of the AGC Intellectual Property Rights used in the Services will not infringe any Third Party Intellectual Property, except that no warranty is given to the extent that infringement arises due to the combination of AGC Intellectual Property Rights used together with the Cell Line, Process, Customer Materials and Customer Intellectual Property Rights and would not occur when the AGC Intellectual Property Rights are used in the production of biologics generally ("Customer-Specific Infringement");

9.2.5 All Product manufactured and supplied under this Agreement and released with a Certificate of Analysis by AGC shall at the date of release conform to the specifications set forth in that Certificate of Analysis;

9.2.6 All Product manufactured under this Agreement shall be manufactured, handled, stored, labelled, packaged and transported in accordance with applicable cGMP requirements, the Commercial Quality Agreement, the applicable BLA and all applicable laws, rules, regulations and guidances in the US or EU (including, without limitation, Section 262 of the PHS Act);

9.2.7 No Product manufactured and supplied under this Agreement shall be (a) adulterated or misbranded within the meaning of the U.S Food, Drug and Cosmetics Act ("FD&C Act"), or (b) an article that may not be introduced into interstate commerce under the provisions of Sections 404 or 505 of the FD&C Act; and

9.2.8 AGC 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 Product under the Agreement.

Mutual Warranties

9.3 Each Party warrants and represents to the other that:

9.3.1 it has the right and corporate authority to enter into this Agreement and perform its obligations hereunder;

9.3.2 it will comply with all applicable laws, rules and regulations in connection with its performance under this Agreement; and

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it shall obtain and during the Term maintain in force all applicable permits and regulatory licenses required in connection with the handling, transport and storage of the Cell Line and Product and performance of the Services.

Exclusion of other express and implied warranties

Except as provided in this Agreement, to the maximum extent permitted by applicable law, except for those express warranties set out above, the Parties neither make nor give any other express or implied (whether by statute, custom or otherwise) warranties in relation to each of their respective obligations, duties or activities owed or performed under this Agreement and hereby exclude any other such express or implied warranty in respect of that subject matter.

10. CONFIDENTIAL INFORMATION

10.1 In consideration of one Party (the “Disclosing Party”) making available its Confidential Information to the other (the “Recipient Party”), the Recipient Party hereby undertakes that it shall:

10.1.1 treat and safeguard as private and confidential all the Disclosing Party’s Confidential Information;

10.1.2 use the Disclosing Party’s Confidential Information only during the Term for those purposes reasonably necessary for the fulfilment of its obligations or exercise of its rights under this Agreement;

10.1.3 ensure the proper and secure storage of the Disclosing Party’s Confidential Information applying no less stringent than standards applied to protection of Recipient Party’s own confidential information but, in any event, no less that reasonable care; and

10.1.4 not at any time without the Disclosing Party’s prior written consent disclose or reveal, whether directly or indirectly, any of the Disclosing Party’s Confidential Information to any person whatsoever except its and its Affiliates’ directors, officers, employees, contractors (including Testing Laboratories), advisors and representatives (“Permitted Recipients”) who have a need to know such information for the purposes hereof and who, prior to the receipt of such Confidential Information, are subject to legally enforceable obligations of confidentiality and non-use at least as stringent as those set forth herein. The Recipient Party shall remain directly responsible to the Disclosing Party for any non-compliance with this Agreement by any of the Recipient Party’s Permitted Recipients.

10.2 The Recipient Party’s obligations in this Agreement regarding the Disclosing Party’s Confidential Information do not apply to information:
10.2.1 which, at the time of its disclosure by the Disclosing Party or generation hereunder, was generally available to 
the public;

10.2.2 which becomes generally available to the public after such disclosure or generation other than by reason of a 
breach of any of the undertakings in this Agreement by the Recipient Party or its Permitted Recipients;

10.2.3 which is, at the time of such disclosure or generation, and as evidenced by the Recipient Party’s written records, 
lawfully already within the Recipient Party’s possession;

10.2.4 was lawfully disclosed to the Recipient Party on a non-confidential basis by a Third Party who is not subject to 
an obligation of confidentiality with respect to such Confidential Information; or

10.2.5 was discovered or created by or for the Recipient Party without the use, application or benefit of any of the 
Disclosing Party’s Confidential Information.

10.3 The Recipient Party may disclose the Disclosing Party’s Confidential Information hereunder:

10.3.1 to the extent such disclosure is reasonably necessary for prosecuting or defending litigation, complying with 
applicable laws or regulations, or exercising its rights or fulfilling its obligations hereunder; provided that if the 
Recipient Party is required by law or regulation to make any such disclosure of the Disclosing Party’s 
Confidential Information it shall, except where impracticable for necessary disclosures (for example in the event 
of medical emergency), give reasonable advance notice to the Disclosing Party of such disclosure requirement 
and shall use its reasonable efforts to assist the Disclosing Party to secure a protective order or confidential 
treatment of such Confidential Information required to be so disclosed; and

10.3.2 such disclosure is reasonably necessary: (a) to such Party’s directors, attorneys, independent accountants or 
financial advisors for the sole purpose of enabling such directors, attorneys, independent accountants or financial 
advisors to provide advice to such Party, provided that in each such case on the condition that such directors, 
atorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations 
substantially consistent with those contained in this Agreement; or (ii) to actual or potential investors, acquirors, 
merger partners, (sub)licensees and other financial or commercial partners solely for the purpose of evaluating or 
carrying out an actual or potential investment, acquisition, merger, collaboration or other transaction; provided 
that in each such case on the condition that such Persons are bound by confidentiality and non-use obligations 
substantially consistent with those contained in the Agreement, and Recipient Party shall remain directly 
responsible to Disclosing Party for any breach by any such Person of such obligations.
Other than the limited and restricted rights of use set out in this Clause 10 and in Clause 11, nothing in this Agreement intends to or has the effect of granting any right, title, license or interest in or to the Recipient Party or Permitted Recipients in respect of the Disclosing Party’s Confidential Information.

If the Recipient Party or any of its Permitted Recipients becomes aware of any misuse of the Confidential Information or a breach or threatened breach of this Clause 10 occurs or becomes apparent, the Recipient Party shall inform the Disclosing Party in writing of such obligation or fact as soon as possible after it is informed, or becomes aware, of it and if possible, before any Confidential Information is disclosed, so that (if the Disclosing Party in its absolute discretion shall see fit) a protective order or other appropriate remedy may be sought. The Recipient Party agrees to reasonably assist and co-operate (and shall procure that each of its Permitted Recipients shall, as appropriate, assist and co-operate) in any action which the Disclosing Party may decide to take.

Upon termination or expiry of this Agreement or at the request of the Disclosing Party, the Recipient Party shall at its election promptly destroy or return to the Disclosing Party any and all Confidential Information (including copies of documents, computer records and records on all other media) then in its possession or under its control except where such Confidential Information is covered under surviving license rights between the Parties. Notwithstanding the foregoing, (a) each Recipient Party may retain a single copy of any document contained the Disclosing Party’s Confidential Information solely for the purpose of determining the scope of the obligations under this Agreement, and (b) the Recipient Party may retain any electronic copies of the Disclosing Party’s Confidential Information held securely in the Recipient Party’s electronic backup storage in accordance with its established document retention policies; subject in each case to the Recipient Party’s continuing confidentiality and non-use obligations under this Agreement with respect to such Confidential Information.

The Parties acknowledge that they have received Confidential Information under other agreements between each other. The Parties hereby agree that Confidential Information received under those earlier agreements may be used for the purposes of performing the Services under this Agreement.

The provisions of this Clause 10 shall survive termination of the Agreement for a period of [***] years.

For the avoidance of doubt, the provisions of this Clause 10 do not restrict the Customer’s right to disclose or otherwise use and exploit the Deliverables after such Deliverables have been Delivered to the Customer.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
10.10 Except as otherwise provided for in this Agreement or required by any applicable law, regulation or order of an administrative agency or court of competent jurisdiction, neither Party shall use the name of the other Party or of the other Party’s Affiliates, directors, officers or employees in any advertising, news release or other promotional release without the prior consent of the other Party, which shall not be unreasonably withheld or delayed.

11. INTELLECTUAL PROPERTY

Pre-Existing Intellectual Property

11.1 Any Intellectual Property owned or Controlled by a Party as of the Effective Date or developed or acquired by such Party during the Term independently from this Agreement without use of the other Party’s Confidential Information (“Background Technology”) shall, as between the Parties, remain the sole and absolute property of the Party that owns or Controls such Background Technology. Nothing in this Agreement shall act as any assignment or transfer of either Party’s Background Technology. A Party’s Background Technology shall not be licensed to the other Party under this Agreement unless an express license is granted hereunder.

Customer’s grant of Intellectual Property License for the Services

11.2 The Customer hereby grants to AGC for the Term a non-exclusive, royalty-free, sublicensable (solely with the prior written consent of the Customer), limited license under the Customer Background Technology and Customer Agreement IPR solely to the extent the same is required and necessary for the proper performance of the Services. This license:

11.2.1 does not prevent the Customer from granting a license to or making any use of its Background Technology or Customer Agreement IPR, and

11.2.2 terminates automatically upon the expiry or termination of this Agreement, whichever is the earlier.

Intellectual Property created in the course of the Services

11.3 Without affecting Clauses 11.1 and 11.2, all data, results, information, processes, materials, trade secrets, know-how and corresponding Intellectual Property newly generated by AGC in its performance of the Services and to the extent [***] (“Customer Agreement IPR”) shall be solely and exclusively owned by Customer. AGC hereby assigns to Customer all right, title and interest in and to all Customer Agreement IPR. AGC shall cooperate with Customer and execute any appropriate documents to fully effect the foregoing. All Customer Agreement IPR shall be deemed to be Customer’s Confidential Information.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
11.4 All Intellectual Property other than Customer IPR generated by AGC under the Services that is useful for general biologics manufacturing activities shall be owned by AGC ("AGC IPR").

11.5 In the event that [***].

License to AGC IPR

11.6 AGC hereby grants to Customer a general, royalty free, sub-licensable, worldwide, perpetual license to use AGC Intellectual Property Rights and AGC IPR to the extent that the same is necessary or useful for the exploitation of the Product or use of the Cell Line or Process to manufacture the Product. Except to Permitted Recipients or as otherwise provided in this Agreement, nothing in the foregoing shall permit Customer to make any disclosure of AGC’s Confidential Information (including AGC’s Know-How) to a Third Party without the express prior written consent of AGC, not to be unreasonably withheld, conditioned or delayed. This license does not prevent AGC granting a license to or making any use of AGC Intellectual Property Rights or AGC Agreement IPR.

Right to file for protection

11.7 Each Party may file patent protection on any Intellectual Property it owns in accordance with this Clause 11 above and the other Party shall promptly upon request co-operate at the requesting Party’s reasonable expense, with any requests to assist or enable the Party’s protection including but not limited to signing and delivering documents and other information necessary for the valid application and prosecution of any such patent.

Notice of Infringement

11.8 Each Party will promptly notify the other Party of any allegation of infringement or misappropriation of any Third Party Intellectual Property due to the handling, storage or use of the Cell Line, Customer Materials, Customer Intellectual Property Rights, AGC Intellectual Property Rights or manufacture of Product hereunder.

Use of Company Materials, Products and Deliverables

11.9 AGC will use the Customer Materials, Products, Deliverables and any documents relating thereto only for the conduct of the Services, and not for any other purpose without Customer’s prior written consent. AGC will retain control over the Customer Materials, Products, Deliverables and any documents relating thereto and, except as expressly agreed in writing by

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Customer, will not transfer or otherwise provide access to any Customer Materials, Products, Deliverables or any documents relating thereto to any other Persons other than those performing Services hereunder and who are subject to like written obligations to protect the Customer Materials, Products, Deliverables and any documents relating thereto. The Customer Materials, Products and Deliverables may have unknown characteristics and AGC will therefore use prudence and reasonable care in the use, handling, storage, transportation and disposition and containment of the Customer Materials, Products and Deliverables.

12. INDEMNITIES AND LIABILITY

Indemnity of AGC

12.1 (a) Subject to Section 12.3, and to the extent permitted by applicable law, Customer shall promptly indemnify, defend and hold harmless AGC and each of its directors, officers, employees, contractors (including Testing Laboratories) and representatives (the “AGC Parties”) against any and all losses, demands, claims, liabilities, damages, costs and expenses (including but not limited to, court costs and reasonable documented attorney’s fees and expenses together with any applicable taxes thereon) (“Liabilities”) arising from any claim, action or proceeding brought or initiated by a Third Party (a “Claim”) that the AGC Parties may or have suffered or incurred directly as a result of the following: (i) any actual or alleged infringement or misappropriation of any Third Party Intellectual Property due to AGC’s use of the Cell Line, Process, Customer Intellectual Property Rights, Customer-Provided Materials, or performance of the Services or manufacture of Product in accordance with this Agreement; (ii) the use, handling, distribution, marketing, sale of the Product manufactured hereunder by or on behalf of a Customer Party; (iii) injury or death caused by the administration of Product manufactured hereunder; (iv) negligence, gross negligence or intentional misconduct committed by a Customer Party; or (v) breach of this Agreement (including any representation or warranty) by Customer.

(b) [***]

(c) The foregoing indemnities shall not apply to the extent the Claims or Liabilities arose from the negligence, gross negligence, breach of this Agreement or the Commercial Quality Agreement, or intentional misconduct of any AGC Party, are attributable to the AGC Materials or are covered by an indemnity under Clause 12.2.

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Indemnity of Customer

12.2 Subject to Section 12.3, and to the extent permitted by applicable law, AGC shall promptly indemnify and hold harmless Customer and each of its directors and officers, employees, agents, contractors or representatives ("Customer Parties") against any and all Liabilities arising from a Claim that the Customer Parties may or have suffered or incurred directly as a result of the following: (i) inaccurate Certificates of Analysis such that the certified Product at the time of Delivery does not meet Specification when certified to meet Specification, failure to manufacture Product according to cGMP, use of improper Batch records, use of contaminated and/or inappropriate Raw Materials; (ii) negligence, gross negligence or intentional misconduct committed by a AGC Party; (iii) breach of this Agreement (including any representation or warranty) by AGC; (iv) any failure of the AGC Materials; or (v) any actual or alleged infringement or misappropriation of any Third Party Intellectual Property due to AGC’s use of the AGC Intellectual Property Rights that is not a Customer-Specific Infringement.

The foregoing indemnities shall not apply to the extent the Claims or Liabilities arose directly from the negligence, gross negligence, breach of this Agreement or the Commercial Quality Agreement or intentional misconduct by any Customer Party or are covered by an indemnity under Clause 12.1.

Indemnification Procedure

12.3 The Party (the “Indemnitee”) that intends to claim indemnification under this Clause 12 shall:

12.3.1 promptly, and in any event within [***] Calendar Days of it receiving notice of the Claim, threat or action, notify the other Party (the “Indemnitor”) in writing in general terms of any Claim, threat or action which has or has the potential to give rise to the Indemnitee seeking to rely on and claim the benefit of the indemnification together with notification of the Indemnitee’s intention to rely on such indemnity, provided that, failure to give such notice shall not relieve the Indemnitor of its indemnification obligations except and only to the extent such failure actually and materially prejudices the ability of the Indemnitor to defend against such Claims, provided that that the foregoing shall not prevent the Indemnitee from complying with the procedural requirement of any proceedings which have been commenced;

12.3.2 not prejudice any defense to any Claim or attempt to settle or compromise such claim;

12.3.3 subject to its other rights and obligations and compliance with the procedures set out in this Clause 12, permit the Indemnitor to have overall control of the conduct of the negotiations and the proceedings including any counterclaim;

12.3.4 cooperate as reasonably requested by the Indemnitor, at the Indemnitor’s expense, in the conduct of such Claim (and any counterclaim); and

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12.3.5 have the right (at its own expense) to engage independent counsel and participate in all proceedings and negotiations whether named or not as a party in the Claim or proceedings.

12.4 Notwithstanding any other provision in this Clause 12, the Indemnitor shall not settle or consent to an adverse judgement in any such claim, demand, action or other proceeding that adversely affects the rights or interests of any Indemnitee or imposes additional obligations (financial or otherwise) on such Indemnitee, without the prior express written consent of such Indemnitee (such consent to be at the Indemnitee’s sole discretion).

Insurance

12.5 Customer shall procure from a reputable insurance carrier commercial general liability insurance including coverage for products and completed operations and contractual liability (including coverage for advertising and personal injury) with a combined single limit of no less than [***] dollars ($[***]) per occurrence and [***] dollars ($[***]) in the aggregate. Customer will maintain such insurance during the Term of this Agreement and for [***] years after the last sale of a Commercial Product, subject to continued availability at commercially reasonable rates. Upon reasonable request, Customer will deliver a certificate of insurance evidencing such coverage and an endorsement of additional insured in favor of AGC.

12.6 AGC shall maintain, at its expense, comprehensive general liability insurance and workers compensation insurance, including product liability insurance, in the amount of [***] dollars ($[***]) per occurrence and [***] dollars ($[***]) in the aggregate. All insurance required under this Agreement shall be maintained during the Term, and AGC shall from time to time provide copies of certificates of such insurance to Customer upon reasonable request. Notwithstanding the preceding sentence, AGC shall be obligated to maintain product liability insurance obtained by it pursuant to this Clause 12.6 during the Term and after expiration or termination of this Agreement for a period [***] years following the Commercial Product expiration date for the last lot of Commercial Product delivered hereunder.

12.7 Each Party will provide the other Party with at least [***] days’ written notice prior to non-renewal, termination or modification of their respective insurance coverage as described above.

Limitation of Liability

12.8 The Parties represent and acknowledge that they have negotiated the terms of this Agreement and have reached agreement on the terms based on their own assessment of their own risks, liabilities and rewards in connection with this Agreement and the Product in addition to having had the benefit of professional legal advice and accordingly the Parties agree that, without prejudice to Clauses 12.9 and 12.10, AGC’s aggregate liability to Customer for any loss or damage suffered by Customer, as a result of breach of this Agreement or of any other liability (including but not limited to negligence, misrepresentation or claim under the indemnities) in respect to any claim arising under this Agreement or in connection with the Services shall be limited to the lesser of (a) the total amounts paid by Customer hereunder [***], or (b) [***] euros (€[***]).

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12.9 Neither AGC nor Customer shall be liable for any loss or damage howsoever caused (even if foreseeable or in the contemplation of AGC or Customer) in respect of:

12.9.1 loss of indirect profits, business, business opportunities or revenue; and
12.9.2 special, indirect or consequential loss.

12.10 Notwithstanding the foregoing, nothing in this Agreement shall purport or attempt or serve to exclude or restrict any liability for (i) gross negligence or intentional misconduct; (ii) any fraud or fraudulent misrepresentation; (iii) amounts owing by a Party under Clause 7 (subject to Clause 14.4); (iv) claims subject to Customer’s indemnification obligations under Clause 12.1(a); or (v) a breach of confidentiality.

13. PRODUCT RECALL

13.1 Subject to Clause 13.3.1, the costs and obligations with respect to any Recall of Product and handling enquiries and contacts from any Regulatory Authority relating to any Recall of Product shall be the responsibility of Customer. Customer shall notify all Regulatory Authorities having jurisdiction over Product (whether or not the issue arose in the jurisdiction controlled by the Regulatory Authority) of any Recall, and shall be responsible for coordinating all necessary activities regarding the action taken. AGC shall, at Customer’s expense, provide all reasonable assistance to Customer in connection with any Recall. The Parties agree to keep each other advised of any Recall, the progress of undertaking any Recall, and to exchange copies of such documentation as may be reasonably required, to assure regulatory compliance with a Recall.

13.2 If either Party has reason to believe that any Product (whether the Product itself or particular Batch(es)) should be Recalled, such Party shall promptly inform the other in writing, to also include the reasons and explanations for the Recall, prior to taking any such action. In addition, Customer shall give AGC prompt written notice of any Recalls that Customer believes were caused by or may have been caused by AGC’s failure to comply with its obligations under this Agreement.

13.3 If any Product is Recalled for safety reasons or due to a mandatory notification from a Regulatory Authority dictating the Recall and, in either case, such reasons are directly a result of AGC’s failure to manufacture Product in accordance with the terms of this Agreement or the Commercial Quality Agreement or [***] (“Manufacturing Failure”), then AGC shall, subject to Clause 12, reimburse Customer for all reasonable expenses actually and properly incurred by Customer in undertaking the Recall of those

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specific Products which are the subject of a Manufacturing Failure. Such payment shall be made within [***] days of Customer providing AGC will a detailed breakdown of such costs and responses to all requests for clarification by AGC with respect thereto. If AGC disputes that the Recall is:

13.3.1  due to safety reasons or mandatory notification from a Regulatory Authority dictating the Recall then the Parties shall mutually select a regulatory expert to evaluate whether the Recall was appropriate to address the safety reason or comply with the Regulatory Authority’s notice (as applicable); and/or

13.3.2  due to AGC’s Manufacturing Failure, then the Parties shall mutually select an independent laboratory to evaluate whether the Product is Defective due to AGC’s Manufacturing Failure; and

the evaluation(s) by the regulatory expert and/or independent laboratory shall be binding on the Parties (other than where such decision is a manifest error). If such evaluation upholds any part of AGC’s dispute then the Parties shall share the costs of the Recall pro rata. Subject to Clauses 9 and 12, any payment by AGC under this Clause 13.3 shall be Customer’s sole remedy for the costs of the Recall.

14.  TERM AND TERMINATION

14.1  This Agreement shall commence on and have effect as of the Effective Date and will, subject to earlier termination in accordance with this Clause 14 or otherwise, continue until terminated by either Party upon at least three years notice (and provided that such notice cannot be provided prior to the 4th anniversary of the Effective Date)(the “Term”).

14.2  Customer may terminate this Agreement (a) in accordance with Clause 5.13, or (b) immediately upon written notice if does not obtain regulatory approval for the Product in a major market.

Events of Termination

14.3  Either Party (“Non-Defaulting Party”) may terminate this Agreement before expiry of the Term with immediate effect upon prior written notice to the other Party (“Defaulting Party”) if:

14.3.1  the Defaulting Party fails to pay any undisputed sum payable under this Agreement within sixty (60) Calendar Days of notice demanding payment served after expiry of the original payment term stipulated in Clause 7;

14.3.2  the Defaulting Party commits a material breach of its obligations under this Agreement and if the breach is capable of remedy, fails to remedy it during a period of thirty (30) Calendar Days starting on the date of receipt of notice from the Non-Defaulting Party generally identifying the breach and requiring it to be remedied;

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14.3.3 the Defaulting Party is (i) generally unable to pay its debts as they become due; or (ii) has an administrator appointed or administration order made against it or an order for winding-up or dissolution made (otherwise than in the course of a bona fide reorganization previously approved in writing by the Non-Defaulting Party) or liquidator appointed and such step is not withdrawn within thirty (30) Calendar Days;

14.3.4 any material permit or regulatory license is permanently revoked preventing the performance of the Services by the Defaulting Party.

Effect of Termination

14.4 Upon termination of this Agreement, Customer shall pay to AGC:

14.4.1 payments due by Customer to AGC in respect of Services performed in accordance with the terms and conditions of this Agreement and the Commercial Quality Agreement, up to and including the day of such termination in full for all completed stages and for partially completed stages a sum calculated on a pro-rata basis having regard to the Batch Price for the cancelled stages (fairly determined by the Project Team having regard to man hours, materials, profit element and irreversible commitments incurred by AGC), less any amounts due to Customer by AGC;

14.4.2 if Customer is the Defaulting Party under Clause 14.3 or upon termination under Clause 5.13 if the Supply Failure results from Customer’s negligence, willful misconduct or breach of this Agreement:

14.4.2.1 in respect of Binding Orders in existence at the date of termination, a payment calculated as [***], provided that if the effective date of termination is on or after [***], such amounts shall be [***];

14.4.2.2 If the Customer failed to order the Minimum Volume in the Calendar Year of such termination, then Customer shall pay to AGC a sum calculated as [***], provided that if the effective date of termination is on or after [***], such amounts shall be [***]; and

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
14.4.4.2.3 [***]

14.4.3 If this Agreement is terminated pursuant to Clause 14.2(b), then AGC’s sole remedy shall be [***].

14.4.4 If the amounts owed by AGC to Customer as of the effective date of termination are greater than the amounts owed to AGC by Customer as of such date, then AGC shall refund the difference to Customer.

14.4.5 payments due at the time of termination pursuant to Clauses 7.10, 7.11 and/or 14 are to be made within [***] days of the effective date of termination.

14.5 Upon termination of this Agreement for any reason, provided the Customer has paid all undisputed sums outstanding and which are properly due under this Agreement, AGC shall, within [***] Calendar Days of:

14.5.1 those payments having been made; or

14.5.2 the date of termination of this Agreement,

(whichsoever is the later) provide the Customer with all Deliverables then manufactured or generated and all transferable work in progress and all Product then manufactured in accordance with Clause 6. [***].

Survival

14.6 Termination or expiry of this Agreement for whatever reason shall not affect the accrued rights or liabilities of either AGC or Customer arising under or out of this Agreement and all provisions which by their terms would to survive this Agreement and including the provisions of Clauses 2.3 (last two sentences only), 2.4, 2.5 (last sentence only), 3.1, 3.2 (first sentence only), 4.6 (last sentence only), 5.12.4, 6, 7 (excluding 7.2 and 7.3), 8.1, 8.2, 8.5.2, 8.6, 9.2.3, 9.2.5, 9.2.6, 9.2.7, 9.4, 10, 11 (excluding 11.2 and 11.8), 12, 14.4., 14.5, 14.6, 15, 16, 17 and 18 shall survive termination or expiry and remain in full force and effect.

15. TECHNOLOGY TRANSFER

15.1 (i) Upon termination or during the notice period regarding termination of this Agreement or the Services other than where termination is for material breach by Customer, (ii) on expiry of this Agreement, or (iii) as provided in Clause 5.13.2 or Clause 5.14, Customer may by written notice to AGC seek assistance from AGC with respect to the transfer to another manufacturer

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of the then-current Process solely for the purpose of manufacturing Product ("Technology Transfer"). Following AGC’s receipt of such notice, the Parties will establish, in good faith, a schedule and plan for effecting such transfer and AGC will thereafter co-operate with Customer in implementing such plan as agreed by the Parties. As part of the Technology Transfer AGC will make available for collection, subject to any Regulatory Obligations, all Customer Materials, Cell Line and one copy of all documentation (to the extent not previously delivered to Customer) generated pursuant to or used in the Services up to the date of termination or expiry. The scope of such Technology Transfer will be agreed upon by the Parties and will include at least the following activities: (a) AGC will provide all pertinent information necessary or useful to manufacture the Product or to support regulatory filings for the Product(s), including, without limitation, analytical testing methods, protocols and reports, Batch production records, master Batch records, production process documentation and standard operating procedures; (b) AGC will provide reasonable assistance and cooperation in order to enable Customer or its designee to manufacture the Product(s); (c) AGC will provide Company with access to Customer’s employees and contractors with expertise in manufacturing to answer Customer’s questions related to such transfer; and (d) AGC will use reasonable efforts to assist Customer to secure supply terms for applicable raw materials from Customer’s suppliers of such raw materials and to identify a Third Party contract manufacturer acceptable to both Parties.

15.2 The obligations on AGC in respect of the Technology Transfer shall only be exercisable by Customer within a period ending [***] months after the date of termination or expiry (whichever is the earlier) and AGC shall not be obliged to commit any greater human resources in the Technology Transfer than [***] FTE hours. Except where such Technology Transfer occurs in connection with AGC’s material breach of this Agreement, Customer shall pay AGC’s costs providing the Technology Transfer at an hourly FTE rate of [***] dollars ($[***]) (to increase annually on the anniversary of the Effective Date in accordance with the agreed rate of inflation) and all other costs shall be charged at cost value [***]. In no event shall a Technology Transfer under this Agreement exceed $[***], unless otherwise agreed upon by the Parties.

15.3 [***]

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
16. **FORCE MAJEURE**

16.1 Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement or the Services to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the other Party ("Impeded Party") including but not limited to fires, earthquakes, floods, embargoes, wars, acts of war (whether war is declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, other substantial similar acts of nature, omissions or delays in acting by any administrative authority or government agency (except for a failure to comply with applicable laws and regulations) or the other Party (a "Force Majeure Situation").

16.2 The Impeded Party shall notify the other Party in writing of any Force Majeure Situation which prevents the Impeded Party from complying with an obligation under this Agreement. If a Force Majeure Situation continues for more than [***] months after notice of such Force Majeure Situation is served, and is adversely affecting the performance of this Agreement, the Party which is not the Impeded Party will have the right, on [***] days’ advance written notice not to expire before the [***] month period to terminate this Agreement. In the case of such termination, Customer will not have a right to reimbursement for any sums paid under this Agreement for which Services have been rendered or any claim for damages as a result of the termination of this Agreement or non-performance of these Services. Notwithstanding any other provision under this Clause 16.2, in the event this Agreement is terminated under this Clause 16.2, Customer shall have the right to seek reimbursement or recoupment for any and all amounts for which Customer has paid Services that were not rendered, including the Reserve Payment. This Clause 16.2 shall not apply to excuse either Party’s payment obligations under this Agreement nor relieve Customer from the payment of Binding Orders.

17. **APPLICABLE LAW, JURISDICTION AND DISPUTE RESOLUTION**

17.1 This Agreement shall be interpreted and governed, and all rights and obligations of the Parties shall be determined, in accordance with the laws of the state of New York (regardless of choice of law provisions). The Parties waive application of the provisions of the 1980 U.N. Convention on Contracts for the International Sale of Goods, as amended.

17.2 Before resorting to litigation, unless exigent relief is required by either Party as determined in its sole, in which case such Party shall be free to seek and be granted temporary, injunctive or equitable relief from any court of competent jurisdiction, the Parties shall use their reasonable efforts to negotiate in good faith and settle amicably any dispute that may arise out of or relate

[***] = **CERTAIN CONFIDENTIAL INFORMATION OMITTED**
to this Agreement (or its construction, validity or termination) (a “Dispute”). If a Dispute cannot be settled through negotiations by appropriate representatives of each of the Parties, either Party may give to the other a notice in writing (a “Dispute Notice”). Within [***] days of the Dispute Notice being given the Parties shall each refer the Dispute to their respective Chief Executive Officers who shall meet in order to attempt to resolve the dispute. If within [***] days of the Dispute Notice (i) the Dispute is not settled by agreement in writing between the Parties or (ii) the Parties have failed to discuss the Dispute or use good faith negotiations, the Dispute may be submitted to and finally be settled by the state and federal courts located in the State of New York. The Parties irrevocably: (a) consent and submit solely to jurisdiction and venue of such courts; (b) agree that such courts will be the sole courts utilized for any Dispute and (c) waive any jurisdictional or venue objections to such courts, including, without limitation, forum non conveniens. Nothing in this MSA shall prohibit (nor force) the Parties to submit to any other dispute resolution forums as they may between themselves subsequently agree to or discuss.

18. MISCELLANEOUS

Fundamental Change

18.1 The occurrence of a Fundamental Change shall not relieve AGC of its responsibility for performance of its obligations under this Agreement. AGC must promptly:

18.1.1 notify Customer as soon as AGC is aware that a Fundamental Change has occurred or is reasonably likely to occur;

18.1.2 upon request, provide to Customer such further information and written assurances, from AGC and its successors that there will be no adverse consequences to the supply of Product to Customer or the performance of AGC obligations under this Agreement resulting from the occurrence of the Fundamental Change. Without prejudice to the generality of this Clause 18.1.2, at Customer’s request, AGC and its successors shall provide Customer with written assurances that AGC’s (or its successor’s, as applicable) ongoing corporate and management culture, capacity, capability and financial viability will continue in a manner sufficient to satisfactorily perform AGC’s obligations under this Agreement.

18.2 Neither AGC not its successor shall be entitled to terminate this Agreement as a result of a Fundamental Change.

18.3 For the avoidance of doubt, a breach of Clause 18.1, shall be deemed to be a material breach of this Agreement.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
Amendment

18.4 Other than as provided for elsewhere in this Agreement in respect of the Timeline, any modification, extension or variation of this Agreement (or any document entered into pursuant to or in connection with this Agreement) shall only be valid if it is in writing and signed by or on behalf of each Party to this Agreement. No modification or variation of this Agreement shall be valid if made by e-mail.

18.5 Unless expressly so agreed, no modification or variation of this Agreement shall constitute or be construed as a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under this Agreement which have already accrued up to the date of such modification or waiver, and the rights and obligations of the Parties under this Agreement shall remain in full force and effect, except and only to the extent that they are so modified or varied.

Assignment

18.6 Except as provided in Clause 18.7, a Party shall not without the prior written consent of the other Party (such consent not to be unreasonably withheld) assign at law or in equity (including by way of a charge or declaration of trust) or delegate any or all of its obligations under this Agreement, or purport to do any of the same. Any purported assignment in breach of this clause shall confer no rights on the purported assignee.

18.7 Customer shall be entitled to assign its rights under this Agreement to any member of Customer’s Group or to a successor by virtue of a merger, acquisition, Change of Control or sale or transfer of substantially all of its assets to which this Agreement relates. Any assignment made pursuant to this Clause shall be subject to the following terms:

18.7.1 no assignment shall relieve Customer of any of its obligations under this Agreement that have accrued prior to the effective date of such assignment; and

18.7.2 Customer shall provide AGC with prompt written notice of such assignment. AGC may continue to deal exclusively with Customer in respect of all matters relating to this Agreement at all times until AGC receives such written notice.

Entire Agreement

18.8 This Agreement, together with its Appendices, constitutes the entire agreement and understanding of the Parties with respect to its subject matter and supersedes any previous agreements or understanding between the Parties relating to such subject matter. If any term of this Agreement conflicts with any term of the Commercial Quality Agreement, the conflicting term of this Agreement shall prevail, except with respect to matters of quality, in which case the conflicting term of the Commercial Quality Agreement shall prevail. For clarity, the Development and Manufacturing Services Agreement between the Parties dated June 10, 2015 shall continue in full force and effect in accordance with its terms.
Waiver
18.9 In no event will any delay, failure or omission (in whole or in part) in enforcing, exercising or pursuing any right, power, privilege, claim or remedy conferred by or arising under this Agreement or by law, be deemed to be or construed as a waiver of that or any other right, power, privilege, claim or remedy in respect of the circumstances in question, or operate so as to bar the enforcement of that, or any other right, power, privilege, claim or remedy, in any other instance at any time or times subsequently.

Severability
18.10 If any provision of this Agreement shall be found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, such invalidity or unenforceability shall not affect the other provisions of this Agreement which shall remain in full force and effect. The Parties agree, in the circumstances referred to in this clause to attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision which achieves to the greatest extent possible the same effect as would have been achieved by the invalid or unenforceable provision. The obligations of the Parties under any invalid or unenforceable provision of this Agreement shall be suspended while an attempt at such substitution is made.

Notices
18.11 Any notice or other communication given or made under this Agreement shall be in writing and in English and signed by or on behalf of the Party giving it and shall be served by hand, delivering it or sending it by prepaid recorded or special delivery post or prepaid international recorded airmail, to the address and for the attention of the relevant Party set out in this Clause 18.11 (or as otherwise notified by that Party hereunder). Any such notice shall be deemed to have been received:

18.11.1 if hand delivered or sent by prepaid recorded or special delivery post or prepaid international recorded airmail, at the time of delivery;

18.11.2 if sent by post (other than by prepaid recorded or special delivery post), [***] Business Days from the date of posting; or

18.11.3 if sent by airmail (other than by prepaid international recorded airmail), [***] Business Days from the date of posting;

Provided that if deemed receipt occurs before 9.00 a.m. on a Business Day the notice shall be deemed to have been received at 9.00 a.m. on that day, and if deemed receipt occurs after 5.00 p.m. on a Business Day, or on any day which is not a Business Day, the notice shall be deemed to have been received at 9.00 a.m. on the next Business Day.

The addresses of the Parties for the purposes of this Clause 18.11 are:

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
or such other address as may be notified in writing from time to time by the relevant Party to the other Party. Any such change to the place of service shall take effect [***] Business Days after notice of the change is received or (if later) on the date (if any) specified in the notice as the date on which the change is to take place.

Counterparts

18.12 This Agreement and any amendment hereto may be executed in any number of counterparts and by the Parties to it on separate counterparts, including by facsimile, .pdf or electronic signature, each of which shall be an original, but all of which together shall constitute one and the same instrument. This Agreement is not effective until each Party has executed at least one counterpart.

No Partnership or Agency

18.13 Nothing in this Agreement is intended to or shall operate to create a partnership or joint venture of any kind between the Parties or to authorize either Party to act as agent for the other, and no Party shall have authority to act in the name or on behalf of or otherwise to bind the other in any way (including but not limited to the making of any representation or warranty, the assumption of any obligation or liability and the exercise of any right or power). Each Party is entering into this Agreement as principal not agent, and may not enforce any of its rights under or in connection with this Agreement for the benefit of any other person.

[Signatures on next page]

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
THIS AGREEMENT has been executed by or on behalf of the Parties on the date at the top of this Agreement.

Signed on behalf of
CMC BIOLOGICS A/S, dba AGC Biologics
by

Name : /s/ Møller
Kasper Møller, PhD
Position : General Manager

Signed on behalf of
HORIZON PHARMA IRELAND LIMITED
by

Name : /s/ Paul Condon
Paul Condon
Position : DIRECTOR

COMMERCIAL SUPPLY AGREEMENT
APPENDIX ONE

Product Specification and Quality Agreement

[***]

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Commercial Supply Agreement – 53
APPENDIX TWO

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Commercial Supply Agreement – 54
EXHIBIT A
AGC’s Standard Form Certificate of Analysis

[***]

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Commercial Supply Agreement – 57
EXHIBIT B

Standard Form Certificate of Compliance

[***]

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Commercial Supply Agreement – 58
COMMERCIAL SUPPLY AGREEMENT

(DRUG PRODUCT)

THIS COMMERCIAL SUPPLY AGREEMENT (this “Agreement”) is entered into and effective this 18th day of November, 2018 (“Effective Date”) by and between Catalent Indiana, LLC (“Catalent”), an Indiana limited liability company with offices at 1300 South Patterson Drive, Bloomington, Indiana 47403, and Horizon Pharma Ireland Limited (“Client”), a company incorporated under the laws of Ireland with offices at Connaught House, 1 Burlington Road, Dublin 4, Ireland. In this Agreement, Catalent and Client each may be referred to individually as a “Party” and together as “Parties.”

RECITALS

WHEREAS, Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services, for pharmaceutical, biotechnology and consumer healthcare companies;

WHEREAS, Client develops, markets and sells pharmaceutical products;

WHEREAS, Client is the successor-in-interest to River Vision Development Corp. (“River Vision”) and Catalent is the successor-in-interest to Cook Pharmica LLC (“Cook”) under that certain Commercial Supply Agreement between River Vision and Cook dated July 7, 2016 (the “Prior CSA”);

WHEREAS, Client desires to have Catalent provide the Services (as defined below) set forth in this Agreement and any Plan (as defined below), and Catalent desires to provide such Services, all pursuant to the terms and conditions in this Agreement; and

WHEREAS, the Parties intend that this Agreement supersede and replace the Prior CSA as of the Effective Date.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the Parties agree as follows:

AGREEMENT

1. Definitions. For purposes of this Agreement, the following terms will have the meanings set forth below:

1.1 “Affiliate” means, (a) with respect to Client or any third party, corporation, firm, partnership or other entity that directly or indirectly controls, is controlled by or is under common control with such entity; and (b) with respect to Catalent, Catalent, Inc. and any corporation, firm, partnership or other entity controlled by Catalent, Inc. For the purposes of this definition, “control” means the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest.
1.2 “Applicable Laws” means, (a) with respect to Client, (i) cGMP and (ii) all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of each jurisdiction in which Bulk Drug Substance or Product is produced, marketed, distributed, used or sold; and (b) with respect to Catalent, (i) cGMP and (ii) all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of the jurisdiction in which Catalent Produces the Product.

1.3 “Batch” means a specific quantity of a Product comprising a number of Units mutually agreed upon between Client and Catalent, and that (a) is intended to have uniform character and quality within specified limits, and (b) is Produced according to a single manufacturing order during the same cycle of Production.

1.4 “Batch Record Package” has the meaning stated in the Quality Agreement.

1.5 “BLA” means a Biologic Licensing Application.

1.6 “Bulk Certificate of Analysis” means a document certifying that Bulk Drug Substance meets all Product Specifications and that the Bulk Drug Substance was manufactured in accordance with CGMPs.

1.7 “Bulk Drug Substance” means the bulk form of the active ingredient identified in the applicable Plan that is used in the Production of Product.

1.8 “Business Review Committee” has the meaning set forth in Section 3.15.


1.10 “Catalent Improvements” means an Invention that is created or conceived by Horizon (whether solely or jointly with Catalent) and which is an improvement, enhancement or modification specific to any of Catalent’s proprietary processes, methods, techniques, materials or equipment for formulating, filling, inspecting, labelling or testing biological products.

1.11 “Catalent Intellectual Property Rights” means (a) all patent and any other intellectual property rights owned or controlled by Catalent or its Affiliates as of the Effective Date; (b) those patent and any other intellectual property rights owned or controlled by Catalent or its Affiliates as of the Effective Date that are further developed or refined in the course of Production; (c) Project Inventions and Catalent Improvements; and (d) those intellectual property rights that are developed by Catalent or its Affiliates outside the performance of the Production
and without the use of Client Confidential Information or Client Intellectual Property Rights and include without limitation, those which
claim, cover or relate to any method, process, know-how, trade secret or other technology owned or controlled by Catalent or its
Affiliates that Catalent may incorporate or use in the course of performing the Production under this Agreement or the Prior Agreement.

1.12 “Catalent Project Product Code” means the identifying alphanumeric code established by Catalent to identify the Product as set forth in
the applicable Plan.

1.13 “Certificate of Analysis” means a document, in the form attached to the Commercial Product Plan, certifying that the Product has met
all Product Specifications and the Product was Produced according to CGMPs.

1.14 “Certificate of Compliance” means a document, in the form attached to the Commercial Product Plan, certifying that the Product was
manufactured and supplied in compliance with CGMP and such other criteria as identified on such document.

1.15 “CGMP” means those current practices, as amended from time to time, related to the manufacture of biopharmaceuticals and
pharmaceuticals as set forth in the FDCA and its counterparts in the EU and such standards of good manufacturing practice as are
required by the FDA, the EMA, and such other Regulatory Authorities (as defined herein) as agreed in the applicable Plan, including
those regulations set forth in the United States Code of Federal Regulations (Title 21, Parts 210-211), as such regulations may be
amended or superseded.

1.16 “Client Confidential Information” means Client’s Confidential Information, which for the avoidance of doubt shall include all
information related to the Client Intellectual Property Rights and the Product, including the Bulk Drug Substance, the portions of the
Process provided to Catalent by Client, and the Product Specification, whether such Client Confidential Information is created,
conceived, or developed by Client or its Affiliates (or on behalf of Client or its Affiliates by a third party) outside of the scope of the
Services or by Catalent for Client in the performance of the Services under this Agreement or the Prior CSA.

1.17 “Client Insurance” has the meaning stated in Article 5.

1.18 “Client Intellectual Property Rights” means (a) all patent and any other intellectual property rights (including rights in data and other
information) owned or controlled by Client or its Affiliates as of the Effective Date, including intellectual property which claim, cover or
relate to the (i) Product, (ii) Client Materials and/or (iii) a method or process relating to the Production of Product; (b) all patent and any
other intellectual property rights (including rights in data and other information) created, conceived, developed or acquired by Client or
its Affiliates (or on behalf of Client or its Affiliates by a third party) outside of the scope of the Services, including performance of the
Production, including intellectual property which claims, covers or relates directly to the (i) Product, (ii) Client Materials and/or (iii) a
method or process relating directly to the Production of the Product; and (c) all patent and any other intellectual property rights in all
Product Inventions.
1.19 “Client Materials” means the Bulk Drug Substance and Client-Supplied Components for use in the Production supplied by Client to Catalent as outlined in the applicable Plan.

1.20 “Client Trademarks” means the proprietary mark(s) for Product owned or controlled by Client as stated in the applicable Plan.

1.21 “Commercial Product Plan” means the document set forth in Exhibit A to this Agreement setting forth information describing the Product and certain standard annexes that further describe activities and standard terms that apply to the Product (and any other applicable products) Produced for Client under the terms of this Agreement. Any changes or additions to the Commercial Product Plan shall be made by written agreement of Catalent and Client. The Commercial Product Plan does not contain any commitment for a Batch. The Commercial Product Plan is incorporated into and forms a part of this Agreement; provided that if there is any conflict between the Commercial Product Plan and the body of this Agreement, the body of this Agreement shall control unless the Commercial Project Plan expressly states the Parties’ intent to supersede a specific term of the Agreement.

1.22 “Component Specifications” means the Specifications for the Components set forth in the applicable Plan including the testing, if any, to be performed for the Components, as set forth in such Plan.

1.23 “Components” means all primary product-contact components (such as vials, plungers, stoppers and syringes) or product-delivery devices (such as secondary devices or injectors) of the type required for Production. All Components will be specified and listed in the applicable Plan and may be identified as either Components supplied by Client (“Client-Supplied Components”) and/or Components supplied by Catalent (“Catalent-Supplied Components”).

1.24 “Confidential Information” of a Party (the “Disclosing Party”) shall mean all information disclosed by or on behalf of the Disclosing Party to the other Party (the “Receiving Party”) or its Affiliates or its and their respective employees, subcontractors, suppliers, agents, distributors, licensees or customers in connection with this Agreement or the Prior CSA or otherwise designated as the Disclosing Party’s Confidential Information hereunder. Confidential Information includes, without limitation, all information concerning the Process, Product Specifications, Client Intellectual Property Rights, Catalent Intellectual Property Rights, Inventions, Price, and Services. The terms of this Agreement are both Parties’ Confidential Information.
1.25 “Damages” means any and all costs, losses, claims, actions, liabilities, fines, penalties, costs and expenses, court costs, and fees and disbursements of counsel, consultants and expert witnesses incurred by a Party (including interest which may be imposed in connection therewith).

1.26 “Dedicated Equipment” means the equipment, if any, identified in a Plan that is purchased or otherwise provided by Catalent or Client and exclusively dedicated to use by Catalent in the provision of the Services.

1.27 “Deliverables” means the data, results and materials generated from the performance of the Services under this Agreement, including Batch records, Certificates of Analysis, Certificates of Compliance and drug history records. All Deliverables, excluding Catalent Confidential Process Information, will be deemed to be Customer Confidential Information.

1.28 “DMF” means Drug Master File, a confidential, detailed document submitted by Catalent to the FDA which contains the chemistry, manufacturing, and controls (also known as “CMC”) information for a drug component or product, or similar document submitted to the EMA or other Regulatory Authority.

1.29 “Effective Date” means the date of this Agreement as set forth above.

1.30 “EMA” mean the European Medicines Agency and any successor agency having substantially the same functions.

1.31 “EU” means the European Union and its member states, as constituted from time to time, and in any event, shall also include the United Kingdom notwithstanding any change to its membership status within the European Union.

1.32 “Facility” means the Catalent manufacturing facility located at 1300 South Patterson Drive, Bloomington, Indiana 47403.

1.33 “FDA” means the United States Food and Drug Administration and any successor agency or entity that may be established hereafter.

1.34 “FDCA” means the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.), as may be amended or superseded following the Effective Date.

1.35 “Firm Order” means any of the following, each of which shall constitute a commitment by Client to purchase and Catalent to Produce Product: (a) a Rolling Forecast which has been accepted by Catalent in accordance with Section 3.6.1; (b) a Purchase Order that has been confirmed in writing by Catalent and is intended by Client to place an order for Product; or (c) an order for Product set forth in a Project Plan. For clarity, a Purchase Order that is issued by Client against the portion of a Rolling Forecast that meets the requirements of subclause (a) above or a Project Plan shall be deemed to be a Firm Order, irrespective of whether Catalent expressly accepts or confirms such Purchase Order.
“Force Majeure” means causes beyond the reasonable control of a Party (or its Affiliates, suppliers, public utilities, or common carriers) including, without limitation, acts of God (including but not limited to earthquake, tornado or hurricane), a change in laws or regulations, actions of any government or agency thereof (other than arising from a failure to comply with Applicable Laws), war, terrorism, civil commotion, damage to or destruction of production facilities or materials, scientific or technical events, labor disturbances (where such labor disturbance is not within the power of the affected Party to settle) and pandemic or epidemic events.

“Indemnitee” has the meaning stated in Section 7.3 (“Procedure for Indemnification”).

“Indemnitor” has the meaning stated in Section 7.3 (“Procedure for Indemnification”).

“Initial Term” has the meaning stated in Section 10.1 (“Initial Term”).

“In-Process Data” means electronic files of IPC (in-process control) and IPM (in-process monitoring) data.

“Inventions” means all innovations, inventions, improvements, original works of authorship, developments, concepts, know-how, data or trade secrets, whether or not patentable, created or conceived pursuant to the performance the Services conducted under this Agreement or the Prior CSA, including the performance of the Production pursuant to a Plan.

“MAA” means marketing authorization application.

“Master Batch Record” means, with respect to each Presentation of Product to be Produced hereunder, a formal set of instructions for the Production of each Presentation of such Product.

“Nonconforming Product” has the meaning stated in Section 4.1 (“Product Conformity”).

“Non-Defaulting Party” has the meaning stated in Article 10.

“Party” or “Parties” has the meaning stated in the opening paragraph.

“Person” means a natural person, a corporation, a partnership, a trust, a joint venture, a limited liability company, any governmental authority or any other entity or organization.

“Plan” means a Commercial Product Plan or Project Plan, as applicable.

“Presentation” means the specific formula and Components used for a Product.
1.50 “Price” has the meaning stated in Section 5.1 (“Product Price”).

1.51 “Process” means the process for the formulation, filtration, filling, lyophilization, inspecting, labeling, packaging and testing of the Product using the Product Specifications in accordance with the Master Batch Record, including any improvements thereto from time to time made as a direct result of the Services during the Term of the Agreement.

1.52 “Process Consumables” shall mean materials used as an aid in the Production of Product that do not become part of the finished Product including but not limited to filters, tubing, Product contact disposables, containers, and bags.

1.53 “Produce” means to perform the Process, and “Production” has the correlative meaning.

1.54 “Producer Price Index” means the U.S. Bureau of Labor Statistics Producer Price Index.

1.55 “Product” means formulated Bulk Drug Substance, as listed in Appendix A, in syringes, cartridges, and/or vials packaged as specified in the applicable Plan.

1.56 “Product Availability Date” means the date that Product is to be made available by Catalent to Client or its designated carrier in accordance with the Delivery Terms.

1.57 “Product Invention” means any Invention that relates directly to the Product and uses Client Materials. For the avoidance of doubt, a Product Invention shall include Inventions made solely by employees or contractors of Catalent, solely by employees or contractors of Client or its Affiliates, or jointly by employees or contractors of Catalent and employees or contractors of Client or its Affiliates. All Product Inventions will be deemed to be Client Confidential Information.

1.58 “Product Requirements” has the meaning stated in Section 4.1 (“Product Conformity”).

1.59 “Product Specifications” means, with respect to each Product, the Specifications for the Product, and/or the stability program that are set forth in the Client-specific standard operating procedures and the Master Batch Records. The Product Specifications include all tests that Catalent is required to conduct or cause to be conducted as specified in the applicable Product Plan. The Product Specifications may be modified from time to time only by a written agreement signed by Client and Catalent.

1.60 “Project Invention” means any Invention created or conceived solely by Catalent that relates to generally applicable methods for the formulation, filling, inspecting, labeling, packaging and testing of biological therapeutics, and that does not by necessity incorporate any Client Confidential Information or Client Intellectual Property Rights, nor requires the use of Client Confidential Information. Project Inventions exclude all Product Inventions.
1.61 “Project Plan” means all document(s) labeled “Project Plan” that refer to this Agreement, and that are signed by an authorized representative of each Party setting forth the proposed course of action for the Production of Product. A Project Plan may include, without limitation, a description of the Product, Components, Regulatory Authorities and the countries where such Product will be used or sold, Presentations, Bulk Drug Substance, and pricing for Product(s) Produced and Services provided under this Agreement as set forth in Section 3.4.

1.62 “Purchase Order” means a form or document by which orders for Product, Raw Materials, or Dedicated Equipment will be placed by Client; provided, however, that the terms and conditions of this Agreement shall be controlling over any terms and conditions included in any Purchase Order, confirmation or other documentation exchanged by the Parties in connection with such Purchase Order, and any term or condition of such Purchase Order, confirmation or other documentation exchanged by the Parties in connection with such Purchase Order that is different from or contrary to the terms and conditions of this Agreement shall be void. All Purchase Orders shall at a minimum specify (a) the quantity of Product ordered, and (b) requested Product Availability Dates, related to each Catalent Project Product Code. A Purchase Order may also be issued in addition to an executed Project Plan (for example, as a means to facilitate Client’s invoicing and payment systems), but in such cases the absence of a Purchase Order shall not limit or be a condition of either Party’s obligations to fulfill any commitments it has made in the Project Plan.

1.63 “Quality Agreement” means the Quality Agreement for CGMP Products and Services between Catalent and Client effective April 5, 2018, as may be amended from time to time.

1.64 “Quality Disposition” means disposition of Product by Catalent’s Quality Assurance department following Catalent Quality review of executed Batch documentation.

1.65 “Raw Materials” means the materials used in the Production of the Product that may become part of the finished Product such as active pharmaceutical ingredient/Bulk Drug Substance, excipients, media components, and buffer components.

1.66 “Reckless Breach” means a Party’s failure, through act or omission, to perform a material obligation specifically set forth in this Agreement or the Quality Agreement, in each case in reckless disregard of the consequences thereof, and such consequences directly affect the safety, identity, strength, purity, or quality of the Product.
1.67 “Regulatory Approval” means all authorizations by the appropriate Regulatory Authority necessary for commercial sale in a jurisdiction.

1.68 “Regulatory Authority” means any national, state, provincial, or local or any foreign or supranational government, governmental, regulatory or administrative authority, agency or commission of any court, tribunal or judicial or arbitral body. “Regulatory Authority” also includes any non-governmental group licensed by an entity described in the preceding sentence to perform inspections, audits and/or reviews.

1.69 “Rolling Forecast” has the meaning stated in Article 3.

1.70 “Safety Data Sheet” or “SDS” is a document that contains information on the potential hazards (health, fire, reactivity and environmental) and how to work safely with the chemical product. It also contains information on the use, storage, handling and emergency procedures all related to the hazards of the material.

1.71 “Services” means all or any part of the activities, including the Production of Product and/or regulatory services for Client, to be performed by Catalent (or any permitted subcontractor) pursuant to this Agreement as further described in the applicable Plan.

1.72 “Specification(s)” means the tests, analytical procedures, and appropriate acceptance criteria that are numerical limits or ranges that establish a set of criteria to which a raw material, component, drug substance or drug product must conform to be acceptable, as set forth in the Commercial Product Plan or, for development services, the applicable Project Plan.

1.73 “Supply Deficiency” means failure by Catalent to Produce and deliver the Batch (or Batches) of Product specified in the relevant Firm Order.

1.74 “Stock Items” means Raw Materials and Components that are used in the performance of Services for Client, and services for other clients of Catalent, including without limitation standard vials, stoppers, and caps. For the avoidance of doubt, Stock Items are Catalent-Supplied Components.

1.75 “Term” has the meaning stated in Section 10.1.

1.76 “Termination Notice Period” has the meaning stated in Section 10.1.

1.77 “Testing Laboratories” means any third party instructed by Catalent and approved in writing by Client to carry out tests on the Bulk Drug Substance and/or the Product.

1.78 “Tests” means the tests to be carried out on the Product (or samples thereof) promptly following delivery of the Product (or samples thereof) to Client, as stated in the applicable Plan.
1.79 “Testing Standards and Procedures” means, with respect to each Product Produced hereunder, the written standards and procedures for evaluating compliance with the applicable Product Specifications, as mutually agreed upon in writing by Client and Catalent and incorporated in the applicable Plan.

1.80 “Unit” means an individually packaged dosage form of a Product, including by way of example only, a vial or prefilled syringe, as specified in the applicable Plan.

1.81 “United States” means the fifty (50) states, the District of Columbia and all of the territories of the United States of America.

2. Sourcing of Materials and Components.

2.1 Delivery of Client Materials. Client, at Client’s sole expense, shall deliver or cause to be delivered the Client Materials as specified in the applicable Plan, all to be delivered to Catalent at least [***] days in advance of the date set forth in the applicable Plan for Production of such Product. Except as may specifically be set forth in the applicable Plan or the Quality Agreement, on receipt of the Bulk Drug Substance and Client-Supplied Components as set forth above, Catalent’s sole obligation with respect to evaluation of the Bulk Drug Substance and Client-Supplied Components shall be to conduct identification testing and to review the accompanying Certificate of Analysis to confirm that the Bulk Drug Substance and Client-Supplied Components (if applicable) conform with the Product Specifications and Component Specifications, respectively.

2.2 Safety Data Sheet. Client shall provide Catalent a Safety Data Sheet for all Client-supplied chemicals (including, if applicable, Bulk Drug Substance) and for each Product. Catalent shall notify Client of any unusual adverse health or environmental occurrence relating to the Product, including, but not limited to any claim or complaint by any Catalent employee or third party that the operations of Catalent pursuant to this Agreement have resulted in any adverse health or safety effect on an employee or third party. Catalent and Client both agree to advise each other immediately of any safety or toxicity problems of which it becomes aware regarding the Product.

2.3 Catalent Obligations Relating to Client Materials. Catalent shall:

2.3.1 at all times use [***] to keep the Client Materials secure and safe from loss or damage;

2.3.2 at all times store and handle the Client Materials under qualified conditions in a secured storage location in accordance with Client’s handling and storage instructions and CGMP;

2.3.3 use the Client Materials solely for the purpose of performing the Services; and

[***] = certain confidential information omitted
2.3.4 not transfer to a third party any part of the Client Materials or the Product, except to Affiliates and permitted subcontractors as may be permitted in the Project Plan.

2.4 **Ownership and Risk of Loss; Client Materials and Product.** Client shall own and continue to own all right, title and interest in and to Client Materials. Except for liability arising from [***] assumes any and all risk of loss, damage, theft or destruction of Client Materials and Product while the Client Materials and Product are in Catalent’s possession or on Catalent’s premises, and [***] with regard thereto in accordance with Section [***] of this Agreement. Upon termination or expiration of this Agreement, Client shall immediately notify Catalent whether Client shall either (a) reclaim possession of Client Materials and Product; or (b) request destruction of Client Materials and Product by Catalent, each at Client’s sole expense. In the event Client fails to provide Catalent such notice within [***] days following termination of this Agreement, Catalent shall notify Client in writing regarding the potential destruction of Client Materials and Product and then may destroy Client Materials and Product at Client’s sole expense if Client does not within [***] business days following Client’s receipt of such notice request such Client Materials and/or Product be shipped to Client or its designee. Catalent shall invoice Client for all reasonable, documented out of pocket costs incurred as a result of the return or destruction of the Client Materials and Product.

2.5 **Vendor and Supplier Audit and Certification.** Catalent shall certify and audit all Product-related vendors and suppliers of Catalent-Supplied Components, Raw Materials, and Process Consumables unless the responsibility for such certifications and audits is specifically assumed by Client under the applicable Plan. Client shall certify and audit all vendors and suppliers of Client-Supplied Materials unless the responsibility for such certification and audits is specifically assumed by Catalent under the applicable Plan and Client shall pay for such audits as set forth therein.

2.6 **Client-Supplied Components.** Client shall supply to Catalent, or cause to be shipped to Catalent, all Client-Supplied Components at Client’s expense.

2.7 **Catalent-Supplied Components.** Catalent will use [***] to purchase the Catalent-Supplied Components with sufficient lead times and in sufficient quantities to meet Client’s Firm Orders for Product, including additional quantities as necessary for efficient supply chain management practices. Catalent and Client shall review Catalent’s inventory management plan as a routine part of joint governance of the Services in accordance with Section 3.15 (“Business Review Committee”). Client shall reimburse Catalent for the Catalent-Supplied Components as set forth in the applicable Plan. Generation of invoices and payment for Catalent-Supplied Components shall be made in accordance with Section 5.3 (“Payment Terms”) of this Agreement.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
3. Purchase and Supply of Product; Performance of Services.

3.1 Agreement to Purchase and Supply. Pursuant to the terms and conditions of this Agreement and the applicable Plan, Client shall purchase from Catalent, on a non-exclusive basis, and Catalent shall use [***] to Produce and deliver to Client, the Product. A Firm Order shall constitute a commitment by Client to purchase and Catalent to Produce Product, in each case subject to the terms and conditions of this Agreement and the applicable Plan.

3.2 Performance. Catalent shall diligently perform the Production and other Services, including the delivery of Deliverables and In-Process Data, as provided in the applicable Plan, and shall use [***] to achieve estimated schedules for the performance of Services and amounts of Product. Catalent shall Produce Product and perform the Services in accordance with CGMP or any other Applicable Laws and in accordance with the Product Requirements, including the requirements set forth in the Quality Agreement with respect to applicable regulatory requirements for commercial distribution in each of the Territories. Catalent shall not incorporate into any Product any Catalent Intellectual Property Rights or intellectual property rights of a third party.

3.3 Reproduction, Rework or Reprocessing. If during the Production of any Batch of Product, any reprocessing, rework, or reproduction is required in order to meet the Product Specifications, Catalent shall, at Catalent’s sole expense, conduct such reprocessing, rework, or reproduction in accordance with CGMPs and the BLA or MAA. Any reprocessing, rework, reproduction, or change which is not covered by CGMPs and the BLA or MAA must be approved in writing by Client prior to implementation. To the extent such reprocessing, rework, reproduction, or change is required as a result of the acts or omissions of Client, Client shall be responsible for, and promptly reimburse Catalent for all reasonable, documented costs and expenses incurred in connection with such reprocessing, rework, reproduction, or change.

3.4 Project Plans and Commercial Product Plans.

3.4.1 Plans. For each Product to be Produced, or other Services to be performed, by Catalent hereunder, the Parties shall execute one or more written Project Plan(s) and/or Commercial Product Plan(s) prior to commencement of any work or commitment by Catalent to purchase or supply any Services, Raw Materials or equipment, or reservation of production capacity or schedule slots. Each Plan shall describe the Production and/or other Services with respect to the applicable Product and certain other relevant terms and conditions for performance of the Production and performance of Services by Catalent under this Agreement. In no event shall Catalent be required to schedule the Production of any Product until a Plan for such Product has been approved in writing by both Catalent and Client. Each agreed upon Plan shall be incorporated herein by reference.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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3.4.2 Modification and Plan Scope Changes. From time to time, but no less often than [***] per quarter, the Parties will meet to review and, if necessary, update, by mutual agreement, each Plan. In the event that the Parties agree to update, modify or expand the scope of a Plan, or to formally approve the accumulated minor project changes to a Project Plan as set forth in the following Section, such amended Plan will become part of this Agreement in the manner stated in Section 3.4.1 upon execution of that Plan by an authorized representative of each Party.

3.4.3 Minor Project Changes. The Catalent project manager shall maintain an ongoing log tracking all Client-requested or Catalent-requested minor changes to the activities and items contained in an executed Project Plan. All such minor changes must be approved in writing by the Client and the Catalent project manager. Catalent is authorized to implement (and invoice Client for) all such approved minor changes, provided that if the estimated total value of such tracked changes exceeds [***] percent ([***]%) of the total price of the Project Plan, then a formal Project Plan amendment must be prepared, agreed to, and executed as set forth in the previous Section. For clarity, this Section 3.4.3 does not apply to any Commercial Product Plan, and any changes to a Commercial Product Plan must be agreed to in writing by Client.

3.5 No Amendment of Agreement. In the event that the terms of any Plan are inconsistent with the terms of this Agreement, this Agreement shall control, unless otherwise explicitly agreed to in writing by the Parties. No Plan shall be deemed to amend this Agreement. Upon execution of any Plan, such plan shall be deemed to be incorporated herein and by reference and made a part of this Agreement (subject to the first sentence of this Section).

3.6 Forecasts, Orders and Capacity.

3.6.1 Forecasts. Client may, at Client’s sole discretion, on or about the [***] day of each month, provide to Catalent a written [***] month rolling forecast of Client’s estimated quantities for each Product (the "Rolling Forecast"), which shall, upon Client’s receipt of written notice of acceptance by Catalent, be binding upon Catalent and Client, and shall constitute a Firm Order, as follows:

Until [***]:

3.6.1.1 The first [***] months of the Rolling Forecast shall be firm and binding;

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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3.6.1.2 the next [***] months (or months [***]) shall be partially firm and binding, with Client having the ability to decrease the quantities therein by up to [***] percent ([***]%) or increase such quantities by up to [***] percent ([***]%) and

3.6.1.3 the next [***] months (or months [***]) non-binding and solely informational for Catalent’s planning purposes.

Beginning with [***]:

3.6.1.4 The first [***] months of the Rolling Forecast shall be firm and binding;

3.6.1.5 the next [***] months (or months [***]) shall be partially firm and binding, with Client having the ability to decrease the quantities therein by up to [***] percent ([***]%) or increase such quantities by up to [***] percent ([***]%) and

3.6.1.6 the next [***] months (or months [***]) non-binding and solely informational for Catalent’s planning purposes.

Any Rolling Forecast that is not rejected in writing by Catalent within [***] business days shall be deemed to have been accepted by Catalent.

3.6.2 **Purchase Orders.** Unless a Purchase Order is submitted with respect to a Firm Order, Client shall not, without the written consent of Catalent, designate a Product Availability Date in such Purchase Order earlier than [***] calendar days from the date Client submits the Purchase Order. For clarity, the Product Availability Date for Firm Orders as described in Section 1.34(a) and (c) shall be as set forth in the corresponding Rolling Forecast or Project Plan, respectively. Upon acceptance of such Purchase Order by Catalent as set forth in Section 3.6.3, Catalent shall supply Client with the quantity of Product ordered by Client by the Product Availability Date. Client will order full Batches based on the expected yield per Batch, as set forth in the applicable Plan. Each Purchase Order must include the requested quantity, the Bulk Drug Substance availability date, the Catalent Project Product Code, Unit or Batch price, and Purchase Order total dollar amount. No other terms or conditions contained in any Client Purchase Order form(s) shall be binding on Catalent. Upon Client’s receipt of Catalent’s confirmation in accordance with Section 3.6.3, such Purchase Order shall become a Firm Order.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
3.6.3 Procedure for Acceptance of Purchase Orders. Within [***] business days following its receipt of a Purchase Order that does not meet the definition of a Firm Order, Catalent shall, if the conditions above are met and Catalent has production capacity available to meet the requested Product Availability Date, provide a written confirmation of acceptance of such Purchase Order setting forth the Product Availability Date for such order. No other terms or conditions contained in any Catalent confirmation or related documentation shall be binding on Client. With respect to Purchase Orders that do not meet the definition of a Firm Order, upon Client’s receipt of the confirmation, and provided that such confirmation is issued within such [***] business day period, such Purchase Order shall become a Firm Order. For clarity, Catalent’s confirmation or other formal acceptance is not required for a Purchase Order submitted with respect to a Firm Order and all such Purchase Orders shall be deemed to be accepted by Catalent.

3.6.4 Delay. If Catalent is unable to meet the Product Availability Date (except when caused by Client’s delay in delivery of Client-Supplied Materials or delays caused by a Component or Raw Material supplier) Catalent shall promptly so notify Client and provide to Client an alternative Product Availability Date which shall not be more than [***] calendar days later than the initial Product Availability Date designated by Client in its Purchase Order. If Catalent does not provide an alternative Product Availability Date that is within that [***] period, Client may cancel, without liability for any cancellation charges, the portion of the Firm Order that Catalent has indicated will not be delivered by the initial Product Availability Date.

3.6.4.1 If Client requests a change in the Product Availability Date for a Batch due to forces beyond Client’s control, such as a delay in the availability of Bulk Drug Substance, Catalent will use [***] to reschedule such Product Availability Date without charge to Client.

3.6.5 Compensation for Unused Production Slot(s) Subject to Firm Order(s).

3.6.5.1 If Client cancels any Firm Order (other than as set forth in Sections 3.6.4, 3.8.1.2, 4.5, 6.1.5, 7.5 and 10.2), Catalent will use [***] to fill any of Client’s unused production slots that are subject to such Firm Order with another customer’s product ordered subsequent to Client’s cancellation. If Catalent is unable to so fill such production slot, then to compensate Catalent for the reserved production capacity and time slot(s) on Catalent’s production schedule, Client shall pay Catalent for all Products that are the subject of such Firm Order (other than Product subject to Section 3.6.4, 3.8.1.2, 4.5, 6.1.5, 7.5 or 10.2) as set forth below in this Section 3.6.5, which shall be Catalent’s sole remedy and Client’s sole liability with respect to such cancellation.

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3.6.5.2 Commencing [***] Client will pay Catalent for cancelled Batches as follows:

[***] [***]
[***] [***]
[***] [***]
[***] [***]

3.7 Storage.

3.7.1 Raw Material and Component Storage. Catalent shall store Raw Materials and Components which are not Stock Items for [***] full calendar months from receipt date of each item, without charge. On the first day of each calendar month thereafter that the Raw Materials and/or Components are stored by Catalent, Catalent shall invoice Client (and Client shall pay) for [***] storage. In no event shall Catalent be required to store any Raw Material or Components for more than [***] days without Catalent’s written consent. For the avoidance of doubt, Catalent shall store Stock Items without charge.

3.7.2 Product Storage. Catalent shall store Products for the [***] which Catalent Quality Disposition for the Products takes place, and for the [***], without charge. On the [***] thereafter that the Products are stored by Catalent, Catalent shall invoice Client (and Client shall pay) for [***] storage. In no event shall Catalent be required to store any Products for more than [***] days without Catalent’s written consent. For purposes of this Section 3.7.2, storage by Catalent of any output from a manufacturing or development activity (such as an engineering batch) shall be subject to storage fees as set forth herein.

3.7.3 Storage Pricing and Off-Site Storage. Catalent shall be permitted to store Product, Raw Materials, and Components in mutually acceptable (as confirmed by the Parties in writing) off-site, third party storage facilities. The applicable Plan may include pricing for storage, and Client agrees to pay for such storage for as long as Product, Raw Materials or Components remain at Catalent’s facility or at a mutually acceptable off-site storage facility. If the applicable Plan does not set forth storage charges, storage shall be charged at Catalent’s storage rates that are in effect at the time the storage occurs.

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3.8 Supply Deficiencies.

3.8.1 Supply Deficiency. If there is a Supply Deficiency, Catalent shall promptly notify Client in writing and Catalent may, in its sole discretion, take one or more of the following steps:

3.8.1.1 utilize suitable production capacity of Catalent or one of its Affiliates (provided that such Affiliate is registered in the applicable BLA or MAA for the Product) not then committed to third party customers; and

3.8.1.2 coordinate and cooperate with Client to reschedule Batches of Product ordered hereunder in order to maximize Catalent’s ability to rectify the Supply Deficiency while minimizing the disruption to any Purchase Order and Firm Order then in force and any commitments to third party customers. Catalent shall notify Client in writing within [***] business days of its initial notice of a Supply Deficiency of Catalent’s new proposed Product Availability Date for each affected order of Product, provided that if such date is not within [***] days of the original Product Availability Date for such order, then Client may cancel such order by written notice to Catalent and shall no further obligation to Catalent with respect to such order or any unused production slots due to such cancellation.

3.8.2 Exclusive Remedy. The provisions of this Section 3.8 (“Supply Deficiencies”) shall be the sole liability of Catalent and sole remedy of Client with respect to any Supply Deficiency, except if the Supply Deficiency is the result of Nonconforming Product(s), in which case Client shall also have the remedies set forth in Article 4. Client shall [***] the Production and/or Firm Order [***].

3.9 Changes in Manufacturing.

3.9.1 Changes to Master Batch Records and Product Specifications. Catalent agrees to inform Client promptly (but in any case not later than [***] days) of the result of any regulatory development or other required changes to Product Specifications that materially affect the Production of the Product. Catalent shall notify Client of and require [***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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timely written approval from Client for changes to Master Batch Records and Product Specifications prior to the Production of subsequent Batches of Product. Provided that Catalent has provided Client with at least [***] days prior written notice, failure of Client to respond in a timely manner may result in: (i) delay in the Product Availability Date; or (ii) loss of a Production slot in Catalent’s schedule; but in either case shall not relieve Client of its obligations to pay Catalent for all activities described in the applicable Project Plan, including any lost Production slot.

3.9.2 **Product-Specific Changes.** If facility, equipment, process or system changes are required of Catalent as a result of requirements set forth by the FDA or any other Regulatory Authority, and such regulatory changes apply solely to the Production and supply of one or more Products, then Client and Catalent will review such requirements and, subject to the Parties’ mutual agreement in writing to such regulatory changes, Client shall bear one hundred percent of the reasonable, documented costs thereof.

3.9.3 **General Changes.** If such regulatory changes apply generally to one or more Products as well as to other products Produced by Catalent for itself or for third parties, then, subject to the Parties’ mutual agreement in writing to such regulatory changes, Client shall pay a pro rata amount of the reasonable cost of such regulatory changes based upon the proportion of time that Facility is dedicated to the Production of Products relative to the Production of such other products.

3.10 **Delivery Terms.** Product shall be delivered to Client, or to a location designated by Client in the Purchase Order, [***] designated by Client on the shipment request form or applicable Plan, at Client’s expense. [***] shall procure, at its cost, insurance covering damage or loss to the Product during shipping. Risk of loss and title for Product shall pass to [***] of Product.

3.11 **Audit; Observation.**

3.11.1 [***] upon [***] days prior written notice, Client shall have the right to conduct an audit of that portion of the Facility used in the Production during normal business hours. In the event there have been major quality issues with Product or Production, Client may reasonably require more frequent audits of the Facility. In addition, on reasonable advance notice to Catalent, Client’s employees or representatives may be present at Catalent’s facilities to observe Catalent performing the Services. Notwithstanding the foregoing notice period, for purposes of confidentiality, safety and to avoid the possibility of contamination, if a third party’s product is being manufactured during the time that Client intends to conduct an audit,

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such audit may be reasonably delayed upon prior written notice to Client. The form, participants and procedures of the audit shall be subject to Catalent’s reasonable prior approval. When conducting an audit, each of Client’s representatives will (a) be subject to a nondisclosure obligation at least as restrictive as the obligations contained in Article 8 ("Confidentiality and Non-Solicitation of Employees"); (b) follow such security and Facility access procedures as reasonably designated by Catalent; (c) be accompanied by a Catalent representative; (d) not enter areas of the Facility at times when any third party’s products are being manufactured to assure protection of the Catalent Confidential Information or the confidential information of a third party; and (e) use [***] to avoid disrupting Catalent’s operations. In addition to an audit by Client, Catalent agrees to reasonably cooperate with applicable Regulatory Authorities and shall permit Product-specific inspections by such Regulatory Authorities.

3.11.2 On reasonable advance notice to Catalent, up to [***] of Client’s employees or representatives may be present at Catalent’s facilities to observe Product Production or other performance of Services, subject to Catalent’s reasonable site rules and regulations.

3.12 Recall. If Client is required to recall any Product because such Product may violate local, state or federal laws or regulations, the laws or regulations of any applicable foreign government or agency or the Product Specifications, or in the event that Client elects to institute a voluntary recall, Client shall be responsible for coordinating such recall. Client shall notify Catalent promptly if any Product is the subject of a recall and provide Catalent with a copy of all documents relating to such recall. Catalent shall cooperate with Client in connection with any recall, at Client’s expense. Client shall be responsible for all of the costs and expenses of such recall. Notwithstanding the foregoing, in the event a recall, product withdrawal or field correction is necessary because [***], Catalent will bear the reasonable costs associated with such recall, product withdrawal or field correction (including but not limited to costs associated with receiving and administering the recalled Product and notification of the recall to those Persons whom Client deems appropriate. Catalent’s liability for costs associated with such recall, product withdrawal or field correction shall not exceed the maximum liability as set forth in Section 7.4.

3.13 Dedicated Equipment.

3.13.1 Selection and Procurement. Catalent shall select and, with Client’s prior written approval, procure the Dedicated Equipment at Client’s sole cost[***]. Catalent shall use [***] to determine whether the Dedicated Equipment conforms to the applicable specifications and will work in the Facility for purpose stated in the Project Plan.

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3.13.2 Use and Storage of Dedicated Equipment. Catalent shall use and store the Dedicated Equipment only in accordance with any written instructions prescribed by Client or the manufacturer of the Dedicated Equipment, and shall perform such routine maintenance and storage for the Dedicated Equipment as is reasonably required by such written instructions and be reimbursed by Client for routine maintenance and storage as set forth in the applicable Plan. All costs for any extraordinary or non-routine maintenance that may be required will be approved in advance by Client, and the applicable Plan will be revised to reflect any additional maintenance costs that may be required during the Term. Except: (i) in connection with such routine maintenance and storage, (ii) as required by the Services; or (iii) as directed in writing by Client, Catalent shall not make any alterations, additions or improvements to the Dedicated Equipment. All alterations, additions or improvements made to the Dedicated Equipment will be at Client’s sole cost and expense.

3.13.3 Ownership and Risk of Loss; Disposition of Equipment. Client shall own and continue to own all right, title and interest in and to any Dedicated Equipment. Client assumes any risk of loss, damage, theft or destruction of the Dedicated Equipment while that Dedicated Equipment is in Catalent’s possession or on Catalent’s premises. Notwithstanding the foregoing, Catalent assumes any risk of loss damage, theft or destruction to the extent resulting from [***]. Upon termination or expiration of this Agreement, Client shall have the right and obligation to, upon reasonable notice, reclaim possession of such Dedicated Equipment at its sole expense (including all costs of disconnection, removal, physical transfer and any subsequent reinstallation and requalification costs). Catalent shall reasonably cooperate with Client to remove and return such Dedicated Equipment to Client in accordance with Client’s written instructions and shall invoice Client for: (i) direct costs incurred; and (ii) any damage other than reasonable wear and tear to the Facility incurred as a result of the use and removal of the Dedicated Equipment. Notwithstanding the above, upon termination or expiration of this Agreement, Client may offer to sell to Catalent, or Catalent may offer to purchase from Client. Neither Catalent nor Client, shall be obligated to make or accept such offers. In the event that Client has not removed the Dedicated Equipment within [***] days after Client’s receipt of Catalent’s written notice that the Dedicated Equipment may be deemed to be abandoned, the Dedicated Equipment shall be deemed to be abandoned and Catalent may dispose of it or use it as it sees fit.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
3.14 **Product Testing and DMF.**

3.14.1 **Testing.** Catalent shall test, or cause to be tested by third party testing facilities audited by Catalent and approved by both Parties, in accordance with the Product Specifications, each Batch of Product Produced pursuant to this Agreement before delivery to Client. A Certificate of Analysis for each Batch of Product delivered to Client shall set forth the items tested by Catalent, specifications, and test results. Catalent shall send, or cause to be sent, such certificates along with one (1) copy of the Batch Record Package to Client prior to or at the same time of shipment of Product to Client and within [***] calendar days after the date of fill if such Batch requires no investigations and/or additional testing. For the avoidance of doubt, Client is solely responsible for final release of each lot of the Product.

3.14.2 **Stability Testing.** At Client’s cost and expense, Catalent or a party selected by Client, may perform all stability testing required to be performed on Production Batches of Product. If performed by Catalent, such testing shall be performed in accordance with the procedures set out in the Client-specific SOPs for the stability protocol and the applicable Plan.

3.14.3 **Drug Master File.** Catalent shall file and maintain the appropriate DMF and related reference applications (e.g. Facility master file) for its Production of each Product hereunder in accordance with 21 CFR 314.420 and other Applicable Laws, as may be amended from time to time, at Catalent’s expense, and Catalent shall provide all needed rights of reference to Client and its Affiliates and the FDA and the EMA. Catalent shall provide reasonable advance written notice to Client prior to amending any DMF that is referenced in a Client regulatory filing.

3.15 **Business Review Committee**

3.15.1 Promptly following the Effective Date, the Parties shall establish a business review committee consisting of at least [***] representatives appointed by Client and at least [***] representatives appointed by Catalent (the “Business Review Committee”). The Parties shall appoint representatives to the Business Review Committee who have appropriate experience and seniority and are authorized to make decisions on operational matters. A Party may exchange any or all of its representatives, and shall inform the other Party before such exchange by providing the names of its new representatives on the Business Review Committee.

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3.15.2 The Parties shall have a meeting of the Business Review Committee no less than [***] a year during the first year after the Effective Date and no less than [***] a year during the following years. Any Party may ask for a meeting of the Business Review Committee if an important issue arises, which meeting shall be scheduled promptly.

3.15.3 The Business Review Committee shall discuss any quality, supply, purchasing, and any other issue arising between the Parties relating to the performance of Services under Agreement.

3.15.4 The Business Review Committee is entitled to make final decisions on all operational issues [***]. These operational decisions are binding for both Parties. [***]

3.15.5 If the resolution of an issue cannot be agreed upon by the members of the Business Review Committee, then such issue shall be escalated to the appropriate senior executives of the Parties in accordance with Section 12.7.

3.15.6 For the avoidance of doubt, the Business Review Committee shall have no authority to amend this Agreement or to determine or waive compliance with any provision hereof. Any decisions of the Business Review Committee (or the senior executives to which an issue has been escalated) which constitutes a change of this Agreement is subject to Section 12.6 of this Agreement. Therefore, decided changes cannot become effective before they are properly executed in an amendment pursuant to Section 12.6.


4.1 Product Conformity. Within [***] calendar days from the date of shipment of both Product and the Batch Record Package to Client, Client shall determine whether such Product conforms to Product Specifications and the Master Batch Record (collectively the “Product Requirements”). If Client believes any shipment of Product (or samples thereof) do not conform to the Product Requirements (“Nonconforming Product”), then Client shall give Catalent written notice thereof as soon as practicable but in no event later than [***] calendar days from the date of shipment of both Product (or samples thereof) and the Batch Record Package and shall, unless otherwise directed by Catalent, return the Product for further testing by Catalent. Failure to provide such written notice and return the Product for further testing by Catalent shall constitute an irrevocable acceptance by Client of such Product and an admission that the Product meets Product Requirements, except as to any Latent Defect. If, after conducting its own testing, Catalent agrees, or it is determined pursuant to Section 4.3 (“Disputes”), that the returned Product fails to meet Product Requirements

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and, to the extent that such failure is not due (in whole or in part) to acts or omissions of Client before or after delivery of such Product or
to a latent defect in a Component that was not discoverable by the exercise of ordinary diligence and reasonable care, the provisions of
Section 4.4 ("Nonconforming Product") shall apply.

4.2 Latent Defect. Client shall have [***] calendar days from the date of discovery of a defect in the Product that could not have reasonably
been discovered at the time of Delivery of the Product which the Client believes renders the Product Nonconforming ("Latent Defect")
to reject such delivered Product (in whole or in part) by written notice thereof to Catalent, indicating the Client’s reason(s) for its belief
that Product is Nonconforming Product. Such rejection [***]; provided that in no event shall Client reject any Product following the
expiry date thereof. The remedies for Product deemed to have a Latent Defect shall be as set forth in Section 4.4. For the avoidance of
doubt, a defect that is caused by an event occurring after Delivery of the Product by Catalent shall not be deemed a Latent Defect.

4.3 Disputes. If there is any dispute concerning whether a Product (or a sample thereof) meets the Product Requirements and/or the reasons
therefor, the Parties shall designate an independent expert (acting as an expert and not as an arbitrator) to determine whether or not the
Product at issue meets the applicable Product Requirements. The decision of such independent expert shall be in writing and shall be
binding on both Catalent and Client. The costs of such independent expert shall be borne by the Parties equally; provided, however that
the Party that is determined to be incorrect in the dispute shall be responsible for all such costs and shall reimburse the prevailing Party
for its share of the costs incurred.

4.4 Nonconforming Product.

4.4.1 In the event a Product is determined to be Nonconforming Product (whether by agreement of Catalent pursuant to Section 4.1
("Product Conformity") or by an independent expert pursuant to Section 4.3 ("Disputes")), all such Nonconforming Product
shall be either returned to Catalent or destroyed, at Catalent’s option, and if elected in writing by Client, then Catalent shall
replace such Nonconforming Product at its own cost and expense (excluding the cost of Bulk Drug Substance, other Raw
Materials, and Components, subject to Section 4.4.3) and shall use [***] to replace such Nonconforming Product in a reasonable
time given any commitments to other Catalent clients or contractually obligated capacity constraints.

4.4.2 If Client does not elect to have Catalent replace such Nonconforming Product, or if Client elects such replacement and Catalent
cannot replace such Nonconforming Product [***].

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In the event that such Nonconforming Product arises from [***], Catalent shall also pay, subject to Section 7.4, the cost of the Bulk Drug Substance used to Produce such Product, irrespective of whether Client requests replacement of such Product and, if Client requests replacement of such Product the costs of the other Raw Materials and Components required for such replacement. For clarity, nothing in this Section shall relieve Client of its obligation under this Agreement to pay for Product that meets the Product Requirements.

4.5 **Client Termination Right.** In the event that Catalent delivers [***] Batches of Nonconforming Product which nonconformance is not the result of (a) acts or omissions of Client or (b) nonconforming Client Materials or a latent defect in a Component that was not discoverable by the exercise of ordinary diligence and reasonable care, Client shall have the right to immediately terminate this Agreement by giving notice to Catalent and shall have no liability to Catalent with respect to any Firm Orders cancelled in connection with such termination.

4.6 **Sole Remedy.** The provisions of this Article 4 ("Nonconforming Product") shall be the sole remedies available to Client with respect to Product that fails to meet Product Requirements. For clarity, Catalent’s indemnification obligations under Section 7.2 shall remain in effect with respect to any such Product.

4.7 **Non-Conforming Client Materials or Latent Defect in Components.** If Product does not meet Product Requirements and cannot be released by Catalent, or Product is rejected by Client, and such Product’s failure to meet the Product Requirements is the result of nonconforming Client Materials or a latent defect in a Component that was not discoverable by the exercise of ordinary diligence and reasonable care, then such non-conformity shall not be deemed the result of the negligence or willful misconduct of Catalent.

5. **Price and Payment.**

5.1 **Product Price.** The price to be paid by Client for Product ("Price") shall be set forth in the Project Plan, and includes all Process steps and Catalent analytical support set forth in the Commercial Product Plan. No more than [***], Catalent may, at its sole discretion, increase the Price of any Product that is not covered by a Firm Order as of the effective date of the Price increase. The Price increase shall not exceed [***] successor [***]. The Price shall be on a Batch basis. For clarity, the Price applicable to any Batch shall be the Price existing at the time that Client places the Purchase Order for such Batch.

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5.2 **Cost Reimbursement.** For all pass-through and out-of-pocket costs specified in the applicable Plan (which may include but is not limited to Raw Materials procured by Catalent, Catalent-Supplied Components, filters, containers, Product-contact disposables, and Dedicated Equipment purchased by Catalent) Client shall reimburse Catalent, at Catalent’s cost [***].

5.3 **Payment Terms.** Catalent shall generate invoices for all fees and cost reimbursements. Invoices for Product will be sent after Catalent’s Quality Disposition of each Batch of Product. Invoices for cost reimbursement will be sent not more than monthly and include reasonable documentation of costs incurred. Client shall pay all invoices (that are not disputed in good faith) within [***] days of the date received by Client. Invoices not disputed within [***] days of receipt shall be deemed accepted and payment shall be made without deduction, deferment, set-off, lien or counterclaim of any nature. Accepted invoices that remain unpaid more than [***] days beyond the scheduled payment due date may be subject to an interest charge equal to [***] percent ([***]%)[***], calculated from the scheduled payment due date forward; provided that in no event shall such annual rate exceed the maximum interest rate permitted by Applicable Law in regard to such payments. Such payments when made shall be accompanied by all interest so accrued. Payments may either be made by check or wire transfer of immediately available funds to the account as Catalent may designate from time to time.

5.4 **Regulatory Services Price.** The price to be paid by Client for regulatory services shall be set forth in a Project Plan.

5.5 **Default in Payment Obligations.** In addition to all other remedies available to Catalent in the event of a Client default, if Client fails to pay any undisputed invoice as required hereunder, Catalent may refuse all further Purchase Orders, refuse to Produce any Product until Client’s account is paid in full, modify the foregoing terms of payment, place the account on a letter of credit basis, require full or partial payment in advance, suspend deliveries of Product until Client provides assurance of performance reasonably satisfactory to Catalent, and/or take other reasonable means as Catalent may determine. The Parties shall seek to resolve any reasonable payment dispute promptly and in good faith.

5.6 **Insurance.**

5.6.1 **Client Insurance.** (a) Client shall maintain, during Client’s conduct of clinical trials with respect to the Product, Clinical Trial Liability that shall cover amounts not less than [***] dollars ($[***]) per claim and in the aggregate, and (b) prior to the first commercial sale of the Product, Client shall procure and maintain, during the Term of this

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Agreement and for a period [***], Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage (collectively (a) and (b), the "Client Insurance"). The Product Liability coverage shall cover amounts not less than [***] dollars ($[***]) per claim and in the aggregate and shall be with an insurance carrier reasonably acceptable to Catalent. Catalent shall be named as an additional insured on the Product Liability coverage and Client promptly shall deliver a certificate of Client Insurance and endorsement of additional insured to Catalent evidencing such coverage. [***] Any deductible and/or self-insurance retention shall be the sole responsibility of Client.

5.6.2 Catalent Insurance. Catalent is, and shall remain during the Term of this Agreement insured for the type of liability that could arise under Section 7.2 ("Catalent Indemnification") of this Agreement. Such insurance shall include products and completed operations liability insurance with a per occurrence limit of not less than [***] United States Dollars ($[***]) or equivalent covering Catalent’s operations arising out of or connecting with this Agreement, providing coverage for bodily injury and property damage claims. Catalent shall be obligated to maintain product liability insurance obtained by it pursuant to this Section during the Term and after expiration or termination of this Agreement for a period of [***]. Catalent shall provide evidence of such insurance to Horizon upon request.

5.7 Taxes. Unless otherwise indicated in writing by Catalent, all prices and charges are exclusive of any applicable taxes, levies, import duties, Goods and Services Tax (GST), Value Added Tax (VAT), and fees of whatever nature, imposed by or under the authority of any governmental body, all of which shall be paid by Client (other than taxes on Catalent’s net income). Indiana sales tax shall be charged on all applicable transactions unless Client has provided to Catalent a properly completed Indiana Exemption Certificate (Form ST-105). To the extent that Client owns any personal property located at the Facility that is subject to property tax, Catalent may be obligated to report such property and Client shall be obligated to file and pay all applicable Monroe County, Indiana property taxes.

[***] = Certain Confidential Information Omitted

6.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows:

6.1.1 Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.

6.1.2 Such Party (i) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (ii) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.

6.1.3 This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

6.1.4 All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained.

6.1.5 The execution and delivery of this Agreement and the performance of such Party’s obligations hereunder (i) do not conflict with or violate any requirement of Applicable Laws or regulations and (ii) do not conflict with, or constitute a default under, any contractual obligation of such Party. Catalent has informed Client, and Client acknowledges, that Catalent is a US Government contractor and that in an emergency, Catalent may be obligated to give US Government production requirements over other production orders. If this occurs, it shall not be deemed a breach by Catalent of its representations and warranties under this clause, or under any other section of this Agreement. [***].

6.2 Representations and Warranties of Client. Client further represents and warrants that:

6.2.1 [***], Client has lawful access to and the right to license or sublicense the Client Confidential Information, Client Intellectual Property Rights and Client Materials to Catalent under and in accordance with the terms of this Agreement.

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6.2.2 Client has not received any notice of infringement or misappropriation of any third party intellectual property rights relating to the Client Confidential Information, Client Intellectual Property Rights and Client Materials used by Catalent under this Agreement and, to Client’s knowledge, Client is not subject to any claim of such infringement or misappropriation.

6.2.3 [***] each of the making, having made, use or importation of the Product, the Client Materials and/or Catalent’s use of the Client Materials in accordance with the applicable Plan do not infringe or misappropriate any third party intellectual property rights.

6.2.4 [***] the SDSs for the Client Materials are accurate and the Client Materials are free from all contaminants including, without limitation, virus, bacteria or other vectors. Client will notify Catalent of any new safety or toxicity issues in accordance with Section 2.2.

6.3 Representations and Warranties of Catalent. Catalent represents, warrants and covenants that: (a) the Production shall be performed at the Facility in accordance with Section 3.2 (“Performance”); (b) the Product when made available at Catalent’s shipping docks in accordance with this Agreement and Client’s instructions shall: (i) meet Product Specifications; (ii) be free from defects in material and workmanship; (iii) have been Produced in accordance with the Quality Agreement, CGMP and Applicable Laws; and (iv) shall not be adulterated or misbranded within the meaning of the FDCA; and (c) [***] Catalent does not and shall not employ, contract with or retain any person directly or indirectly to perform Services under this Agreement if such person is debarred under 21 U.S.C. 335a (a) or (b) or other equivalent laws, rules, regulations or standards of any other relevant jurisdiction, and it will immediately disclose in writing to Client if any employee or agent is debarred, or if any action or investigation is pending or [***] threatened, relating to the debarment of Catalent or any person performing services related to this Agreement; and (d) [***]. Catalent’s Production process does not infringe or misappropriate any third party intellectual property rights and Catalent is not subject to any claim or notice of infringement or misappropriation of any third party intellectual property rights relating to its Production process.

6.4 THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS SECTION 6 (“REPRESENTATIONS AND WARRANTIES”) ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS, ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR [***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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7. Indemnification; Limitation of Liability; Waiver of Subrogation.

7.1 Client Indemnification. Client shall indemnify, defend and hold harmless Catalent, its Affiliates, and their directors, officers, employees and agents (collectively, “Catalent Indemnitees”) against any Damages, whether or not foreseeable or in the contemplation of Catalent or Client, that Catalent suffers as a result of any third party claims, third party suits or third party actions arising from: (a) any breach of the representations and warranties set forth in Sections 6.1 (“Mutual Representations and Warranties”) and 6.2 (“Representations and Warranties of Client”); (b) the distribution or use of the Product (including product liability or bodily injury with respect to the Product), except to the extent such loss, damage, costs and expenses are directly caused by Catalent’s breach of Section 6.3 of this Agreement; (c) negligence (active, passive or imputed), gross negligence or willful misconduct of any Client Indemnitee in relation to the use, processing, storage or sale of the Product; or (d) any claims by third parties alleging Catalent’s use of the Client Materials, Client Confidential Information, Client Intellectual Property Rights or the Product Specifications in accordance with this Agreement infringes any rights (including, without limitation, any intellectual or other proprietary rights) of any third party (whether or not Client knew or should have known about such alleged infringement) except to the extent Catalent infringes any rights of any third parties by application of Catalent’s Production techniques or any Catalent Intellectual Property Rights while performing the Services; in each case (a) – (d), except to the extent the Damages are a result of any Catalent Indemnitee’s negligence (active, passive or imputed), gross negligence or willful misconduct or breach of this Agreement.

7.2 Catalent Indemnification. Subject to the limitations set forth in Section 7.4(b), Catalent shall indemnify, defend and hold harmless Client, its Affiliates, and their directors, officers, employees, and agents (collectively, “Client Indemnitees”) against any Damages, whether or not foreseeable or in the contemplation of Client or Catalent, that Client suffers as a result of any third party claims, third party suits or third party actions arising from Catalent’s breach of Section 6.1 (“Mutual Representation and Warranties”) or 6.3 (“Representations and Warranties of Catalent”); or (b) negligence (active, passive or imputed), gross negligence or willful misconduct of any Catalent Indemnitee, except to the extent the Damages are a result of: (a) any Client Indemnitee’s negligence (active, passive or imputed), gross negligence or willful misconduct or breach of this Agreement; or (b) any claims by third parties alleging Catalent’s use of the Client Materials, Client Confidential Information, Client Intellectual Property Rights or the Product Specifications in accordance with this Agreement infringes any rights (including,
without limitation, any intellectual or other proprietary rights) of any third party (whether or not Client knew or should have known about such alleged infringement) except to the extent Catalent infringes any rights of any third parties by application of Catalent’s Production techniques or any Catalent Intellectual Property Rights while performing the Services.

7.3 **Procedure for Indemnification.** A Party (the “**Indemnitee**”) that intends to claim indemnification under Sections 7.1 (“Client Indemnification”) or 7.2 (“Catalent Indemnification”) shall promptly notify the other Party (the “**Indemnitor**”) of any claim, demand, action or other proceeding for which the Indemnitee intends to claim such indemnification. The Indemnitor shall have the right to participate in, and to the extent the Indemnitor so desires, to assume the defense thereof with counsel selected by the Indemnitor; provided, however, that the Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitor, if representation of the Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitee and any other Party represented by such counsel in such proceeding. The indemnity obligations under Sections 7.1 (“Client Indemnification”) and 7.2 (“Catalent Indemnification”) shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the prior express written consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed. The failure to deliver notice to the Indemnitor within a reasonable time after notice of any such claim or demand, or the commencement of any such action or other proceeding, to the extent prejudicial to its ability to defend such claim, demand, action or other proceeding, shall relieve such Indemnitor of any liability to the Indemnitee under Sections 7.1 (“Client Indemnification”) and 7.2 (“Catalent Indemnification”) with respect thereto, and the omission so to deliver notice to the Indemnitor shall not relieve it of any liability that it may have to the Indemnitee otherwise than under Sections 7.1 (“Client Indemnification”) and 7.2 (“Catalent Indemnification”). The Indemnitor may not settle or otherwise consent to an adverse judgment in any such claim, demand, action or other proceeding that diminishes the rights or interests of the Indemnitee without the prior express written consent of the Indemnitee, which consent shall not be unreasonably withheld or delayed. The Indemnitee, its employees and agents shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation and defense of any claim, demand, action or other proceeding covered by this Section 7.3 (“Procedure for Indemnification”).

7.4 **Limitation of Liability.**

7.4.1 **IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR TO ANY THIRD PARTY UNDER THIS AGREEMENT FOR ANY PUNITIVE DAMAGES OR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS, BUSINESS OR REVENUE) EVEN IF ADVISED OR AWARE OF THE POSSIBILITY OF SUCH DAMAGES.**
7.4.2 In addition, without prejudice or modification to the terms of Sections 7.1 ("Client Indemnification"), 7.2 ("Catalent Indemnification") and 7.3 ("Procedure for Indemnification"), the liability of each Party to the other Party, its permitted assigns and successors in interest, for any loss suffered by such other Party or its permitted assigns and successors in interest, arising as a direct result of a breach of this Agreement, or of any other liability, including without limitation, misrepresentation and negligence (whether active, passive or imputed), arising out of this Agreement and Production hereunder, including without limitation the production and/or supply of the Product, each Party’s liability shall be limited to the payment of Damages in an amount which shall not exceed an amount equal to [***] for the Batch(es) that gave rise to the liability. Notwithstanding the above, in no event shall Catalent’s total aggregate liability per Product (regardless of presentation) in any calendar year for all claims of all types exceed [***] dollars ($[***]) per Product (regardless of presentation) supplied under this Agreement.

7.4.3 The limitations of liability set forth in this Section 7.4 will not apply to [***].

7.5 Abatement. Notwithstanding anything to the contrary in this Agreement, in the event that Production is held, in a suit or proceeding, to infringe any intellectual property rights of a third party (or to constitute the misappropriation of a trade secret of a third party) and Production is enjoined, or Catalent has an objective basis (confirmed by an opinion of its legal counsel) for believing that it is likely to be found to infringe or constitute a misappropriation, or is likely to be enjoined, then Catalent shall, at its option, either (i) procure the right to continue Production or (ii) modify the Production so that it becomes non-infringing or no longer constitutes a misappropriation, provided that such modification has no adverse effect on Client hereunder; provided, however, that if (i) and (ii) are not reasonably practicable, then either Party shall have the right, in its sole discretion, to terminate this Agreement by giving written notice to the other Party. The termination shall be effective [***] months after the date the notice is given, provided that: (i) Catalent shall not be obligated to continue Production if Production is enjoined; and (ii) if Production is not enjoined and Client requests in writing that Catalent continue Production during such [***] period, Client shall indemnify Catalent for any damages or expenses (including attorney fees) that Catalent incurs as a result of continuing the Production. In addition, if such infringement relates to the application of Catalent’s Production techniques or any Catalent Intellectual Property Rights, then Client shall have no liability with respect to any orders cancelled in connection with such termination.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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7.6 Waiver of Subrogation. All Catalent Supplied Components and equipment (other than Dedicated Equipment owned by Client) used by Catalent in the Production of Product (collectively, “Catalent Property”) shall at all times remain the property of Catalent and Catalent assumes risk of loss for such property until delivery of Product to a common carrier as specified under Section 3.10 (“Delivery Terms”). Catalent hereby waives any and all rights of recovery against Client, or against its directors, officers, employees, agents or representatives, for any loss or damage to Catalent Property to the extent the loss of damage is covered by insurance (whether or not such insurance is described in this Agreement). Client assumes all risk of loss for all Client Materials supplied by Client, Dedicated Equipment owned by Client, and all Product (collectively, “Client Property”), provided that such loss did not arise from [***]. Client hereby waives any and all rights of recovery against Catalent, or against its directors, officers, employees, agents or representatives, for any loss or damage to the Client Property to the extent the loss of damage is covered by insurance (whether or not such insurance is described in this Agreement).

7.7 Limitations an Essential Element of the Agreement. The Parties are willing to enter into this Agreement only in consideration of and in reliance upon the provisions of this Agreement limiting their exposure to loss or liability. Such provisions are an essential part of the bargain underlying this Agreement and have been reflected in the pricing and other consideration specified in this Agreement. Both Parties understand and agree that the exclusion of warranties, limitation of liability and the limitation of remedies allocate risks between the Parties as authorized under Applicable Laws.

8. Confidentiality and Non-Solicitation of Employees.

8.1 Confidential Information. Each Receiving Party agrees that during the Term of this Agreement and for a period of [***] years thereafter, it will keep the Confidential Information of the Disclosing Party secret and confidential, protect such Confidential Information with at least the same degree of care as it normally exercises to protect its own Confidential Information of a similar nature, respect the Disclosing Party’s proprietary rights therein and make use of and permit to be made use of such information only as necessary to perform its obligations and exercise its rights under this Agreement. The Receiving Party may not disclose or permit the Confidential Information of the Disclosing Party to be disclosed to any third party except as expressly provided herein without the Disclosing Party’s prior written consent.

8.2 Disclosure of Confidential Information. The Receiving Party shall grant access to the Confidential Information of the Disclosing Party only to its Affiliates, subcontractors, suppliers, employees, consultants and contractors and, in the case of Client as the Receiving Party, partners and collaborators, who reasonably need to know such information for purposes such Party’s exercise of its rights or performance of its obligations under this Agreement and who are subject to the written or otherwise legally enforceable obligations of confidentiality with respect to such Confidential Information at least as stringent as those set forth herein.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

CONFIDENTIAL
8.3 Exceptions to Confidentiality. The obligations of Article 8 shall not apply to Confidential Information to the extent that it:

8.3.1 is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party in breach of this Article 8, generally known or available;

8.3.2 is known by the Receiving Party at the time of receiving such information or the generation of such information hereunder, as shown by contemporaneous written records;

8.3.3 is furnished after the Effective Date to the Receiving Party by a third party, without breach of and not subject to any obligation of confidentiality; or

8.3.4 is independently developed by the Receiving Party without use of or reference to Confidential Information of the Disclosing Party, as shown by independent written records, contemporaneous with such development.

Notwithstanding anything to the contrary in this Article 8, the Receiving Party may disclose the Disclosing Party’s Confidential Information if it is required to be disclosed under any statutory, regulatory, stock exchange or similar legislative requirement or court order, provided, however, that (a) the Receiving Party gives the Disclosing Party prior written notice of such required disclosure and assists the Disclosing Party in its [***] to prevent or limit such disclosure; and (b) the Confidential Information so disclosed otherwise remains the Confidential Information of the Disclosing Party for the purposes of Article 8.

8.4 Return of Confidential Information. Upon any expiration or termination of this Agreement, each Party will use diligent efforts (including without limitation a diligent search of files and computer storage devices) to return or destroy all Confidential Information of the other Party and all copies, summaries, compilations, extracts or other derivatives thereof, except to the extent such Confidential Information is necessary to exercise any right surviving termination of this Agreement. Additionally, each Party will be allowed to keep one archival copy of any Confidential Information of the other Party solely for record keeping and for the purpose of determining its rights and obligations hereunder and subject to this Article 8.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
8.5 **Restrictions on Soliciting or Hiring Employees.** During the Term of the Agreement and for [***] months after the Agreement terminates or expires, neither Party shall knowingly, directly or indirectly, hire or employ any person who is an employee of the other Party during the Term (or was an employee of the other Party during the preceding [***] months) and directly involved in the Production. Nothing in this Section shall prohibit a Party from hiring or employing candidates that respond to a general advertisement that is not targeted at the other Party’s employees.

8.6 **Remedies.** Each Party acknowledges and agrees that the other Party may not have an adequate remedy at law for a violation of this Article 8 and therefore shall be entitled to seek enforcement of this Article 8 by temporary or permanent injunctive or mandatory relief obtained in any court of competent jurisdiction, and without prejudice to any other rights and/or remedies which may be available to such Party at law or in equity.

8.7 **Use of Name.** Except as set forth in Section 9.6 (“Trademarks”), neither Party shall use the name or trademarks of the other Party, except to the extent that a Party is permitted to use the Confidential Information of the other Party or required to do so pursuant to this Article 8, without the prior written consent of such other Party, such consent not to be unreasonably withheld. Notwithstanding the foregoing, Client may inform third parties that Catalent is the manufacturer and supplier of Product. Under no circumstances shall either Party state or imply in any promotional material, publication or other published announcement that the other Party has tested or approved any product.

9. **Intellectual Property.**

9.1 **Disclosure.** Subject to the obligations of confidentiality set forth in Article 8 (“Confidential Information”), each Party shall disclose to the other Party any and all Inventions made pursuant to the activities undertaken relating to this Agreement at least quarterly or as may otherwise be agreed to in writing by the Parties.

9.2 **Catalent Intellectual Property Rights.** Catalent shall solely own all right, title and interest in and to the Catalent Intellectual Property Rights. To the extent that the making, use, sale, or offer for sale, of the Product Produced hereunder or under the Prior CSA by or on behalf of Client or its Affiliates requires a license under the Catalent Intellectual Property Rights, Catalent hereby grants a nonexclusive, royalty-free license under the Catalent Intellectual Property Rights to Client and its Affiliates to make, use, sell, or offer for sale and have such activities done on its behalf (but not to have made or import) the Product and with no right to sublicense. Client shall not, without Catalent’s prior written consent, use the Catalent Intellectual Property Rights for any purpose other than as contemplated herein.

9.3 **Client Intellectual Property Rights.** Client shall solely own all right, title and interest in and to the Client Intellectual Property Rights. Client hereby grants a nonexclusive, royalty-free, non-sublicenseable license under the Client Intellectual Property Rights (including the Client Confidential Information and

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
9.4 Inventions.

9.4.1 All Project Inventions and Catalent Improvements shall be owned by Catalent. To the extent that a Project Invention or Catalent Improvement is patentable, Catalent shall have the right but not the obligation to file, prosecute and maintain any patents or patent applications claiming or covering any Project Invention.

9.4.2 Client shall solely own all right, title, and interest in and to all Product Inventions and Deliverables. Catalent hereby assigns, and to the extent not presently assignable shall assign, all right, title and interest in and to Product Inventions and Deliverables to Client. Client shall have the right but not the obligation to file, prosecute and maintain any patents or patent applications claiming all Product Inventions.

9.4.3 Each Party shall bear the expense of activities relating to its own filing, prosecution and maintenance of any patent or patent applications provided for by this Section 9.4 ("Inventions"). Each Party shall execute all writings or take such acts, at the other Party’s expense, as may be reasonably required for either Party to fully enjoy the rights and licenses granted pursuant to this Section 9.4 ("Inventions").

9.4.4 The Parties do not anticipate the joint conception or creation of any Inventions. In the event of any jointly conceived or created Invention, other than a Catalent Improvement (which shall be subject to Section 9.4.1), the Parties shall discuss in good faith whether any patent application should be filed with respect to such Invention and the Parties’ respective rights and responsibilities therefor.

9.5 No Implied Licenses. Except as expressly set forth in this Agreement, nothing contained in this Agreement shall be construed as granting, by implication, estoppel or otherwise, any licenses or rights under any patents or other intellectual property rights. Only licenses and rights granted expressly herein shall be of legal force and effect.
9.6 Trademarks.

9.6.1 Catalent License. Client grants to Catalent a non-exclusive, royalty free license to use the Client Trademarks for the sole purpose of allowing Catalent to fulfill its responsibilities under this Agreement. Such license shall not be transferable in whole or in part.

9.6.2 Client Ownership. Client shall be solely responsible for selecting, registering and enforcing the Client Trademarks used to identify the Product and except as set forth in Section 9.6.1 (“Catalent License”) and shall have sole and exclusive rights in such Client Trademarks.

10. Term and Termination.

10.1 Initial Term. This Agreement shall be effective on the Effective Date and shall continue for sixty (60) months thereafter (the “Initial Term”), unless earlier terminated in accordance with the terms of this Agreement. This Agreement will be renewed automatically for two (2) additional twenty-four (24) month periods commencing at the expiration of the Initial Term and any extensions thereof unless either the Client or Catalent terminates the Agreement by giving the other party written notice of intent to terminate at least twenty-four (24) months prior to the expiration of the Initial Term or any extension thereof (the “Termination Notice Period”). The Initial Term as may be extended is referred to herein as the “Term.”

10.2 Termination for Breach.

10.2.1 Generally. Except as provided in Section 10.2.2 (“Exhaustion”), the failure by either Party (the “Defaulting Party”) to comply with any of the Defaulting Party’s material obligations under this Agreement shall entitle the other Party (the “Non-Defaulting Party”) to give to the Defaulting Party notice specifying the nature of the default and requiring the Defaulting Party to cure such default. If such default is not cured within fifteen (15) days (in the case of a payment default) or thirty (30) days (in the case of a non-payment default) after the receipt of such notice (or, if such default reasonably cannot be cured within such period or if the Defaulting Party shall not commence and diligently continue actions to cure such default during such period), the Non-Defaulting Party shall be entitled, without prejudice to any of the other rights conferred on it by this Agreement or available to it at law, in equity or under this Agreement, to terminate this Agreement (and, if Client is the Non-Defaulting Party, any then-outstanding Firm Orders) by giving further notice to the Defaulting Party, to take effect immediately upon delivery thereof. The right of either Party to terminate this Agreement, as provided in this Section 10.2.1 (“Generally”), shall not be affected in any way by its waiver or failure to take action with respect to any previous default.

10.2.2 Exhaustion. No default based on a claimed failure of any Product to conform to the Product Specifications shall be the subject of a notice under Section 10.2.1 (“Generally”) until unless all procedures and remedies specified in Article 4 (“Nonconforming Product”) shall have first been exhausted. Furthermore, no inability by either Party to perform caused by an event of Force Majeure shall be the subject of a notice under Section 10.2.1 (“Generally”).
10.3 Termination for Insolvency. Subject to any limitations imposed by Applicable Laws, either Party shall have the right to terminate this Agreement by giving notice to the other Party in the event that:

10.3.1 Such other Party shall have: (i) voluntarily commenced any proceeding or filed any petition seeking relief under the bankruptcy, insolvency or other similar laws of any jurisdiction, (ii) applied for, or consented to, the appointment of a receiver, trustee, custodian, sequestrator, conciliator, administrator or similar official for it or for all or substantially all of its property, (iii) filed an answer admitting the material allegations of a petition filed against or in respect of it in any such proceeding, (iv) made a general assignment for the benefit of creditors of all or substantially all of its assets, (v) become unable generally, or admitted in writing its inability, to pay all or substantially all of its debts as they become due, or (vi) taken corporate action for the purpose of effecting any of the foregoing; or

10.3.2 An involuntary proceeding shall have been commenced, or any involuntary petition shall have been filed, in a court of competent jurisdiction seeking: (i) relief in respect of such other Party, or of its property, under the bankruptcy, insolvency or similar laws of any jurisdiction, (ii) the appointment of a receiver, trustee, custodian, sequestrator, conciliator, administrator or similar official for such other Party or for all or substantially all of its property, or (iii) the winding-up or liquidation of such other Party; and, in each case, such proceeding or petition shall have continued undismissed for sixty (60) days or an order or decree approving or ordering any of the foregoing shall have continued unstayed, unappealed and in effect for thirty (30) days.

10.4 Consequences of Termination.

10.4.1 Payments Upon and After Termination. Upon expiration or termination of this Agreement Client shall pay Catalent for all work completed subject to and in accordance with the terms of this Agreement and, if the Agreement was not terminated by Client pursuant to Section 10.2, all Firm Orders (including all binding Purchase Orders) that are in place as of the date of termination. All such payments shall be made within [***] days of Client’s receipt of a correct invoice therefor from Catalent. For clarity, if Client terminates this Agreement pursuant to Section 10.2, then Client shall have no liability to Catalent with respect to any orders cancelled in connection with such termination. Any payments to be made under this Section 10.4.1 shall be offset against any credits in Client’s account, and any amounts remaining after such offset shall be promptly reimbursed to Client.
10.4.2 Services During Termination Notice Period. Except if Catalent terminates this Agreement pursuant to Section 10.2 or 10.3, during the Termination Notice Period, Catalent shall Produce all Product that is subject to all Firm Orders in accordance with this Agreement and deliver such Product to Client. For the avoidance of doubt, this Agreement shall remain in full force and effect during the Termination Notice Period.

10.5 Accrued Rights; Surviving Obligations.

10.5.1 Accrued Rights. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of either Party prior to such termination or expiration. Such termination or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of this Agreement.

10.5.2 Surviving Obligations. All of the Parties’ respective rights and obligations under (a) Sections 1 (“Definitions”), 2.3 (“Catalent Obligations Relating to Client Materials”), 2.4 (“Ownership and Risk of Loss; Client Materials and Product”), 3.12 (“Recall”), 3.14 (“Product Testing and DMF”), 4 (“Nonconforming Product”), 5.1 (“Product Price”), 5.2 (“Cost Reimbursement”), 5.3 (“Payment Terms”), 5.6 (“Insurance”), 6 (“Representations and Warranties”), 7 (“Indemnification; Limitation of Liability; Waiver of Subrogation”), 8 (“Confidentiality and Non-Solicitation of Employees”), 9 (“Intellectual Property”), 10.4 (“Consequences of Termination”), 10.5 (“Accrued Rights; Surviving Obligations”), 11.7 (“Records”), 11.9 (“Ownership of Regulatory Filings”), and Article 12 (“Miscellaneous”) (except for Sections 12.12 (“Subcontracting”) through and including 12.16 (“Importer of Record”) of this Agreement, and (b) Sections 2 (“Overall Responsibilities”), 3 (“Definitions”), and Section 5 (“Specific Responsibilities”) items 4.3, 4.10, 6, 8, 9, 11.2, 11.3, 14, 15 and 16 of the Quality Agreement shall survive termination, relinquishment or expiration of this Agreement.

10.5.3 On or before the effective date of any termination or expiration, Catalent shall promptly transfer to Client all compounds or other materials and supplies provided to Catalent by or on behalf of Client, including any Bulk Drug Substance, and all information in its possession and used in connection with the development and manufacture of the Product. Notwithstanding the above, Catalent may retain originals or copies (as the case may be) of information related to the manufacture of the Product for quality, regulatory, or record keeping purposes, subject to Article 8.
11. Regulatory.

11.1 Permits. Each Party shall be responsible, at its own expense, to obtain and maintain all permits and licenses required for it to carry out its obligations hereunder.

11.2 Regulatory Approvals. Client will advise Catalent of document requirements in support of NDA and/or BLA and similar applications required of foreign governments and agencies that relate to the Services, including amendments, license applications, supplements and maintenance of such. Catalent will provide documents and assist Client in preparation of submissions to Regulatory Authorities (both U.S. and foreign) designated by Client in support of Client’s NDAs and/or BLAs, similar applications required of foreign governments and licenses. All regulatory submission preparation and maintenance performed by Catalent for Client shall be specified in a Project Plan or Commercial Product Plan for regulatory services.

11.3 Compliance with CGMPs; Monitoring of Records. If and as required by a Project Plan, Catalent shall monitor and maintain records respecting its compliance with CGMPs in the manner provided by the Quality Agreement, including the process of establishment and implementation of the operating procedures and the training of personnel as are reasonably necessary to assure such compliance.

11.4 Regulatory Authority Inspections. At Client’s request, Catalent will authorize Regulatory Authorities to review related applications on Client’s behalf. Catalent will notify Client within [***] business days of all contacts with Regulatory Authorities (both written and verbal) related to each Product. Catalent shall inform Client of the result of any regulatory inspection which directly affects the Production of a Product, including any notice of inspection, notice of violation or other similar notice received by Catalent affecting Production, Facility, testing, storage or handling of a Product. In the event of an FDA inspection which directly involves a Product, Client shall be immediately informed of the issuance of the Notice of Inspection (FDA Form 482). In the event that there are inspectional observations (FDA Form 483), Client shall be informed immediately and shall have the opportunity to review and provide Catalent with comments to Catalent’s response. Client shall provide its comments to the response of these observations within [***] business days. The contents of Catalent’s response shall be determined by Catalent in its sole discretion. Catalent shall provide Client with a copy of Catalent’s response as provided to such Regulatory Authority as set forth in the Quality Agreement.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
11.5 **Regulatory Communications and Correspondence.** Except as provided in Section 11.4 ("Regulatory Authority Inspections"), any and all other communications from and to the FDA or other Regulatory Authorities related to the Production of the Product at the Facility shall be handled in accordance with the terms and conditions of the Quality Agreement, or as otherwise agreed in writing by Catalent and Client.

11.6 **Regulatory Filings and Maintenance.** Client shall be solely responsible for preparing and submitting to the FDA all documents necessary for the Regulatory Approval of Product including adverse drug experience reports, field alert reports, periodic reports and applications for renewals, variations, supplements and amendments. Catalent shall prepare and maintain all manufacturing files, certificates, authorizations, data and other records that directly pertain to the Production of the Product, as further set forth in the Quality Agreement or as otherwise agreed in writing by Catalent and Client.

11.7 **Records.** Catalent shall maintain the records required by the terms and conditions of the Quality Agreement, or as otherwise agreed to in writing by Catalent and Client in a Project Plan. Catalent agrees that, in response to any complaint, or in the defense by Client of any litigation, hearing, regulatory proceeding or investigation relating to the Production of Product, Catalent shall use [***] to make available to Client (during normal business hours and upon reasonable prior written notice) such Catalent employees and records as may be reasonably necessary to permit the effective response to, defense of, or investigation of such matters, subject to appropriate confidentiality protections. Client shall reimburse Catalent for all reasonable, documented costs and expenses incurred by Catalent in connection with the performance of Catalent’s obligations under the immediately preceding sentence, except to the extent that such litigation, hearing, regulatory proceeding or investigation arises from Catalent’s breach of this Agreement, gross negligence or willful misconduct.

11.8 **Notification.** Each Party shall promptly notify the other of new regulatory requirements of which it becomes aware that are relevant to the Production of a Product under this Agreement and that are required by the FDA, any other applicable Regulatory Authority or other Applicable Laws or governmental regulations. The Parties shall confer with each other with respect to the best means to comply with such requirements.

11.9 **Ownership of Regulatory Filings.** Client shall be the sole owner of all regulatory filings and all governmental approvals obtained by Client from any Regulatory Authority with respect to the Product. Notwithstanding the foregoing, and for the avoidance of doubt, all rights in and to Catalent Intellectual Property Rights and Catalent Confidential Information shall remain entirely vested in Catalent.

[***] = **CERTAIN CONFIDENTIAL INFORMATION OMITTED**
12. Miscellaneous.

12.1 Assignment. Neither Party may assign this Agreement without the prior written consent of the other Party, which consent will not be unreasonably withheld. Notwithstanding the foregoing, either Party may, without the prior consent of the other Party, assign this Agreement to its Affiliate(s) or to the successor entity in connection with a merger or acquisition, or to an entity acquiring substantially all of the product line or business operations of the assigning Party to which this Agreement pertains, provided that such Affiliate, successor or acquiring entity will expressly assume in writing the obligation to perform in accordance with the terms and conditions of this Agreement. Any purported assignment not in compliance with this Section 12.1 (“Assignment”) shall be void.

12.2 Severability. If any item or provision of this Agreement shall to any extent be invalid or unenforceable, it shall be severed from this Agreement, and the remainder of the provisions of this Agreement shall not be affected thereby, and each term and provision of this Agreement shall be valid and shall be enforced to the fullest extent permitted by Applicable Law, and the Parties will negotiate in good faith to modify the Agreement to preserve (to the extent possible) their original intent.

12.3 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties hereto to the other shall be in writing, delivered personally or by internationally recognized express courier, such as Federal Express or DHL, postage prepaid (where applicable), addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the address or in accordance with this Section 12.3 (“Notices”) and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

If to Catalent:

Catalent Indiana, LLC
1300 South Patterson Drive
Bloomington, Indiana 47403
Attention: [***]
E-Mail: [***]

With a copy to:

Catalent Pharma Solutions, LLC
14 Schoolhouse Road
Somerset, NJ 08873
Attention: [***]
E-Mail: [***]

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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12.4 **Governing Law.** The Agreement shall be governed by and construed in accordance with the laws of the [***].

12.5 **Venue, Jurisdiction.** Any action or proceeding brought by either Party seeking to enforce any provision of, or based on any right arising out of, this Agreement must be brought against either Party in the courts of the State of Delaware. Each Party (a) hereby irrevocably submits to the jurisdiction of the state courts of the State of Delaware and to the jurisdiction of any United States District Court in the State of Delaware, for the purpose of any suit, action, or other proceeding arising out of or based upon this Agreement or the subject matter hereof brought by any Party or its successors or assigns, (b) hereby waives, and agrees not to assert, by way of motion, as a defense, or otherwise, in any such suit, action, or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action, or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court, and (c) hereby waives and agrees not to seek any review by any court of any other jurisdiction that may be called upon to grant an enforcement of the judgment of any such Delaware state or federal court.

12.6 **Entire Agreement.** This Agreement and the Quality Agreement constitutes the entire and exclusive agreement between the Parties with respect to the subject matter hereof and supersedes and cancels all previous discussions, agreements, representations, commitments and writing in respect thereof, including the Prior CSA. For clarity, such termination of the Prior CSA does not release either Party from any liability or obligation, or affect either Party’s rights or remedies, accruing thereunder prior to the Effective Date. No amendment or addition to this
Agreement shall be effective unless reduced to writing and executed by an authorized representative of each Party. In the event of a conflict between the provisions of this Agreement and the provisions of any exhibits or attachments hereto, including any Plan, the provisions of this Agreement shall govern.

12.7 Attempts to Amicably Resolve Disputes.

12.7.1 To avoid litigation and to resolve any conflicts that arise during the performance of the Services or thereafter, Catalent and Client agree that, prior to the commencement of litigation by either Party, the Parties shall engage in executive mediation. Either Party may seek executive mediation by delivering a written request for such mediation to the other. Delivery of such request may be made by hand or by electronic mail. The request shall be addressed to the following individuals:

Catalent: [***]
Client: [***]

12.7.2 Within [***] business days of the delivery of such request, each Party shall appoint a company executive who is not directly involved in the dispute to meet with the other Party’s company executive for the purpose of resolving the dispute. No later than [***] business days of their appointment, the two executives shall meet to consider the dispute. They may request such information as either deems necessary and may meet jointly or separately with party representatives involved in the dispute. The two appointed executives shall use good faith efforts to reach a resolution of the dispute.

12.7.3 If a resolution is reached, it shall be reduced to writing and shall be final and binding on the Parties.

12.7.4 If the two executives cannot reach agreement within [***] business days of their initial meeting, unless the two executives agree to additional review time, either Party may thereafter pursue any remedy at law or in equity.

12.7.5 Notwithstanding anything herein to the contrary, each Party shall have the right at any time to seek injunctive relief or a temporary restraining order or the like from any court of competent jurisdiction at any time as it may deem prudent to protect its Confidential Information and intellectual property rights.

12.8 Waiver. No waiver of any rights shall be effective unless consented to in writing by the Party to be charged and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
12.9 **Independent Contractors.** Catalent and Client each acknowledge that they shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture, agency or any type of fiduciary relationship. Neither Catalent nor Client shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior consent of the other Party to do so.

12.10 **Affiliate(s).** Any licenses granted under this Agreement by a Party will be deemed to be granted both to the other Party and the other Party’s Affiliate(s). Catalent shall cause its Affiliate(s) involved in the provision of the Services to comply fully with the provisions of this Agreement to the extent such provisions specifically relate to, or are intended to specifically relate to, its Affiliate(s), as though such Affiliate(s) were expressly named as joint obligors hereunder. Each Party will be responsible for all acts and omissions of its Affiliates as if they were such Party hereunder.

12.11 **Counterparts/Facsimile.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile signatures and signatures exchanged electronically or by .pdf shall have the same force and effect as original signatures.

12.12 **Subcontracting.** Catalent shall not subcontract any of its obligations hereunder except with Client’s prior written consent. Catalent will ensure that each such subcontractor agrees to be bound by obligations similar to those contained herein, including without limitation the obligations set forth in Sections 8 and 9. Catalent will be responsible for all acts and omissions of its subcontractors as if they were Catalent hereunder.

12.13 **Force Majeure.** Neither Party shall be liable for failure to perform its obligations under this Agreement (or for a delay in the performance of such obligations), and neither shall be deemed in breach of its obligations, if such failure or delay is due to Force Majeure. In event of Force Majeure, the Party affected thereby shall promptly notify the other Party and use [***] to cure or overcome the same and resume performance of its obligations hereunder. If an event of Force Majeure continues and causes a Party to delay its performance of its obligations for more than [***] days, then the other Party shall have the right upon written notice to terminate this Agreement without any liability to the other Party (including for any Firm Orders cancelled in connection with such termination).

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
12.14 **Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by one Party to the other are, for all purposes of Section 365(n) of Title XI of the United States Code (“Title XI”), licenses of rights to “intellectual property” as defined in Title XI. If a Party seeks or involuntarily is placed under Title XI and the trustee rejects this Agreement as contemplated under 11 U.S.C. 365(n)(1), the other Party hereby elects, pursuant to Section 365(n) of Title XI, to retain all rights granted to it under this Agreement to the extent permitted by Applicable Law.

12.15 **Exporter of Record.** Client shall be the exporter of record for any Product shipped out of the United States. Client warrants that all shipments of Product exported from the United States will be made in compliance with all export laws and regulations and all applicable import laws and regulations of the country of importation. Client shall be responsible for obtaining any licenses or government authorization(s) necessary for exportation from the United States, and for ensuring that all domestic and international shipments are made in accordance with all Applicable Laws and regulations, including but not limited to Department of Transportation and Department of Homeland Security regulations related to transportation of biological agents. Client’s designated carrier and freight forwarder shall solely be Client’s agent. Client shall select and pay the freight forwarder and such designated freight forwarder shall solely be responsible for preparing and filing any relevant declarations or other documents required for the export. Client shall bear all costs and expenses associated with this Section 12.15 (“Exporter of Record”).

12.16 **Importer of Record.** In the event any material or equipment to be supplied by Client, including without limitation Client-Supplied Components and Bulk Drug Substance, is imported into the United States for delivery to Catalent (“Imported Goods”), such Imported Goods shall be imported DDP Bloomington, IN (Incoterms 2010). Client shall be deemed to be the “Importer of Record” of such Imported Goods. As the Importer of Record, Client shall be responsible for all aspects of the Imported Goods including, without limitation (a) payment of all tariffs, duties, customs, fees, expenses and charges payable in connection with the importation and delivery of the Imported Goods, and (b) keeping all records, documents, correspondence and tracking information required by Applicable Laws, rules and regulations arising out of or in connection with the importation or delivery of the Imported Goods.

12.17 **Quality Agreement.** The safety, quality control, and quality assurance aspects of the Services shall be pursuant to the Quality Agreement. In the event of a conflict between the provisions of this Agreement and the provisions of the Quality Agreement, the provisions of this Agreement shall govern; provided that in the event of a conflict between this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with CGMP and all other regulatory obligations as they pertain to the Product, the provisions of the Quality Agreement shall govern. The Quality Agreement is subject to the terms of this Agreement and, accordingly, any material breach of the Quality Agreement shall be deemed to be a material breach of this Agreement.
12.18 Construction; Captions. Each Party acknowledges that it participated in the negotiation and preparation of this Agreement and that it had the opportunity to consult with an attorney of its choice in connection therewith. Ambiguities, if any, in this Agreement shall not be construed against either Party, irrespective of which Party may be deemed to have drafted the Agreement or authorized the ambiguous provision. Capitalized terms defined in the singular shall include the plural and vice versa. The terms “includes” and “including” mean “includes, without limitation,” and “including, without limitation,” respectively. “Shall” and “will” are synonyms. “Or” is used in the inclusive sense (“and/or”) unless the context clearly requires otherwise. Titles, headings and other captions are for convenience only and shall not affect the meaning or interpretation of this Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be signed by their duly authorized representatives to be effective as of the Effective Date.

Catalent Indiana, LLC

By: /s/ Authorized Signatory
[***]

Horizon Pharma Ireland Limited

By: /s/ Alan Mac Neice
Name: Alan Mac Neice
Title: Director

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
1) Teprotumumab
License Agreement

by and among

F. Hoffmann-La Roche Ltd,

a Swiss corporation;

Hoffmann-La Roche Inc.

a New Jersey corporation

and

River Vision LLC, a Delaware limited liability company
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License Agreement

THIS LICENSE AGREEMENT ("Agreement") is entered into as of the Effective Date by and among:

F. Hoffmann-La Roche Ltd, a corporation organized and existing under the laws of Switzerland, with its principal office at Grenzacherstrasse 124, CH-4070 Basel, Switzerland ("Roche Basel") and Hoffmann-La Roche Inc., a corporation organized and existing under the laws of New Jersey, with its principal office at 340 Kingsland Street, Nutley, New Jersey 07110, U.S.A. ("Roche Nutley"); Roche Basel and Roche Nutley together referred to as “Roche”)

and

River Vision LLC, a limited liability company organized and existing under the laws of Delaware, with its principal office at One Rockefeller Plaza, New York NY, 10020, U.S.A. ("River Vision").

Recitals

WHEREAS, Roche has conducted certain research and development related to, and possesses certain intellectual property rights with respect to teprotumumab, an antibody to IGF-1R ("Compound" as further defined below); and

WHEREAS, River Vision desires to obtain, and Roche is willing to grant to River Vision, an exclusive, royalty-bearing license, with the right to sublicense, under the Roche Patents and Roche Know-How (as defined below), to develop, have developed, commercialize, have commercialized, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import and have imported Compound and/or Product, as appropriate, in the Field in the Territory, subject to the terms and conditions hereof; and

WHEREAS, Roche desires to obtain, and River Vision is willing to grant to Roche, certain rights with respect to Compound and Product, subject to the terms and conditions hereof.

Agreement

NOW, THEREFORE, in consideration of the foregoing premises and mutual promises, terms, conditions, and covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Definitions

1.1 “Affiliate” shall mean, with respect to either party: (i) an entity which owns, directly or indirectly, a controlling interest in such party; (ii) an entity in which such party owns, either directly or indirectly, a controlling interest; or (iii) an entity, in which a controlling ownership, directly or indirectly, is common to the controlling ownership in such party, whereby “controlling interest” shall mean more than 50% (or if the jurisdiction where such entity is domiciled prohibits majority foreign ownership of such entity, the maximum foreign ownership interest permitted under such laws, provided that such ownership actually allows control of such entity) of the securities or other ownership interest representing the equity with the rights to vote in the designation of the governing bodies of such entity, or any other agreement or arrangement allowing the factual or legal control
of the decisions of such entity or its governing bodies. Anything to the contrary in this paragraph notwithstanding (i) Chugai Pharmaceutical Co., Ltd., 1-9, Kyobashi 2-chome, Chuo-ku, Tokyo, 104-8301, Japan ("Chugai") shall not be deemed an Affiliate of Roche unless Roche notifies River Vision that Roche wishes for Chugai to be deemed an Affiliate of Roche, and (ii) any entities that are Affiliated with River Vision as a result of NRM’s Affiliation with River Vision, shall not be deemed an Affiliate of River Vision unless River Vision notifies Roche that River Vision wishes for any such entity to be deemed an Affiliate of River Vision.

1.2 “Alliance Manager” shall have the meaning provided in Section 2.7.

1.3 “Agreement” shall mean this agreement.

1.4 “Appendix” shall mean an appendix to this Agreement.

1.5 “Approval” shall mean the first approval, license, registration, or authorization of any country, federal, supranational, state or local regulatory agency, department, bureau or other government entity that are necessary for the manufacture, use, storage, import, transport and/or sale of a Product in such jurisdiction.

1.6 “BLA” shall mean a Biologics License Application, or similar application for marketing approval of the Product in the Field submitted to the FDA, or a foreign equivalent of the FDA.

1.7 “BLA Filing” shall mean the date on which the first BLA for Product in any country of the Territory has been submitted which BLA has been accepted (but not yet approved) by the applicable Regulatory Authority.

1.8 “Business Day” shall mean 9.00am to 5.00pm local time on a day other than a Saturday, Sunday or bank or other public or federal holiday in Switzerland or USA.

1.9 “Cabilly License Agreement” shall mean the agreement entered into between River Vision and Roche on or before the Effective Date, as amended now or in the future.

1.10 “Calendar Year” shall mean the period of time beginning on January 1 and ending December 31, except for the first year which shall begin on the Effective Date and end on December 31.

1.11 “Calendar Quarter” shall mean the four quarters of a Calendar Year, each Calendar Quarter starting on January 1, April 1, July 1 and October 1.

1.12 “Change of Control” shall have the meaning provided in Section 18.5.

1.13 “Chugai Agreement” shall mean the License Agreement relating to the Compound between Chugai and F. Hoffmann-La Roche Ltd dated March 7, 2008 for the territory of Japan, as amended now or in the future.

1.14 “Combination Product” shall mean any product that contains, in addition to a Compound, one or more other pharmaceutically active ingredients.
1.15 “Commercially Reasonable Efforts” shall mean (i) with respect to River Vision’s obligation under this Agreement to develop or commercialize Product, the level of efforts required to carry out such obligation in a sustained manner consistent with the efforts a similarly situated biopharmaceutical company or pharmaceutical company, as the case may be, devotes to its products of similar market potential, profit potential or strategic value, based on conditions then prevailing and (ii) with respect to Roche, the level of efforts required to carry out a particular obligation under this Agreement in a sustained manner consistent with the efforts a similarly situated biopharmaceutical company or pharmaceutical company, as the case may be, devotes to its products of similar market potential, profit potential or strategic value, based on conditions then prevailing.

1.16 “Compound” shall mean Roche’s proprietary compound teprotumumab, as specified in Appendix 1

1.17 “Confidential Information” shall mean any and all information, data or know-how (including but not limited to Know-How), whether technical or non-technical, oral or written (and if disclosed orally, memorialized in writing within [***] days of such oral disclosure), that is disclosed by one party or its Affiliates (“Disclosing Party”) to the other party or its Affiliates (“Receiving Party”). Information shall not include any information, data or know-how which:

   (i) was generally available to the public at the time of disclosure, or information which becomes available to the public after disclosure by the Disclosing Party other than through fault (whether by action or inaction) of the Receiving Party,

   (ii) can be shown by cogent written records to have been already known to the Receiving Party prior to its receipt from the Disclosing Party,

   (iii) is obtained at any time lawfully from a Third Party under circumstances permitting its use or disclosure,

   (iv) is developed independently by the Receiving Party as evidenced by written records other than through knowledge of Confidential Information,

   (v) is required to be disclosed by the Receiving Party to comply with a court or administrative order providing the Receiving Party furnishes prompt notice (in no event less than [***] days) to the Disclosing Party to enable it to resist such disclosure, or

   (vi) is approved in writing by the Disclosing Party for release by the Receiving Party.

The terms of this Agreement shall be considered Confidential Information of both parties.

1.18 “Control” or “Controlled” shall mean, with respect to Compound, Product or any Know-How, Patents, Confidential Information or other intellectual property rights, possession by a party of the ability (whether by ownership, license or otherwise) to grant access to, to grant use of, or to grant a license or a sublicense to Compound or Product under such Know-How, Patents or intellectual property rights without violating the terms of any agreement or other arrangement with any Third Party.

***Certain Confidential Information Omitted
1.19 “Data Room” shall mean the due diligence data room containing all data and information Controlled by River Vision as of the applicable Review Period pertaining to Compound and/or Product, including but not limited to pre-clinical and clinical data, River Vision Patents, regulatory correspondence, CMC data related to the program River Vision generated since the Effective Date.

1.20 “Drug Product” shall mean Compound that has undergone all processing stages up to and including lyophilization but not including the labeling and secondary packaging.

1.21 “Effective Date” shall mean June 15, 2011.

1.22 “EU” shall mean the European Community and all its present and future member countries.

1.23 “FDA” shall mean the US Federal Food and Drug Administration and any successor agency thereof.

1.24 “FDCA” shall mean the Food, Drug and Cosmetics Act of the US.

1.25 “Field” shall mean treatment or prevention of human diseases and conditions, except Oncology.

1.26 “First Commercial Sale” shall mean the first sale of a Product by River Vision or its Affiliates to a Third Party for end use or consumption of such Product in a country after the Regulatory Authority of such country has granted Regulatory Approval or, if no such Regulatory Approval or similar marketing approval is required, the date upon which such Product first commercially launched in such country. Sale to an Affiliate shall not constitute a First Commercial Sale.

1.27 “[***] Agreement” shall mean the agreement between [***] and Roche dated June 6, 2002, as amended now or in the future.

1.28 “[***] Agreement” shall mean the agreement between [***] and Roche dated November 1, 2003, as amended now or in the future.

1.29 “ICD-Classification” shall mean the then current International Classifications of Diseases and Related Health Problems of the World Health Organization (WHO).

1.30 “Indication” shall mean those indications defined within a block (e.g. block H36 “Retinal disorders in diseases classified elsewhere”) of the ICD Classification.

1.31 “Initiation” of a clinical trial shall mean the first administration of a Product to a patient in a clinical trial related to Compound or Product.

***Certain Confidential Information Omitted
1.32 “Insolvency Event” shall mean circumstances under which a party:
   a) has a receiver, bankruptcy trustee or similar officer appointed over all or a material part of its assets or undertaking;
   b) passes a resolution for winding-up (other than a winding-up for the purpose of, or in connection with, any solvent amalgamation or reconstruction) or a court makes an order to that effect or a court makes an order for administration (or any equivalent order in any jurisdiction); or
   c) is subject to voluntary or involuntary bankruptcy or judicial restructuring proceedings.

1.33 “Invention” shall mean an invention that is conceived or reduced to practice in connection with any activity carried out pursuant to this Agreement. Under this definition, an Invention may be made by employees, agents or consultants of River Vision solely or jointly with a Third Party (a “River Vision Invention”), by employees, agents or consultants of the Roche Group solely or jointly with a Third Party (a “Roche Invention”), or jointly by employees, agents or consultants of River Vision and a member of the Roche Group with or without a Third Party (a “Joint Invention”).

1.34 “Joint Intellectual Property” shall mean the Joint Patents and Joint Know-How.

1.35 “Joint Know-How” means Know-How that is developed by one or more employees, agents or consultants of River Vision or any of its Affiliates, on the one hand, and one or more employees, agents or consultants of Roche or any of its Affiliates, on the other hand, under this Agreement.

1.36 “Joint Patents” or “Joint Patent Rights” shall mean Patent Rights that claim Joint Know-How.

1.37 “Know-How” shall mean data, knowledge and information, and materials, including but not limited to all tangible and intangible techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, knowledge, know-how, skill, experience, analytical and quality control data, results, descriptions and compositions of matter, chemical manufacturing data, data and results from toxicological, pharmacological, preclinical and clinical testing and studies, assays, platforms, materials, samples, formulations, specifications, quality control testing data, that are necessary or useful for the discovery, manufacture, development or commercialization of Compound or Product.

1.38 “[***] Agreement” shall be the agreement between [***] (along with any successors and assigns, “[***]”) and Roche relating to NMB1 dated December 7, 2009, as amended now or in the future.

1.39 “Net Sales” shall mean, with respect to River Vision the amount of gross sales of a Product in the Territory invoiced by River Vision or its Affiliates or Partners to Third Parties, as reduced by the following deductions to the extent actually allowed or incurred with respect to such sales: [***]
[***]. If Product is sold as part of a Combination Product (as defined below), then the parties shall meet approximately [***] prior to anticipated First Commercial Sale to negotiate, on a country-by-country basis, in good faith and agree to an appropriate adjustment to Net Sales, on a country-by-country basis, to reflect the relative significance of the Compound and other pharmaceutically active ingredients contained in the Combination Product. If the parties cannot reach agreement, then the Net Sales of the Combination Product, for the purposes of determining royalty payments, shall be determined by [***].

1.40 “NRM” shall mean Narrow River Management LLC.

1.41 “Oncology” shall mean any indication defined within Chapter II of the ICD Classification, or in a chapter that replaces Chapter II in successor versions of the ICD Classification. For the purposes of clarity, in the ICD-10 classification, any block within the range C01 to D48 shall fall within the definition of Oncology.

1.42 “Patent Rights” or “Patents” shall mean (a) patents, re-examinations, reissues, renewals, extensions, supplementary protection certificates, and term restorations, and (b) pending applications for patents, including, without limitation, provisional applications, continuations, continuations-in-part, divisional and substitute applications, including, without limitation, inventors’ certificates.

1.43 “Partner” shall mean an entity with which River Vision will enter or has entered a Partner Agreement.

1.44 “Partner Agreement” shall mean any agreement between River Vision and a Third Party granting rights to develop and/or commercialise the Compound and/or the Product (including but not limited to a sub-license agreement with a Third Party or an assignment of this Agreement to a Third Party but not a Change of Control), other than a sub-contract pursuant to Section 2.4.

1.45 “Pharmacovigilance Agreement” shall mean an agreement entered into by the parties to set forth the responsibilities and obligations of the parties with respect to the procedures and timeframes for compliance with the applicable laws and regulations pertaining to safety reporting of the Products and related activities.
1.46 “Phase 2 Trial” shall mean a human clinical trial that would satisfy the requirements for a Phase 2 study as defined in 21 C.F.R. § 312.21(a), (or its successor regulation), and the foreign equivalent thereof.

1.47 “Phase 3 Trial” shall mean a human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or its successor regulation), and the foreign equivalent thereof.

1.48 “Process Manufacture Transfer” shall mean the actual transfer of the Process Manufacture Know-How listed in Appendix 3, such transfer to occur not earlier than the first anniversary of the Effective Date.

1.49 “Process Manufacture Know-How” shall mean the part of the Roche Know-How (described in Appendix 3) that will only be disclosed to River Vision after payment of the Process Manufacture Transfer Payment.

1.50 “Process Manufacture Transfer Payment” shall have the meaning provided in Section 9.3(a).

1.51 “Product” shall mean any pharmaceutical or therapeutic product containing the Compound, and includes without limitation Combination Products. If a given Product is commercialized in different formulations or dosage forms, then such formulations and dosage forms shall be considered as one single Product.

1.52 “Regulatory Approval” shall mean any and all approvals (including price and reimbursement approvals, if required), licenses, registrations, or authorizations of any country, federal, supranational, state or local regulatory agency, department, bureau or other government entity that are necessary for the manufacture, use, storage, import, transport and/or sale of a Product in such jurisdiction.

1.53 “Regulatory Authority” shall mean the FDA for the US and any equivalent governmental agency or body competent in a country (or group of countries like the European Union) to grant Regulatory Approval or other authorizations or licenses required for the development, manufacturing, marketing, reimbursement and/or pricing of pharmaceutical products in such country.


1.55 “River Vision Know-How” shall mean, to the extent used for the development, manufacture or commercialization of Compound or Product based thereon, information not included in the River Vision Patents that River Vision, any of its Partners or any of its Affiliates Controls on the Effective Date or during the Term, provided however that Roche Know-How shall not be deemed River Vision Know-How.

1.56 “River Vision Patents” shall mean, to the extent used for the development, manufacture or commercialization of Compound or Product based thereon, all Patents that River Vision, any of its Partners or any of its Affiliates Controls as of the Effective Date or during the Term, provided however that the Roche Patents shall not be deemed River Vision Patents.
1.57 “River Vision Studies” shall mean the studies to be performed by River Vision with Drug Product, as described in Appendix 4.

1.58 “Roche Intellectual Property” shall mean the Roche Patents, the Roche Know-How and Roche’s interest in the Joint Intellectual Property.

1.59 “Roche Know-How” shall mean the Know-How Controlled by Roche listed in Appendix 3 of this Agreement. The term Roche Know-How shall include Process Manufacture Know-How.

1.60 “Roche Patents” shall mean the Patents or Patent Rights Controlled by Roche as exhaustively listed in Appendix 2 of this Agreement, along with all Patents and Patent Rights that claim priority to one or more of such Patents or Patent Rights so listed in such Appendix 2.

1.61 “Royalty Term” shall mean, in the case of any Product in any country of the Territory, the period of time commencing on the date of First Commercial Sale of such Product in such country and ending upon the later of:

   (a) the expiration of the last-to-expire Valid Claim within the Roche Patents and/or Joint Patent Rights covering the composition, use or manufacture of such Product in such country where such activity occurs, or

   (b) ten (10) years after the date of First Commercial Sale of such Product in such country.

1.62 “Section” shall mean a section of this Agreement.

1.63 “Supported Shelf Age” shall have the meaning provided in Section 6.1(c).

1.64 “Term” shall have the meaning provided in Section 15.1.

1.65 “Territory” shall mean all countries and territories of the world, except Japan.

1.66 “Third Party” shall mean an entity or person other than (a) Roche or its Affiliates and (b) River Vision or its Affiliates.

1.67 “US” or “United States” means the United States of America and its territories and possessions.

1.68 “Valid Claim” shall mean a claim contained in:

   (a) an issued and unexpired Roche Patent or Joint Patent Rights which has not been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through abandonment, reissue, disclaimer or otherwise; or
(b) a patent application that is included in the Roche Patents or Joint Patent Rights that has been prosecuted in good faith and pending for less than [***] years. If a claim or a patent application that ceased to be a Valid Claim under clause (b) of the preceding sentence because of the passage of time later issues as a part of a patent within clause (a) of the preceding sentence, then it shall again be considered a Valid Claim effective as of the issuance of such patent.

2. RIVER VISION LICENSES

2.1 License grants.

(a) General. Subject to the terms and conditions of this Agreement, Roche hereby grants to River Vision (i) an exclusive (even as to Roche), royalty-bearing license, under the Roche Intellectual Property to develop, have developed, commercialize, have commercialized, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import and have imported Compound and/or Product in the Field in the Territory, and (ii) subject to the terms of Section 11, an exclusive license and right to enforce the Roche Patents against anyone making, using, selling, offering for sale or importing any IGF-1 R antibody (in addition to Compound and Product) in the Field in the Territory, other than for this clause (ii) those IGF-1 R antibodies (but not including Compound or Product) developed and commercialized by Roche with its Affiliates and licensees. For clarity, River Vision is not granted any license or right to practice the Roche Patents under clause (ii), but rather to enforce the Roche Patents as provided in such clause (ii).

(b) Rights in Japan. If Chugai terminates its agreement with Roche relating to the Compound to Roche or such agreement otherwise terminates for any reason, then (i) the Territory shall automatically be deemed to include the territory of Japan, (ii) Roche shall automatically license and transfer to River Vision any Patents, Know-How, Regulatory Approvals, regulatory documentation or filings, and other rights or documentation Controlled by Roche or any of its Affiliates as a result of such termination, and (iii) such Patents and Know-how (including those within the Territory) shall be deemed Roche Patents and Roche Know-How. Roche hereby grants as of the Effective Date a non-exclusive sub-license to the improvements (as defined in the Chugai Agreement) made by Chugai under the Chugai Agreement to develop, have developed, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import and have imported Compound and/or Product in the Field in the Territory. Such improvements shall be deemed Roche Patents and Roche Know-How, subject to any third party obligations.

(c) Rights in Oncology. If Roche, at its own discretion, elects to out-license the rights to the Compound in Oncology, then River Vision shall have the exclusive option right to extend the Field to Oncology. Roche will provide written notice to River Vision of its intent to license its rights with respect to Oncology. River Vision shall have [***] days after receipt of such notice to notify Roche of its intention to exercise its option right. If River Vision elects to exercise its option right, then the parties shall negotiate and enter into the terms for such extension of the Field in good faith.

***Certain Confidential Information Omitted
2.2 Sub-Licenses.

(a) Under the [***] Agreement. Roche hereby grants an exclusive (even as to Roche) sub-license of the rights licensed to Roche under the [***] Agreement solely to develop, have developed, commercialize, have commercialized, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import and have imported Compound and/or Product in the Field in the Territory. The sublicense granted under this Section 2.2 shall be subject to the rights and obligations and undertakings of Roche, as applicable and consistent with the [***] Agreement (a copy of which is attached hereto as Appendix 5, and incorporated herein by reference). Roche shall act as the sole direct contact with [***] in relation to the sublicense under this Section 2.2.

(b) Under the [***] Agreement. Roche hereby grants an exclusive (even as to Roche) sublicense of the rights licensed to Roche under the [***] Agreement solely to develop, have developed, commercialize, have commercialized, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import and have imported Compound and/or Product in the Field in the Territory. The sublicense granted under this Section 2.2 shall be subject to the rights and obligations and undertakings of Roche, as applicable and consistent with the [***] Agreement (a copy of which is attached hereto as Appendix 6, and incorporated herein by reference). Roche shall act as the sole direct contact with [***] in relation to the sublicense under this Section 2.2.

(c) Under the [***] Agreement. Roche hereby grants an exclusive (even as to Roche) sublicense of the rights licensed to Roche under the [***] Agreement solely to develop, have developed, commercialize, have commercialized, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import and have imported Compound and/or Product in the Field in the Territory. The sublicense granted under this Section 2.2 shall be subject to the rights and obligations and undertakings of Roche, as applicable and consistent with the [***] Agreement (a copy of which is attached hereto as Appendix 7, and incorporated herein by reference). Roche shall act as the sole direct contact with [***] in relation to the sublicense under this Section 2.2.

(d) Compliance with terms. River Vision shall comply with the terms of the [***] Agreement, the [***] License Agreement and the [***] License Agreement, to the extent such terms are disclosed in the respective Appendices attached hereto.

(e) Sub-license agreements. Roche shall not amend the [***] Agreement, the [***] Agreement or the [***] Agreement in a manner that materially affects any such sub-licenses hereunder, shall perform its obligations under such agreements, shall use Commercially Reasonable Efforts to enforce and maintain such agreements with respect to the Compound and/or the Product, and shall promptly notify River Vision in writing of any threatened or actual termination or notice regarding same with respect to such agreements with respect to the Compound and/or the Product. Roche shall provide copies of any amendments to such agreements (with reasonable redactions) to River Vision once executed. If any such agreement terminates or may terminate, Roche shall use Commercially Reasonable Efforts to maintain the applicable sublicense to River Vision; if Roche is not able to maintain the applicable sublicense, River Vision shall have the right to attempt to cure any breach giving rise to such actual or threatened termination and may credit any amounts paid by River Vision to maintain any such sublicense against any amounts owed to Roche hereunder, provided that such amounts credited against any amounts owed to Roche hereunder shall not exceed the amount owed by Roche for the respective license. River Vision shall inform Roche of any intended interactions with [***], [***] or [***], as applicable.

***Certain Confidential Information Omitted
2.3 Right to Sublicense to its Affiliates. Subject to Roche’s rights under Section 3, River Vision shall have the right to grant written sublicenses to its Affiliates under its rights granted under Section 2.1 and Section 2.2, without prior approval of Roche and solely to the extent necessary to develop, commercialize, make, use, offer for sale, sell or import (and have others do the same) Compound and/or Product in the Field in the Territory. If River Vision grants such a sublicense, River Vision shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the Affiliate to the same extent as they apply to River Vision for all purposes. River Vision assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such Affiliate and shall itself account to Roche for all payments due under this Agreement by reason of such sublicense.

2.4 Sub-Contractors. River Vision has the right to sub-contract the work performed under this Agreement. However, River Vision shall only sub-contract the manufacture of the Compound or Product [***]. Any sub-contract agreement shall include the right to disclose (i) a copy of the Agreement and confidential information to Roche and (ii) the right to assign the agreement to Roche, including the right to transfer of the ownership of data, information and results arising therefrom to Roche to the same extent as to River Vision.

2.5 Right to enter into a Partner Agreement with Third Parties. Subject to Roche’s rights under Section 3, River Vision shall have the right to enter into a Partner Agreement, including but not limited to granting sublicenses to Partners under its rights granted under Section 2.1 and Section 2.2. Any rights granted to a Third Party under this Agreement shall be solely to the extent necessary to develop, commercialize, make, use, offer for sale, sell or import (and have others do the same) Compound and/or Product in the Field in the Territory. River Vision shall ensure that all of the applicable terms and conditions of this Agreement, including the obligations under the [***] Agreement, the [***] Agreement and the [***] Agreement, shall apply to the Partner under the Partner Agreement to the same extent as they apply to River Vision for all purposes. River Vision assumes full responsibility for the performance of all obligations and observance of all terms so imposed on the Partner under such Partner Agreement and shall itself account to Roche for all payments due under this Agreement. The Partner of River Vision shall have no right to further sub-license rights to develop and commercialise the Compound or Product to a Third Party, with the understanding that co-promotion or distribution or other marketing arrangements are permitted.

River Vision shall disclose a copy of the draft Partner Agreement to Roche, subject to redaction of financial terms. [***].

2.6 Know-How Transfer.

(a) Roche Know-How transfer. Promptly after the Effective Date, Roche will transfer the Roche Know-How listed in Appendix 3 to River Vision, with the exception of the Process Manufacture Know-How. The Process Manufacture Know-How will be transferred within [***] days after written request from River Vision.

(b) Technical Support. If River Vision has made the Process Manufacture Transfer Payment, then Roche will provide up to [***] man days of technical support free of charge in order to assist River Vision with the Process Manufacture Transfer to a CMO agreed between Roche and River Vision. This support shall be used in the [***] month period that starts with the receipt by Roche of the Process Manufacture Transfer Payment. Further technical support from Roche will be provided at Roche’s discretion and, if such support is provided by Roche, charged at Roche’s standard commercial rate applicable at that time.

***Certain Confidential Information Omitted
(c) Follow-up Questions. Roche shall provide up to [***] hours for general questions and [***] hours for regulatory questions free of charge.

(d) No further obligation. Roche shall have no obligation to transfer any Know-How or to provide technical support other than expressly stated in this Section 2.6.

2.7 Alliance Manager. To facilitate communication between the parties, each party shall designate an Alliance Manager within thirty (30) days after the Effective Date. The Roche Alliance Manager and his/her counterpart at River Vision shall be the primary points of contact between the parties with respect to all matters arising under this Agreement. Each party may change its Alliance Manager from time to time in its sole discretion, effective upon notice to the other party of such change.

2.8 Freedom-to-Operate. River Vision hereby grants to Roche a non-exclusive, perpetual, worldwide, royalty-free license, with the right to sublicense, under the River Vision Patents, to operate, utilize or improve those IGF-1 R antibodies (but not including Compound or Product) developed and commercialized by Roche with its Affiliates and licensees, but only in Oncology.

2.9 Retained Rights. Roche shall retain the right for Roche and its Affiliates and licensees to use the Compound for internal pre-clinical purposes in and outside of the Field; provided that no studies requiring reporting to Regulatory Authorities in the Territory will be conducted in the Field. Except as permitted by this Agreement or any other agreement between the parties, Roche and its Affiliates and licensees will not use the Compound or Product for any other purpose, nor will Roche or any of its Affiliates or licensees practice any of the Patents or Know-How (including, without limitation, any Roche Intellectual Property) exclusively licensed or sub-licensed to River Vision hereunder within the scope of those licenses in the Field in the Territory.

3. Roche’s Right of First Offer.

3.1 Notice to Roche by River Vision. If River Vision, at any time during the Term but not earlier than availability of the data generated under the first of the River Vision Studies to be completed, intends to (i) enter into a Partner Agreement relating to the Compound and/or the Product or (ii) undergo a Change of Control or (iii) enter into Phase 3 Trial with the Compound without a Partner, then River Vision shall have the obligation to inform Roche in writing accordingly and give Roche access to the Data Room.

3.2 Process. Within [***] days following the receipt by Roche of such written notice, Roche shall review the Data Room ("Review Period"). If Roche is interested in taking the project back, then the parties shall have [***] days from the date of the expiry of the Review Period to exclusively negotiate the terms to regain the rights to the Compound and/or the Product (i.e. to take the license for the whole program back and ownership under the River Vision Patents and Know-How or, if transfer of ownership is not possible, a perpetual, exclusive license for the whole program) (the “Negotiation Period”). If (i) the parties, after good faith discussions in the Negotiation Period, cannot agree on the structure and terms of such agreement or (ii) Roche confirms ***Certain Confidential Information Omitted
in writing to River Vision that it is not interested in regaining the rights to the Compound and/or the Product, then River Vision shall be free to enter into a Partner Agreement with a Third Party or to undergo a Change of Control and this Section 3 will have no further force or effect, subject to the limitations specified in Sections 2.5 and 18.4 with respect thereto. Notwithstanding the foregoing, if River Vision (1) does not enter into a Partner Agreement or does not undergo a Change of Control but continues the development and/or commercialisation of the Compound and/or Product and (2) at any time during the Term thereafter there is additional material clinical data available as compared to the clinical data previously reviewed by Roche in the Data Room, and (3) River Vision thereafter intends to enter into a Partner Agreement relating to the Compound and/or the Product or undergo a Change of Control, then Roche’s Right of First Offer under this Section 3 shall apply one more time again. If (a) Roche does not regain its rights to the Compound and/or the Product if offered to Roche a second time under this Section 3.2 and (b) River Vision thereafter intends to enter into a Partner Agreement or to undergo a Change of Control, then Roche shall have a non-exclusive right under this Section 3.2 to negotiate the terms to regain the rights to the Compound and/or the Product.

4. DILIGENCE AND REPORTING

4.1 Diligence. River Vision shall use Commercially Reasonable Efforts to develop and commercialize the Compound and/or Product in the Field in the Territory.

4.2 Reporting.

(a) Prior to First Commercial Sale. During the Term up to First Commercial Sale of the Product, River Vision shall have the obligation to submit detailed annual reports to Roche summarizing development progress of the Product, including the Development Plan, pursuant to Section 5.1. The first such annual report shall be provided on the first anniversary of the Effective Date. Each subsequent annual report shall be provided on subsequent anniversaries of the Effective Date.

(b) After First Commercial Sale. From the First Commercial Sale of the Product during the Term, River Vision shall inform Roche in a detailed report regarding the commercialization of Products in the Field in the Territory by River Vision, its Affiliates and Partners. The first such annual report shall be provided on the first anniversary of the First Commercial Sale. Each subsequent annual report shall be provided on subsequent anniversaries of the First Commercial Sale.

5. DEVELOPMENT

5.1 Responsibility. River Vision, at its sole cost, shall use Commercially Reasonable Efforts to conduct the development of Compound and/or Product in the Field in the Territory.

5.2 Development Plan. River Vision will conduct (or have conducted) the development of the Compound and Product in the Field in the Territory in accordance with a written plan ("Development Plan"). River Vision shall send a then current version of the Development Plan to Roche at each anniversary of the Effective Date. If River Vision wishes to improve the manufacturing process of the Compound or the Product resulting in a change of the cell bank expressing the Compound, then River Vision shall provide written notice to Roche of the nature of such intended work [***].

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5.3 **Different Product.** If, as a result of any permitted work performed pursuant to Section 5.2, River Vision uses a new master cell line to develop and subsequently commercializes a Compound and/or a Product as a new biological entity (in addition to a first Compound and/or Product), so that such Compound and/or Product qualifies for an independent period of data exclusivity based on it being a new biological entity under a separate regulatory process, then such Compound and/or Product shall be a separate Product for purposes of Section 9.

6. **SUPPLY**

6.1 **Clinical Supply of Product.**

(a) **Responsibility.** River Vision shall be solely and exclusively responsible at its own expense for the manufacture and supply of clinical supplies of the Product. River Vision shall supply at its own cost all clinical supply of Product during the Term, either by itself, or through a Third Party.

(b) **Supply.** Notwithstanding Section 6.1(a), Roche shall supply to River Vision Drug Product as specified in Appendix 4 purely for the purposes of conducting the River Vision Studies. Roche shall have no obligation to produce, process or test such Drug Product, except as explicitly stated in this Section 6 or on Appendix 4. The parties shall enter into a Quality Agreement within ninety (90) days of the Effective Date.

(c) **Restrictions of Use.** River Vision shall not administer to any patient Drug Product supplied by Roche that has an actual shelf age higher than the shelf age supported by the last real-time stability data within specification ("Supported Shelf Age"). In this context actual shelf age means the period of time between present date and the manufacturing date of the respective batch. Supported Shelf Age is stated in Appendix 4 and will be revised and communicated to River Vision in written form with each future stability report, and will become integral part of Appendix 4 together with the supportive stability report.

6.2 **Commercial Supply of Product.** River Vision shall be solely and exclusively responsible at its own expense for the commercial manufacture and commercial supply of Product for sale in the Territory, either by itself or through Third Parties.

7. **REGULATORY**

7.1 **Responsibility.** River Vision, at its sole cost, shall pursue all regulatory affairs related to Product in the Field in the Territory including the preparation and filing of applications for Regulatory Approval, as well as any or all governmental approvals required to develop, have developed, make, have made, use, have used, import, have imported sell and have sold Compound and/or Product. River Vision shall be responsible for pursuing, compiling and submitting all regulatory filing documentation, and for interacting with regulatory agencies, for Compound and Product in all countries in the Territory. River Vision shall own and file in their discretion all regulatory filings and Regulatory Approvals for the Compound and Product in all countries of the Territory. River Vision shall supply Roche with a copy of all material communications related to Compound and Product to or from the regulatory agencies.

***Certain Confidential Information Omitted***
7.2 IND. River Vision shall establish a separate IND or equivalent under which to conduct their clinical trials of the Compound and Product in the Field in the Territory. River Vision shall submit draft protocols to Roche for review and approval as long as patients are still being treated in Roche trials sponsored or supported by Roche. River Vision and its Affiliates and Partners shall have the right to cross-reference any IND or other regulatory documentation of Roche or any of its Affiliates regarding Compound or Product.

7.3 Informed Consent forms. Any Informed Consent forms with patients under any River Vision study shall include the right to transfer samples, data and information to Roche.

7.4 Pharmacovigilance Agreement. The parties agree that they shall execute a separate Pharmacovigilance Agreement if deemed applicable prior to, but no later than, the date on which River Vision establishes either a separate IND or equivalent under which they intend to initiate their first clinical trial of the Compound or Product in the Field in the Territory.

8. COMMERCIALIZATION

River Vision, at its own expense, shall have sole responsibility and decision making authority for the marketing, commercialization, promotion, sale and distribution of Products in the Field in the Territory.

9. RIVER VISION PAYMENT OBLIGATIONS

9.1 License Fee. River Vision shall pay to Roche a one time, non-refundable, non-creditable payment of [***] CHF ([***] CHF) within [***] days after the Effective Date. Any non-royalty payments payable to Genentech under the Cabilly License Agreement shall be creditable in full against amounts payable to Roche hereunder.

9.2 Execution of a Partner Agreement. River Vision shall pay to Roche a one time, non-refundable, non-creditable payment in the amount of CHF [***] ([***] CHF) within [***] days after the execution of a Partner Agreement or a Change of Control.

9.3 Process Manufacture Transfer and Other Payments.

(a) River Vision shall make a one time, non-refundable, non-creditable payment in the amount of CHF [***] ([***] CHF) within [***] days after the date of the initiation of the Process Manufacture Know-How transfer (the “Process Manufacture Transfer Payment”).

(b) River Vision shall make a one time, non-refundable, non-creditable payment in the amount of [***] ([***] CHF) within [***] days after the date on which [***].

***Certain Confidential Information Omitted
(c) If the payments under Sections 9.3(a) and (b) have not been made when River Vision enters into a Partner Agreement or undergoes a Change of Control, as applicable, such payments shall be due within [***] days after the effective date of the Partner Agreement or the Change of Control, as applicable.

9.4 Development Event Payments

(a) For the first Indication.

River Vision shall pay up to a total of CHF [***] (CHF [***]) in relation to the achievements of events with respect to each Product for the first Indication developed for the applicable Product. The development event payments under this Section 9.4(a) shall be paid for the first Indication on a Product-by-Product basis as follows:

<table>
<thead>
<tr>
<th>Development Event</th>
<th>Event Payment in [***] CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
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<td>[***]</td>
<td>[***]</td>
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<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>Total</td>
<td>[***]</td>
</tr>
</tbody>
</table>

Each of the foregoing payments shall be paid no more than once for each Product.

(b) For the second and each subsequent Indication

River Vision shall pay up to a total of CHF [***] (CHF [***]) per Indication in relation to the achievements of events with respect to each Product for the second and each subsequent Indication developed for the applicable Product. The development event payments under this Section 9.4(b) shall be paid for the second and each subsequent Indication on a Product-by-Product basis as follows:

<table>
<thead>
<tr>
<th>Development Event</th>
<th>Event Payment in [***] CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
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<td>[***]</td>
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<td>[***]</td>
<td>[***]</td>
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<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>Total</td>
<td>[***]</td>
</tr>
</tbody>
</table>

***Certain Confidential Information Omitted
(c) Development Event Payments for the territory of Japan

In addition to payments due under paragraph (a) and (b) above, River Vision shall pay up to a total of CHF [***] (CHF [***]) in relation to the achievements of events with respect to each Product for the first Indication developed for the applicable Product. The development event payments under this Section 9.4(c) shall be paid for the first Indication on a Product-by-Product basis as follows:

<table>
<thead>
<tr>
<th>Development Event</th>
<th>Event Payment in [***] CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>Total</td>
<td>[***]</td>
</tr>
</tbody>
</table>

Each of the foregoing payments shall be paid no more than once for each Product.

In addition to payments due under paragraphs (a) and (b) above, River Vision shall pay up to a total of CHF [***] (CHF [***]) per Indication in relation to the achievements of events with respect to each Product for the second and each subsequent Indication developed for the applicable Product. The development event payments under this Section 9.4(c) shall be paid for the second and each subsequent Indication on a Product-by-Product basis as follows:

<table>
<thead>
<tr>
<th>Development Event</th>
<th>Event Payment in [***] CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>Total</td>
<td>[***]</td>
</tr>
</tbody>
</table>

If Chugai terminates the Chugai Agreement [***], and Japan is within the Territory under this Agreement, then all applicable payments under this Section 9.4(c) shall be due.

(d) Development Event Payments for the second Product and each subsequent Product

For the second Product and each subsequent Product, the development event payments payable to Roche under Sections 9.4(a), 9.4(b) and 9.4(c) shall be reduced by [***]%.

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9.5 Sales Based Events

River Vision shall pay to Roche up to a total of CHF [***] (CHF [***]) based on aggregate Calendar Year Net Sales of a Product in the Territory:

<table>
<thead>
<tr>
<th>Net Sales Threshold</th>
<th>Payment [***] CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Calendar Year Net Sales in the Territory of a Product exceed CHF [***] CHF</td>
<td>[***]</td>
</tr>
<tr>
<td>Total Calendar Year Net Sales in the Territory of a Product exceed CHF [***] CHF</td>
<td>[***]</td>
</tr>
<tr>
<td>Total Calendar Year Net Sales in the Territory of a Product exceed CHF [***] CHF</td>
<td>[***]</td>
</tr>
<tr>
<td>TOTAL</td>
<td>[***]</td>
</tr>
</tbody>
</table>

Each of the sales based event payments shall be paid no more than once, at first occurrence of the event for the Product in the Territory first reaching the respective Net Sales Threshold, irrespective of whether or not the previous sales based event payment was triggered by the same or by a different Product, and shall be non-refundable and non-creditable.

9.6 Royalties.

Royalties shall be payable by River Vision on Net Sales of Products on a Product-by-Product and country-by-country basis until the expiry of the Royalty Term. Thereafter, the licenses set forth in Section 2 shall be fully paid up and royalty-free for a Product in a country.

The following royalty rates shall apply to the respective tiers of aggregate Calendar Year Net Sales of a Product in the Territory, on an incremental basis, as follows:

<table>
<thead>
<tr>
<th>Tier of Calendar Year Net Sales in million CHF</th>
<th>Percent (%) of Net Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>9</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>12</td>
</tr>
</tbody>
</table>

For example, if Net Sales of a Product in the Territory, for a given Calendar Year, are CHF [***], then the royalty rate applicable on such Net Sales of such Product for that year shall be calculated as follows:

[***].

9.7 Credit of Royalty Payments

River Vision may credit [***] of the royalties payable to Genentech under the Cabilly License Agreement against the royalties payable to Roche under Section 9.6.

9.8 Third Party Payments

Roche shall be responsible at its sole expense for making any payments under the [***] Agreement, the [***] Agreement and the [***] Agreement.

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River Vision shall be responsible for and pay or have paid any consideration owed to any Third Party in relation to Third Party intellectual property rights, except with respect to any payments owed under the [***] Agreement, the [***] Agreement and the [***] Agreement in accordance with the terms of such agreements. Such Third Party payments shall not be deductible against the amounts payable under this Agreement or refundable under this Agreement. [***].

10. GENERAL PAYMENT PROVISIONS

10.1 Accounting and reporting

(a) Timing of Payments.

(i) All payments made under Section 9.4 shall be non-refundable and non-creditable. River Vision shall inform Roche by written notice within [***] days after the occurrence of the respective event and the respective payment shall be made within [***] days after the occurrence of the respective event.

(ii) River Vision shall calculate royalties on Net Sales quarterly as of March 31, June 30, September 30 and December 31 (each being the last day of an “Accounting Period”) and shall pay royalties on Net Sales within the [***] days after the end of each Accounting Period in which such Net Sales occur.

(b) Late Payment. Any payment under this Agreement that is not paid on or before the date such payment is due shall bear interest, to the extent permitted by applicable law, at [***] percentage points above the average one-month Euro Interbank Offered Rate (EURIBOR), as reported by Reuters from time to time, calculated on the number of days such payment is overdue.

(c) Currency of Payment. Royalties on Net Sales shall be paid by River Vision in Swiss Francs.

(d) Currency Conversion. When calculating the Sales for countries other than Switzerland, River Vision shall convert the amount of such sales in currencies other than Swiss Francs into Swiss Francs using for internal foreign currency translation River Vision’s then current standard practices actually used on a consistent basis in preparing its audited financial statements.

10.2 Reporting. With each payment River Vision shall provide Roche in writing for the relevant Calendar Quarter on a Product-by-Product basis the following information:

a) Gross Sales on a country-by-country basis in local currencies;
b) Net Sales on a country-by-country basis in local currencies;
c) Net Sales on a country-by-country basis in Swiss Francs;
d) Total Net Sales in the Territory in Swiss Francs;
e) Total royalty payable in Swiss Francs; and
f) Exchange rates used for the conversion to Swiss Francs made under Section 10.1(d) and Section 10.2(c).

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10.3 Taxes
Roche shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made to Roche under this Agreement.

If provision is made in law or regulation of any country for withholding of taxes of any type, levies or other charges with respect to any royalty or other amounts payable under this Agreement, then River Vision shall promptly pay such tax, levy or charge for and on behalf of Roche to the proper governmental authority, and shall promptly furnish Roche with receipt of payment. River Vision shall be entitled to deduct any such tax, levy or charge actually paid from royalty or other payment due to Roche or be promptly reimbursed by Roche if no further payments are due to Roche. Each party agrees to reasonably assist the other party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

10.4 Auditing
(a) Roche’s Right to Audit
River Vision shall keep, and shall require its Affiliates and Partners to keep, full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all royalties payable under this Agreement. Such books of accounts shall be kept at their principal place of business. At the expense of Roche, Roche has the right to engage Roche’s then current worldwide independent public accountant to perform, on behalf of Roche an audit of such books and records of River Vision and its Affiliates and Partners, that are deemed necessary by the public accountant to report on Net Sales of Product for the period or periods requested by Roche and the correctness of any report or payments made under this Agreement. Upon timely request and at least [***] working days’ prior written notice from Roche, such audit shall be conducted in the countries specifically requested by Roche, during regular business hours in such a manner as to not unnecessarily interfere with River Vision’s normal business activities, and shall be limited to results in the [***] calendar years prior to audit notification.

Such audit shall not be performed more frequently than once per Calendar Year nor more frequently than once with respect to records covering any specific period of time.

All information, data documents and abstracts herein referred to shall be used only for the purpose of verifying royalty statements, shall be treated as River Vision Confidential Information subject to the obligations of this Agreement and need neither be retained more than [***] year after completion of an audit hereof, if an audit has been requested; nor more than [***] years from the end of the calendar year to which each shall pertain; nor more than [***] year after the date of termination of this Agreement.

(b) Sharing of draft reports. The auditors shall share all draft reports with Roche and River Vision before the final document is issued; the auditors shall not interpret the agreement. The final report shall be shared by Roche and River Vision.
(c) Over-or Underpayment. If the audit is undisputed and reveals an overpayment, Roche shall reimburse River Vision for the amount of the overpayment within [***] days. If the audit is undisputed and reveals an underpayment, River Vision shall make up such underpayment with the next royalty payment or, if no further royalty payments are owed to Roche, River Vision shall reimburse Roche for the amount of the underpayment within [***] days. River Vision shall pay for the out-of-pocket audit costs if the underpayment of River Vision exceeds [***]% of the aggregate amount of royalty payments owed with regard to the royalty statements subject of the audit. Section 10.1(b) shall apply to this Section 10.4(c), interest to run from the date such audit is reported to the parties.

(d) Duration of Audit Rights. The failure of Roche to request verification of any royalty calculation within the period during which corresponding records must be maintained under this Section 10.4 will be deemed to be acceptance of the royalty payments and reports.

11. INTELLECTUAL PROPERTY

11.1 Ownership of Patent Rights. River Vision shall own all River Vision Inventions, Roche shall own all Roche Inventions, and River Vision and Roche shall jointly own all Joint Inventions. River Vision and Roche each shall require all of its employees, agents and consultants to assign all inventions related to Products made by them to Roche and River Vision, as the case may be. The determination of inventorship for Inventions worldwide shall be in accordance with US inventorship laws.

11.2 Patent prosecution and maintenance. Roche shall have the first right (but not the obligation) to prepare, file, prosecute and maintain all Roche Patents at Roche’s sole expense. River Vision shall have the first right (but not the obligation) to prepare, file, prosecute and maintain all River Vision Patents at River Vision’s sole expense. The party responsible for the filing, prosecution and maintenance of any Roche Patents or River Vision Patents (the “Responsible Party”) shall provide the other party with a reasonable opportunity to review drafts of proposed patent applications with respect to Patents owned solely by the Responsible Party that claim the manufacture, use or sale of Compound or Product being developed or commercialized by either party, if appropriate, depending on the contents of the submission. The Responsible Party shall consider in good faith the requests and suggestions of the other party with respect to the content and strategies for such patent applications. For clarity, Roche is not obliged to and River Vision has no right request Roche to prepare, file, prosecute and maintain general claims of the Roche Patents going beyond the Compound and/or Product or any other IGF-1 R antibody. Notwithstanding anything in this Section 11 to the contrary, Roche’s rights with respect to River Vision Patents for prosecution, defense, enforcement and otherwise under this Section 11 will extend only to Compound and/or Product in the Field, and further Roche will not seek to enforce any River Vision Patents without the consent of River Vision.

11.3 Assignment of Patents. If Roche is no longer interested in prosecuting or maintaining any of the Roche Patents, then Roche shall notify River Vision thereof and Roche shall assign such Roche Patents to River Vision (or license on an exclusive basis all claim scope to River Vision if any such assignment is not possible under applicable patent law), provided that River Vision shall bear the costs for such assignments and for all future costs. All Patent Rights so assigned from Roche to River Vision shall remain Roche Patents as defined in this Agreement. If River Vision is no longer interested in prosecuting or maintaining any of the River Vision Patents, then River Vision shall notify Roche thereof by at least [***] days prior written notice.

***Certain Confidential Information Omitted

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11.4 Prosecution of Joint Patent Rights. River Vision shall be the Responsible Party for preparing, filing, prosecuting or maintaining Joint Patents, with the parties’ sharing equally the expense thereof. River Vision shall not discontinue prosecution or maintenance of Joint Patents without at least [***] days prior written notice to Roche. If River Vision decides to discontinue prosecution or maintenance of any Joint Patents, Roche shall have the option to continue to prosecute or maintain such Joint Patents, at Roche’s sole expense.

11.5 Cooperation of the Parties. Each party agrees to cooperate in the preparation, filing and prosecution of any Patents under this Agreement and in the obtaining of any patent extensions, supplementary protection certificates and the like with respect to any such Patent. Such cooperation includes, but is not limited to: (a) executing all papers and instruments, or requiring its employees, agents or consultants, to execute such papers and instruments and to enable the Responsible Party to apply for and to prosecute and maintain patent applications in any country; and (b) promptly informing the Responsible Party of any matters coming to such party’s attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications; and (c) the Responsible Party regularly update the other party on the status of all Patents, including any dates for action required or due dates for payments. River Vision shall have the right using a form mutually agreed to by the parties to record its exclusive license under the Roche Patents in countries in the Territory.

11.6 Infringement by Third Parties.

(a) Infringement. Each party shall promptly provide written notice to the other party during the Term of any known infringement or suspected infringement by a Third Party of any Roche Patents, River Vision Patents (if any) or Joint Patents (if any), or of any invalidity or unenforceability assertion or challenge to any such patents, or of any unauthorized use or misappropriation of Roche Know-How, and shall provide the other party with all evidence in its possession supporting such infringement, assertion or challenge or unauthorized use or misappropriation. For clarity, any challenge amounting to a reexamination, interference or opposition will be addressed by Sections 11.2 through 11.5.

(b) Defense and Enforcement. Within a period of [***] days after either party provides or receives such written notice with respect to its Patents (“Decision Period”), the party that has the first right to enforce any such Patents as set forth on Schedule 11.6(b) (the “First Party”) that are allegedly infringed, in its sole discretion, shall decide whether or not to initiate a suit or take other appropriate action with respect to any allegedly infringing activities in the Field (including without limitation defending any assertion or challenge) and shall notify the other party in writing of its decision in writing (“Suit Notice”).

If the First Party for its Patents are allegedly infringed decides to bring a suit or take action with respect to any allegedly infringing activities in the Field and provides a respective Suit Notice, then such party may immediately commence such suit or take such action. If such party (i) does not in writing advise the other party within the Decision Period that it will commence suit or take action, or (ii) fails to commence suit or take action within a reasonable time after providing Suit Notice, then the other party shall thereafter have the right to commence suit or take action with respect to any allegedly infringing activities in the Field and shall provide written notice to the party whose Patents are allegedly infringed of any such suit commenced or action taken by the other party.

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Upon written request, the party bringing suit or taking action (‘Initiating Party’) shall keep the other party informed of the status of any such suit or action and shall provide the other party with copies of all substantive documents and communications filed in such suit or action. The Initiating Party shall have the sole and exclusive right to control any such suit or action, including but not limited to selecting counsel for any such suit or action. If each of the parties elects to be an Initiating Party with respect to the same allegedly infringing activities within the Field, then the parties shall meet and agree on how to manage the resulting suits and actions (including with respect to the process set forth in Section 11.7). If River Vision is the Initiating Party with respect to the Compound Patent, upon Roche request, River Vision and Roche shall jointly agree in good faith on the strategy on how to bring suit or take action with respect to such Compound Patent, such discussions to be held in good faith, and failure to agree shall not jeopardize timing regarding any such suit or action.

The Initiating Party shall, except as provided below, pay all expenses of the suit or action, including, without limitation, the Initiating Party’s attorneys’ fees, damages and court costs.

If the Initiating Party believes it reasonably necessary, upon written request the other party shall join as a party to the suit or action, but shall be under no obligation to participate, except to the extent that such participation is required as the result of its being a named party to the suit or action. Alternatively, at the Initiating Party’s request, the other party will bring the suit or action in the other party’s name, if the Initiating Party reasonably believes that the Initiating Party does not have standing to bring the suit or action, and in such event, the Initiating Party will still control the suit or action as provided above. At the Initiating Party’s written request, the other party shall offer reasonable assistance to the Initiating Party in connection therewith at no charge to the Initiating Party except for reimbursement of reasonable out-of-pocket expenses incurred by the other party in rendering such assistance. The other party shall have the right to participate and be represented in any such suit or action by its own counsel at its own expense.

The Initiating Party shall not settle, agree to a consent judgment or otherwise voluntarily dispose of the suit or action without the written consent of the other party, which consent shall not be unreasonably withheld or delayed; provided that if River Vision is the Initiating Party, any such consent from Roche is not required if River Vision grants a permitted sub-license under Sections 2.5 and 3.

Except as otherwise agreed by the parties in connection with a cost-sharing arrangement, any recovery realized as a result of litigation described in this Section 11.6 (whether by way of settlement or otherwise) will be first allocated to reimbursement of unreimbursed legal fees and expenses incurred by the Initiating Party(ies), then toward reimbursement of any unreimbursed legal fees and expenses of the other party if not an Initiating Party, and then the remainder will be shared between the parties by allocating (i) [***]% to River Vision and [***] to Roche for those Patents infringed where River Vision is the Initiating Party, (ii) [***]% to Roche and [***] to Roche for those Patents infringed where Roche is the Initiating Party, and (iii) if there are Patents infringed for which River Vision is the Initiating Party for one or more of those Patents and Roche is the Initiating Party for one or more of those Patents, [***].

***Certain Confidential Information Omitted
(c) Exclusion. For clarity, this Section 11.6 shall not apply to the [***] Agreement, the [***] Agreement and the [***] Agreement.

11.7 Hatch-Waxman. Notwithstanding anything herein to the contrary, should a party receive a certification for a Product pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417, known as the Hatch-Waxman Act), as amended, or its equivalent in a country other than the US, then such party shall immediately provide the other party with a copy of such certification. The First Party for any such Patent shall have [***] days from date on which it receives or provides a copy of such certification to provide written notice to the other party (“H-W Suit Notice”) whether the First Party will bring suit at its expense within a [***] day period from the date of such certification. Should such [***] day period expire without the First Party bringing suit or providing such H-W Suit Notice, then the other party shall be free to immediately bring suit with respect to such Patent as the Initiating Party.

11.8 Biosimilar or interchangeable biological products. Notwithstanding anything herein to the contrary, within [***] years after the approval of a Product which has been licensed in the US as a biological product under 42 USC 262(a), and as may be needed from time to time thereafter, the parties shall consult as to potential strategies with respect to unexpired US Patent Rights which cover the Product; such consultation shall occur at least [***] days before such [***] anniversary. Specifically, in anticipation of a receipt by the Product’s reference product sponsor (“Reference Product Sponsor”) of a biosimilar or interchangeable product application pursuant to the Biologics Price Competition and Innovation Act of 2009 (Public Law 111-148), the parties will discuss the Reference Product Sponsor’s likely course of action with regard to each such US Patent Right in the procedural steps set forth under 42 USC §262(l), including a general plan for timely communication between the parties in light of the statutory response deadlines.

11.9 Patent Term Extensions. The parties shall use Commercially Reasonable Efforts to obtain all available patent term extensions, adjustments or restorations, or supplementary protection certificates (“SPCs”, and together with patent term extensions, adjustments and restorations, “Patent Term Extensions”). Roche shall execute such authorizations and other documents and take such other actions as may be reasonably requested by River Vision to obtain such Patent Term Extensions, including without limitation designating River Vision as its agent for such purpose as provided in 35 U.S.C. Section 156. All filings for such Patent Term Extensions shall be made by Roche; provided, that in the event that Roche elects not to file for a Patent Term Extension, Roche shall (a) promptly inform River Vision of its intention not to file and (b) grant the right to file for such Patent Term Extension to River Vision as its agent, such acts to occur well in advance of any deadlines for applying for any such Patent Term Extensions for River Vision to act thereupon. Each party shall execute such authorizations and other documents and take such other actions as may be reasonably requested by the other party to obtain such extensions. The parties shall cooperate with each other in gaining patent term restorations, extensions and/or SPCs wherever applicable to such Roche Patents.

***Certain Confidential Information Omitted
12. TRADEMARKS AND LABELING

River Vision shall own all trademarks used on or in connection with Product in the Territory, and shall, at its sole cost, be responsible for procurement, maintenance, enforcement and defense of all trademarks used on or in connection with Product in the Territory.

If requested by Roche and to the extent permitted by applicable law, all packaging and labeling shall display that the Product has been “licensed from Roche”.

13. REPRESENTATIONS AND WARRANTIES

13.1 Mutual representations and warranties. Each party represents and warrants to the other that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action; and (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

13.2 Roche representations and warranties. Roche represents and warrants to River Vision that, as of the Effective Date: (a) Roche has not received written notice from any Third Party claiming that the manufacture, use or sale of Compound or Product infringes any Patent of any Third Party; (b) Roche is not aware of any Patent that would be infringed by Compound in the Field in the Territory by River Vision; (c) Roche is not a party to any legal action, suit or proceeding relating to Compound or Product; (d) Roche has the full right, power and authority to grant all of the right, title and interest in the licenses, sub-licenses and other rights granted to River Vision under this Agreement; (e) the Roche Patents constitute all of the Patents owned or in-licensed by Roche or any of its Affiliates that are necessary to develop, commercialize, make, use, sell, offer for sale, and import Compound or Product (other than as disclosed by Roche to River Vision before the Effective Date); (f) Roche has Control of all the Roche Patents; and (g) the [***] Agreement, the [***] License Agreement and the [***] License Agreement are in full force and effect.

13.3 Limitations. Except as provided in Section 13.2, Roche makes no representation or warranty that all intellectual property rights necessary for River Vision to make, have made, use, sell, offer for sale and import the Compound or the Product in the Territory have been granted to River Vision under Section 2. Roche did not perform an exhaustive and final search for Third Party patents or an evaluation thereof for Compound and technologies relevant under this Agreement. Roche will not keep River Vision updated about further searches or analyses of Third Party patents nor will it keep River Vision updated about any further developments of any Third Party rights or steps taken or intended to be taken by Roche with regard to such Third Party rights.
13.4 Disclaimer. Except as expressly set forth herein and elsewhere in this Agreement, THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED “AS IS” AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

13.5 Debarment. River Vision represents and warrants that it has never been debarred under 21 U.S.C. §335a, disqualified under 21 C.F.R. §312.70 or §812.119, sanctioned by a Federal Health Care Program (as defined in 42 U.S.C §1320 a-7(b)), including without limitation the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any other similar Federal or state agency or program. In the event River Vision receives notice of debarment, suspension, sanction, exclusion, ineligibility or disqualification under the above-referenced statutes, River Vision shall immediately notify Roche in writing and Roche shall have the right, but not the obligation, to terminate this Agreement, effective, at Roche’s option, immediately or at a specified future date, with the consequences set forth in Section 15.4(a).

14. CONFIDENTIALITY; PUBLICATION

14.1 Non-Use and Non-Disclosure. During the Term of this Agreement and for [***] years thereafter, a Receiving Party shall (i) treat Confidential Information provided by Disclosing Party as it would treat its own information of a similar nature, (ii) take all reasonable precautions not to disclose such Confidential Information to Third Parties, without the Disclosing Party’s prior written consent, and (iii) not use such Confidential Information other than for fulfilling its obligations under this Agreement. For the purposes of this Section 14, Roche Know-How shall be considered Confidential Information of both parties.

14.2 Authorized disclosure. Each party may disclose Confidential Information of the other party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patents as permitted by this Agreement;
(b) prosecuting or defending litigation as permitted by this Agreement;
(c) complying with applicable court orders or governmental regulations; and
(d) disclosure to (i) Affiliates, (ii) for River Vision, NRM and potential or actual subcontractors, Partners, assignees and Change of Control counterparties, (iii) Third Parties in connection with due diligence or similar investigations by such Third Parties, and (iv) disclosure to potential Third Party investors or financial institutions or advisors (including, without limitation, for River Vision, on behalf of NRM), provided, in each case, that any such Third Party agrees to be bound by obligations of confidentiality and non-use, such obligations of confidentiality to contain a confidentiality period of at least [***] years or [***] but not less than [***] years.

***Certain Confidential Information Omitted
Notwithstanding the foregoing, in the event a party is required to make a disclosure of the other party’s Confidential Information pursuant to Sections 14.2(b) or 14.2(c), it will, except where impracticable, give reasonable advance notice to the other party of such disclosure and use efforts to secure confidential treatment of such information at least as diligently as such party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. The parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by the parties with the Securities and Exchange Commission (or any other relevant agency or body related to a regulated stock exchange) or as otherwise required by law.

14.3 Publications. River Vision shall have the right to publish any papers regarding results and other information regarding Compound and/or Product, including oral presentations and abstracts. River Vision shall provide Roche with a copy of any proposed papers at least [***] days prior to submission for publication so as to provide Roche with an opportunity to review drafts of the proposed papers. River Vision shall consider in good faith the requests and suggestions of Roche.

Roche shall have the right to publish (i) the results of past and ongoing studies and (ii) any particular work that must be disclosed by law. Roche shall provide River Vision with a copy of any proposed papers at least [***] days prior to submission for publication so as to provide River Vision with an opportunity to review drafts of the proposed papers. Roche shall consider in good faith the requests and suggestions of River Vision.

14.4 Use of name or trademarks. Neither party shall use the other party’s or its Affiliates’ names, with respect to Roche including but not limited to the compound code name “[***]”, “[***]” or “[***]”, or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.

14.5 Publicity. It is understood that the parties intend to issue a joint press release announcing the execution of this Agreement at a mutually agreed upon time (the “Initial Press Release”). Thereafter both parties may desire or be required to issue subsequent press releases relating to the Agreement or activities hereunder. The parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such subsequent press releases prior to the issuance thereof, provided that a party may not unreasonably withhold or delay consent to such subsequent releases, and that either party may issue such subsequent press releases as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations or for appropriate market disclosure. In addition, following the Initial Press Release announcing this Agreement, either party shall be free to disclose, without the other party’s prior written consent, the existence of this Agreement, the fact that River Vision has taken a license from Roche to the Compound and Product for development and commercialization in the Field, and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

15. TERM

15.1 Term. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated pursuant to Section 15.2, continue until the expiration of the Royalty Term (the “Term”).

***Certain Confidential Information Omitted
15.2 Termination. Subject to Section 15.4:

(a) Breach. A party (“Non-Breaching Party”) shall have the right to terminate this Agreement in its entirety in the event the other party (“Breaching Party”) is in breach of any of its obligations under this Agreement. The non-Breaching Party shall provide written notice to the Breaching Party, which notice shall identify the breach. The Breaching Party shall have a period of ninety (90) days after such written notice is provided to cure such breach (“Peremptory Notice Period”). If such breach is not cured within the Peremptory Notice Period, this Agreement shall effectively terminate, unless there exists a bona fide dispute as to whether such breach occurred or such breach has been cured, whereupon such Peremptory Notice Period shall be tolled and shall not expire until such dispute is settled pursuant to Section 17, whereupon thereafter the Breaching Party may attempt to cure such breach if in the wrong. Non-payment by River Vision is considered a breach under this Agreement.

(b) Insolvency. A party shall have the right to terminate this Agreement, if the other party incurs an Insolvency Event; provided, however, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the party that incurs the Insolvency Event consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

(c) Challenging the Roche Patent Rights. If River Vision is challenging the validity of the Roche Patent Rights, then Roche shall have the right to terminate this Agreement in its entirety with immediate effect. Section 15.4(a) shall apply mutatis mutandis.

15.3 Termination by River Vision without a Cause. If River Vision wishes to terminate the Agreement, River Vision shall notify Roche in writing and Roche and River Vision shall discuss in good faith methods to avoid such termination. If however, the Parties cannot agree on a method to avoid such termination within thirty (30) days of such notice, and River Vision continues to wish to terminate this Agreement, then the following shall apply: River Vision shall have the right to terminate this Agreement in its entirety within six (6) months of such notice before First Commercial Sale of the Product or within nine (9) months of such notice after the First Commercial Sale of the Product. The effective date of termination under this Section 15.3 shall be the date six (6) months (or nine (9) months as the case may be) after River Vision provides such notice to Roche.

15.4 Consequences of Breach and Termination

(a) Breach by River Vision

(i) Both parties shall discuss in good faith and shall attempt to agree on the extent of damages caused by River Vision’s breach of its obligations under this Agreement, and appropriate compensation for damages as may be applicable. Roche shall retain all its remedies as against River Vision in addition to those provided in this Agreement (including, without limitation, when clause (ii) below applies). Notwithstanding anything in this Section 15 to the contrary, if River Vision disputes the breach as specified in Section 15.2(a) and/or any remedy therefor, then in lieu of any of the remedies specified below in clause (ii) of this Section 15.4(a), the parties agree to have the ICC under Section 17 determine (1) whether any breach has occurred (and if any such breach is found to have occurred, subject to the subsequent cure period provided in Section 15.2(a)) and (2) an appropriate remedy in proportion to any such uncured breach. For clarity, Roche shall not be required to seek, before the ICC or otherwise, to terminate this Agreement upon any breach by River Vision.
(ii) If River Vision elects not to dispute the alleged breach and/or the remedy therefor as provided in clause (i) above, then the following shall apply:

(a) Roche shall notify River Vision its decision on whether or not it shall terminate this Agreement within ninety (90) days after the expiration of the Peremptory Notice Period. Such notice shall contain the information to which extent Roche wishes to continue the development and commercialization of the Compound and/or Product.

(b) Upon any termination by Roche for breach by River Vision, all rights and licenses granted by Roche to River Vision under this Agreement shall also terminate on the effective date of termination. River Vision shall, upon Roche’s written request, to the extent River Vision has the right to do so, assign and transfer to Roche, [* ***] all regulatory filings and approvals, Product specific trademarks, and all data, including clinical data, samples, materials and information, in River Vision’s possession and Control related to Product necessary for the development and commercialization of the Product. Upon request of Roche, River Vision shall assign clinical trial agreements to the extent permitted.

(c) Roche shall, upon such transfer, have the right to disclose such filings, approvals and data to (i) governmental agencies to the extent required or desirable to secure government approval for the development, manufacturing or sale of Product, (ii) Third Parties acting on behalf of Roche, its Affiliates or licensees, to the extent reasonably necessary solely for the development, manufacture, or sale of Product, and (iii) Third Parties to the extent reasonably necessary to market Product.

(d) Roche shall have [* ***] solely for Roche, its Affiliates or licensees to develop, manufacture and have manufactured, use to sell, sell, promote, export and import the applicable Products in the Territory. Upon request of Roche, any license agreements between River Vision and a Third Party relating to Product shall be either assigned to Roche, or if this is not possible, sub-licensed to Roche to the extent permitted under the then prevailing conditions.

**Breach by Roche**

(i) Both parties shall discuss in good faith and shall attempt to agree on the extent of damages caused by Roche’s breach of its obligations under this Agreement, and appropriate compensation for damages as may be applicable. River Vision shall retain all its remedies as against Roche in addition to those provided in this Agreement (including, without limitation, when clause (ii) below applies). Notwithstanding anything in this Section 15 to the contrary, if Roche disputes the breach as specified in Section 15.2(a) and/or any remedy therefor, then in lieu of any of the remedies specified below in clause (ii) of this Section 15.4(b), the parties agree to have the ICC under Section 17 determine (1) whether any breach has occurred (and if any such breach is found to have occurred, subject to the subsequent cure period provided in Section 15.2(a)) and (2) an appropriate remedy in proportion to any such uncured breach. For clarity, River Vision shall not be required to seek, before the ICC or otherwise, to terminate this Agreement upon any breach by Roche.

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(ii) If Roche elects not to dispute the alleged breach or the remedy therefor as provided in clause (i) above, then the following shall apply:

(a) Upon any breach by Roche for which River Vision has the right to terminate this Agreement under Section 15.2, River Vision shall have the right to terminate this Agreement in accordance with Section 15.2, with the consequences set forth in Section 15.4(c). If River Vision does not practice its aforementioned right to terminate, then River Vision may retain the rights and licenses granted by Roche under this Agreement after the expiration of the Peremptory Notice Period and this Agreement shall not terminate but rather shall continue in full force and effect. River Vision shall notify Roche its decision on whether or not it shall terminate this Agreement within ninety (90) days after the expiration of the Peremptory Notice Period.

(c) Termination by River Vision without Cause

(i) Roche shall inform River Vision within thirty (30) days after the notice of termination under this Section 15.4(c) whether or not and to which extent Roche wishes to continue the development and commercialization of the Compound and/or Product.

(ii) Upon any termination by River Vision under this Section 15.4(c), all rights and licenses granted by Roche to River Vision under this Agreement shall terminate in their entirety.

(iii) River Vision shall, upon Roche’s written request, to the extent it has the right to do so, assign to Roche, [***] all Product regulatory filings and approvals and Product-specific trademarks (including but not limited to data, including clinical data, samples, materials and information) in River Vision’s possession and Control. If requested by Roche, River Vision shall assign clinical trial agreements to the extent permitted.

Roche shall have [***] solely for Roche, its Affiliates or licensees to develop, have developed, commercialize, have commercialized, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import and have imported the applicable Products in the Territory.

Roche shall, upon such transfer, have the right to disclose such filings, approvals and data to (i) governmental agencies to the extent required or desirable to secure government approval for the development, manufacture or sale of Product; (ii) Third Parties acting on behalf of Roche, its Affiliates or licensees, to the extent reasonably necessary solely for the development, manufacture, or sale of Product, or (iii) Third Parties to the extent reasonably necessary to market Product.

Upon request of Roche, any agreements between River Vision and a Third Party relating to Product shall be either assigned to Roche, or if this is not possible, sub-licensed to Roche to the extent permitted under the then prevailing conditions.

15.5 Other Obligations

(a) Obligations Related to Ongoing Activities

(i) From the date of notice of termination until the effective date of termination, this Agreement shall remain in full force and effect

(ii) If Roche has provided notice to River Vision pursuant to Section 15.4(c)(i) that it does not wish to continue the development and commercialization of the Compound and/or Product, then River Vision (A) has the right to cancel all ongoing obligations and (B) shall complete all non-cancellable obligations at its own expense.

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(iii) If Roche has provided notice to River Vision pursuant to Section 15.4(c) that Roche wishes to continue the development and/or commercialization of the Compound and/or Product, then, at Roche’s request, River Vision shall [***] continue non-clinical activities ongoing as of the date of notice of termination (for clarity, the treatment of clinical trials is addressed below).

(iv) If Roche has provided notice to River Vision pursuant to Section 15.4(c) that Roche wishes to continue the development and/or commercialization of the Product, then, upon the request of Roche, River Vision shall complete [***], any clinical studies related to the Product that are being conducted under its IND (or equivalent) for the Product and are ongoing as of the notice of termination; provided, however, that Roche agrees [***] in completing such clinical studies and provided further that each of River Vision and Roche in their respective reasonable judgment has concluded that completing any such clinical studies does not present an unreasonable risk to patient safety.

(v) In any case, after the effective date of termination, River Vision shall not have any obligation to perform and/or complete any new activities or to make any payments for performing or completing any new activities under this Agreement, except as expressly stated in Section 15.5(a)(iii).

(b) Obligations Related to Manufacturing. If (i) Roche has provided notice to River Vision that Roche wishes to continue the development and/or commercialization of the Product, and (ii) Product is then being manufactured, then, upon the request of Roche, River Vision shall use Commercially Reasonable Efforts to manufacture and supply (or have manufactured or supplied, as the case may be) Product to Roche for a period which shall not exceed [***] months from the effective date of the termination of this Agreement at a price to be agreed by the parties in good faith. Roche shall use Commercially Reasonable Efforts to take over the manufacturing as soon as possible after the effective date of termination.

(c) Royalty and Payment Obligations

Expiration or termination of this Agreement (or any provision hereof) for any reason shall be without prejudice to any right that shall have accrued to the benefit of a party prior to such expiration or termination, including without limitation damages arising from any breach under this Agreement.

Termination of this Agreement by a party, for any reason, shall not release River Vision from any obligation to pay royalties or make any payments to Roche which are due and payable prior to the effective date of termination. Termination of this Agreement by a party, for any reason, will release River Vision from any obligation to pay royalties or make any payments to Roche which would otherwise become due or payable on or after the effective date of termination.

(d) Survival. Expiration or termination of this Agreement shall not relieve a party from any obligation that is expressly indicated to survive such expiration or termination. In addition to the termination consequences set forth in Section 15.4, the following provisions shall survive termination or expiration of this Agreement: 2.8 (Freedom-to-operate); 11. Intellectual Property; 14. Confidentiality/Publication; 16. Indemnification, 17. Dispute Resolution, Governing Law and Jurisdiction, and the following provisions of 18. General Provisions: 18.2, 18.3, 18.6, 18.7, 18.8, 18.10, 18.11 and 18.12.

***Certain Confidential Information Omitted
16. INDEMNIFICATION

16.1 Roche indemnification. Roche hereby agrees to save, defend, indemnify and hold harmless River Vision and its officers, directors, employees, consultants and agents ("River Vision Indemnitees") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys’ fees ("Indemnified Losses"), to which any such River Vision Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Indemnified Losses arise out of the breach by Roche of any obligation, representation, warranty, covenant or agreement made by it under this Agreement, except to the extent such Indemnified Losses result from the negligence or willful misconduct of any River Vision Indemnitee (including without limitation any item subject to indemnification by River Vision under Section 16.2).

16.2 River Vision indemnification. River Vision hereby agrees to save, defend, indemnify and hold harmless Roche and its officers, directors, employees, consultants and agents ("Roche Indemnitees") from and against any and all Indemnified Losses, to which any such Roche Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Indemnified Losses arise out of (i) the breach by River Vision of any representation, warranty, covenant or agreement made by it under this Agreement, or (ii) the development, manufacture, use, handling, storage, sale or other disposition of the Compound and/or any Product by River Vision or any of its Affiliates or Partners (including but not limited to (1) Product liability claims and (2) infringement of Third Party patents, other than those for this clause (2) Patents sub-licensed to River Vision by Roche under the [***] Agreement, the [***] Agreement or the [***] Agreement or any in-licensed Roche Patents provided that River Vision has complied with the applicable terms of this Agreement), except to the extent such Indemnified Losses result from the negligence or willful misconduct of any Roche Indemnitee (including without limitation any item subject to indemnification by Roche under Section 16.1).

16.3 Control of defense. If the event an River Vision Indemnitee or Roche Indemnitee (as the case may be) seeks indemnification under Section 16.1 or 16.2, it shall inform the other party (the “Indemnifying Party”) of a claim as soon as reasonably practicable after it receives notice of the claim, shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim, provided that the Indemnifying Party shall not settle any such claim without the prior written consent of any affected Roche Indemnitee or River Vision Indemnitee (as the case may be), if such settlement contains any admission of fault of such River Vision Indemnitee or Roche Indemnitee (as the case may be).
17. Dispute Resolution, Governing Law and Jurisdiction

17.1 Dispute resolution. Any dispute arising under or relating to the parties rights and obligations under this Agreement will be referred to the Chief Executive Officer of River Vision or his designee and the Head of Roche Partnering of Roche with authority to resolve such dispute, for resolution. In the event the two individuals referred to in the preceding sentence are unable to resolve such dispute within [***] days of such dispute being referred to the officers, then, upon the written request of either party to the other party, the dispute shall be addressed as provided in Section 17.2.

17.2 Governing law and jurisdiction.

This Agreement shall be governed by and construed in accordance with the laws of Switzerland, without reference to its conflict of laws principles and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention).

If a dispute cannot be resolved in application of Section 17.1, then such dispute shall be finally settled under the rules of arbitration of the International Chamber of Commerce ("ICC") by three arbitrators.

Each party shall nominate one arbitrator. Should the claimant fail to appoint an arbitrator in the request for arbitration within [***] days of being requested to do so, or if the respondent should fail to appoint an arbitrator in its answer to the request for arbitration within [***] days of being requested to do so, the other party shall request the ICC court to make such appointment.

The arbitrators nominated by the parties shall, within [***] days from the appointment of the arbitrator nominated in the answer to the request for arbitration, and after consultation with the parties, agree and appoint a third arbitrator, who will act as a chairman of the arbitral tribunal. Should such procedure not result in an appointment within the [***] day time limit, either party shall be free to request the ICC court to appoint the third arbitrator.

Where there is more than one claimant and/or more than one respondent, the multiple claimants or respondents shall jointly appoint one arbitrator. In other respects the provisions of this Section 17.1 shall apply.

If any party-appointed arbitrator or the third arbitrator resigns or ceases to be able to act, a replacement shall be appointed in accordance with the arrangements provided for in this Section 17.1.

Basel, Switzerland, shall be the seat of the arbitration.

The language of the arbitration shall be English. Documents submitted in the arbitration (the originals of which are not in English) shall be submitted together with an English translation.

This arbitration agreement does not preclude either party seeking conservatory or interim measures from any court of competent jurisdiction including, without limitation, the courts having jurisdiction by reason of either party’s domicile. Conservatory or interim measures sought by either party in any one or more jurisdictions shall not preclude the arbitral tribunal granting conservatory or interim measures. Conservatory or interim measures sought by either party before the arbitral tribunal shall not preclude any court of competent jurisdiction granting conservatory or interim measures.

In the event that any issue shall arise which is not clearly provided for in this arbitration agreement the matter shall be resolved in accordance with the ICC arbitration rules.

***Certain Confidential Information Omitted
18. General Provisions

18.1 No implied licenses. No right or license under any Patents or Know-How is granted or shall be granted by implication. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement. Each party hereby expressly reserves the right to practice, and to grant licenses under, the Patents and Know-How Controlled by such party for any and all purposes other than as expressly provided herein or for the specific purposes for which the other party has been granted an exclusive license under this Agreement.

18.2 Relationship between the parties. The parties’ relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the parties. Neither party is a legal representative of the other party and neither party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other party for any purpose whatsoever.

18.3 Non-waiver. The failure of a party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party.

18.4 Assignment. Neither party shall have the right to assign the present Agreement or any part thereof to any Third Party other than Affiliates without the prior written approval of the other Party, such approval not to be unreasonably withheld or delayed.

18.5 Change of Control. River Vision shall not have the right to undergo a Change of Control without the prior written approval of Roche, such approval not to be unreasonably withheld or delayed. For purposes of this Agreement, “Change of Control” shall mean, with respect to River Vision, (i) a merger, reorganization or consolidation involving River Vision in which the members of River Vision, immediately prior to the merger, reorganization or consolidation, would not, immediately after the merger, reorganization or consolidation, beneficially own (directly or indirectly) membership interests representing in the aggregate more than fifty percent (50%) of the combined voting power of the entity issuing cash or securities in the merger, reorganization or consolidation (or of its ultimate parent entity, if any), or (ii) a person or entity becomes the beneficial owner of more than fifty percent (50%) of the voting securities of River Vision, other than directly from River Vision; however, “Change of Control” will not include any transaction effected for equity or debt financing purposes pursuant to which River Vision receives cash therefor, provided River Vision does not grant any sublicense of the rights granted to River Vision by Roche in Section 2.1(a) as part of such transaction. For purposes of this Section 18.4 and the last sentence of Section 2.5, River Vision shall have the right to provide the identity of the counterparty to the proposed Partner Agreement or Change of Control, and Roche shall indicate within [***] business days if Roche approves such proposed transaction (and if Roche fails to reply in such [***]-day period, then such approval will be deemed given).

***Certain Confidential Information Omitted
18.6 No Third Party beneficiaries. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it.

18.7 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, then such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

18.8 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile confirmed thereafter by any of the foregoing, to the party to be notified at its address(es) given below, or at any address such party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if mailed, [***] days after the date of postmark; or (c) if delivered by overnight courier, the next business day the overnight courier regularly makes deliveries.

If to River Vision, notices must be addressed to:

River Vision, LLC
Narrow River Management
One Rockefeller Plaza, Ste. 1204
New York, NY 10020 U.S.A.
Attention: David Madden, Principal
Facsimile: [***]

If to Roche, notices must be addressed to:

Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, NJ 07110, USA
Attention: Corporate Secretary
Facsimile: [***]

And:

F.Hoffmann-La Roche Ltd
Grenzacherstrasse 124
CH-4070 Basel
Switzerland
Attention: Legal Department
Facsimile: [***]

In the event of a change of notice address, recipient or both, a party shall provide the other party written notice pursuant to this Section 18.8 setting forth the new address and/or recipient, as appropriate.

***Certain Confidential Information Omitted
18.9 Force majeure. Except for the obligation to make payment when due, each party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such party’s reasonable control including but not limited to Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, any strike or labor disturbance, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the party has not caused such event(s) to occur. Notice of a party’s failure or delay in performance due to force majeure must be given to the other party within [***] days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any party be required to prevent or settle any labor disturbance or dispute.

18.10 Interpretation. All references to days in this Agreement shall mean calendar days, unless otherwise specified. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the parties regarding this Agreement shall be in the English language. All headings in this Agreement are for convenience only and shall not affect the meaning of any provision hereof. “Herein,” “hereby,“ “hereunder,” “hereof” and other equivalent words refer to this Agreement as an entirety and not solely to the particular portion of this Agreement in which any such word is used. All definitions set forth herein shall be deemed applicable whether the words defined are used herein in the singular or the plural. Each party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting party shall not apply.

18.11 Binding Effect. This Agreement shall inure to the benefit of and be binding upon the parties, their Affiliates, and their respective successors and assigns.

18.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument.

[Remainder of this page intentionally left blank.]

***Certain Confidential Information Omitted

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IN WITNESS WHEREOF, the parties have executed this LICENSE AGREEMENT as of the date first above written.

**F. HOFFMANN-LA ROCHE LTD**

By: /s/ Andrew Jefferson  
Name: Andrew Jefferson  
Title: Global Licensing Director  
Date: 23/6/11

By: /s/ Dr. Melanie Frey Wick  
Name: Dr. Melanie Frey Wick  
Title: Legal Counsel  
Date: June 23, 2011

**RIVER VISION LLC**

By: NARROW RIVER MANAGEMENT, LP  
MANAGING MEMBER

By: /s/ Frank J. D’Angelo  
Name: Frank J. D’Angelo  
Title: V.P.

Date:

By: /s/ D. Madden  
Name: D. Madden  
Title: Principal  
Date:
Appendix 1

Compound
teprotumumab is a human IgG1 antibody binding to IGFIR [***]

[Remainder of this page intentionally left blank.]

***Certain Confidential Information Omitted
Appendix 2
Roche Patents

[***]

***Certain Confidential Information Omitted
Appendix 3
Roche Know-How:

[***]

***Certain Confidential Information Omitted
Appendix 4
River Vision Studies:
[***]
Supply of Drug Product and Supported Shelf Life under Sections 6.1(b) and 6.1(c):

River Vision will send a written order to Roche to ship Drug Product with no less than [***] months lead time from the delivery date.

The order shall contain: (a) the order number, (b) quantity of Drug Product vials, (c) invoicing address and (d) delivery date. Roche shall deliver Drug Product according to Table I EXW (Incoterms 2000) to the delivery address named by River Vision. The delivery address for the material shall be communicated to Roche no fewer than [***] days prior to the agreed delivery date.

With each shipment of Drug Product, Roche will send the packing list, the Certificate of Analysis for the batches included in the shipment, the current Material Safety Data Sheet and a pro forma invoice. In addition, Roche will provide River Vision with the documents listed in Table II. Roche guarantees that it has manufactured Product in conformity with the Product specifications, all applicable laws and regulations, and in accordance with cGMP.

[***]

***Certain Confidential Information Omitted
Appendix 5
Redacted copy of [***] Agreement

See attached.

[Remainder of this page intentionally left blank.]

***Certain Confidential Information Omitted
Appendix 6
Redacted copy of [***] Agreement

See attached.

[Remainder of this page intentionally left blank.]

***Certain Confidential Information Omitted
Appendix 7
Redacted copy of [***] Agreement

See attached.

[Remainder of this page intentionally left blank.]

***Certain Confidential Information Omitted
Schedule 11.6(b)
Patents and First Parties
[***]

[Remainder of this page intentionally left blank.]

***Certain Confidential Information Omitted
Amendment No 1 to License Agreement

This Amendment No 1 to License Agreement ("Amendment") is entered into as of the 19th of November, 2012 ("Effective Date") by and among:

F. Hoffmann-La Roche Ltd, a corporation organized and existing under the laws of Switzerland, with its principal office at Grenzacherstrasse 124, CH-4070 Basel, Switzerland ("Roche Basel") and Hoffmann-La Roche Inc., a corporation organized and existing under the laws of New Jersey, with its principal office at 340 Kingsland Street, Nutley, New Jersey 07110, U.S.A. ("Roche Nutley"); Roche Basel and Roche Nutley together referred to as "Roche"

and

River Vision LLC, a limited liability company organized and existing under the laws of Delaware, with its principal office at One Rockefeller Plaza, New York NY, 10020, U.S.A. ("River Vision").

WHEREAS, River Vision and Roche wish to amend the agreement to as follows:

I. Section 2.4 shall be deleted and replaced by the following:

"2.4. Sub-Contractors. River Vision has the right to sub-contract the work performed under this Agreement. Any sub-contract agreement shall include the right to disclose (i) a copy of the Agreement and confidential information to Roche and (ii) the right to assign the agreement to Roche, including the right to transfer of the ownership of data, information and results arising therefrom to Roche to the same extent as to River Vision."

II. Section 2.5 shall be deleted and replace by the following:

"2.5 Right to enter into a Partner Agreement with Third Parties. Subject to Roche’s rights under Section 3, River Vision shall have the right to enter into a Partner Agreement, including but not limited to granting sublicenses to Partners under its rights granted under Section 2.1 and Section 2.2. Any rights granted to a Partner under this Agreement shall be solely to the extent necessary to develop, commercialize, make, use, offer for sale, sell or import (and have others do the same) Compound and/or Product in the Field in the Territory. River Vision shall ensure that all of the applicable terms and conditions of this Agreement, including the obligations under the [***] Agreement, the [***] Agreement and the [***] Agreement, shall apply to the Partner under the Partner Agreement to the same extent as they apply to River Vision for all purposes. River Vision assumes full responsibility for the performance of all obligations and observance of all terms so imposed to the Partner under such Partner Agreement and shall itself account to Roche for all payments due under this Agreement. The Partner of River Vision shall have no right to further sub-license rights to develop and commercialise the Compound or Product to a Third Party, with the understanding that co-promotion or distribution or other marketing arrangements are permitted.

Any sublicenses granted by River Vision to a Partner under the [***] Agreement, the [***] Agreement and the [***] Agreement shall be subject to prior approval of Roche. For clarity, River Vision is free to sub-contract any rights under such agreements.

River Vision shall disclose a copy of the draft Partner Agreement to Roche, subject to redaction of financial terms.

***Certain Confidential Information Omitted
III. Section 18.4 of the Agreement shall be deleted and replaced by the following:

“Section 18.4. Assignment. Neither party shall have the right to assign the present Agreement or any part thereof to any Third Party other than (I) Affiliates or (II) in connection with a Change of Control as contemplated by Section 18.5, without the prior written approval of the other Party, such approval not to be unreasonably withheld or delayed.”

IV. Section 18.5 of the Agreement shall be deleted and replaced by the following:

“Section 18.5. Change of Control. Subject to Roche’s right of first offer under Section 3 hereof, River Vision shall have the right to undergo a Change of Control. For purposes of this Agreement, “Change of Control shall mean, with respect to River Vision, (i) a merger, reorganization or consolidation involving River Vision in which the members of River Vision, immediately prior to the merger, reorganization or consolidation, would not, immediately after the merger, reorganization or consolidation, beneficially own (directly or Indirectly) membership interests representing in the aggregate more than fifty percent (50%) of the combined voting power of the entity issuing cash or securities in the merger, reorganization or consolidation (or of its ultimate parent entity, if any), or (ii) a person or entity becomes the beneficial owner of more than fifty percent (50%) of the voting securities of River Vision, other than directly from River Vision; however, “Change of Control” will not Include any transaction effected for equity or debt financing purposes pursuant to which River Vision receives cash therefor, provided River Vision does not grant any sublicense of the rights granted to River Vision by Roche as part of such transaction.”

V. Capitalized terms shall have the same meaning as defined in the Agreement.

VI. Except as expressly stated herein, no other changes are made to the Agreement and all other terms and conditions of the Agreement remain in full force and effect.

VII. This Amendment enters into effect on the Effective Date.
IN WITNESS WHEREOF, the parties have executed this **AMENDMENT NO. 1 TO THE LICENSE AGREEMENT** as of the date first above written.

**F. HOFFMANN-LA ROCHE LTD**

By: /s/ Christophe Carissimo  
Name: Christophe Carissimo  
Title: Global Licensing Director  
Date: Nov 19, 2012

By: /s/ Dr. Melanie Frey Wiek  
Name: Dr. Melanie Frey Wiek  
Title: Legal Counsel  
Date: November 19, 2012

**HOFFMANN-LA ROCHE INC.**

By: /s/ Joseph S. McCracken  
Name: Joseph S. McCracken  
Title: Vice President  
Date: November 19, 2012

By: /s/ D. Madden  
Name: D. Madden  
Title: Principal  
Date: 11/19/2012

**RIVER VISION LLC**

BY: **NARROW RIVER MANAGEMENT, LP**

MANAGING MEMBER

By: /s/ D. Madden  
Name: D. Madden  
Title: Principal  
Date: 11/19/2012
This Amendment No. 2 to License Agreement ("Amendment") is entered into as of the 1st of February 2013 ("Effective Date") by and among:

F. Hoffmann-La Roche Ltd, a corporation organized and existing under the laws of Switzerland, with its principal office at Grenzacherstrasse 124, CH-4070 Basel, Switzerland ("Roche Basel") and Hoffmann-La Roche Inc., a corporation organized and existing under the laws of New Jersey, with its principal office at 340 Kingsland Street, Nutley, New Jersey 07110, U.S.A. ("Roche Nutley"); Roche Basel and Roche Nutley together referred to as "Roche"

and

River Vision Development Corp., a corporation organized and existing under the laws of Delaware, with its principal office at One Rockefeller Plaza, New York NY, 10020, U.S.A.

WHEREAS, River Vision Development Corp. is successor in interest to River Vision LLC and River Vision Development Corp. and Roche wish to amend the agreement to as follows:

I. The table "II. Material" in Process, Manufacturing Know how on page 61 of Appendix 3 shall be amended by the addition of the following after the existing table under the titles

[***]

***Certain Confidential Information Omitted
II. Capitalized terms shall have the same meaning as defined in the Agreement.

III. Except as expressly stated herein, no other changes are made to the Agreement and all other terms and conditions of the Agreement remain in full force and effect.
IV. This Amendment enters into effect on the Effective Date.

[Remainder of this page intentionally left blank.]
IN WITNESS WHEREOF, the parties have executed this AMENDMENT NO. 2 TO THE AGREEMENT as of the date first above written.

F. HOFFMANN-LA ROCHE LTD

By: /s/ Christoph Sarry
Name: Dr. Christoph Sarry
Title: Global Alliance Director
Date: 14/02/2013

By: /s/ Melanie Frey Wick
Name: Dr. Melanie Frey Wick
Title: Legal Counsel
Date: February 14, 2013

HOFFMANN-LA ROCHE INC.

By: /s/ Joseph S. McCracken
Name: Joseph S. McCracken
Title: Vice President
Date: 21-Feb-2013

By: /s/ D Madden
Name: D Madden
Title: Chief Executive Officer
Date: 5 February 2013

Apprv’d As To Form LAW DEPT.

By /s/ MDM ________________________________
Amendment No 3 to License Agreement

THIS AMENDMENT NO. 3 TO LICENSE AGREEMENT ("Amendment") is entered into as of the 1st of February 2013 ("Effective Date") by and among:

F. HOFFMANN-LA ROCHE LTD, a corporation organized and existing under the laws of Switzerland, with its principal office at Grenzacherstrasse 124, CH-4070 Basel, Switzerland ("Roche Basel") and Hoffmann-La Roche Inc., a corporation organized and existing under the laws of New Jersey, with its principal office at 340 Kingsland Street, Nutley, New Jersey 07110, U.S.A. ("Roche Nutley"; Roche Basel and Roche Nutley together referred to as "Roche")

and

RIVER VISION DEVELOPMENT CORP., a limited liability company organized and existing under the laws of Delaware, with its principal office at One Rockefeller Plaza, Suite 1204, New York, NY, 10020, U.S.A. ("RV").

WHEREAS, River Vision and Roche wish to amend the agreement as follows:

I. The table “II. Material” in Process, Manufacturing Know how on page 61 of Appendix 3 shall be amended by the addition of the following table after the existing table under the titles

[***]

***Certain Confidential Information Omitted
IN WITNESS WHEREOF, the parties have executed this AMENDMENT NO. 3 TO THE AGREEMENT as of the date first above written.

F. HOFFMANN-LA ROCHE LTD

By: /s/ Christophe Carissimo
Name: Christophe Carissimo
Title: Global Head Transaction Excellence
Date: May 31, 2013

Hoffmann-La Roche Inc.

By: /s/ John P. Parise
Name: John P. Parise
Title: Authorized Signatory
Date: June 4, 2013

Apprv’d As To Form LAW DEPT.

By: /s/ MM

By: /s/ Melanie Frey Wick
Name: Dr. Melanie Frey Wick
Title: 
Date: May 31, 2013

RIVER VISION DEVELOPMENT CORP.

By: /s/ D Madden
Name: D Madden
Title: CEO
Date: 6/11/13

For: F. Hoffmann-La Roche Ltd.

For: Hoffmann-La Roche Inc.

For: River Vision Development Corp.

Apprv’d As To Form LAW DEPT.

By: /s/ MM

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***Certain Confidential Information Omitted***
This Amendment No. 4 to License Agreement ("Amendment") is entered into as of the 21st of October 2013 ("Effective Date") by and among:

F. Hoffmann-La Roche Ltd., a corporation organized and existing under the laws of Switzerland, with its principal office at Grenzacherstrasse 124, CH-4070 Basel, Switzerland ("Roche Basel") and Hoffmann-La Roche Inc., a corporation organized and existing under the laws of New Jersey, with its principle office at 340 Kingsland Street, Nutley, New Jersey 07110, U.S.A. ("Roche Nutley"); Roche Basel and Roche Nutley together referred to as "Roche"

and

River Vision Development Corp., a limited liability company organized and existing under the laws of Delaware, with its principal office at One Rockefeller Plaza, Suite 1204, New York NY, 10020, U.S.A. ("River Vision").

WHEREAS, River Vision and Roche wish to amend the agreement as follows:

I. The table "II. Material" in Process, Manufacturing Know how on page 61 of Appendix 3 shall be amended by the addition of the following after the existing table under the titles

[***]

II. Capitalized terms shall have the same meaning as defined in the Agreement.

III. Except as expressly stated herein, no other changes are made to the Agreement and all other terms and conditions of the Agreement remain in full force and effect.

IV. This Amendment enters into effect on the Effective Date.

[Remainder of this page intentionally left blank.]

***Certain Confidential Information Omitted
IN WITNESS WHEREOF, the parties have executed this AMENDMENT NO. 4 TO THE AGREEMENT as of the date first above written.

F. HOFFMANN-LA ROCHE LTD

By: /s/ Vikas Kabra
Name: Vikas Kabra
Title: Head of Transaction Excellence

Date: ____________

HOFFMANN-LA ROCHE INC.

By: /s/ John P. Parise
Name: John P. Parise
Title: Authorized Signatory

Date: ____________

RIVER VISION DEVELOPMENT CORP.

By: /s/ D Madden
Name: D Madden
Title: CEO

Date: Oct/18/13

Apprv’d As To Form LAW DEPT.

By /s/ GB ________________________________

By: /s/ Melanie Frey Wick
Name: Dr. Melanie Frey Wick
Title: Legal Counsel

Date: July 16, 2014
This Amendment No. 5 to License Agreement ("Amendment") is entered into as of the 11th of November 2013 (“Effective Date”) by and among:

F. Hoffmann-La Roche Ltd, a corporation organized and existing under the laws of Switzerland, with its principal office at Grenzacherstrasse 124, CH-4070 Basel, Switzerland ("Roche Basel") and Hoffmann-La Roche Inc., a corporation organized and existing under the laws of New Jersey, with its principal office at 340 Kingsland Street, Nutley, New Jersey 07110, U.S.A. ("Roche Nutley"); Roche Basel and Roche Nutley together referred to as "Roche"

and

River Vision LLC, a limited liability company organized and existing under the laws of Delaware, with its principal office at One Rockefeller Plaza, New York NY, 10020, U.S.A. ("River Vision").

WHEREAS, River Vision and Roche wish to amend the agreement to as follows:

I. The table “II. Material” in Process, Manufacturing Know how on page 61 of Appendix 3 was amended in Amendment No. 2 and Amendment No. 4 with lines as follows:

   Amendment No. 2
   [***]

   Amendment No. 4
   [***]

   Remarks of the Amendments No. 2 and No. 4 for the test material as mentioned above will be completely replaced by the following remark:

   ***Certain Confidential Information Omitted
II. Capitalized terms shall have the same meaning as defined in the Agreement.

III. Except as expressly stated herein, no other changes are made to the Agreement and all other terms and conditions of the Agreement remain in full force and effect.

IV. This Amendment enters into effect on the Effective Date.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK.]

***Certain Confidential Information Omitted
IN WITNESS WHEREOF, the parties have executed this AMENDMENT NO. 1 TO THE LICENSE AGREEMENT as of the date first above written.

F. HOFFMANN-LA ROCHE LTD

By: /s/ Christophe Carissimo
Name: Christophe Carissimo
Title: Global Head Transaction Excellence
Date: Nov 14, 2013

By: /s/ Dr. Melanie Frey Wiek
Name: Dr. Melanie Frey Wiek
Title: Legal Counsel
Date: November 14, 2013

HOFFMANN-LA ROCHE INC.

By: /s/ John Parise
Name: John Parise
Title: Authorized Signatory
Date: November 20, 2013

By: /s/ D. Madden
Name: D. Madden
Title: CEO
Date: 12 November 2013

RIVER VISION LLC
THIS AMENDMENT NO. 6 TO LICENSE AGREEMENT ("Amendment") is entered into as of the 18th December 2014 ("Effective Date") by and among:

F. HOFFMANN-LA ROCHE LTD, a corporation organized and existing under the laws of Switzerland, with its principal office at Grenzacherstrasse 124, CH-4070 Basel, Switzerland ("Roche Basel") and Hoffmann-La Roche Inc., a corporation organized and existing under the laws of New Jersey, with its principle office and place of business at 150 Clove Road, 8th Floor, Little Falls, New Jersey 07424, U.S.A. ("Roche Little Fall"); Roche Basel and Roche Little Falls together referred to as "Roche")

and

RIVER VISION DEVELOPMENT CORP., a limited liability company organized and existing under the laws of Delaware, with its principal office at One Rockefeller Plaza, New York NY, 10020, U.S.A. ("River Vision").

WHEREAS, River Vision and Roche wish to amend the agreement as follows:

I. The table “II. Material” in Process, Manufacturing Know how on page 61 of Appendix 3 shall be amended by the addition of the following after the existing table

[***]

***Certain Confidential Information Omitted
II. Capitalized terms shall have the same meaning as defined in the Agreement.

III. Except as expressly stated herein, no other changes are made to the Agreement and all other terms and conditions of the Agreement remain in full force and effect.

IV. This Amendment enters into effect on the Effective Date.

[Remainder of this page intentionally left blank.]
IN WITNESS WHEREOF, the parties have executed this AMENDMENT NO. 6 TO THE AGREEMENT as of the date first above written.

F. HOFFMANN-LA ROCHE LTD

By: /s/ Timothy Steven
Name: Timothy Steven
Title: Global Alliance Director
Date: 8th Jan 2015

By: /s/ Melanie Frey Wick
Name: Dr. Melanie Frey Wick
Title: Legal Counsel
Date: 8th January 2015

HOFFMANN-LA ROCHE INC.

By: /s/ John P. Parise
Name: John P. Parise
Title: Authorized Signatory
Date: Jan 13, 2015

By: /s/ D Madden
Name: D Madden
Title: CEO
Date: 12/17/14

APPRV’d As To Form LAW DEPT.

By /s/ __________________________
Amendment No. 7 to the License Agreement

This Amendment No. 7 to the License Agreement ("Amendment") is entered into as of the 24th of June 2015 ("Effective Date") by and among:

F. Hoffmann-La Roche Ltd., a corporation organized and existing under the laws of Switzerland, with its principal office at Grenzacherstrasse 124, CH-4070 Basel, Switzerland ("Roche Basel") and Hoffmann-La Roche Inc., a corporation organized and existing under the laws of the State of New Jersey, with its principal office and place of business at 150 Clove Road, 8th Floor, Little Falls, NJ 07424, USA ("Roche Little Falls"; Roche Little Falls and Roche Basel together referred to as "Roche").

And

River Vision Development Corp, a corporation organized and existing under the laws of Delaware, with its principal office at One Rockefeller Plaza, Suite 1204, New York, NY 10020, USA ("River Vision").

Whereas, Roche and River Vision wish to amend the agreement as follows:

I. The Table (II. Material in Process, Manufacturing Know-How on page 61 of Appendix 3 shall be amended as follows:

[***]

II. Capitalized terms used herein shall have the same meaning as defined in the Agreement.

***Certain Confidential Information Omitted
III. Except as previously stated herein, no other changes are made to the Agreement and all other terms and conditions of the Agreement remain in effect.

IV. This Amendment enters into effect on the Effective Date.

In witness whereof, the parties have executed this Amendment No. 7 to the Agreement as of the date first above written.

F. Hoffmann-La Roche Ltd

By: /s/ Tim Steven  
Name: Tim Steven  
Title: Alliance Director  
Date: 21st July 2015

By: /s/ Melanie Frey Wick  
Name: Dr. Melanie Frey Wick  
Title:  
Date: ______________

Hoffmann-La Roche Inc.

By: /s/ David P. McDede  
Name: David P. McDede  
Title: VP Treasurer  
Date: 21 July 2015

By: /s/ D Madden  
Name: D Madden  
Title: CEO  
Date: 6/26/15

River Vision Development Corp.

By: /s/ Tim Steven  
Name: Tim Steven  
Title: Alliance Director  
Date: 21st July 2015

By: /s/ Melanie Frey Wick  
Name: Dr. Melanie Frey Wick  
Title:  
Date: ______________

Apprv’d As To Form LAW DEPT.

By /s/ MM
Amendment No. 8 to the License Agreement

This Amendment No. 8 to the License Agreement ("Amendment") is entered into as of the 13th of November 2015 ("Effective Date") by and among:

F. Hoffmann-La Roche Ltd., a corporation organized and existing under the laws of Switzerland, with its principal office at Grenzacherstrasse 124, CH-4070 Basel, Switzerland ("Roche Basel") and Hoffmann-La Roche Inc., a corporation organized and existing under the laws of the State of New Jersey, with its principal office and place of business at 150 Clove Road, 8th Floor, Little Falls, NJ 07424, USA ("Roche Little Falls"; Roche Little Falls and Roche Basel together referred to as "Roche").

And

River Vision Development Corp, a corporation organized and existing under the laws of Delaware, with its principal office at One Rockefeller Plaza, Suite 1204, New York, NY 10020, USA ("River Vision").

Whereas, Roche and River Vision wish to amend the agreement as follows:

I. The Table (II. Material in Process, Manufacturing Know-How on page 61 of Appendix 3 shall be amended as follows:

[***]

II. Capitalized terms used herein shall have the same meaning as defined in the Agreement.

III. Except as previously stated herein, no other changes to the Agreement and all other terms and conditions of the Agreement remain in effect.

***Certain Confidential Information Omitted
IV. This Amendment enters into effect on the Effective Date.

In witness whereof, the parties have executed this Amendment No. 8 to the Agreement as of the date first above written.

F. Hoffmann-La Roche Ltd

By: ________________________________  By: ________________________________
Name: ______________________________
Title: ______________________________
Date: ____________________

Hoffmann-La Roche Inc.

By: ________________________________  By: ________________________________
Name: ______________________________
Title: ______________________________
Date: ____________________

River Vision Development Corp.

By: ________________________________  By: ________________________________
Name: ______________________________
Title: ______________________________
Date: ____________________
Amendment No. 9 to the License Agreement

This Amendment No. 9 to the License Agreement ("Amendment") is entered into as of the 21st of October, 2016 ("Effective Date") by and among F. Hoffmann-La Roche Ltd, a corporation organized and existing under the laws of Switzerland, with its principal office at Grenzacherstrasse 124, CH-4070 Basel, Switzerland ("Roche Basel") and Hoffmann-La Roche Inc., a corporation organized and existing under the laws of the State of New Jersey, with its principal office and place of business at 150 Clove Road, Suite 8, Little Falls, NJ 07424, USA ("Roche Little Falls"); Roche Little Falls and Roche Basel together referred to as "Roche").

And

River Vision Development Corp, a corporation organized and existing under the laws of Delaware, with its principal office at One Rockefeller Plaza, Suite 1204, New York, NY 10020, USA ("River Vision").

WHEREAS, Roche and River Vision wish to amend the agreement as follows:

I. Section 11.6 shall be deleted and replaces by the following

"11.6 Infringement by Third Parties.

(a) Infringement. Each party shall promptly provide written notice to the other party during the Term of any known infringement or suspected infringement by a Third Party of any Roche Patents, River Vision Patents (if any) or Joint Patents (if any), or of any invalidity or unenforceability assertion or challenge to any such patents, or of any unauthorized use or misappropriation of Roche Know-How, and shall provide the other party with all evidence in its possession supporting such infringement, assertion or challenge or unauthorized use or misappropriation. For clarity, any challenge amounting to a reexamination, interference or opposition will be addressed by Sections 11.2 through 11.5.

(b) Defense and Enforcement. Within a period of [***] days ("Decision Period") after either party (i) provides or receives such written notice with respect to its Patents and (ii) such notice relates to the (a) Compound and/or Product in the Field or (b) an IGF-1R antibody of a third party in the Field ("Affected Patents"), the party that has the first right to enforce any such Affected Patents as set forth on Schedule 11.6(b) (the "First Party") that are allegedly infringed, in its sole discretion, shall decide whether or not to initiate a suit or take other appropriate action with respect to any allegedly infringing activities in the Field (including without limitation defending any assertion or challenge) and shall notify the other party in writing of its decision in writing ("Suit Notice").

***Certain Confidential Information Omitted
If the First Party for its Affected Patents are allegedly infringed decides to bring a suit or take action with respect to any allegedly infringing activities in the Field and provides a respective Suit Notice, then such party may immediately commence such suit or take such action. If such party (i) does not in writing advise the other party within the Decision Period that it will commence suit or take action, or (ii) fails to commence suit or take action within a reasonable time after providing Suit Notice, then the other party shall thereafter have the right to commence suit or take action with respect to any allegedly infringing activities in the Field and shall provide written notice to the party whose Affected Patents are allegedly infringed of any such suit commenced or action taken by the other party.

Upon written request, the party bringing suit or taking action (“Initiating Party”) shall keep the other party informed of the status of any such suit or action and shall provide the other party with copies of all substantive documents and communications filed in such suit or action. The Initiating Party shall have the sole and exclusive right to control any such suit or action, including but not limited to selecting counsel for any such suit or action. If each of the parties elects to be an Initiating Party with respect to the same allegedly infringing activities within the Field, then the parties shall meet and agree on how to manage the resulting suits and actions (including with respect to the process set forth in Section 11.7). If River Vision is the Initiating Party with respect to the Compound Patent, upon Roche request, River Vision and Roche shall jointly agree in good faith on the strategy on how to bring suit or take action with respect to such Compound Patent, such discussions to be held in good faith, and failure to agree shall not jeopardize timing regarding any such suit or action.

The Initiating Party shall, except as provided below, pay all expenses of the suit or action, including, without limitation, the Initiating Party’s attorneys’ fees, damages and court costs. If the Initiating Party believes it reasonably necessary, upon written request the other party shall join as a party to the suit or action, but shall be under no obligation to participate, except to the extent that such participation is required as the result of its being a named party to the suit or action. Alternatively, at the Initiating Party’s request, the other party will bring the suit or action in the other party’s name, if the Initiating Party reasonably believes that the Initiating Party does not have standing to bring the suit or action, and in such event, the Initiating Party will still control the suit or action as provided above. At the Initiating Party’s written request, the other party shall offer reasonable assistance to the Initiating Party in connection therewith at no charge to the Initiating Party except for reimbursement of reasonable out-of-pocket expenses incurred by the other party in rendering such assistance. The other party shall have the right to participate and be represented in any such suit or action by its own counsel at its own expense.

The Initiating Party shall not settle, agree to a consent judgment or otherwise voluntarily dispose of the suit or action without the written consent of the other party, which consent shall not be unreasonably withheld or delayed; provided that if River Vision is the Initiating Party, any such consent from Roche is not required if River Vision grants a permitted sub-license under Sections 2.5 and 3.

Except as otherwise agreed by the parties in connection with a cost-sharing arrangement, any recovery realized as a result of litigation described in this Section 11.6 (whether by way of settlement or otherwise) will be first allocated to reimbursement of unreimbursed legal fees and expenses incurred by the Initiating Party(ies), then toward reimbursement of any unreimbursed legal fees and expenses of the other party if not an Initiating Party, and then the remainder will be shared between the parties by allocating (i) [***]% to River Vision.

***Certain Confidential Information Omitted***
and [***] to Roche for those Affected Patents infringed where River Vision is the Initiating Party, (ii) [***]% to Roche and [***] to Roche for those Affected Patents infringed where Roche is the Initiating Party, and (iii) if there are Affected Patents infringed for which River Vision is the Initiating Party for one or more of those Affected Patents and Roche is the Initiating Party for one or more of those Patents[***].

(c) Exclusion. For clarity, this Section 11.6 shall not apply to the [***] Agreement, the [***] Agreement and the [***] Agreement.

II. Appendix 1 of the Agreement shall be deleted and replaced by Appendix 1 attached to this Amendment No. 9.

III. Appendix 2 of the Agreement shall be deleted and replaced by Appendix 2 attached to this Amendment No. 9.

IV. In case the validity of any patent family member of the Roche Patents summarized under [***] in Appendix 2 is challenged by a Third Party, Roche shall have the right to decide at its own discretion how to defend such patent family member or about further steps to be taken with respect to (including the decision to abandon) such patent family member of the Roche Patents summarized under [***]. Roche shall inform River Vision accordingly.

V. Capitalized terms used herein shall have the same meaning as defined in the Agreement.

VI. Except as previously stated herein, no other changes to the Agreement and all other terms and conditions of the Agreement remain in effect.

VII. This Amendment No. 9 enters into effect on the Effective Date.
In witness whereof, the parties have executed this Amendment No. 9 to the Agreement as of the date first above written.

F. Hoffmann-La Roche Ltd

By: /s/ Timothy Steven
Name: Timothy Steven
Title: Global Alliance Director
Date: 9th May 2017

By: /s/ Melanie Wick
Name: Melanie Wick
Title: Legal Counsel

Hoffmann-La Roche Inc.

By: /s/ John Parise
Name: John Parise
Title: Assistant Secretary
Date: May 9, 2017

By: /s/ D Madden
Name: D Madden
Title: CEO
Date: May 5 / 2017
teprotumumab is a human IgG1 antibody binding to IGFIR [***]

***Certain Confidential Information Omitted***
Appendix 2

Roche Patents

***Certain Confidential Information Omitted
EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement (this “Agreement”) is entered into as of this 5th day of December, 2012 (the “Effective Date”), by and between River Vision Development Corp., a Delaware corporation with a principal place of business located at One Rockefeller Plaza, New York, NY, 10020 (“Licensee”) and Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, a California corporation with a principal place of business located at 1124 West Carson Street, Torrance, CA, 90502 (“Licensor”).

WHEREAS, Licensor owns the Patent Rights (as defined below);

WHEREAS, Licensor and Licensee desire that Licensee attempt to develop and commercialize a Licensed Product (as defined below) based in part on the invention claimed in the Patent Rights; and WHEREAS, Licensee desires to grant an exclusive license to Licensee to enable such development and commercialization.

NOW, THEREFORE, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Definitions.

Whenever used in this Agreement with an initial capital letter, the terms defined in this Article 1, whether used in the singular or the plural, will have the meanings specified below.

1.1 “Affiliate” means, with respect to a person, organization or entity, any person, organization or entity controlling, controlled by or under common control with, such person, organization or entity. For purposes of this definition only, “control” of another person, organization or entity will mean the possession, directly or indirectly, of the power to direct or cause the direction of the activities, management or policies of such person, organization or entity, whether through the ownership of voting securities, by contract or otherwise.

1.2 “Calendar Quarter” means each of the periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31 during the Term.

1.3 “Combination Product” means a combination of materials or products sold for a single price and consisting of one or more Licensed Products and one or more other active ingredients. All references to Licensed Product in this Agreement shall be deemed to include Combination Product.

1.4 “First Commercial Sale” means, on a country by country basis, the date of the first sale to a third party of a Licensed Product, in such country, by Licensee or any of its Affiliates or Sublicensees after receipt of marketing approval in such country.

1.
1.5 “Force Majeure” means any occurrence beyond the reasonable control of a Party that (a) prevents or substantially interferes with the performance by such Party of any of its obligations hereunder and (b) occurs by reason of any act of God, flood, fire, explosion, earthquake, strike, lockout, labor dispute, casualty or accident, or war, revolution, civil commotion, act of terrorism, blockage or embargo, or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or of any subdivision, authority or representative of any such government.

1.6 “Licensed Product” means any product, the making, using or selling of which is covered by a Valid Claim in the country in which such product is made, used or sold.

1.7 “Net Sales” means the gross amount billed or invoiced by or on behalf of Licensee, its Affiliates and Sublicensees (in each case, the “Invoicing Entity”) for Licensed Product as reduced by the following deductions to the extent actually allowed or incurred with respect to such sales: (a) transportation charges, and other shipping charges, such as insurance, (b) sales, value-added and excise taxes, customs, duties, and any other governmental charges, to the extent imposed upon the sale of the Licensed Product and paid by the selling party, provided that no income taxes shall be deducted from gross sales of Licensed Product to calculate Net Sales, (c) distributor fees, rebates or allowances actually granted, allowed or incurred, including but not limited to government and managed care rebates, (d) quantity discounts, cash discounts or chargebacks actually granted, allowed or incurred, and (e) allowances or credits to customers or write offs of invoiced amounts, not in excess of the selling price of Licensed Product, on account of governmental requirements, rejections, recalls, or returns. If Licensed Product is sold as part of a Combination Product (as defined below), then the Net Sales of the Combination Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product on a country-by-country basis, during the applicable royalty reporting period, by the fraction, A/(A+B), where A is the average sale price of the Licensed Product when sold separately in finished form and B is the average sale price of the other pharmaceutical product(s) included in the Combination Product when sold separately in finished form, in each case during the applicable royalty reporting period or, if sales of both the Licensed Product and the other product(s) did not occur in such period, then in the most recent royalty reporting period in which sales of both occurred. In the event that such average sale price cannot be determined for both the Licensed Product and all other pharmaceutical product(s) included in the Combination Product, Net Sales for the purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the fraction of C/(C+D) where C is the fair market value of the Licensed Product and D is the fair market value of all other pharmaceutical product(s) included in the Combination Product.

1.8 “Patent Rights” means: (a) the patents listed in Exhibit 1.8; (b) any patent or patent application that claims priority to, and is a divisional, continuation, reissue, renewal, reexamination, substitution or extension of, any patent identified in (a); (c) any patents issuing on any patent application identified in (a) or (b), including any reissues, renewals, reexaminations, substitutions or extensions thereof; (d) any claim of a divisional, continuation or continuation-in-part application or patent (including any reissues, renewals, reexaminations, substitutions or extensions thereof) that is entitled to the priority date of, and is directed specifically to subject matter specifically described in, at least one of the patents or patent applications identified in (a), (b) or (c); (e) any foreign counterpart (including PCTs) of any patent or patent application
identified in (a), (b) or (c) or of the claims identified in (d); and (f) any supplementary protection certificates, pediatric exclusivity periods, any other patent term extensions and exclusivity periods and the like of any patents and patent applications identified in (a) through (e); provided, that, in the case of (b) through (f) above, solely to the extent owned or controlled by Licensor.

1.9 “Sublicense” means any right granted, license given or agreement entered into by Licensee to or with any other person or entity, under or with respect to or permitting any use or exploitation of any of the Patent Rights or otherwise permitting the development, manufacture, marketing, distribution, use and/or sale of Licensed Products.

1.10 “Sublicensee” means any person or entity granted a Sublicense.

1.11 “Term” means the term of this Agreement as set forth in Section 10.1.

1.12 “Valid Claim” means: (a) a claim of an issued and unexpired patent within the Patent Rights that has not been (i) held permanently revoked, unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, (ii) rendered unenforceable through disclaimer or otherwise, (iii) abandoned or (iv) permanently lost through an interference or opposition proceeding without any right of appeal or review.

2. License.

2.1 License Grant. Subject to the terms and conditions set forth in this Agreement, Licensor hereby grants to Licensee an exclusive, worldwide, royalty-bearing license under its interest in the Patent Rights to research, develop, use, make, have made, offer for sale, sell, have sold, import, have imported, distribute and have distributed Licensed Products; provided, however, that:

2.1.1 Licensor retains the right to practice the Patent Rights within the scope of the license granted above, for non-commercial research, educational and scholarly purposes only (which, for clarity, shall not include the conduct of clinical trials); and

2.1.2 the United States federal government retains rights in the Patent Rights pursuant to 35 U.S.C. §§ 200-212 and 37 C.F.R. § 401 et seq., and any right granted in this Agreement greater than that permitted under 35 U.S.C. §§ 200-212 or 37 C.F.R. § 401 et seq. will be subject to modification as may be required to conform to the provisions of those statutes and regulations.

2.2 Affiliates. The license granted to Licensee under Section 2.1 includes the right to have some or all of Licensee’s rights or obligations under this Agreement exercised or performed by one or more of Licensee’s Affiliates on Licensee’s behalf.

2.3 Sublicenses. Licensee will be entitled to grant Sublicenses to third parties under the license granted pursuant to Section 2.1 subject to the terms of this Section 2.3. Any such Sublicense shall be on terms and conditions in compliance with and not inconsistent with the terms of this Agreement.
3. Consideration for Grant of License.

3.1 Equity.

3.1.1 Initial Grant. Licensee shall issue to Licensor [***] shares of its common stock (the “Shares”) pursuant to a subscription agreement to be entered into by and between the parties within [***] days after the Effective Date.

3.1.2 Representations and Warranties. Licensee hereby represents and warrants to Licensor that the Shares, when issued pursuant to the terms hereof, shall, upon such issuance, be duly authorized, validly issued, fully paid and nonassessable.

3.2 Royalty on Net Sales.

3.2.1 Royalty Rate. Licensee shall pay Licensor an amount equal to [***] percent ([***]%) of Net Sales of all Licensed Products during the Term.

3.2.2 Third Party Royalty Set-Off. If Licensee obtains a license from a third party to intellectual property rights relating to [***] that Licensee reasonably determines is required to avoid or to resolve a claim of infringement or misappropriation, it may offset up to [***] percent ([***]%) of any royalty payments due thereunder with respect to sales of Licensed Products against the royalty payments that are due to Licensor with respect to Net Sales of such Licensed Products in such country; provided, that, in no event shall the royalty payments to Licensor with respect to such Licensed Products be reduced by more than [***] percent ([***]%) of the amount otherwise due.

4. Reports; Payments; Records.

4.1 Reports and Payments.

4.1.1 Reports. Within [***] days after the conclusion of [***] commencing with [***] in which Net Sales are generated, Licensee shall deliver to Licensor a report containing the following information (in each instance, with a Licensed Product-by-Licensed Product and country-by-country breakdown):

4.1.1.1 the number of units of Licensed Products sold, leased or otherwise transferred by Licensee, its Affiliates and Sublicensees for the applicable [***];

4.1.1.2 the gross amount billed or invoiced for Licensed Products sold, leased or otherwise transferred by Licensee, its Affiliates and Sublicensees during the applicable [***];

4.1.1.3 a calculation of Net Sales for the applicable [***], including an itemized listing of allowable deductions;

***Certain Confidential Information Omitted
4.1.1.4 the total amount payable to Licensor in U.S. Dollars for the applicable [***], together with the exchange rates used for conversion.

4.1.2 Payment. Within [***] days after the end of [***], Licensee shall pay Licensor all amounts due with respect to Net Sales for the applicable [***].

4.2 Payment Currency. All payments due under this Agreement will be paid in U.S. Dollars. Conversion of foreign currency to U.S. Dollars will be made at the conversion rate existing in the United States (as reported in the Wall Street Journal) on the last working day of the applicable [***]. Such payments will be without deduction of exchange, collection or other charges.

4.3 Records. Licensee shall maintain, and shall cause its Affiliates to maintain, and include in each Sublicense Agreement an obligation of each Sublicensee to maintain, complete and accurate records of Licensed Products that are made, used, sold, leased or transferred under this Agreement, any amounts payable to Licensor in relation to such Licensed Products, which records shall contain sufficient information to permit Licensor to confirm the accuracy of any reports or notifications delivered to Licensor under Section 4.1. Licensee, its Affiliates and/or its Sublicensees, as applicable, shall retain such records relating to a given [***] for at least [***] years after the conclusion of that [***], during which time Licensor will have the right, at its expense, to cause an independent, certified public accountant (or, in the event of a non-financial audit, other appropriate auditor) reasonably acceptable to Licensee to inspect such records during normal business hours for the purposes of verifying the accuracy of any reports and payments delivered under this Agreement and Licensee’s compliance with the terms hereof. Such accountant or other auditor, as applicable, will execute a standard form of confidentiality agreement with Licensee, shall not disclose to Licensor any information other than information relating to the accuracy of reports and payments delivered under this Agreement. The parties shall reconcile any underpayment or overpayment within [***] days after the accountant delivers the results of the audit. If any audit performed under this Section 4.3 reveals an underpayment in excess of [***] percent ([***]%) in any calendar year, Licensee shall reimburse Licensor for all amounts incurred in connection with such audit. Licensor may exercise its rights under this Section 4.3 only [***] per audited entity and only with reasonable (not less than [***] days) prior notice to Licensee.

4.4 Late Payments. Any payments by Licensee that are not paid on or before the date such payments are due under this Agreement will bear interest at the lower of (a) [***] percent ([***]%) [***] and (b) the maximum rate allowed by law. Interest will accrue beginning on the first day following the due date for payment and will be compounded [***]. Payment of such interest by Licensee shall not limit, in any way, Licensor’s right to exercise any other remedies Licensor may have as a consequence of the lateness of any payment.

4.5 Payment Method. Each payment due to Licensor under this Agreement shall be paid by check or wire transfer of funds to Licensor’s account in accordance with written instructions provided by Licensor. If made by wire transfer, such payments shall be marked so as to refer to this Agreement.

5. ***Certain Confidential Information Omitted
4.6 Withholding and Similar Taxes. All amounts to be paid to Licensor pursuant to this Agreement shall be without deduction of exchange, collection, or other charges, and, specifically, without deduction of withholding or similar taxes or other government imposed fees or taxes, except as permitted in the definition of Net Sales.


5.1 Control. Licensor will be responsible for the preparation, filing, prosecution, protection and maintenance of all Patent Rights, using independent patent counsel reasonably acceptable to Licensee. Licensor will: (a) subject to Section 5.2, prepare, file, prosecute, protect and maintain Patent Rights in all countries that Licensee may request in writing; (b) instruct such patent counsel to furnish the Licensee with copies of all correspondence relating to the Patent Rights from the United States Patent and Trademark Office (USPTO) and any other patent office, as well as copies of all proposed responses to such correspondence in time for Licensee to review and comment on such response; (c) give Licensee an opportunity to review the text of each patent application before filing; (d) consult with Licensee with respect thereto; (e) supply Licensee with a copy of each application as filed, together with notice of its filing date and serial number; (f) supply Licensee with copies of information disclosure statements prior to filing and provide Licensee with an opportunity to supplement such information; and (g) keep Licensee advised of the status of actual and prospective patent filings. Licensee shall give Licensee the opportunity to provide comments on and make requests of Licensor concerning the preparation, filing, prosecution, protection and maintenance of the Patent Rights, and shall consider such comments and requests in good faith; however, final decision-making authority shall vest in Licensor.

5.2 Expenses. Subject to Section 5.3 below, Licensee shall reimburse Licensor for all documented, out-of-pocket expenses incurred by Licensor pursuant to this Article 5 in connection with the preparation, filing, prosecution, protection and maintenance by Licensor of the Patent Rights within [***] days after the date of each invoice from Licensor for such expenses. In addition, within [***] days after the Effective Date, Licensee shall pay to Licensor [***] as reimbursement for certain out-of-pocket expenses incurred by Licensor prior to the Effective Date with respect to the preparation, filing, prosecution, protection and maintenance of Patent Rights.

5.3 Abandonment. If Licensee decides that it does not wish to pay for the preparation, filing, prosecution, protection or maintenance of any Patent Rights in a particular country (“Abandoned Patent Rights”), Licensee shall provide Licensor with prompt written notice of such election. Upon receipt of such notice by Licensor, Licensee shall be released from its obligation to reimburse Licensor for the expenses incurred thereafter as to such Abandoned Patent Rights; provided, however, that expenses authorized prior to the receipt by Licensor of such notice shall be deemed incurred prior to the notice. In the event of Licensee’s abandonment of any Patent Rights, any license granted by Licensor to Licensee hereunder with respect to such Abandoned Patent Rights will terminate, and Licensee will have no rights whatsoever to exploit such Abandoned Patent Rights. Licensor will then be free, without further notice or obligation to Licensee, to grant rights in and to such Abandoned Patent Rights to third parties.

***Certain Confidential Information Omitted

6.

6.1 Notice. In the event either party becomes aware of any possible or actual infringement of any Patent Rights with respect to Licensed Products (an “Infringement”), that party shall promptly notify the other party and provide it with details regarding such Infringement.

6.2 Suit by Licensee. Licensee shall have the exclusive right, but not the obligation, to take action in the prosecution, prevention, or termination of any Infringement. Before Licensee commences an action with respect to any Infringement, Licensee shall consider in good faith the views of Licensor as to whether to sue. Should Licensee elect to bring suit against an infringer, Licensee shall keep Licensor reasonably informed of the progress of the action and shall give Licensor a reasonable opportunity in advance to consult with Licensee and offer its views about major decisions affecting the litigation. Licensee shall give careful consideration to those views, but shall have the right to control the action. Should Licensee elect to bring suit against an infringer and Licensor is joined as party plaintiff in any such suit, Licensor shall have the right to approve the counsel selected by Licensee to represent Licensee and Licensor, such approval not to be unreasonably withheld. The expenses of such suit or suits that Licensee elects to bring, including any expenses incurred by Licensor due to its involvement as a party plaintiff or other involvement at the express request of Licensee in conjunction with the prosecution of such suits or the settlement thereof, shall be paid for entirely by Licensee; provided, that, to the extent Licensor elects to participate in such suit or suits and be represented in such suit or suits by counsel of its choice (apart from counsel retained by Licensee), it shall do so at its sole expense. Licensee shall not compromise or settle such litigation without the prior written consent of Licensor, which consent shall not be unreasonably withheld or delayed. In the event Licensee exercises its right to sue pursuant to this Section 6.2, it shall first reimburse itself out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorneys’ fees, necessarily incurred in the prosecution of any such suit. If, after such reimbursement, any funds shall remain from said recovery, then Licensor shall receive an amount equal to [***] percent ([*%]) of such funds and the remaining [***] percent ([*%]) of such funds shall be retained by Licensee.

6.4 Cooperation. Each party agrees to cooperate fully in any action under this Article 6.

7. Representations and Warranties; Limitation of Liability.

7.1 Licensor represents and warrants as of the Effective Date that:

7.1.1 it is the owner by assignment from the listed inventors of all Patent Rights and the inventions described and claimed therein, and it has the right to grant the licenses to Licensee under this Agreement;

7.1.2 to the best knowledge of Licensor, the Patent Rights include all patents and patent applications owned and controlled by Licensor with respect to the technology claimed therein related to the heretofore agreed upon aspect of technology being pursued by Licensee;

7. ***Certain Confidential Information Omitted
7.1.3 it has taken all necessary action to authorize the execution and delivery of this Agreement by its representatives who carried out such execution and delivery, and to authorize the performance of its obligations hereunder;

7.1.4 to the best knowledge of Licensor, the Patent Rights have been filed and prosecuted in good faith;

7.1.5 Licensor has not received any notice from any third party that any third party patent, patent application or other intellectual property rights would be infringed (i) by practicing any process or method covered by the Patent Rights, or (ii) by making, using, offering for sale, selling or importing Licensed Products; and

7.1.6 Licensor has not received any notice of any Infringement (as defined in Section 6.1).

7.2 Compliance with Law. Licensee represents and warrants that it will comply, and will ensure that its Affiliates comply and shall include in each Sublicense agreement an obligation for each Sublicensee to comply, with all local, state, and international laws and regulations relating to the development, manufacture, use, sale and importation of Licensed Products. Without limiting the foregoing, Licensee represents and warrants that it will comply, and will ensure that its Affiliates comply, with all United States export control laws and regulations.

7.3 No Warranty.

7.3.1 NOTHING CONTAINED HEREIN SHALL BE DEEMED TO BE A WARRANTY BY LICENSOR THAT THE PATENT RIGHTS WILL AFFORD ADEQUATE OR COMMERCIA LLY WORTHWHILE PROTECTION.

7.3.2 LICENSOR MAKES NO WARRANTIES WHATSOEVER AS TO THE COMMERCIAL OR SCIENTIFIC VALUE OF THE PATENT RIGHTS. LICENSOR MAKES NO REPRESENTATION THAT THE PRACTICE OF THE PATENT RIGHTS OR THE DEVELOPMENT, MANUFACTURE, USE, SALE OR IMPORTATION OF ANY LICENSED PRODUCT, OR ANY ELEMENT THEREOF, WILL NOT INFRINGE THE PATENT OR PROPRIETARY RIGHTS OF ANY THIRD PARTY.

7.3.3 EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY TECHNOLOGY, PATENTS, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH PARTY HEREBY DISCLAIMS WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING.

7.4 Limitation of Liability. Except with respect to matters for which Licensee is obligated to indemnify Licensor under Article 8, neither party will be liable to the other with respect to any subject matter of this Agreement under any contract, negligence, strict liability or other legal or equitable theory for (a) any indirect, incidental, consequential or punitive damages or lost profits or (b) cost of procurement of substitute goods, technology or services.
8. Indemnification and Insurance.

8.1 Indemnification. Licensor and its current and former directors, governing board members, trustees, officers, faculty, medical and professional staff, employees, students, and agents and their respective successors, heirs and assigns, (collectively, “Indemnitees”), will be indemnified, defended by counsel and held harmless by the Licensee from and against any third party claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys’ fees and other costs and expenses of defense) based upon, arising out of, or otherwise relating to this Agreement and any Sublicense, including without limitation any cause of action relating to product liability (collectively, “Claims”). The previous sentence will not apply to any Claim that results from the gross negligence or willful misconduct of an Indemnitee or from any breach of a representation made under Section 7.1 by Licensor. An indemnified party shall provide Licensee with prompt notice of any claim for which indemnification may be sought pursuant to this Agreement. Notwithstanding the foregoing, the delay or failure of any Indemnitee to give reasonably prompt notice to Licensee of any such claim shall not affect the rights of such Indemnitee unless, and then only to the extent that, such delay or failure is prejudicial to or otherwise adversely affects Licensee.

Licensor shall cooperate as reasonably requested (at the expense of Licensee) in the investigation and defense of any Claim. Licensor shall permit Licensee to assume direction and control of the defense of the Claim (including the right to settle the Claim); provided, however, that Licensee shall not settle any Claim without the prior written consent of Licensor where such settlement (a) would include any admission of liability on the part of any Indemnitee, (b) would impose any restriction on any Indemnitee’s conduct of any of its activities or (c) would not include an unconditional release of all Indemnitees from all liability for claims that are the subject matter of the settled Claim. Licensee shall, at its own expense, provide attorneys acceptable to Licensor to defend against any actions brought or filed against an Indemnitee with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

8.2 Insurance.

8.2.1 Beginning at the time any Licensed Product is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Licensee, or by an Affiliate, Sublicensee or agent of Licensee, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than $[***] per incident and $[***] annual aggregate and naming the Indemnitees as additional insureds. During clinical trials of any such Licensed Product, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in such equal or lesser amount as is consistent with industry standards, naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide: (a) product liability coverage and (b) broad form contractual liability coverage for Licensee’s indemnification obligations under this Agreement.

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8.2.2 If Licensee elects to self-insure all or part of the limits described above in Section 8.2.1 (including deductibles or retentions that are in excess of $[***] annual aggregate) such self-insurance program must be reasonably acceptable to Licensor. The minimum amounts of insurance coverage required shall not be construed to create a limit of Licensee’s liability with respect to its indemnification obligations under this Agreement.

8.2.3 Licensee shall provide Licensor with written evidence of such insurance upon request of Licensor. Licensee shall provide Licensor with written notice at least [***] days prior to the cancellation, non-renewal or material change in such insurance and shall obtain replacement insurance providing comparable coverage within such [***] day period.

9. Term and Termination.

9.1 Term. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Article 10, shall continue in full force and effect until the expiration of the last to expire Valid Claim (the “Term”).

9.2 Termination.

9.2.1 Termination Without Cause. Licensee may terminate this Agreement upon sixty (60) days prior written notice to Licensor.

9.2.2 Termination for Default.

9.2.2.1 In the event that either party commits a material breach of its obligations under this Agreement and fails to cure that breach within sixty (60) days after receiving written notice thereof, the other party may terminate this Agreement immediately upon written notice to the party in breach.

9.2.2.2 If Licensee defaults in any of its obligations under Section 8.2, then Licensor may terminate this Agreement without further notice to Licensee if Licensee has not cured such default within thirty (30) days of written notice of such default from Licensor.

9.2.3 Bankruptcy. Licensor may terminate this Agreement upon notice to Licensee if Licensee becomes insolvent, is adjudged bankrupt, applies for judicial or extra-judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee (or the like) in bankruptcy appointed by reason of its insolvency, or in the event an involuntary bankruptcy action is filed against Licensee and not dismissed within ninety (90) days, or if Licensee becomes the subject of liquidation or dissolution proceedings or otherwise discontinues business.

9.3 Effect of Termination.

9.3.1 Termination of Rights. Upon termination of this Agreement by either party pursuant to any of the provisions of Section 9.2: (a) the rights and licenses granted to Licensee under Article 2 shall terminate, all rights in and to and under the Patent Rights will revert to Licensor and neither Licensee nor its Affiliates may make any further use or exploitation of the Patent Rights and (b) any existing Sublicense shall terminate to the extent of such terminated license; provided, however, that notwithstanding the foregoing, each Sublicensee that is not at such time in breach of its Sublicense agreement shall have the right to obtain a license from **Certain Confidential Information Omitted**

10. **Certain Confidential Information Omitted**
Licensor on the same terms and conditions as set forth herein, which shall not impose any representations, warranties, obligations or liabilities on Licensor that are not included in this Agreement, provided that (i) the scope of the license granted directly by Licensor to such Sublicensee shall be co-extensive with the scope of the license granted by Licensee to such Sublicensee, (ii) if the sublicense granted to such Sublicensee was non-exclusive, such Sublicensee shall not have the right to participate in the prosecution or enforcement of the Patent Rights under the license granted to it directly by Licensor and (iii) if there is more than one Sublicensee, each Sublicensee that is granted a direct license shall be responsible for a pro rata share of the reimbursement due under Section 5.2 of this Agreement (based on the number of direct licenses under the Patent Rights in effect on the date of reimbursement).

9.3.2 Accruing Obligations. Termination or expiration of this Agreement shall not relieve the parties of obligations accruing prior to such termination or expiration, including obligations to pay amounts accruing hereunder up to the date of termination or expiration. After the date of termination or expiration (except in the case of termination by Licensor pursuant to Section 8.2), Licensee, its Affiliates and Sublicensees (a) may sell Licensed Products then in stock and (b) may complete the production of Licensed Products then in the process of production and sell the same; provided that, in the case of both (a) and (b), Licensee shall pay the applicable royalties and payments to Licensor in accordance with Article 3, provide reports and audit rights to Licensor pursuant to Article 4 and maintain insurance in accordance with the requirements of Section 8.2.

9.4 Survival. The parties’ respective rights, obligations and duties under Articles 4, 8, 9 and 10 and Sections 7.2, 7.3 and 7.4, as well as any rights, obligations and duties which by their nature extend beyond the expiration or termination of this Agreement, shall survive any expiration or termination of this Agreement.

10. Miscellaneous.

10.1 Entire Agreement. This Agreement is the sole agreement with respect to the subject matter hereof and except as expressly set forth herein, supersedes all other agreements and understandings between the parties with respect to the same.

10.2 Notices. Unless otherwise specifically provided, all notices required or permitted by this Agreement shall be in writing and may be delivered personally, or may be sent by facsimile, overnight delivery or certified mail, return receipt requested, to the following addresses, unless the parties are subsequently notified of any change of address in accordance with this Section 10.2:

If to Licensee: River Vision Development Corp.
c/o Narrow River Management LP
One Rockefeller Plaza
New York, NY 10020
Attn: David Madden
If to Licensor:
Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center
1124 West Carson Street
Torrance, CA 90502
Attn.: Art Zweben

Any notice shall be deemed to have been received as follows: (a) by personal delivery, upon receipt; (b) by overnight delivery, one business day after transmission; (c) by certified mail, as evidenced by the return receipt.

10.3 Governing Law and Jurisdiction. This Agreement will be governed by, and construed in accordance with, the substantive laws of the State of California, without giving effect to any choice or conflict of law provision, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted.

10.4 Amendment; Waiver. This Agreement may be amended, modified, superseded or canceled, and any of the terms may be waived, only by a written instrument executed by each party or, in the case of waiver, by the party waiving compliance. The delay or failure of either party at any time or times to require performance of any provisions hereof shall in no manner affect the rights at a later time to enforce the same. No waiver by either party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

10.5 Assignment and Successors. This Agreement may not be assigned by either party without the consent of the other, which consent shall not be unreasonably withheld, except that each party may, without such consent, assign this Agreement and the rights, obligations and interests of such party to any of its Affiliates, to any purchaser of all or substantially all of its assets to which the subject matter of this Agreement relates, or to any successor corporation resulting from any merger or consolidation of such party with or into such corporation; provided, in each case, that the assignee agrees in writing to be bound by the terms of this Agreement. Any assignment purported or attempted to be made in violation of the terms of this Section 10.5 shall be null and void and of no legal effect.

10.6 Force Majeure. Neither party will be responsible for any failure or delay in performing any of its obligations under this Agreement, and shall not be deemed in breach of this Agreement, if such failure or delay is due to a Force Majeure; provided, that, the nonperforming party shall use commercially reasonable efforts to avoid or remove such causes of the Force Majeure and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.

12.
10.7 Severability. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the parties that the remainder of this Agreement shall not be affected.

10.8 Confidentiality. Licensor agrees to keep confidential all information disclosed in writing to Licensor pursuant to Sections 4.1.1 and 4.3 of this Agreement (collectively, the “Confidential Information”); provided, however, that the confidentiality obligation shall not apply to any information that is or becomes part of the public domain other than by Licensor’s breach of this Section 10.8 or is required to be disclosed by Licensor pursuant to interrogatories, requests for information or documents, subpoena, civil investigative demand issued by a court or governmental agency or as otherwise required by law (provided that, in such case, Licensor shall notify Licensee promptly upon receipt thereof and give Licensee sufficient advance notice to permit it to seek a protective order or other similar order with respect to such information); and provided further that (a) to the extent that it is reasonably necessary, Licensor may disclose Confidential Information to (i) its employees on a need-to-know basis and on condition that such employees abide by the obligations set forth in this Section 10.8 and (ii) in confidence, to lawyers, accountants and financial advisors and (b) Licensor may include in its annual reports totals derived from Confidential Information (without attribution to Licensee) that show revenues generated by the patents and patent applications licensed under this Agreement.

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

Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center

By: /s/ David I. Meyer
Name: David I. Meyer, PhD
Title: President and Chief Executive Officer

River Vision Development Corp.

By: /s/ Dave Madden
Name: Dave Madden
Title: Chief Executive Officer
## Exhibit 1.8

**Patent Rights**

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***Certain Confidential Information Omitted***

14.
1. GENERAL.

(a) Relationship to Prior Plans. This Plan is intended as the successor to the Horizon Pharma, Inc. 2011 Equity Incentive Plan (the “2011 Plan”) with respect to grants to Employees. From and after 12:01 a.m. on the Effective Date, all outstanding stock awards granted under the 2011 Plan and the Horizon Pharma, Inc. 2005 Stock Plan (the “2005 Plan”) and, together with the 2011 Plan, the “Prior Plans”) shall remain subject to the terms of the 2011 Plan or the 2005 Plan, as applicable; provided, however, any Ordinary Shares subject to outstanding stock awards granted under the Prior Plans that expire, terminate or are forfeited for any reason prior to exercise or settlement, and any Ordinary Shares that are repurchased or redeemed because of the failure to meet a contingency or condition required to vest such Ordinary Shares (the “Returning Shares”) shall immediately be added to the Share Reserve (as described below) as and when such Ordinary Shares become Returning Shares and shall become available for issuance pursuant to Awards granted hereunder. All Awards granted on or after the Effective Date of this Plan shall be subject to the terms of this Plan.

(b) Eligible Award Recipients. The persons eligible to receive Awards are Employees. The persons eligible to receive Inducement Awards are Employees who meet the criteria set forth in Section 3(f).


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

2. ADMINISTRATION.

(a) Administration by Board. The Board shall administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in Section 2(c). Notwithstanding anything to the contrary set forth herein, only an Inducement Committee has the power to grant Inducement Awards.
(b) Powers of Board. The Board shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

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

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

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

(iv) To accelerate the time at which an Award may first be exercised or the time during which an Award or any part thereof will vest in accordance with the Plan, notwithstanding the provisions in the Award stating the time at which it may first be exercised or the time during which it will vest.

(v) To suspend or terminate the Plan at any time. Suspension or termination of the Plan shall not impair rights and obligations under any Award granted while the Plan is in effect except with the written consent of the affected Participant.

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

(vii) To submit any amendment to the Plan for shareholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of (A) Section 162(m) of the Code regarding the exclusion of performance-based compensation from the limit on corporate deductibility of compensation paid to Covered Employees, (B) Section 422 of the Code regarding incentive stock options or (C) Rule 16b-3.
(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; provided however, that except with respect to amendments that disqualify or impair the status of an Incentive Stock Option, a Participant’s rights under any Award shall not be impaired by any such amendment unless (A) the Company requests the consent of the affected Participant, and (B) such Participant consents in writing. Notwithstanding the foregoing, subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Awards without the affected Participant’s consent if necessary to maintain the qualified status of the Award as an Incentive Stock Option or to bring the Award into compliance with Section 409A of the Code.

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

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

(c) Delegation to Committee.

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

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

(iii) Inducement Awards. Notwithstanding any other provision of the Plan to the contrary, all Inducement Awards must be granted by an Inducement Committee.

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

(e) Cancellation and Re-Grant of Stock Awards. Neither the Board nor any Committee shall have the authority to: (i) reduce the exercise price of any outstanding Options or Stock Appreciation Rights under the Plan, or (ii) cancel any outstanding Options or Stock Appreciation Rights that have an exercise price or strike price greater than the current Fair
Market Value of the Ordinary Shares in exchange for cash or other Stock Awards under the Plan, unless the stockholders of the Company have approved such an action within twelve (12) months prior to such an event, provided that the exercise price of any such outstanding Options or Stock Appreciation Rights under the Plan may not be reduced below the nominal value of an Ordinary Share.

3. SHARES SUBJECT TO THE PLAN.

(a) Share Reserve.

(i) Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of Ordinary Shares of the Company that may be issued pursuant to Stock Awards after the Effective Date shall not exceed 63,852,130 shares, which is the sum of (i) 22,052,130 Ordinary Shares, which is the total reserve that was approved as of the Effective Date in connection with the adoption of the Plan, including, but not limited to, the shares remaining available for issuance under the Prior Plans and the Returning Shares, (ii) 14,000,000 additional Ordinary Shares approved by the Company’s shareholders at the 2015 annual general meeting, (iii) 6,000,000 additional Ordinary Shares approved by the Company’s shareholders at the 2016 annual general meeting, (iv) 10,800,000 new Ordinary Shares approved by the Company’s shareholders at the 2018 Annual Meeting, and (v) 9,000,000 new Ordinary Shares approved by the Company’s shareholders at the 2019 annual general meeting (the total of (i)-(v), the “Share Reserve”) and (vi) 2,000,000 Ordinary Shares that may be issued pursuant to Inducement Awards granted under Section 3(f) of the Plan. For clarity, the limitation in this Section 3(a)(i) is a limitation on the number of Ordinary Shares that may be issued pursuant to the Plan. Accordingly, this Section 3(a)(i) does not limit the granting of Stock Awards except as provided in Section 7(a). Shares may be issued in connection with a merger or acquisition as permitted by, as applicable, NASDAQ Marketplace Rule 4350(i)(1)(A)(iii), NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable stock exchange rules, and such issuance shall not reduce the number of Ordinary Shares available for issuance under the Plan. Furthermore, if a Stock Award or any portion thereof (i) expires or otherwise terminates without all of the Ordinary Shares covered by such Stock Award having been issued or (ii) is settled in cash (i.e., the Participant receives cash rather than Ordinary Shares), such expiration, termination or settlement shall not reduce (or otherwise offset) the number of Ordinary Shares that may be available for issuance under the Plan.

(ii) Subject to subsection 3(b) and except with respect to Inducement Awards, the number of Ordinary Shares available for issuance under the Plan shall be reduced by: (i) one (1) Ordinary Share for each Ordinary Share issued pursuant to (A) an Option granted under Section 5, or (B) a Stock Appreciation Right granted under Section 5 with respect to which the strike price is at least one hundred percent (100%) of the Fair Market Value of the underlying Ordinary Shares on the date of grant; (ii) 1.29 Ordinary Shares for each Ordinary Share pursuant to a Restricted Share Award, Restricted Stock Unit Award, Performance Stock Award, Other Stock Award or any other stock award granted under the Plan prior to May 3, 2018 that is not described in subsection (i) above and that is not a 2018 Executive Award, and (iii) 1.40 Ordinary Shares for each Ordinary Share issued pursuant to (A) a 2018 Executive Award, or (B) a Restricted Stock Award, Restricted Stock Unit Award, Performance Stock Award, Other Stock Award or any other stock award granted under the Plan on or after May 3, 2018 that is not described in subsection (i) above.
(b) Reversion of Shares to the Share Reserve.

(i) Shares Available For Subsequent Issuance. If any Stock Award is forfeited back to the Company or Ordinary Shares are redeemed or repurchased by the Company or any Affiliate (in accordance with applicable Irish law) because of the failure to meet a contingency or condition required to vest such Ordinary Shares, then the Ordinary Shares that are forfeited, redeemed or repurchased shall revert to and again become available for issuance under the Plan. Notwithstanding the provisions of this Section 3(b)(i), to the extent (i) there is issued an Ordinary Share pursuant to a Stock Award under the Plan (other than an Option or Stock Appreciation Right), and (ii) there are any Returning Shares granted under the Prior Plans pursuant to an award other than an Option or Stock Appreciation Right, and such Ordinary Share becomes available for issuance under the Plan pursuant to Section 1(a), Section 3(a)(i) or this Section 3(b)(i), then the number of Ordinary Shares available for issuance under the Plan shall increase by 1.29 shares for each such Ordinary Share returning to the Plan prior to May 3, 2018 and 1.40 shares for each such Ordinary Share returning to the Plan on or after May 3, 2018. Notwithstanding the foregoing, any Inducement Shares that become available for issuance under the Plan pursuant to this subsection 3(b)(i) will only become available for issuance pursuant to Inducement Awards.

(ii) Shares Not Available For Subsequent Issuance. If any Ordinary Shares subject to a Stock Award are not delivered to a Participant because the Stock Award is exercised through a reduction of Ordinary Shares subject to the Stock Award (i.e., “net exercised”), the number of Ordinary Shares that are not delivered to the Participant shall not remain available for issuance under the Plan. Also, any Ordinary Shares withheld by the Company pursuant to Section 8(g) or withheld or tendered as consideration for the exercise of an Option or purchase of any other Stock Award shall not again become available for issuance under the Plan. Further, any Ordinary Shares repurchased by the Company on the open market with the proceeds of the exercise or purchase price of a Stock Award granted under the Plan or a stock award granted under any of the Prior Plans shall not become available for issuance under the Plan.

(c) Incentive Stock Option Limit. Notwithstanding anything to the contrary in this Section 3 and, subject to the provisions of Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of Ordinary Shares that may be issued pursuant to the exercise of Incentive Stock Options shall be the number of shares subject to the Plan’s Share Reserve.

(d) Section 162(m) Limitation on Annual Grants. Subject to the provisions of Section 9(a) relating to Capitalization Adjustments and except with respect to Inducement Awards, at such time as the Company may be subject to the applicable provisions of Section 162(m) of the Code, a maximum of three million (3,000,000) Ordinary Shares subject to Options, Stock Appreciation Rights and Other Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least one hundred percent (100%) of the Fair Market Value on the date any such Stock Award is granted may be granted to any Participant during any calendar year. Notwithstanding the foregoing, if any additional Options, Stock Appreciation Rights or Other Stock Awards whose value is determined by reference to an
increase over an exercise or strike price of at least one hundred percent (100%) of the Fair Market Value on the date the Stock Awards are granted to any Participant during any calendar year, compensation attributable to the exercise of such additional Stock Awards shall not satisfy the requirements to be considered “qualified performance-based compensation” under Section 162(m) of the Code unless such additional Stock Award is approved by the Company’s shareholders.

(e) **Source of Shares.** The Ordinary Shares issuable under the Plan shall be authorized but unissued or reacquired Ordinary Shares, including Ordinary Shares redeemed or repurchased by the Company or any Affiliate on the open market or otherwise, in accordance with applicable Irish Law.

(f) **Inducement Shares.** This subsection 3(f) will apply with respect to the 2,000,000 Ordinary Shares reserved under this Plan by action of the Board (or a committee thereof) to be used exclusively for the grant of Inducement Awards in compliance with NASDAQ Listing Rule 5635(c)(4) (the "Inducement Shares"). Notwithstanding anything to the contrary in this Plan, an Inducement Award may be granted only to an Employee who has not previously been an Employee or a non-Employee Director of the Company or an Affiliate, or following a bona fide period of non-employment, as an inducement material to the individual’s entering into employment with the Company within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules.

(g) **Minimum Vesting Requirements.** No Award granted on or after the 2018 Annual Meeting and no 2018 Executive Award may vest (or, if applicable, be exercisable) until at least twelve (12) months following the date of grant of the Award; provided, however, that up to five percent (5%) of the Share Reserve may be subject to Awards granted on or after the 2018 Annual Meeting or which are 2018 Executive Awards that do not meet such vesting (and, if applicable, exercisability) requirements.

(h) **Dividends and Dividend Equivalents.** Dividends or dividend equivalents may be paid or credited, as applicable, with respect to any Ordinary Shares subject to a Restricted Stock Award, Restricted Stock Unit Award, or 2018 Executive Award as determined by the Board and contained in the applicable Award Agreement; provided, however, that (i) no dividends or dividend equivalents may be paid with respect to any such shares before the date such shares have vested under the terms of such Award Agreement, (ii) any dividends or dividend equivalents that are credited with respect to any such shares will be subject to all of the terms and conditions applicable to such shares under the terms of such Award Agreement (including, but not limited to, any vesting conditions), and (iii) any dividends or dividend equivalents that are credited with respect to any such shares will be forfeited to the Company on the date, if any, such shares are forfeited to or repurchased by the Company due to a failure to meet any vesting conditions under the terms of such Award Agreement. Dividend or dividend equivalents may not be paid or credited with respect to any Stock Awards other than as specified above.
4. ELIGIBILITY.

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

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

5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

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

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

(b) Exercise Price. Subject to the provisions of Section 4(b) regarding Ten Percent Shareholders, the exercise price (or strike price) of each Option or SAR shall be not less than one hundred percent (100%) of the Fair Market Value of the Ordinary Shares subject to the Option or SAR on the date the Option or SAR is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise price (or strike price) lower than one hundred percent (100%) of the Fair Market Value of the Ordinary Shares subject to the Option or SAR if such Option or SAR is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Sections 409A and, if applicable, 424(a) of the Code, provided that in all cases the exercise price is not less than the nominal value of an Ordinary Share. Each SAR will be denominated in Ordinary Shares equivalents.
(c) Purchase Price for Options. The purchase price of Ordinary Shares acquired pursuant to the exercise of an Option shall be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below; provided, however, that where Ordinary Shares are issued pursuant to the exercise of an Option, the nominal value of each newly issued Ordinary Share is fully paid up. The Board shall have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to utilize a particular method of payment. The permitted methods of payment are as follows:

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

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

(iii) if the option is a Nonstatutory Stock Option, by a “net exercise” arrangement pursuant to which the Company will reduce the number of Ordinary Shares issuable upon exercise by the largest whole number of Ordinary Shares with a Fair Market Value that does not exceed the aggregate exercise price; provided, however, that:

1. the Company shall accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole Ordinary Shares to be issued;

2. irrespective of whether a “net exercise” arrangement is used, the nominal value of each newly issued Ordinary Shares will be fully paid up in cash; and

3. Ordinary Shares will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) Ordinary Shares issuable upon exercise are reduced to pay the exercise price pursuant to the “net exercise,” (B) Ordinary Shares are delivered to the Participant as a result of such exercise, and (C) Ordinary Shares are withheld to satisfy tax withholding obligations;

(iv) deduction from salary due and payable to an Employee by the Company or any Affiliate; or

(v) in any other form of legal consideration that may be acceptable to the Board and permissible under applicable law.

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

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

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

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

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

(f) Vesting Generally. The total number of Ordinary Shares subject to an Option or SAR may vest and therefore become exercisable in periodic
installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or
may not be exercised (which may be based on the satisfaction of Performance Goals or other criteria) as the Board may deem appropriate. The vesting
provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the
minimum number of Ordinary Shares as to which an Option or SAR may be exercised.
(g) **Termination of Continuous Service.** Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company or any Affiliate, if a Participant’s Continuous Service terminates (other than for Cause or upon the Participant’s death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Participant’s Continuous Service (or such longer or shorter period specified in the applicable Award Agreement), or (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the time specified herein or in the Award Agreement (as applicable), the Option or SAR shall terminate.

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

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

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

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

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

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARs.

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

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) services to the Company or an Affiliate or (C) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law, provided however, that where Ordinary Shares are issued pursuant to a Restricted Stock Award the nominal value of each newly issued Ordinary Share is fully paid up.
(ii) Vesting. Ordinary Shares awarded under a Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

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

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

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

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Ordinary Shares subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Ordinary Shares subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law, provided, however, that where Ordinary Shares are issued pursuant to a Restricted Stock Unit Award, the nominal value of each newly issued Ordinary Share is fully paid up.

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

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

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the Ordinary Shares (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.
(v) Termination of Participant’s Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant’s termination of Continuous Service.

(c) Performance Awards.

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award that may vest or may be exercised contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Stock Award may, but need not, require the completion of a specified period of Continuous Service. The length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained shall be conclusively determined by the Committee, in its sole discretion. Except with respect to Inducement Awards, the maximum number of shares covered by an Award that may be granted to any Participant in a calendar year attributable to Stock Awards described in this Section 6(c)(i) (whether the grant, vesting or exercise is contingent upon the attainment during a Performance Period of the Performance Goals) shall not exceed three million (3,000,000) Ordinary Shares. The Board may provide for or, subject to such terms and conditions as the Board may specify, may permit a Participant to elect for, the payment of any Performance Stock Award to be deferred to a specified date or event. In addition, to the extent permitted by applicable law and the applicable Award Agreement, the Board may determine that cash may be used in payment of Performance Stock Awards.

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

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

(d) **Other Stock Awards.** Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Ordinary Shares, including the appreciation in value thereof (e.g., options or share rights with an exercise price or strike price less than 100% of the Fair Market Value of the Ordinary Shares at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Board shall have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of Ordinary Shares (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards; provided, however, that where Ordinary Shares are issued pursuant to any Other Stock Award, the nominal value of each newly issued Ordinary Share is fully paid up.

7. **Covenants of the Company.**

(a) **Availability of Shares.** During the terms of the Stock Awards, the Company shall keep available at all times the authorized but unissued Ordinary Shares reasonably required to satisfy such Stock Awards.

(b) **Securities Law Compliance.** The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell Ordinary Shares upon exercise of the Stock Awards; provided, however, that this undertaking shall not require the Company to register under the Securities Act the Plan, any Stock Award or any Ordinary Shares issued or issuable pursuant to any such Stock Award. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Ordinary Shares under the Plan, the Company shall be relieved from any liability for failure to issue and sell Ordinary Shares upon exercise of such Stock Awards unless and until such authority is obtained. A Participant shall not be eligible for the grant of a Stock Award or the subsequent issuance of Ordinary Shares pursuant to the Stock Award if such grant or issuance would be in violation of any applicable securities law.
(c) No Obligation to Notify or Minimize Taxes. The Company and its Affiliates shall have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company and its Affiliates shall have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of a Stock Award or a possible period in which the Stock Award may not be exercised. The Company and its Affiliates have no duty or obligation to minimize the tax consequences of a Stock Award to the holder of such Stock Award.

**8. MISCELLANEOUS.**

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

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

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

(d) No Employment or Other Service Rights. Nothing in the Plan, any Stock Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto shall confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Stock Award was granted or shall affect the right of the Company or an Affiliate to terminate the employment of an Employee with or without notice and with or without cause.

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

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

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

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

(i) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Ordinary Shares or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company or an Affiliate. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant’s termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.
(j) Compliance with Section 409A. To the extent that the Board determines that any Award granted hereunder is subject to Section 409A of the Code, the Award Agreement evidencing such Award shall incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code. To the extent applicable, the Plan and Award Agreements shall be interpreted in accordance with Section 409A of the Code. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the Ordinary Shares are publicly traded and a Participant holding an Award that constitutes “deferred compensation” under Section 409A of the Code is a “specified employee” for purposes of Section 409A of the Code, no distribution or payment of any amount shall be made upon a “separation from service” before a date that is six (6) months following the date of such Participant’s “separation from service” (as defined in Section 409A of the Code without regard to alternative definitions thereunder) or, if earlier, the date of the Participant’s death.

(k) Personal Data. It shall be a term and condition of every Award that a Participant agrees and consents to:

(i) the collection, use and processing of his Personal Data by the Company or any Subsidiary and the transfer of his Personal Data to any third party administrator of the Plan and any broker through whom Shares are to be sold on behalf of a Participant;

(ii) the Company, its Subsidiaries or any third party administrator of the Plan, transferring the Participant’s Personal Data amongst themselves for the purposes of implementing, administering and managing the Plan and the issue of Awards and the acquisition of Ordinary Shares pursuant to Awards;

(iii) the use of Personal Data by any such person for any such purposes; and

(iv) the transfer to and retention of Personal Data by third parties (including any situated outside the European Economic Area) for or in connection with such purposes.

(l) Clawback/Recovery. Awards under the Plan shall be subject to any compensation recoupment policy that the Company may adopt from time to time that is applicable by its terms to the Participant.

9. ADJUSTMENTS UPON CHANGES IN ORDINARY SHARES; OTHER CORPORATE EVENTS.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board shall appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a)(i) and 3(f), (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(a)(ii), (iii) the class(es) and maximum number of securities that may be awarded to any person pursuant to Sections 3(d) and 6(c)(i), and (iv) the class(es) and number of securities and price per Ordinary Share subject to outstanding Stock Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive.

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

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

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

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

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

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

10. TERMINATION OR SUSPENSION OF THE PLAN.

(a) Plan Term. The Board may suspend or terminate the Plan at any time. Unless terminated sooner by the Board, the Plan shall automatically terminate on May 16, 2024. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

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

11. EFFECTIVE DATE OF PLAN.

The Plan originally became effective on the Effective Date. This amendment and restatement of the Plan document is effective on May 2, 2019, provided that this amendment and restatement of the Plan is approved by the Company’s shareholders at the annual general meeting of the shareholders of the Company held on such date.

12. CHOICE OF LAW.

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

(a) “2011 Plan Available Reserve” means the number of shares of common available for issuance pursuant to the grant of future awards under the 2011 Plan determined as of immediately prior to the Effective Date.

(b) “2018 Annual Meeting” means the annual general meeting of the shareholders of the Company held in 2018.

(c) “2018 Executive Award” means an Award granted prior to the 2018 Annual Meeting that may vest, in part, subject to approval of the amendment and restatement of the Plan by the Company’s shareholders at the 2018 Annual Meeting.

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

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

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

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

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

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

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

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

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the shareholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) the shareholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur, except for a liquidation into a parent corporation;

(iv) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by shareholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or
(v) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the “Incumbent Board”) cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

For the avoidance of doubt, any one or more of the above events may be effected pursuant to (i) a compromise or arrangement sanctioned by the Irish courts under section 201 of the Companies Act 1963 (as may be amended, updated or replaced from time to time) (the “1963 Act”) or (ii) a scheme, contract or offer which has become binding on all shareholders pursuant to Section 204 of the 1963 Act, or (iii) a bid pursuant to Regulation 23 or 24 of the European Communities (Takeover Bids (Directive 2004/25/EC)) Regulations 2006.

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

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

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

(m) “Company” means Horizon Therapeutics Public Limited Company (formerly known as Horizon Pharma Public Limited Company), a company incorporated under the laws of Ireland.

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

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

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

(i) a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

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

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

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

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

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

(t) “Effective Date” means the original effective date of this Plan, which was immediately prior to the effective time of the merger between Horizon Pharma, Inc. and Horizon Pharma Public Limited Company pursuant to the Transaction Agreement and Plan of Merger dated March 18, 2014.
(u) “Employee” means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, shall not cause a Director to be considered an “Employee” for purposes of the Plan.

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


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

(y) “Fair Market Value” means, as of any date, the value of the Ordinary Shares determined as follows:

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

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

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

(z) “Horizon” means Horizon Pharma, Inc. a Delaware corporation.
(aa) “Incentive Stock Option” means an option granted pursuant to Section 5 of the Plan that is intended to be, and qualifies as, an “incentive stock option” within the meaning of Section 422 of the Code.

(bb) “Inducement Award” means a Stock Award granted pursuant to Section 3(f) of the Plan.

(cc) “Inducement Committee” means a Committee consisting of the majority of the Company’s independent directors or the Company’s independent compensation committee, in either case in accordance with NASDAQ Listing Rule 5635(c)(4).

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

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

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

(gg) “Option” means an Incentive Stock Option or a Nonstatutory Stock Option to purchase Ordinary Shares granted pursuant to the Plan.

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

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

(jj) “Ordinary Shares” or “Shares” means the ordinary shares in the capital of the Company with a nominal value of US$0.0001 per share.

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

(ll) “Other Stock Award Agreement” means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement shall be subject to the terms and conditions of the Plan.
Outside Director means a Director who either (i) is not a current employee of the Company or an “affiliated corporation” (within the meaning of Treasury Regulations promulgated under Section 162(m) of the Code), is not a former employee of the Company or an “affiliated corporation” who receives compensation for prior services (other than benefits under a tax-qualified retirement plan) during the taxable year, has not been an officer of the Company or an “affiliated corporation,” and does not receive remuneration from the Company or an “affiliated corporation,” either directly or indirectly, in any capacity other than as a Director, or (ii) is otherwise considered an “outside director” for purposes of Section 162(m) of the Code.

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

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

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

Performance Criteria means the one or more criteria that the Board shall select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that shall be used to establish such Performance Goals may be based on any one of, or combination of, the following as determined by the Board: (i) earnings (including earnings per share and net earnings); (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) total shareholder return; (v) return on equity or average shareholder’s equity; (vi) return on assets, investment, or capital employed; (vii) share price; (viii) margin (including gross margin); (ix) income (before or after taxes); (x) operating income; (xi) operating income after taxes; (xii) pre-tax profit; (xiii) operating cash flow; (xiv) sales or revenue targets; (xv) increases in revenue or product revenue; (xvi) expenses and cost reduction goals; (xvii) improvement in or attainment of working capital levels; (xviii) economic value added (or an equivalent metric); (xix) market share; (xx) cash flow; (xxi) cash flow per share; (xxii) share price performance; (xxiii) debt reduction; (xxiv) implementation or completion of projects or processes; (xxv) customer satisfaction; (xxvi) shareholders’ equity; (xxvii) capital expenditures; (xxviii) debt levels; (xxix) operating profit or net operating profit; (xxx) workforce diversity; (xxxi) growth of net income or operating income; (xxxii) billings; and (xxxiii) to the extent that an Award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the Board.

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

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

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

(uu) “Personal Data” has the same meaning as defined in the Data Protection Acts 1988 and 2003.

(vv) “Plan” means this Horizon Therapeutics Public Limited Company 2014 Equity Incentive Plan.

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

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

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

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

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

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

(ccc) “Stock Appreciation Right” or “SAR” means a right to receive the appreciation on Ordinary Shares that is granted pursuant to the terms and conditions of Section 5.
(ddd) “Stock Appreciation Right Agreement” means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement shall be subject to the terms and conditions of the Plan.

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

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

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

(hh) “Ten Percent Shareholder” means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) shares possessing more than ten percent (10%) of the total combined voting power of all classes of shares of the Company or any Affiliate.
Pursuant to your Stock Option Grant Notice ("Grant Notice") and this Option Agreement (the "Agreement"), Horizon Therapeutics Public Limited Company (the "Company") has granted you an option under its 2014 Equity Incentive Plan (the "Plan") to purchase the number of the Company’s Ordinary Shares indicated in your Grant Notice at the exercise price indicated in your Grant Notice. Capitalized terms not explicitly defined in this Agreement but defined in the Plan shall have the same definitions as in the Plan.

The details of your option are as follows:

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

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

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

4. **Method of Payment.** Payment of the applicable exercise price is due in full upon exercise of all or any part of your option. All amounts due are payable in United States dollars based, if applicable, upon the local currency to United States dollar exchange rate published in the West Coast edition of The Wall Street Journal on the date of exercise of your option (or, if the date of exercise is not a business day in the United States, the preceding business day in the United States). You may not exercise your option, and no obligation shall arise upon the Company to procure the issue or transfer of the Ordinary Shares, unless and until the Company and/or any Affiliate are satisfied in their absolute discretion that you have fully paid up in cash (or by check) the nominal value of each Ordinary Share subject to the exercised portion of the option. You may elect to make payment of the remaining portion of the option exercise price by remittance for the amount payable or in any other manner permitted by your Grant Notice, which may include one or more of the following:

   a. Provided that at the time of exercise the Ordinary Shares are publicly traded and quoted regularly in a source the Board deems reliable, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Ordinary Shares, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds.
b. If this option is a Nonstatutory Stock Option, subject to the consent of the Company at the time of exercise, by a “net exercise” arrangement pursuant to which the Company will reduce the number of Ordinary Shares issuable upon exercise of your option by the largest whole number of Ordinary Shares with a Fair Market Value that does not exceed the aggregate exercise price; provided, however, that:

1) the Company shall accept a cash or other payment from you to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole Ordinary Shares to be issued;

2) Ordinary Shares will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) Ordinary Shares issuable upon exercise are reduced to pay the exercise price pursuant to the “net exercise,” (B) Ordinary Shares are delivered to you as a result of such exercise, and (C) Ordinary Shares are withheld to satisfy tax withholding obligations.

5. **Whole Shares.** You may exercise your option only for whole Ordinary Shares.

6. **Securities Law Compliance.** Notwithstanding anything to the contrary contained herein, you may not exercise your option unless the Ordinary Shares issuable upon such exercise are then registered under the Securities Act or, if such Ordinary Shares are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with other applicable laws and regulations governing your option, including, without limitation, the laws and regulations of the United States and your country of residence, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations.

7. **Term.** You may not exercise your option before the commencement of its term or after its term expires. The term of your option commences on the Date of Grant and expires upon the earliest of the following:

a. immediately upon the termination of your Continuous Service for Cause;

b. three (3) months after the termination of your Continuous Service for any reason other than Cause, Disability or death, provided that if during any part of such three (3)-month period you may not exercise your option solely because of the condition set forth in the preceding paragraph relating to “Securities Law Compliance,” your option shall not expire until the earlier of the Expiration Date or until it shall have been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service;

c. twelve (12) months after the termination of your Continuous Service due to your Disability;
d. eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause;

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

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

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

8. Exercise.

a. You may exercise the vested portion of your option (and the unvested portion of your option if your Grant Notice so permits) during its term by following the option exercise instructions specified in your StockCross Financial Services brokerage account including adequate provision for payment of the option exercise price to the Company together with such additional documents as the Company may then require.

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

c. By exercising your option you agree that, as a condition to any exercise of your option, if you do not pay the nominal value of the Ordinary Shares by cash or check, such nominal value will be automatically deducted from salary or base wages due and payable to you.

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

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

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

11. WITHHOLDING OBLIGATIONS.

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

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

c. You may not exercise your option and no obligation shall arise upon the Company to procure the issue or transfer of the Ordinary Shares unless and until the Company and/or any Affiliate are satisfied in their absolute discretion that either (i) you have made payment, or have made arrangements satisfactory to the Company and/or any Affiliate for the payment to it of such sum as is sufficient to meet any withholding liability to Taxation (defined below) in any jurisdiction which is or would be recoverable from you following exercise of your option and/or the issue of Ordinary Shares by the Company arising from such exercise, and in respect of which the Company and/or any Affiliate is liable to account in any jurisdiction; or (ii) you have entered into an agreement with the Company and/or an Affiliate (in a form satisfactory to the Company or such Affiliate) to ensure that such a payment is made by you including, without limitation, amounts in respect of any employers’ social security (or the local law equivalent thereof) or other forms of Taxation. Accordingly, you may not be able to exercise
your option when desired even though your option is vested, and the Company shall have no obligation to issue a certificate for such Ordinary Shares or release such Ordinary Shares from any escrow provided for herein unless such obligations are satisfied. “Taxation” shall include all forms of taxation including employees’ and employers’ social security, income tax and any other taxes of whatever nature in any jurisdiction together with any amount payable by an Affiliate in respect of which the Affiliate has a duty to account as a result of any laws of any jurisdiction relating to taxation.

12. PERSONAL DATA. You understand that your employer, if applicable, the Company, and/or its Affiliates hold certain personal information about you. This information include your name, home address, telephone number, date of birth, social security or equivalent tax identification number, salary, nationality, job title, and details of your option grant and all Ordinary Shares subject to such grant that have been granted, cancelled, vested, unvested, or are outstanding (the “Personal Data”).

You hereby declare your express consent to allowing your employer to transfer your Personal Data (name, home address, telephone number, date of birth, salary, nationality, job title, and details of the option grant and all Ordinary Shares subject to such grant) outside the country in which you are employed or retained to its Affiliates, Horizon Pharma, Inc. and Horizon Pharma USA, Inc. which are located in the United States and their parent entity, Horizon Therapeutics Public Limited Company (together such entities are the “Company Group”). The legal persons for whom such Personal Data are intended are: Horizon Therapeutics Public Limited Company, Horizon Pharma, Inc., Horizon Pharma USA, Inc., StockCross Financial Services and any other third party entity providing option and/or Plan administration services to the Company and for the sole purpose of facilitating the transactions contemplated by this Stock Agreement. You have the right to access and correct your Personal Data by applying to the Company representative identified on the Grant Notice (the “Representative”). You have the right to revoke this consent at any time with future effect towards the Company Group by providing written notice to the Representative of such revocation (the “Revocation Notice”). You may also elect to exercise your option, to the extent such option is vested, by following the option exercise instructions specified in your StockCross Financial Services brokerage account and making provision for payment of the applicable option exercise price to the Company concurrently with your Revocation Notice, in which case your consent revocation will become effective as soon as administratively practicable following the execution of your option exercise election and the issuance of the Ordinary Shares subject to the option to you. If you do not follow the option exercise instructions specified in your StockCross Financial Services brokerage account or provide for payment of the option exercise price along with your Revocation Notice, or to the extent your option is unvested at the time you elect to provide a Revocation Notice, your consent revocation will become effective and your option shall automatically immediately terminate and be forfeited, and you will not receive any Ordinary Shares or any other consideration in respect of such forfeited option.

13. ADDITIONAL ACKNOWLEDGEMENTS. You hereby consent and acknowledge that:
a. Participation in the Plan is voluntary and therefore you must accept the terms and conditions of the Plan and this option as a condition to participating in the Plan and receipt of this option.

b. The Plan is discretionary in nature and the Company can amend, cancel, or terminate it at any time.

c. This option and any other options under the Plan are voluntary and occasional and do not create any contractual or other right to receive future options or other benefits in lieu of future options, even if similar options have been granted repeatedly in the past.

d. All determinations with respect to any such future options, including, but not limited to, the time or times when such options are made, the number of Ordinary Shares, and performance and other conditions applied to the options, will be at the sole discretion of the Company.

e. The value of the Ordinary Shares and this option is an extraordinary item of compensation, which is outside the scope of your employment, service contract or consulting agreement, if any. This option shall not form part of any past, current or future entitlement to remuneration or benefits which you may have under any contract of employment with the Company nor form any part of any such contract of employment between you and the Company.

f. The Ordinary Shares, this option, or any income derived therefrom are a potential bonus payment not paid in lieu of any cash salary compensation and not part of normal or expected compensation or salary for any purposes, including, but not limited to, calculating any termination, severance, resignation, redundancy, end of service payments, bonuses, long-service awards, life or accident insurance benefits, pension or retirement benefits or similar payments.

g. In the event of the involuntary termination of your Continuous Service, your eligibility to receive Ordinary Shares or payments under the option or the Plan, if any, will terminate effective as of the date that you are no longer actively employed or retained regardless of any reasonable notice period mandated under local law, except as expressly provided in the option.

h. The future value of the Ordinary Shares is unknown and cannot be predicted with certainty. You do not have, and will not assert, any claim or entitlement to compensation, indemnity or damages arising from the termination of this option or diminution in value of the Ordinary Shares and you irrevocably release the Company, its Affiliates and, if applicable, your employer, if different from the Company, from any such claim that may arise.

i. The Plan and this option set forth the entire understanding between you, the Company and any Affiliate regarding the acquisition of the Ordinary Shares and supersedes all prior oral and written agreements pertaining to this option.

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

15. OTHER DOCUMENTS. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company’s policy permitting officers, directors and other specified individuals to sell shares only during certain “window” periods and the Company’s insider trading policy, in effect from time to time.

16. NOTICES. Any notices provided for in your option or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting the Option you consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

17. MISCELLANEOUS.
   a. The rights and obligations of the Company under your option shall be transferable to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by the Company’s successors and assigns. Your rights and obligations under your option may only be assigned with the prior written consent of the Company.
   b. You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your option.
   c. You acknowledge and agree that you have reviewed your option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your option, and fully understand all provisions of your option.
   d. This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.
   e. All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.
18. GOVERNING PLAN DOCUMENT. Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of your option and those of the Plan, the provisions of the Plan shall control. In addition, your option (and any compensation paid or shares issued under your option) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

19. SEVERABILITY. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

20. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of the option subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating the Employee’s benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company’s or any Affiliate’s employee benefit plans.

21. AMENDMENT. This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that no such amendment adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the grant as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the option which is then subject to restrictions as provided herein.
Horizon Therapeutics Public Limited Company (the “Company”), pursuant to its 2014 Equity Incentive Plan (the “Plan”), hereby grants to you an option (the “Option”) to purchase the Company’s Ordinary Shares. The following specific terms of the Option can be obtained by logging on to your StockCross brokerage account: [Optionholder, Date of Grant, Vesting Commencement Date, Number of Ordinary Shares Subject to Option, Exercise Price (Per Share), Total Exercise Price, Expiration Date, Type of Grant (Incentive Stock Option or Nonstatutory Stock Option), Exercise Schedule, Vesting Schedule and Payment]. These specific terms are incorporated by reference into this Grant Notice. This Option is subject to all of the terms and conditions as set forth herein and in the Option Agreement and the Plan, all of which are available on the StockCross website.

Additional Terms/Acknowledgements: You must electronically accept the Option by logging into your StockCross account. If you have not set-up your StockCross brokerage account, the following information provided below will assist you in this process. Failure to do so may result in forfeiture of the Option. By electronically accepting the Option, you acknowledge receipt of, and understand and agree to, this Stock Option Grant Notice, the Option Agreement and the Plan. You further acknowledge that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between you and the Company regarding the acquisition of shares in the Company and supersede all prior oral and written agreements on that subject with the exception of awards previously granted and delivered to you under the Plan.

STOCKCROSS FINANCIAL SERVICES BROKERAGE ACCOUNT

Horizon currently utilizes StockCross Financial Services as our online broker. StockCross Financial Services offers an internet website for viewing option data and for buying or selling your stock options.

To open your brokerage account (if you have not yet done so)
- Go to the StockCross website at www.stockcross.com
- Select the Green “Open an Account” menu item.
- Under the New Account Application screen, select “Employee Stock Plan Account” button to proceed with the brokerage application.
- If any additional documentation is needed, StockCross will contact you directly.
- Once the account is fully processed, you will receive a welcome email from StockCross, containing your account number and other useful information. This is generally within 72 hours.

If you have any questions or comments completing the brokerage application, please contact StockCross Corporate Services at 800-338-3965.

Viewing your Award
- Login to www.trading.stockcross.com using your StockCross account number and password established during registration
- Once logged into your StockCross account, select the menu item “Employee Stock Plan.” This will bring you into another window screen which provides a summary of your equity grants. Please note that to view this information, you will need to disable popup blockers.
- Select “Portfolio.” This will show you all equity grants that you have been granted.

Accepting your Award
- Login to www.trading.stockcross.com using your StockCross user name and password established during registration
• Once logged into your StockCross account, select the link to Employee Stock Plans under the menu item “Employee Stock Plan.” This will bring you into another window screen which provides a summary of your equity grants. **Please note that to view this information, you will need to disable popup blockers.**

• Select “My Portfolio.” This will show you all equity grants that you have been granted.

• For your new equity grant, in the first column, click on the Orange “Accept Grant” Action Button.

• This will take you to an electronic acceptance window. For your reference, the Equity Agreement applicable to the Award is provided. If you agree with the terms and conditions of your equity grant, Place your name in the signature box, type your name below, and check the agreement box. Click “Accept Grant to complete the acceptance.

**IMPORTANT REMINDER:** In order to avoid forfeiture of your Award, you must electronically accept your Award **30 days prior to your first vesting date.**

Contact Horizon Therapeutics plc’s Senior Manager, Accounting and Global Equity Plan Administrator Garry Devine at 224-383-3037 or email gdevine@horizontherapeutics.com with any further questions regarding your awards.
Pursuant to the Restricted Stock Unit Grant Notice (the “Grant Notice”) and this Restricted Stock Unit Agreement (the “Agreement”) and in consideration of your services, Horizon Therapeutics Public Limited Company (the “Company”) has granted you a Restricted Stock Unit Award (the “Award”) under its 2014 Equity Incentive Plan (the “Plan”) for the number of restricted stock units referenced in the Grant Notice. Capitalized terms not explicitly defined in this Agreement shall have the same meanings given to them in the Plan or the Grant Notice, as applicable. Except as otherwise explicitly provided herein, in the event of any conflict between the terms in this Agreement and the Plan, the terms of the Plan shall control.

The details of your Award, in addition to those set forth in the Grant Notice and the Plan, are as follows.

1. **Grant of the Award.** This Award represents your right to be issued on a future date the number of Ordinary Shares that is equal to the number of restricted stock units indicated in the Grant Notice (the “Stock Units”) at the Purchase Price per Ordinary Share specified in your Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the “Account”) the number of Stock Units subject to the Award.

2. **Vesting.** Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service. Upon such termination of your Continuous Service, the Stock Units credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in such Stock Units or the Ordinary Shares to be issued in respect of such portion of the Award.

3. **Method of Payment.** On or before the time you receive a distribution of the Ordinary Shares in settlement of your Stock Units, you hereby authorize the Company or any Affiliate to satisfy the payment of the Purchase Price per Ordinary Share with respect to such Ordinary Shares by withholding such payment from payroll and any other cash amounts otherwise payable to you. If no cash amounts are otherwise payable to you by the Company and available for such deduction, you must provide timely payment of the applicable Purchase Price to the Company via cash or check and no obligation shall arise upon the Company to procure the issue or transfer of the Ordinary Shares unless and until the Company and/or any Affiliate are satisfied in their absolute discretion that you have satisfied such payment requirement. All amounts due are payable in United States dollars based, if applicable, upon the local currency to United States dollar exchange rate published in the West Coast edition of The Wall Street Journal on the applicable payment date (or, if such date is not a business day in the United States, the preceding business day in the United States).
4. NUMBER OF STOCK UNITS, ORDINARY SHARES AND PURCHASE PRICE.

a. The number of Stock Units subject to your Award and the Purchase Price per Ordinary Share may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Furthermore, the Purchase Price per Ordinary Share will be automatically adjusted from time to time, as applicable, such that it shall at all times be equal to the nominal value per Ordinary Share as then in effect. In no event will the Purchase Price per Ordinary Share be less than the nominal value per Ordinary Share.

b. Any additional Stock Units that become subject to the Award pursuant to this Section 4, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Stock Units covered by your Award.

c. Notwithstanding the provisions of this Section 4, no fractional shares or rights for fractional Ordinary Shares shall be created pursuant to this Section 4. The Board shall, in its discretion, determine an equivalent benefit for any fractional shares or fractional shares that might be created by the adjustments referred to in this Section 4.

5. SECURITIES LAW COMPLIANCE. You may not be issued any shares in respect of your Award unless either (i) the shares are registered under the Securities Act; or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award also must comply with other applicable laws and regulations governing the Award, including, without limitation, the laws and regulations of the United States and your country of residence, and you will not receive such shares if the Company determines that such receipt would not be in material compliance with such laws and regulations.

6. TRANSFER RESTRICTIONS. Your Award is not transferable, except by will or by the laws of descent and distribution. In addition to any other limitation on transfer created by applicable securities laws, you agree not to assign, hypothecate, donate, encumber or otherwise dispose of any interest in any of the Ordinary Shares subject to the Award until the shares are issued to you in accordance with Section 7 of this Agreement. After the shares have been issued to you, you are free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such shares provided that any such actions are in compliance with the provisions herein, any applicable Company policies (including, but not limited to, insider trading and window period policies) and applicable securities laws. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, shall thereafter be entitled to receive any distribution of Ordinary Shares to which you were entitled at the time of your death pursuant to this Agreement.

7. DATE OF ISSUANCE.

a. To the extent the Award is exempt from application of Section 409A of the Code and any state law of similar effect (collectively “Section 409A”), the Company will deliver to you a number of Ordinary Shares equal to the number of vested Stock Units subject to your Award, including any additional Stock Units received pursuant to Section 4 above that relate to those vested Stock Units, on the applicable vesting date(s). However, if a scheduled
delivery date falls on a date that is not a business day, such delivery date shall instead fall on the next following business day. Notwithstanding the
foregoing, in the event that (i) any shares covered by your Award are scheduled to be delivered on a day (the “Original Distribution Date”) that does not
occur: (A) during an open “window period” applicable to you under the Company’s policy permitting officers, directors and other designated individuals
to sell shares only during certain “window” periods, in effect from time to time (the “Policy”), (B) on a day on which you are permitted to sell Ordinary
Shares pursuant to a written plan that meets the requirements of Rule 10b5-1 under the Exchange Act, as determined by the Company in accordance
with the Policy, or (C) on a date when you are otherwise permitted to sell Ordinary Shares on the open market, and (ii) the Company elects not to satisfy
its tax withholding obligations by withholding shares from your distribution or withholding from other compensation otherwise payable to you by the
Company, then such shares shall not be delivered on such Original Distribution Date and shall instead be delivered on the first business day of the next
occurring open “window period” applicable to you pursuant to such Policy (regardless of whether you are still providing continuous services at such
time) or the next business day when you are not prohibited from selling Ordinary Shares in the open market, but in no event later than the fifteenth
(15th) day of the third calendar month of the calendar year following the calendar year in which the shares covered by the Award vest. Delivery of the
shares pursuant to the provisions of this Section 7(a) is intended to comply with the requirements for the short-term deferral exemption available under
Treasury Regulations Section 1.409A-1(b)(4) and shall be construed and administered in such manner. The form of such delivery of the shares (e.g., a
stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

b. The provisions of Appendix A to this Agreement will apply to the extent the Award is subject to, and not exempt from, application of
Section 409A (a “Non-Exempt Award”).

8. DIVIDENDS. You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution
that does not result from a Capitalization Adjustment as provided in the Plan; provided, however, that this sentence shall not apply with respect to any
Ordinary Shares that are delivered to you in connection with your Award after such shares have been delivered to you.

9. RESTRICTIVE LEGENDS. The shares issued in respect of your Award shall be endorsed with appropriate legends determined by the Company.

10. AWARD NOT A SERVICE CONTRACT.

a. Your Continuous Service with the Company or an Affiliate is not for any specified term and may be terminated by you or by the
Company or an Affiliate at any time, for any reason, with or without cause and with or without notice. Nothing in this Agreement (including, but not
limited to, the vesting of your Award pursuant to the schedule set forth in the Grant Notice or the issuance of the shares in respect of your Award), the
Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to
continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate
regarding the fact or nature of future positions, future work assignments, future compensation or any other
term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

b. By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice is earned only by continuing as an employee, director or consultant at the will of the Company (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a “reorganization”). You further acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with your right or the Company’s right to terminate your Continuous Service at any time, with or without cause and with or without notice.

II. WITHHOLDING OBLIGATIONS.

a. On or before the time you receive a distribution of the shares subject to your Award, or at any time thereafter as requested by the Company, you hereby authorize any required withholding from the Ordinary Shares issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate which arise in connection with your Award (the “Withholding Taxes”). Additionally, the Company may, in its sole discretion, satisfy all or any portion of the Withholding Taxes obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company; (ii) causing you to tender a cash payment, (iii) permitting or requiring you to enter into a “same day sale” commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a “FINRA Dealer”) whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Restricted Stock Units to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company and/or its Affiliates; or (iv) withholding Ordinary Shares from the Ordinary Shares issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date Ordinary Shares are issued to pursuant to Section 7) equal to the amount of such Withholding Taxes; provided, however, that the number of such Ordinary Shares so withheld shall not exceed the amount necessary to satisfy the Company’s required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income; and provided further, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, such share withholding procedure shall be subject to the express prior approval of the Company’s Compensation Committee.
b. Unless the tax withholding obligations of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to deliver to you any Ordinary Shares pursuant to this Award.

c. No obligation shall arise upon the Company to procure the issue or transfer of the Ordinary Shares unless and until the Company and/or any Affiliate are satisfied in their absolute discretion that either (i) you have made payment, or have made arrangements satisfactory to the Company and/or any Affiliate for the payment to it of such sum as is sufficient to meet any withholding liability to Taxation (defined below) in any jurisdiction which is or would be recoverable from you in connection with the vesting or the Award or the issuance of Ordinary Shares by the Company in settlement of the Award, and in respect of which the Company and/or any Affiliate is liable to account in any jurisdiction; or (ii) you have entered into an agreement with the Company and/or an Affiliate (in a form satisfactory to the Company or such Affiliate) to ensure that such a payment is made by you including, without limitation, amounts in respect of any employers’ social security (or the local law equivalent thereof) or other forms of Taxation. Accordingly, the Company shall have no obligation to issue a certificate for such Ordinary Shares or release such Ordinary Shares from any escrow provided for herein unless such obligations are satisfied. “Taxation” shall include all forms of taxation including employees’ and employers’ social security, income tax and any other taxes of whatever nature in any jurisdiction together with any amount payable by an Affiliate in respect of which the Affiliate has a duty to account as a result of any laws of any jurisdiction relating to taxation.

12. PERSONAL DATA. You understand that your employer, if applicable, the Company, and/or its Affiliates hold certain personal information about you. This information include your name, home address, telephone number, date of birth, social security or equivalent tax identification number, salary, nationality, job title, and details of your Award and all Ordinary Shares subject to your Award that have been granted, cancelled, vested, unvested, or are outstanding (the “Personal Data”).

You hereby declare your express consent to allowing your employer to transfer your Personal Data (name, home address, telephone number, date of birth, salary, nationality, job title, and details of the Award and all Ordinary Shares subject to such grant) outside the country in which you are employed or retained to its Affiliates, Horizon Pharma, Inc. and Horizon Pharma USA, Inc. which are located in the United States and their parent entity, Horizon Therapeutics Public Limited Company (together such entities are the “Company Group”). The legal persons for whom such Personal Data are intended are: Horizon Therapeutics Public Limited Company, Horizon Pharma, Inc., Horizon Pharma USA, Inc., StockCross Financial Services and any other third party entity providing equity award and/or Plan administration services to the Company and for the sole purpose of facilitating the transactions contemplated by this Agreement. You have the right to access and correct your Personal Data by applying to the Company representative identified on the Grant Notice (the “Representative”). You have the right to revoke this consent at any time with future effect towards the Company Group by providing written notice to the Representative of such revocation (the “Revocation Notice”) and as soon as administratively practicable following the Representative’s receipt of the Revocation Notice your consent revocation will become effective and your Award shall automatically immediately terminate and be forfeited, and you will not receive any Ordinary Shares or any other consideration in respect of such forfeited Award.

5.
13. ADDITIONAL ACKNOWLEDGEMENTS. You hereby consent and acknowledge that:

a. Participation in the Plan is voluntary and therefore you must accept the terms and conditions of the Plan and this Award as a condition to participating in the Plan and receipt of the Award.

b. The Plan is discretionary in nature and the Company can amend, cancel, or terminate it at any time.

c. This Award and any other equity awards granted under the Plan are voluntary and occasional and do not create any contractual or other right to receive future awards or other benefits in lieu of future awards, even if similar awards have been granted repeatedly in the past.

d. All determinations with respect to any such future awards, including, but not limited to, the time or times when such awards are granted, the number of Ordinary Shares, and performance and other conditions applied to the awards, will be at the sole discretion of the Company.

e. The value of the Ordinary Shares and this Award is an extraordinary item of compensation, which is outside the scope of your employment, service contract or consulting agreement, if any. This Award shall not form part of any past, current or future entitlement to remuneration or benefits which you may have under any contract of employment with the Company nor form any part of any such contract of employment between you and the Company.

f. The Ordinary Shares, this Award, or any income derived therefrom are a potential bonus payment not paid in lieu of any cash salary compensation and not part of normal or expected compensation or salary for any purposes, including, but not limited to, calculating any termination, severance, resignation, redundancy, end of service payments, bonuses, long-service awards, life or accident insurance benefits, pension or retirement benefits or similar payments.

g. In the event of the involuntary termination of your Continuous Service, your eligibility to receive Ordinary Shares or payments under the Award or the Plan, if any, will terminate effective as of the date that you are no longer actively employed or retained regardless of any reasonable notice period mandated under local law, except as expressly provided in the Agreement.

h. The future value of the Ordinary Shares is unknown and cannot be predicted with certainty. You do not have, and will not assert, any claim or entitlement to compensation, indemnity or damages arising from the termination of this award or diminution in value of the Ordinary Shares and you irrevocably release the Company, its Affiliates and, if applicable, your employer, if different from the Company, from any such claim that may arise.
The Plan and this Agreement set forth the entire understanding between you, the Company and any Affiliate regarding the acquisition of the Ordinary Shares and supersedes all prior oral and written agreements pertaining to this Award.

14. **UNSECURED OBLIGATION.** Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company’s obligation, if any, to issue shares pursuant to this Agreement. You shall not have voting or any other rights as a shareholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 7 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a shareholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

15. **OTHER DOCUMENTS.** You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b) (1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company’s policy permitting officers, directors and other specified individuals to sell shares only during certain “window” periods and the Company’s insider trading policy, in effect from time to time.

16. **NOTICES.** Any notices provided for in your Award or the Plan shall be given in writing (including electronically) and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award you consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

17. **MISCELLANEOUS.**

   a. The rights and obligations of the Company under your Award shall be transferable to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by the Company’s successors and assigns. Your rights and obligations under your Award may only be assigned with the prior written consent of the Company.

   b. You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

   c. You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award, and fully understand all provisions of your Award.
d. This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

e. All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

18. GOVERNING PLAN DOCUMENT. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Except as expressly provided in this Agreement, in the event of any conflict between the provisions of your Award and those of the Plan, the provisions of the Plan shall control. In addition, your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

19. SEVERABILITY. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

20. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating the Employee’s benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company’s or any Affiliate’s employee benefit plans.

21. AMENDMENT. This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that no such amendment adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the grant as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.
22. **NO OBLIGATION TO MINIMIZE TAXES.** The Company has no duty or obligation to minimize the tax consequences to you of this Award and will not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so.
Appendix A

The provisions set forth on this Appendix A shall apply to the extent the Award is a Non-Exempt Award and shall supersede any provisions to the contrary set forth in the Plan or in any other section of the Agreement to which this Appendix A is attached.

1. The provisions of this Section 1 are intended to apply to the extent your Award is a Non-Exempt Award because of the terms of a severance arrangement or other agreement between you and the Company, if any, that provide for acceleration of vesting of your Award and issuance of the shares in respect of the Award upon your termination of employment or separation from service (as such term is defined in Section 409A(a)(2)(A)(i) of the Code (and without regard to any alternative definition thereunder) (“Separation from Service”) and such severance benefit does not satisfy the requirements for an exemption from application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(4) or 1.409A-1(b)(9) (“Non-Exempt Severance Arrangement”). To the extent your Award is a Non-Exempt Award due to application of a Non-Exempt Severance Arrangement, the following provisions in this Section 1 of Appendix A shall supersede anything to the contrary in Section 6(a) of the Award Agreement.

a. If your Award vests in the ordinary course during your Continuous Service in accordance with the vesting schedule set forth in the Grant Notice, without accelerating vesting under the terms of a Non-Exempt Severance Arrangement, in no event will the shares be issued in respect of your Award any later than the later of: (i) December 31st of the calendar year that includes the applicable vesting date and (ii) the 60th day that follows the applicable vesting date.

b. If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were in effect as of the date of grant of your Award as of the date of grant, then the shares will be earlier issued in respect of your Award upon your Separation from Service in accordance with the terms of the Non-Exempt Severance Arrangement, but in no event later than the 60th day that follows the date of your Separation from Service. However, if at the time the shares would otherwise be issued you are subject to the distribution limitations contained in Section 409A applicable to “specified employees,” as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six (6) months following the date of your Separation from Service, or, if earlier, the date of your death that occurs within such six month period.

c. If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were not in effect as of the date of grant of the Award and, therefore, are not a part of the terms of your Award on the date of grant, then such acceleration of vesting of your Award shall not accelerate the issuance date of the shares, but the shares shall instead be issued on the same schedule as set forth in the Grant Notice as if they had vested in the ordinary course during your Continuous Service, notwithstanding the vesting acceleration of the Award. Such issuance schedule is intended to satisfy the requirements of payment on a specified date or pursuant to a fixed schedule, as provided under Treasury Regulations Section 1.409A-3(a)(4).
2. Permitted Treatment of Non-Exempt Awards Upon a Corporate Transaction for Employees and Consultants. The provisions in this Section 2 shall apply and shall supersede anything to the contrary that may be set forth in the Plan with respect to the permitted treatment of your Non-Exempt Award in connection with a Corporate Transaction if you were either an Employee or Consultant upon the applicable date of grant of your Non-Exempt Award.

   a. Vested Non-Exempt Awards: To the extent your Non-Exempt Award has vested in accordance with its terms upon or prior to the date of a Corporate Transaction (such portion of your Non-Exempt Award is a “Vested Non-Exempt Award”), then the following provisions shall apply.

      1) If the Corporate Transaction is also a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company’s assets, as described in Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A-3(i)(5) (a “409A Change of Control”), then the surviving or acquiring corporation (or its parent company) (the “Acquiring Entity”) may not assume, continue or substitute your Vested Non-Exempt Award. Upon the 409A Change of Control the settlement of your Vested Non-Exempt Award will automatically be accelerated and the shares will be immediately issued in respect of your Vested Non-Exempt Award. Alternatively, the Company may instead provide that you will receive a cash settlement equal to the Fair Market Value of the shares that would otherwise be issued to you upon the 409A Change of Control.

      2) If the Corporate Transaction is not also a 409A Change of Control, then the Acquiring Entity must either assume, continue or substitute your Vested Non-Exempt Award. The shares to be issued in respect of your Vested Non-Exempt Award shall be issued to you by the Acquiring Entity on the same schedule that the shares would have been issued to you if the Corporate Transaction had not occurred. In the Acquiring Entity's discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to you on such issuance dates, with the determination of the Fair Market Value of the shares made on the date of the Corporate Transaction.

   b. Unvested Non-Exempt Awards. To the extent your Non-Exempt Award has not vested in accordance with its terms upon or prior to the date of any Corporate Transaction, (such portion of your Non-Exempt Award is an “Unvested Non-Exempt Award”), then the following provisions shall apply.

      1) If the Acquiring Entity will not assume, substitute or continue your Unvested Non-Exempt Award, then such Award shall automatically terminate and be forfeited upon the Corporate Transaction with no consideration payable to you in respect of your forfeited Unvested Non-Exempt Award. Notwithstanding the foregoing, to the extent permitted and in compliance with the requirements of Section 409A, the Company may in its discretion determine to elect to accelerate the vesting and settlement of the Unvested Non-Exempt Award upon the Corporate Transaction, or instead substitute a cash payment equal to the Fair Market Value of such shares that would otherwise be issued to you, as further provided in Section 4(b) below. In the absence of such discretionary election by the Company, your Unvested Non-Exempt Award shall be forfeited without payment of any consideration to you if the Acquiring Entity will not assume, substitute or continue your Unvested Non-Exempt Award in connection with the Corporate Transaction.
2) The foregoing treatment shall apply with respect to all Unvested Non-Exempt Awards upon any Corporate Transaction, and regardless of whether or not such Corporate Transaction is also a 409A Change of Control.

3. Permitted Treatment of Non-Exempt Awards Upon a Corporate Transaction for Non-Employee Directors. If you were a Director but not an Employee on the applicable grant date of your Non-Exempt Award and (“Non-Exempt Director Award”), the following provisions shall apply and shall supersede anything to the contrary that may be set forth in the Plan with respect to the permitted treatment of your Non-Exempt Director Award in connection with a Corporate Transaction.

   a. If the Corporate Transaction is also a 409A Change of Control then the Acquiring Entity may not assume, continue or substitute your Non-Exempt Director Award. Upon the 409A Change of Control the vesting and settlement of your Non-Exempt Director Award will automatically be accelerated and the shares will be immediately issued to you in respect of the Non-Exempt Director Award. Alternatively, the Company may provide that you will instead receive a cash settlement equal to the Fair Market Value of the shares that would otherwise be issued to you upon the 409A Change of Control pursuant to the preceding provision.

   b. If the Corporate Transaction is not also a 409A Change of Control, then the Acquiring Entity must either assume, continue or substitute your Non-Exempt Director Award. Unless otherwise determined by the Board, your Non-Exempt Director Award will remain subject to the same vesting and forfeiture restrictions that were applicable to the Award prior to the Corporate Transaction. The shares to be issued in respect of your Non-Exempt Director Award shall be issued to you by the Acquiring Entity on the same schedule that the shares would have been issued to you if the Corporate Transaction had not occurred. In the Acquiring Entity’s discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to you on such issuance dates, with the determination of Fair Market Value made on the date of the Corporate Transaction.

4. General Superseding Provisions. The provisions in this Section 4 shall apply and supersede anything to the contrary that may be set forth in the Plan, the Grant Notice or in any other section of the Agreement with respect to the permitted treatment of your Non-Exempt Award:

   a. Any exercise by the Board of discretion to accelerate the vesting of your Non-Exempt Award shall not result in any acceleration of the scheduled issuance dates for the shares in respect of the Non-Exempt Award unless earlier issuance of the shares upon the applicable vesting dates would be in compliance with the requirements of Section 409A.

   b. The Company explicitly reserves the right to earlier settle your Non-Exempt Award to the extent permitted and in compliance with the requirements of Section 409A, including pursuant to any of the exemptions available in Treasury Regulations Section 1.409A-3(j)(4)(ix).
c. To the extent the terms of your Non-Exempt Award provide that it will be settled upon a Change in Control or Corporate Transaction, to the extent it is required for compliance with the requirements of Section 409A, the Change in Control or Corporate Transaction event triggering settlement must also constitute a 409A Change of Control. To the extent the terms of your Non-Exempt Award provides that it will be settled upon a termination of employment or termination of Continuous Service, to the extent it is required for compliance with the requirements of Section 409A, the termination event triggering settlement must also constitute a Separation From Service. However, if at the time the shares would otherwise be issued to you in connection with your “separation from service” you are subject to the distribution limitations contained in Section 409A applicable to “specified employees,” as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six (6) months following the date of your Separation From Service, or, if earlier, the date of your death that occurs within such six month period.

5. Section 409A Compliance. The provisions in this Agreement for delivery of the shares in respect of the Non-Exempt Award are intended to comply with the requirements of Section 409A so that the delivery of the shares to you in respect of your Non-Exempt Award will not trigger the additional tax imposed under Section 409A, and any ambiguities herein will be so interpreted.
Pursuant to the Restricted Stock Unit Grant Notice (the “Grant Notice”) and this Restricted Stock Unit Agreement (the “Agreement”) and in consideration of your services, Horizon Therapeutics Public Limited Company (the “Company”) has granted you a Restricted Stock Unit Award (the “Award”) under its 2014 Equity Incentive Plan (the “Plan”) for the number of restricted stock units referenced in the Grant Notice. Capitalized terms not explicitly defined in this Agreement shall have the same meanings given to them in the Plan or the Grant Notice, as applicable. Except as otherwise explicitly provided herein, in the event of any conflict between the terms in this Agreement and the Plan, the terms of the Plan shall control.

The details of your Award, in addition to those set forth in the Grant Notice and the Plan, are as follows.

1. GRANT OF THE AWARD. This Award represents your right to be issued on a future date the number of Ordinary Shares that is equal to the number of restricted stock units indicated in the Grant Notice (the “Stock Units”) at the Purchase Price per Ordinary Share specified in your Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the “Account”) the number of Stock Units subject to the Award.

2. VESTING. Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service. Upon such termination of your Continuous Service, the Stock Units credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in such Stock Units or the Ordinary Shares to be issued in respect of such portion of the Award.

3. METHOD OF PAYMENT. On or before the time you receive a distribution of the Ordinary Shares in settlement of your Stock Units, you hereby authorize the Company or any Affiliate to satisfy the payment of the Purchase Price per Ordinary Share with respect to such Ordinary Shares by withholding such payment from payroll and any other cash amounts otherwise payable to you. If no cash amounts are otherwise payable to you by the Company and available for such deduction, you must provide timely payment of the applicable Purchase Price to the Company via cash or check and no obligation shall arise upon the Company to procure the issue or transfer of the Ordinary Shares unless and until the Company and/or any Affiliate are satisfied in their absolute discretion that you have satisfied such payment requirement. All amounts due are payable in United States dollars based, if applicable, upon the local currency to United States dollar exchange rate published in the West Coast edition of The Wall Street Journal on the applicable payment date (or, if such date is not a business day in the United States, the preceding business day in the United States).
4. **NUMBER OF STOCK UNITS, ORDINARY SHARES AND PURCHASE PRICE.**

   (a) The number of Stock Units subject to your Award and the Purchase Price per Ordinary Share may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Furthermore, the Purchase Price per Ordinary Share will be automatically adjusted from time to time, as applicable, such that it shall at all times be equal to the nominal value per Ordinary Share as then in effect. In no event will the Purchase Price per Ordinary Share be less than the nominal value per Ordinary Share.

   (b) Any additional Stock Units that become subject to the Award pursuant to this Section 4, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Stock Units covered by your Award.

   (c) Notwithstanding the provisions of this Section 4, no fractional shares or rights for fractional Ordinary Shares shall be created pursuant to this Section 4. The Board shall, in its discretion, determine an equivalent benefit for any fractional shares or fractional shares that might be created by the adjustments referred to in this Section 4.

5. **SECURITIES LAW COMPLIANCE.** You may not be issued any shares in respect of your Award unless either (i) the shares are registered under the Securities Act; or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award also must comply with other applicable laws and regulations governing the Award, including, without limitation, the laws and regulations of the United States and your country of residence, and you will not receive such shares if the Company determines that such receipt would not be in material compliance with such laws and regulations.

6. **TRANSFER RESTRICTIONS.**

   (a) Your Award is not transferable, except by will or by the laws of descent and distribution. In addition to any other limitation on transfer created by applicable securities laws, you agree not to assign, hypothecate, donate, encumber or otherwise dispose of any interest in any of the Ordinary Shares subject to the Award until the shares are issued to you in accordance with Section 7 of this Agreement, subject to the additional restrictions set forth in Section 6(b) below. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, shall thereafter be entitled to receive any distribution of Ordinary Shares to which you were entitled at the time of your death pursuant to this Agreement.

   (b) Any Ordinary Shares issued to you in settlement of the Award may not be transferred, sold or otherwise disposed of by you within the one (1) year period that commences on the date the shares are issued to you (the “Holding Period”); provided that nothing in this Section 6(b) shall prohibit the disposition of Ordinary Shares in connection with a Change in Control or the withholding of shares that would otherwise be issued pursuant to the Award in satisfaction of applicable withholding taxes. After the Holding Period has expired, you are free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such issued Ordinary Shares provided that any such actions are in compliance with the provisions herein, any applicable Company policies (including, but not limited to, insider trading and window period policies) and applicable securities laws.
7. **DATE OF ISSUANCE.**

(a) To the extent the Award is exempt from application of Section 409A of the Code and any state law of similar effect (collectively “Section 409A”), the Company will deliver to you a number of Ordinary Shares equal to the number of vested Stock Units subject to your Award, including any additional Stock Units received pursuant to Section 4 above that relate to those vested Stock Units, on the applicable vesting date(s). However, if a scheduled delivery date falls on a date that is not a business day, such delivery date shall instead fall on the next following business day. Delivery of the shares pursuant to the provisions of this Section 7(a) is intended to comply with the requirements for the short-term deferral exemption available under Treasury Regulations Section 1.409A-1(b)(4) and shall be construed and administered in such manner. The form of such delivery of the shares (e.g., a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

(b) The provisions of Appendix A to this Agreement will apply to the extent the Award is subject to, and not exempt from, application of Section 409A (a “Non-Exempt Award”).

8. **DIVIDENDS.** You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment as provided in the Plan; provided, however, that this sentence shall not apply with respect to any Ordinary Shares that are delivered to you in connection with your Award after such shares have been delivered to you.

9. **RESTRICTIVE LEGENDS.** The shares issued in respect of your Award shall be endorsed with appropriate legends determined by the Company.

10. **AWARD NOT A SERVICE CONTRACT.**

(a) Your Continuous Service with the Company or an Affiliate is not for any specified term and may be terminated by you or by the Company or an Affiliate at any time, for any reason, with or without cause and with or without notice. Nothing in this Agreement (including, but not limited to, the vesting of your Award pursuant to the schedule set forth in the Grant Notice or the issuance of the shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.
(b) By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice is earned only by continuing as an employee, director or consultant at the will of the Company (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "reorganization"). You further acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with your right or the Company’s right to terminate your Continuous Service at any time, with or without cause and with or without notice.

11. WITHHOLDING OBLIGATIONS.

(a) On or before the time you receive a distribution of the shares subject to your Award, or at any time thereafter as requested by the Company, you hereby authorize any required withholding from the Ordinary Shares issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate which arise in connection with your Award, as calculated based upon the maximum permitted withholding rate (the "Withholding Taxes"). Additionally, unless you satisfy the requirements set forth in Section 11(b) the Company will satisfy the Withholding Taxes obligation relating to your Award by withholding Ordinary Shares from the Ordinary Shares issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date Ordinary Shares are issued to pursuant to Section 7) equal to the amount of such Withholding Taxes; provided, however, that the number of such Ordinary Shares so withheld shall not exceed the amount necessary to satisfy the Company’s tax withholding obligations as calculated using the maximum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes (the "Share Withholding Procedure"). Any adverse consequences to you arising in connection with such Share Withholding Procedure shall be your sole responsibility.

(b) Unless you timely provide Horizon with each of the following, a Share Withholding Procedure will be automatically applied to your Award:

(i) Written notice at least 10 days prior to the vesting date that you intend to pay the Withholding Taxes via a cash or check payment, and

(ii) Cash or check payment of the total amount of the Withholding Taxes by the vesting date.

If the Share Withholding Procedure is applied to your Award then on the Vesting Date Horizon will automatically reduce the number of shares issuable pursuant to your Award by the maximum number of whole Horizon shares with a fair market value that at such time does not exceed the Withholding Taxes, and you will be issued only the net remaining number of Horizon 4.
shares. Any remaining portion of the Withholding Taxes that is less than the fair market value of one Horizon share will be withheld from other payroll compensation otherwise payable to you. In determining the fair market value of Horizon’s shares for such purposes, the closing price of Horizon’s shares on the Vesting Date will apply.

(c) Unless the tax withholding obligations of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to deliver to you any Ordinary Shares pursuant to this Award.

(d) No obligation shall arise upon the Company to procure the issue or transfer of the Ordinary Shares unless and until the Company and/or any Affiliate are satisfied in their absolute discretion that either (i) you have made payment, or have made arrangements satisfactory to the Company and/or any Affiliate for the payment to it of such sum as is sufficient to meet any withholding liability to Taxation (defined below) in any jurisdiction which is or would be recoverable from you in connection with the vesting or the Award or the issuance of Ordinary Shares by the Company in settlement of the Award, and in respect of which the Company and/or any Affiliate is liable to account in any jurisdiction; or (ii) you have entered into an agreement with the Company and/or an Affiliate (in a form satisfactory to the Company or such Affiliate) to ensure that such a payment is made by you including, without limitation, amounts in respect of any employers’ social security (or the local law equivalent thereof) or other forms of Taxation. Accordingly, the Company shall have no obligation to issue a certificate for such Ordinary Shares or release such Ordinary Shares from any escrow provided for herein unless such obligations are satisfied. “Taxation” shall include all forms of taxation including employees’ and employers’ social security, income tax and any other taxes of whatever nature in any jurisdiction together with any amount payable by an Affiliate in respect of which the Affiliate has a duty to account as a result of any laws of any jurisdiction relating to taxation.

12. PERSONAL DATA. You understand that your employer, if applicable, the Company, and/or its Affiliates hold certain personal information about you. This information include your name, home address, telephone number, date of birth, social security or equivalent tax identification number, salary, nationality, job title, and details of your Award and all Ordinary Shares subject to your Award that have been granted, cancelled, vested, unvested, or are outstanding (the “Personal Data”).

You hereby declare your express consent to allowing your employer to transfer your Personal Data (name, home address, telephone number, date of birth, salary, nationality, job title, and details of the Award and all Ordinary Shares subject to such grant) outside the country in which you are employed or retained to its Affiliates, Horizon Pharma, Inc. and Horizon Pharma USA, Inc. which are located in the United States and their parent entity, Horizon Therapeutics Public Limited Company (together such entities are the “Company Group”). The legal persons for whom such Personal Data are intended are: Horizon Therapeutics Public Limited Company, Horizon Pharma, Inc., Horizon Pharma USA, Inc., StockCross Financial Services and any other third party entity providing equity award and/or Plan administration services to the Company and for the sole purpose of facilitating the transactions contemplated by this Agreement. You have the right to access and correct your Personal Data by applying to the Company representative identified on the Grant Notice (the “Representative”). You have the right to revoke this consent at any time with future effect towards the Company Group by providing written notice to the
Representative of such revocation (the “Revocation Notice”) and as soon as administratively practicable following the Representative’s receipt of the Revocation Notice your consent revocation will become effective and your Award shall automatically immediately terminate and be forfeited, and you will not receive any Ordinary Shares or any other consideration in respect of such forfeited Award.

13. ADDITIONAL ACKNOWLEDGEMENTS. You hereby consent and acknowledge that:

(a) Participation in the Plan is voluntary and therefore you must accept the terms and conditions of the Plan and this Award as a condition to participating in the Plan and receipt of the Award.

(b) The Plan is discretionary in nature and the Company can amend, cancel, or terminate it at any time.

(c) This Award and any other equity awards granted under the Plan are voluntary and occasional and do not create any contractual or other right to receive future awards or other benefits in lieu of future awards, even if similar awards have been granted repeatedly in the past.

(d) All determinations with respect to any such future awards, including, but not limited to, the time or times when such awards are granted, the number of Ordinary Shares, and performance and other conditions applied to the awards, will be at the sole discretion of the Company.

(e) The value of the Ordinary Shares and this Award is an extraordinary item of compensation, which is outside the scope of your employment, service contract or consulting agreement, if any. This Award shall not form part of any past, current or future entitlement to remuneration or benefits which you may have under any contract of employment with the Company nor form any part of any such contract of employment between you and the Company.

(f) The Ordinary Shares, this Award, or any income derived therefrom are a potential bonus payment not paid in lieu of any cash salary compensation and not part of normal or expected compensation or salary for any purposes, including, but not limited to, calculating any termination, severance, resignation, redundancy, end of service payments, bonuses, long-service awards, life or accident insurance benefits, pension or retirement benefits or similar payments.

(g) In the event of the involuntary termination of your Continuous Service, your eligibility to receive Ordinary Shares or payments under the Award or the Plan, if any, will terminate effective as of the date that you are no longer actively employed or retained regardless of any reasonable notice period mandated under local law, except as expressly provided in the Agreement.

(h) The future value of the Ordinary Shares is unknown and cannot be predicted with certainty. You do not have, and will not assert, any claim or entitlement to compensation, indemnity or damages arising from the termination of this award or diminution in value of the Ordinary Shares and you irrevocably release the Company, its Affiliates and, if applicable, your employer, if different from the Company, from any such claim that may arise.

6.
The Plan and this Agreement set forth the entire understanding between you, the Company and any Affiliate regarding the acquisition of the Ordinary Shares and supersedes all prior oral and written agreements pertaining to this Award.

14. **Unsecured Obligation.** Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company’s obligation, if any, to issue shares pursuant to this Agreement. You shall not have voting or any other rights as a shareholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 7 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a shareholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

15. **Other Documents.** You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company’s policy permitting officers, directors and other specified individuals to sell shares only during certain “window” periods and the Company’s insider trading policy, in effect from time to time.

16. **Notices.** Any notices provided for in your Award or the Plan shall be given in writing (including electronically) and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award you consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

17. **Miscellaneous.**

   (a) The rights and obligations of the Company under your Award shall be transferable to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by the Company’s successors and assigns. Your rights and obligations under your Award may only be assigned with the prior written consent of the Company.

   (b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.
You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award, and fully understand all provisions of your Award.

This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

18. **GOVERNING PLAN DOCUMENT.** Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Except as expressly provided in this Agreement, in the event of any conflict between the provisions of your Award and those of the Plan, the provisions of the Plan shall control.

19. **CLAWBACK /RECOUPEMENT.** Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment or recovery by the Company in accordance with the terms of: (i) the Company’s Incentive Compensation Recoupment Policy, (ii) The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, and (iii) any compensation recovery policy otherwise required by applicable law or listing requirements, in each case to the extent applicable.

20. **SEVERABILITY.** If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

21. **EFFECT ON OTHER EMPLOYEE BENEFIT PLANS.** The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company’s or any Affiliate’s employee benefit plans.

22. **AMENDMENT.** This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that no such amendment adversely affecting your rights hereunder may be made without your written consent. Without limiting the
foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the grant as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

23. **NO OBLIGATION TO MINIMIZE TAXES.** The Company has no duty or obligation to minimize the tax consequences to you of this Award and will not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by accepting this Award, you have agreed that you have done so or knowingly and voluntarily declined to do so.
Appendix A

The provisions set forth on this Appendix A shall apply to the extent the Award is a Non-Exempt Award and shall supersede any provisions to the contrary set forth in the Plan or in any other section of the Agreement to which this Appendix A is attached.

1. The provisions of this Section 1 are intended to apply to the extent your Award is a Non-Exempt Award because of the terms of a severance arrangement or other agreement between you and the Company, if any, that provide for acceleration of vesting of your Award and issuance of the shares in respect of the Award upon your termination of employment or separation from service (as such term is defined in Section 409A(a)(2)(A)(i) of the Code (and without regard to any alternative definition thereunder) (“Separation from Service”) and such severance benefit does not satisfy the requirements for an exemption from application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(4) or 1.409A-1(b)(9) (“Non-Exempt Severance Arrangement”). To the extent your Award is a Non-Exempt Award due to application of a Non-Exempt Severance Arrangement, the following provisions in this Section 1 of Appendix A shall supersede anything to the contrary in Section 6(a) of the Award Agreement.

(a) If your Award vests in the ordinary course during your Continuous Service in accordance with the vesting schedule set forth in the Grant Notice, without accelerating vesting under the terms of a Non-Exempt Severance Arrangement, in no event will the shares be issued in respect of your Award any later than the later of: (i) December 31st of the calendar year that includes the applicable vesting date and (ii) the 60th day that follows the applicable vesting date.

(b) If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were in effect as of the date of grant of your Award and, therefore, are part of the terms of your Award as of the date of grant, then the shares will be earlier issued in respect of your Award upon your Separation from Service in accordance with the terms of the Non-Exempt Severance Arrangement, but in no event later than the 60th day that follows the date of your Separation from Service. However, if at the time the shares would otherwise be issued you are subject to the distribution limitations contained in Section 409A applicable to “specified employees,” as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six (6) months following the date of your Separation from Service, or, if earlier, the date of your death that occurs within such six month period.

(c) If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were not in effect as of the date of grant of the Award and, therefore, are not a part of the terms of your Award on the date of grant, then such acceleration of vesting of your Award shall not accelerate the issuance date of the shares, but the shares shall instead be issued on the same schedule as set forth in the Grant Notice as if they had vested in the ordinary course during your Continuous Service notwithstanding the vesting acceleration of the Award. Such issuance schedule is intended to satisfy the requirements of payment on a specified date or pursuant to a fixed schedule, as provided under Treasury Regulations Section 1.409A-3(a)(4).
2. **Permitted Treatment of Non-Exempt Awards Upon a Corporate Transaction for Employees and Consultants.** The provisions in this Section 2 shall apply and shall supersede anything to the contrary that may be set forth in the Plan with respect to the permitted treatment of your Non-Exempt Award in connection with a Corporate Transaction if you were either an Employee or Consultant upon the applicable date of grant of your Non-Exempt Award.

(a) **Vested Non-Exempt Awards:** To the extent your Non-Exempt Award has vested in accordance with its terms upon or prior to the date of a Corporate Transaction (such portion of your Non-Exempt Award is a “Vested Non-Exempt Award”), then the following provisions shall apply.

(i) If the Corporate Transaction is also a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company’s assets, as described in Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A-3(i)(5) (a “409A Change of Control”), then the surviving or acquiring corporation (or its parent company) (the “Acquiring Entity”) may not assume, continue or substitute your Vested Non-Exempt Award. Upon the 409A Change of Control the settlement of your Vested Non-Exempt Award will automatically be accelerated and the shares will be immediately issued in respect of your Vested Non-Exempt Award. Alternatively, the Company may instead provide that you will receive a cash settlement equal to the Fair Market Value of the shares that would otherwise be issued to you upon the 409A Change of Control.

(ii) If the Corporate Transaction is not also a 409A Change of Control, then the Acquiring Entity must either assume, continue or substitute your Vested Non-Exempt Award. The shares to be issued in respect of your Vested Non-Exempt Award shall be issued to you by the Acquiring Entity on the same schedule that the shares would have been issued to you if the Corporate Transaction had not occurred. In the Acquiring Entity’s discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to you on such issuance dates, with the determination of the Fair Market Value of the shares made on the date of the Corporate Transaction.

(b) **Unvested Non-Exempt Awards:** To the extent your Non-Exempt Award has not vested in accordance with its terms upon or prior to the date of any Corporate Transaction, (such portion of your Non-Exempt Award is an “Unvested Non-Exempt Award”), then the following provisions shall apply.

(i) If the Acquiring Entity will not assume, substitute or continue your Unvested Non-Exempt Award, then such Award shall automatically terminate and be forfeited upon the Corporate Transaction with no consideration payable to you in respect of your forfeited Unvested Non-Exempt Award. Notwithstanding the foregoing, to the extent permitted and in compliance with the requirements of Section 409A, the Company may in its discretion determine to elect to accelerate the vesting and settlement of the Unvested Non-Exempt Award upon the Corporate Transaction, or instead substitute a cash payment equal to the Fair Market Value of such shares that would otherwise be issued to you, as further provided in Section 4(b) below. In the absence of such discretionary election by the Company, your Unvested Non-Exempt Award shall be forfeited without payment of any consideration to you if the Acquiring Entity will not assume, substitute or continue your Unvested Non-Exempt Award in connection with the Corporate Transaction.

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(ii) The foregoing treatment shall apply with respect to all Unvested Non-Exempt Awards upon any Corporate Transaction, and regardless of whether or not such Corporate Transaction is also a 409A Change of Control.

3. Permitted Treatment of Non-Exempt Awards Upon a Corporate Transaction for Non-Employee Directors. If you were a Director but not an Employee on the applicable grant date of your Non-Exempt Award and ("Non-Exempt Director Award"), the following provisions shall apply and shall supersede anything to the contrary that may be set forth in the Plan with respect to the permitted treatment of your Non-Exempt Director Award in connection with a Corporate Transaction.

(a) If the Corporate Transaction is also a 409A Change of Control then the Acquiring Entity may not assume, continue or substitute your Non-Exempt Director Award. Upon the 409A Change of Control the vesting and settlement of your Non-Exempt Director Award will automatically be accelerated and the shares will be immediately issued to you in respect of the Non-Exempt Director Award. Alternatively, the Company may provide that you will instead receive a cash settlement equal to the Fair Market Value of the shares that would otherwise be issued to you upon the 409A Change of Control pursuant to the preceding provision.

(b) If the Corporate Transaction is not also a 409A Change of Control, then the Acquiring Entity must either assume, continue or substitute your Non-Exempt Director Award. Unless otherwise determined by the Board, your Non-Exempt Director Award will remain subject to the same vesting and forfeiture restrictions that were applicable to the Award prior to the Corporate Transaction. The shares to be issued in respect of your Non-Exempt Director Award shall be issued to you by the Acquiring Entity on the same schedule that the shares would have been issued to you if the Corporate Transaction had not occurred. In the Acquiring Entity’s discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to you on such issuance dates, with the determination of Fair Market Value made on the date of the Corporate Transaction.

4. General Superseding Provisions. The provisions in this Section 4 shall apply and supersede anything to the contrary that may be set forth in the Plan, the Grant Notice or in any other section of the Agreement with respect to the permitted treatment of your Non-Exempt Award:

(a) Any exercise by the Board of discretion to accelerate the vesting of your Non-Exempt Award shall not result in any acceleration of the scheduled issuance dates for the shares in respect of the Non-Exempt Award unless earlier issuance of the shares upon the applicable vesting dates would be in compliance with the requirements of Section 409A.

(b) The Company explicitly reserves the right to earlier settle your Non-Exempt Award to the extent permitted and in compliance with the requirements of Section 409A, including pursuant to any of the exemptions available in Treasury Regulations Section 1.409A-3(j)(4)(ix).
(c) To the extent the terms of your Non-Exempt Award provide that it will be settled upon a Change in Control or Corporate Transaction, to the extent it is required for compliance with the requirements of Section 409A, the Change in Control or Corporate Transaction event triggering settlement must also constitute a 409A Change of Control. To the extent the terms of your Non-Exempt Award provides that it will be settled upon a termination of employment or termination of Continuous Service, to the extent it is required for compliance with the requirements of Section 409A, the termination event triggering settlement must also constitute a Separation From Service. However, if at the time the shares would otherwise be issued to you in connection with your “separation from service” you are subject to the distribution limitations contained in Section 409A applicable to “specified employees,” as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six (6) months following the date of your Separation From Service, or, if earlier, the date of your death that occurs within such six month period.

5. **Section 409A Compliance.** The provisions in this Agreement for delivery of the shares in respect of the Non-Exempt Award are intended to comply with the requirements of Section 409A so that the delivery of the shares to you in respect of your Non-Exempt Award will not trigger the additional tax imposed under Section 409A, and any ambiguities herein will be so interpreted.
Horizon Therapeutics Public Limited Company (the “Company”), pursuant to its 2014 Equity Incentive Plan (the “Plan”), hereby grants to you a restricted stock unit award (the “Award”) to purchase the Company’s Ordinary Shares. The following specific terms of the Award can be obtained by logging on to your StockCross brokerage account: [Participant, Date of Grant, Vesting Commencement Date, Number of Restricted Stock Units, Purchase Price per Ordinary Share, Vesting Schedule and Issuance Schedule]. These specific terms are incorporated by reference into this Grant Notice. This Award is subject to all of the terms and conditions as set forth herein and in the Restricted Stock Unit Agreement (the “Award Agreement”) and the Plan, all of which are available on the StockCross website. Capitalized terms are defined in the Plan or the Award Agreement shall have the meanings set forth in the Plan or the Award Agreement. The Purchase Price per Ordinary Share that may be issued in settlement of your Award is equal to the nominal value per Ordinary Share as of the Date of Grant and is subject to adjustment as provided in Section 4 of the Award Agreement.

Additional Terms/Acknowledgements: You must electronically accept the Award by logging into your StockCross account. If you have not set-up your StockCross brokerage account, the following information provided below will assist you in this process. Failure to do so may result in forfeiture of the Award. By electronically accepting the Award, you acknowledge receipt of, and understand and agree to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. You further acknowledge that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement, and the Plan set forth the entire understanding between you and the Company regarding the acquisition of shares in the Company and supersede all prior oral and written agreements on that subject with the exception of: (i) any written employment or severance arrangement that would provide for vesting acceleration of the Award upon the terms and conditions set forth therein, or (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law. By accepting this Award, the Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

STOCKCROSS FINANCIAL SERVICES BROKERAGE ACCOUNT
Horizon currently utilizes StockCross Financial Services as our online broker. StockCross Financial Services offers an internet website for viewing option data and for buying or selling your stock options.

To open your brokerage account (if you have not yet done so)
• Go to the StockCross website at www.stockcross.com
• Select the Green “Open an Account” menu item.
• Under the New Account Application screen, select “Employee Stock Plan Account” button to proceed with the brokerage application.
• If any additional documentation is needed, StockCross will contact you directly.
• Once the account is fully processed, you will receive a welcome email from StockCross, containing your account number and other useful information. This is generally within 72 hours.

If you have any questions or comments completing the brokerage application, please contact StockCross Corporate Services at 800-338-3965.

Viewing your Award
• Login to www.trading.stockcross.com using you StockCross account number and password established during registration
• Once logged into your StockCross account, select the menu item “Employee Stock Plan.” This will bring you into another window screen which provides a summary of your equity grants. **Please note that to view this information, you will need to disable popup blockers.**

• Select “Portfolio.” This will show you all equity grants that you have been granted.
Accepting your Award

- Login to www.trading.stockcross.com using your StockCross user name and password established during registration.
- Once logged into your StockCross account, select the link to Employee Stock Plans under the menu item “Employee Stock Plan.” This will bring you into another window screen which provides a summary of your equity grants. Please note that to view this information, you will need to disable popup blockers.
- Select “My Portfolio.” This will show you all equity grants that you have been granted.
- For your new equity grant, in the first column, click on the Orange “Accept Grant” Action Button.
- This will take you to an electronic acceptance window. For your reference, the Equity Agreement applicable to the Award is provided. If you agree with the terms and conditions of your equity grant, place your name in the signature box, type your name below, and check the agreement box. Click “Accept Grant to complete the acceptance.

IMPORTANT REMINDER: In order to avoid forfeiture of your Award, you must electronically accept your Award 30 days prior to your first vesting date.

Contact Horizon Therapeutics plc’s Senior Manager, Accounting and Global Equity Plan Administrator Garry Devine at 224-383-3037 or email gdevine@horizontherapeutics.com with any further questions regarding your awards.
Pursuant to the Restricted Stock Grant Notice (the "Grant Notice") and this Restricted Stock Unit Agreement (the "Agreement") and in consideration of your services, Horizon Therapeutics Public Limited Company (the "Company") has granted you a Restricted Stock Unit Award (the "Award") under its 2014 Equity Incentive Plan (the "Plan") and its Equity Long Term Incentive Program ("Program") for the number of restricted stock units referenced in the Grant Notice. Capitalized terms not explicitly defined in this Agreement shall have the same meanings given to them in the Plan, Program or the Grant Notice, as applicable. Except as otherwise explicitly provided herein, in the event of any conflict between the terms in this Agreement and the Plan or Program, the terms of the Plan or Program shall control.

The details of your Award, in addition to those set forth in the Grant Notice, the Program and the Plan, are as follows.

1. **GRANT OF THE AWARD.** This Award represents your right to be issued on a future date the number of Ordinary Shares that is equal to the number of restricted stock units indicated in the Grant Notice (the "Stock Units") which vest at the Purchase Price per Ordinary Share specified in your Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "Account") the number of Stock Units subject to the Award. As provided in the Program, the Award may be settled via a Substitute Cash Payment in lieu of an issuance of Ordinary Shares.

2. **VESTING.** Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the Vesting Criteria. Except as otherwise specified in the Program or the Vesting Criteria, upon termination of your Continuous Service, the Stock Units credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in such Stock Units or the Ordinary Shares to be issued in respect of such portion of the Award.

3. **METHOD OF PAYMENT.** On or before the time you receive a distribution of the Ordinary Shares in settlement of your Stock Units, you hereby authorize the Company or any Affiliate to satisfy the payment of the Purchase Price per Ordinary Share with respect to such Ordinary Shares by withholding such payment from payroll and any other cash amounts otherwise payable to you. If no cash amounts are otherwise payable to you by the Company and available for such deduction, you must provide timely payment of the applicable Purchase Price to the Company via cash or check and no obligation shall arise upon the Company to procure the issue or transfer of the Ordinary Shares unless and until the Company and/or any Affiliate are satisfied in their absolute discretion that you have satisfied such payment requirement. All amounts due are payable in United States dollars based, if applicable, upon the local currency to United States dollar exchange rate published in the West Coast edition of The Wall Street Journal on the applicable payment date (or, if such date is not a business day in the United States, the preceding business day in the United States).
4. **NUMBER OF STOCK UNITS, ORDINARY SHARES AND PURCHASE PRICE.**

(a) The number of Stock Units subject to your Award and the Purchase Price per Ordinary Share may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Furthermore, the Purchase Price per Ordinary Share will be automatically adjusted from time to time, as applicable, such that it shall at all times be equal to the nominal value per Ordinary Share as then in effect. In no event will the Purchase Price per Ordinary Share be less than the nominal value per Ordinary Share.

(b) Any additional Stock Units that become subject to the Award pursuant to this Section 4, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Stock Units covered by your Award.

(c) Notwithstanding the provisions of this Section 4, no fractional shares or rights for fractional Ordinary Shares shall be created pursuant to this Section 4. The Board shall, in its discretion, determine an equivalent benefit for any fractional shares or fractional shares that might be created by the adjustments referred to in this Section 4.

5. **SECURITIES LAW COMPLIANCE.** You may not be issued any shares in respect of your Award unless either (i) the shares are registered under the Securities Act; or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award also must comply with other applicable laws and regulations governing the Award, including, without limitation, the laws and regulations of the United States and your country of residence, and you will not receive such shares if the Company determines that such receipt would not be in material compliance with such laws and regulations.

6. **TRANSFER RESTRICTIONS.** Your Award is not transferable, except by will or by the laws of descent and distribution. In addition to any other limitation on transfer created by applicable securities laws, you agree not to assign, hypothecate, donate, encumber or otherwise dispose of any interest in any of the Ordinary Shares subject to the Award until the shares are issued to you in accordance with Section 7 of this Agreement. After the shares have been issued to you, you are free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such shares provided that any such actions are in compliance with the provisions herein, any applicable Company policies (including, but not limited to, insider trading and window period policies) and applicable securities laws. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, shall thereafter be entitled to receive any distribution of Ordinary Shares to which you were entitled at the time of your death pursuant to this Agreement.

7. **DATE OF ISSUANCE.** The Company will deliver to you a number of Ordinary Shares equal to the number of vested Stock Units subject to your Award, including any additional Stock Units received pursuant to Section 4 above that relate to those vested Stock Units, as soon as administratively practicable following the date of the Committee’s
determination of the number of Stock Units that will vest, but in no event later than 30 days following the date of such determination. Delivery of the shares pursuant to the provisions of this Section 7(a) is intended to comply with the requirements for the short-term deferral exemption available under Treasury Regulations Section 1.409A-1(b)(4) and shall be construed and administered in such manner. The form of such delivery of the shares (e.g., a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

8. **DIVIDENDS.** You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment as provided in the Plan; provided, however, that this sentence shall not apply with respect to any Ordinary Shares that are delivered to you in connection with your Award after such shares have been delivered to you.

9. **RESTRICTIVE LEGENDS.** The shares issued in respect of your Award shall be endorsed with appropriate legends determined by the Company.

10. **AWARD NOT A SERVICE CONTRACT.**

    (a) Your Continuous Service with the Company or an Affiliate is not for any specified term and may be terminated by you or by the Company or an Affiliate at any time, for any reason, with or without cause and with or without notice. Nothing in this Agreement (including, but not limited to, the vesting of your Award pursuant to the schedule set forth in the Grant Notice or the issuance of the shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

    (b) By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice is earned only by continuing as an employee, director or consultant at the will of the Company (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a “reorganization”). You further acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with your right or the Company’s right to terminate your Continuous Service at any time, with or without cause and with or without notice.
11. **WITHHOLDING OBLIGATIONS.**

(a) On or before the time you receive a distribution of the shares subject to your Award, or at any time thereafter as requested by the Company, you hereby authorize any required withholding from the Ordinary Shares issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate which arise in connection with your Award, as calculated based upon the maximum permitted withholding rate (the “Withholding Taxes”). The Company will satisfy the Withholding Taxes obligation relating to your Award by withholding Ordinary Shares from the Ordinary Shares issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date Ordinary Shares are issued to pursuant to Section 7) equal to the amount of such Withholding Taxes; provided, however, that the number of such Ordinary Shares so withheld shall not exceed the amount necessary to satisfy the Company’s tax withholding obligations as calculated using the maximum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes. Accordingly, on the applicable vesting date(s) Horizon will automatically reduce the number of shares issuable pursuant to your Award by the maximum number of whole Horizon shares with a fair market value that at such time does not exceed the Withholding Taxes, and you will be issued only the net remaining number of Horizon shares (the “Share Withholding Procedure”). Any remaining portion of the Withholding Taxes that is less than the fair market value of one Horizon share will be withheld from other payroll compensation otherwise payable to you. In determining the fair market value of Horizon’s shares for such purposes, the closing price of Horizon’s shares on the applicable vesting date will apply. Any adverse consequences to you arising in connection with such Share Withholding Procedure shall be your sole responsibility.

(b) Unless the tax withholding obligations of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to deliver to you any Ordinary Shares pursuant to this Award.

12. **PERSONAL DATA.** You understand that your employer, if applicable, the Company, and/or its Affiliates hold certain personal information about you. This information include your name, home address, telephone number, date of birth, social security or equivalent tax identification number, salary, nationality, job title, and details of your Award and all Ordinary Shares subject to your Award that have been granted, cancelled, vested, unvested, or are outstanding (the “Personal Data”).

You hereby declare your express consent to allowing your employer to transfer your Personal Data (name, home address, telephone number, date of birth, salary, nationality, job title, and details of the Award and all Ordinary Shares subject to such grant) outside the country in which you are employed or retained to its Affiliates, Horizon Pharma, Inc. and Horizon Pharma USA, Inc. which are located in the United States and their parent entity, Horizon Therapeutics Public Limited Company (together such entities are the “Company Group”). The legal persons for whom such Personal Data are intended are: Horizon Therapeutics Public Limited Company, Horizon

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13. ADDITIONAL ACKNOWLEDGEMENTS. You hereby consent and acknowledge that:

(a) Participation in the Plan is voluntary and therefore you must accept the terms and conditions of the Plan and this Award as a condition to participating in the Plan and receipt of the Award.

(b) The Plan is discretionary in nature and the Company can amend, cancel, or terminate it at any time.

(c) This Award and any other equity awards granted under the Plan are voluntary and occasional and do not create any contractual or other right to receive future awards or other benefits in lieu of future awards, even if similar awards have been granted repeatedly in the past.

(d) All determinations with respect to any such future awards, including, but not limited to, the time or times when such awards are granted, the number of Ordinary Shares, and performance and other conditions applied to the awards, will be at the sole discretion of the Company.

(e) The value of the Ordinary Shares and this Award is an extraordinary item of compensation, which is outside the scope of your employment, service contract or consulting agreement, if any. This Award shall not form part of any past, current or future entitlement to remuneration or benefits which you may have under any contract of employment with the Company nor form any part of any such contract of employment between you and the Company.

(f) The Ordinary Shares, this Award, or any income derived therefrom are a potential bonus payment not paid in lieu of any cash salary compensation and not part of normal or expected compensation or salary for any purposes, including, but not limited to, calculating any termination, severance, resignation, redundancy, end of service payments, bonuses, long-service awards, life or accident insurance benefits, pension or retirement benefits or similar payments.

(g) In the event of the involuntary termination of your Continuous Service, your eligibility to receive Ordinary Shares or payments under the Award or the Plan, if any, will terminate effective as of the date that you are no longer actively employed or retained regardless of any reasonable notice period mandated under local law, except as expressly provided in the Agreement.
The future value of the Ordinary Shares is unknown and cannot be predicted with certainty. You do not have, and will not assert, any claim or entitlement to compensation, indemnity or damages arising from the termination of this award or diminution in value of the Ordinary Shares and you irrevocably release the Company, its Affiliates and, if applicable, your employer, if different from the Company, from any such claim that may arise.

The Plan, the Program the Vesting Criteria and this Agreement set forth the entire understanding between you, the Company and any Affiliate regarding the acquisition of the Ordinary Shares and supersedes all prior oral and written agreements pertaining to this Award.

14. **UNSECURED OBLIGATION.** Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company’s obligation, if any, to issue shares pursuant to this Agreement. You shall not have voting or any other rights as a shareholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 7 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a shareholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

15. **OTHER DOCUMENTS.** You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company’s policy permitting officers, directors and other specified individuals to sell shares only during certain “window” periods and the Company’s insider trading policy, in effect from time to time.

16. **NOTICES.** Any notices provided for in your Award or the Plan shall be given in writing (including electronically) and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award you consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

17. **MISCELLANEOUS.**

(a) The rights and obligations of the Company under your Award shall be transferable to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by the Company’s successors and assigns. Your rights and obligations under your Award may only be assigned with the prior written consent of the Company.
(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award, and fully understand all provisions of your Award.

(d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

18. GOVERNING PLAN DOCUMENT. Your Award is subject to all the provisions of the Plan and the Program, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan and the Program. Except as expressly provided in this Agreement, in the event of any conflict between the provisions of your Award and those of the Plan or the Program, the provisions of the Plan or Program shall control.

19. CLAWBACK/RECOUPMENT. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment or recovery by the Company in accordance with the terms of: (i) the Company’s Incentive Compensation Recoupment Policy, (ii) The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, and (iii) any compensation recovery policy otherwise required by applicable law or listing requirements, in each case to the extent applicable.

20. SEVERABILITY. If all or any part of this Agreement, the Plan or the Program is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement, the Plan or the Program not declared to be unlawful or invalid. Any Section of this Agreement, the Plan or the Program (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

21. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company’s or any Affiliate’s employee benefit plans.
22. **AMENDMENT.** This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that no such amendment adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the grant as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

23. **NO OBLIGATION TO MINIMIZE TAXES.** The Company has no duty or obligation to minimize the tax consequences to you of this Award and will not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by accepting the Award, you have agreed that you have done so or knowingly and voluntarily declined to do so.
Horizon Therapeutics Public Limited Company (the “Company”), pursuant to its 2014 Equity Incentive Plan (the “Plan”) and its Equity Long Term Incentive Program that became effective on January 5, 2018 (the “Program”), granted to you a restricted stock unit award (the “Award”) to purchase the Company’s Ordinary Shares. The following specific terms of the Award can be obtained by logging on to your StockCross brokerage account: Participant, Date of Grant, Number of Restricted Stock Units, Purchase Price per Ordinary Share, and Vesting Criteria.

These specific terms are incorporated by reference into this Grant Notice. This Award is subject to all of the terms and conditions as set forth herein and in the Restricted Stock Unit Agreement (the “Award Agreement”), the Plan, the Program, and the Vesting Criteria, all of which are available on the StockCross website. Capitalized terms are defined in the Plan or the Award Agreement shall have the meanings set forth in the Plan, the Program or the Award Agreement. The Purchase Price per Ordinary Share that may be issued in settlement of your Award is equal to the nominal value per Ordinary Share as of the Date of Grant and is subject to adjustment as provided in Section 4 of the Award Agreement. The Award is subject to all the terms and conditions of the Program and the Vesting Criteria, and in the event of any conflict between the terms of the Program or the Vesting Criteria and the terms set forth in this Restricted Stock Unit Grant Notice or the Award Agreement, the terms of the Program or Vesting Criteria shall control.

Additional Terms/Acknowledgements: You must electronically accept the Award by logging into your StockCross account. If you have not set-up your StockCross brokerage account, the following information provided below will assist you in this process. Failure to do so may result in forfeiture of the Award. By electronically accepting the Award, you acknowledge receipt of, and understand and agree to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. You further acknowledge that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement, the Program and the Plan set forth the entire understanding between you and the Company regarding the acquisition of shares in the Company and supersede all prior oral and written agreements on that subject with the exception of: (i) any written employment or severance arrangement that would provide for vesting acceleration of the Award upon the terms and conditions set forth therein, or (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law. By accepting this Award, the Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

STOCKCROSS FINANCIAL SERVICES BROKERAGE ACCOUNT

Horizon currently utilizes StockCross Financial Services as our online broker. StockCross Financial Services offers an internet website for viewing Award data and for buying or selling shares that may be issued in settlement of your Award.

To open your brokerage account

- Go to the StockCross website at www.stockcross.com.
- Select the red “Employee Stock Plans” menu item.
- Under the “Get Started” window, select the blue menu button “Open an Account.”
- Under the New Account Application screen, select “Employee Stock Option Plan ESOP” button to proceed with the brokerage application.
- You will receive a welcome email from StockCross within 72 hours, containing your account number and other useful information
If you have any questions or comments completing the brokerage application, please contact the StockCross New Accounts team at 800-225-6196 ext. 2442.
Viewing your Award

- Login to [www.stockcross.com](http://www.stockcross.com) using your StockCross account number and password established during registration.
- Once logged into your StockCross account, select the menu item “Employee Stock Plan.” This will bring you into another window screen which provides a summary of your equity grants. **Please note that to view this information, you will need to disable popup blockers.**
- Select “My Portfolio.” This will show you all equity grants that you have been granted.

Accepting your Award

- Login to [www.stockcross.com](http://www.stockcross.com) using your StockCross account number and password established during registration.
- Once logged into your StockCross account, select the menu item “Employee Stock Plan.” This will bring you into another window screen which provides a summary of your equity grants. **Please note that to view this information, you will need to disable popup blockers.**
- Select “My Portfolio.” This will show you all equity grants that you have been granted.
- Selecting “View” will take you to an electronic acceptance window. For your reference, the Equity Plan Agreement applicable to the Award is provided. If you agree with the terms and conditions of your equity grant, select the green “Accept” button.

**IMPORTANT REMINDER:** In order to avoid forfeiture of your Award, you must electronically accept your Award 30 days prior to your first vesting date.

Contact Horizon Therapeutics plc’s Senior Manager, Accounting and Global Equity Plan Administrator Garry Devine at 224-383-3037 or email gdevine@horizontherapeutics.com with any further questions regarding your awards.
1. GENERAL.

(a) Eligible Award Recipients. The persons eligible to receive Awards are Non-employee Directors and Consultants. This Plan is intended as the successor to the Horizon Pharma, Inc. 2011 Equity Incentive Plan with respect to grants to Non-employee Directors and Consultants.

(b) Available Awards. The Plan provides for the grant of the following Awards: (i) Nonstatutory Stock Options, (ii) Stock Appreciation Rights, (iii) Restricted Stock Awards, (iv) Restricted Stock Unit Awards, and (v) Other Stock Awards.

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

2. ADMINISTRATION.

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

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

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

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

(iii) To settle all controversies regarding the Plan and Awards granted under it.
(iv) To accelerate the time at which an Award may first be exercised or the time during which an Award or any part thereof will vest in accordance with the Plan, notwithstanding the provisions in the Award stating the time at which it may first be exercised or the time during which it will vest.

(v) To suspend or terminate the Plan at any time. Suspension or termination of the Plan shall not impair rights and obligations under any Award granted while the Plan is in effect except with the written consent of the affected Participant.

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

(vii) To submit any amendment to the Plan for shareholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of Rule 16b-3.

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

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

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Non-employee Directors or Consultants who are foreign nationals or provide services outside the United States.
(c) Delegation to Committee.

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

(ii) Rule 16b-3 Compliance. The Committee may consist solely of two or more Non-Employee Directors, in accordance with Rule 16b-3.

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

(e) Cancellation and Re-Grant of Stock Awards. Neither the Board nor any Committee shall have the authority to: (i) reduce the exercise price of any outstanding Options or Stock Appreciation Rights under the Plan, or (ii) cancel any outstanding Options or Stock Appreciation Rights that have an exercise price or strike price greater than the current Fair Market Value of the Ordinary Shares in exchange for cash or other Stock Awards under the Plan, unless the stockholders of the Company have approved such an action within twelve (12) months prior to such an event, provided that the exercise price of any such outstanding Options or Stock Appreciation Rights under the Plan may not be reduced below the nominal value of an Ordinary Share.

3. SHARES SUBJECT TO THE PLAN.

(a) Share Reserve.

(i) Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of Ordinary Shares of the Company that may be issued pursuant to Stock Awards after the Effective Date shall not exceed Two Million Two Hundred Fifty Thousand (2,250,000) Ordinary Shares. For clarity, the limitation in this Section 3(a)(i) is a limitation on the number of Ordinary Shares that may be issued pursuant to the Plan. Accordingly, this Section 3(a)(i) does not limit the granting of Stock Awards except as provided in Section 7(a). Shares may be issued in connection with a merger or acquisition as permitted by, as applicable, NASDAQ Marketplace Rule 4350(i)(1)(A)(iii), NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable stock exchange rules, and such issuance shall not reduce the number of Ordinary Shares available for issuance under the Plan. Furthermore, if a Stock Award or any portion thereof (i) expires or otherwise terminates without all of the Ordinary Shares covered by such Stock Award having been issued or (ii) is settled in cash (i.e., the Participant receives cash rather than Ordinary Shares), such expiration, termination or settlement shall not reduce (or otherwise offset) the number of Ordinary Shares that may be available for issuance under the Plan.

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(ii) Subject to subsection 3(b), the number of Ordinary Shares available for issuance under the Plan shall be reduced by: (i) one (1) Ordinary Share for each Ordinary Share issued pursuant to (A) an Option granted under Section 5, or (B) a Stock Appreciation Right granted under Section 5 with respect to which the strike price is at least one hundred percent (100%) of the Fair Market Value of the underlying Ordinary Shares on the date of grant; (ii) 1.29 Ordinary Shares for each Ordinary Share issued pursuant to a Restricted Stock Award, Restricted Stock Unit Award, or Other Stock Award granted prior to May 2, 2019, and (iii) 1.40 Ordinary Shares for each Ordinary Share issued pursuant to a Restricted Stock Award, Restricted Stock Unit Award, or Other Stock Award granted on or after May 2, 2019.

(b) Reversion of Shares to the Share Reserve.

(i) Shares Available For Subsequent Issuance. If any Stock Award is forfeited back to the Company or Ordinary Shares are redeemed or repurchased by the Company or any Affiliate (in accordance with applicable Irish law) because of the failure to meet a contingency or condition required to vest such Ordinary Shares, then the Ordinary Shares that are forfeited, redeemed or repurchased shall revert to and again become available for issuance under the Plan. Notwithstanding the provisions of this Section 3(b)(i), to the extent there is issued an Ordinary Share pursuant to a Stock Award under the Plan (other than an Option or Stock Appreciation Right) and such Ordinary Share becomes available for issuance under the Plan pursuant to Section 3(a)(i) or this Section 3(b)(i), then the number of Ordinary Shares available for issuance under the Plan shall increase by 1.29 shares for each such Ordinary Share returning to the Plan prior to May 2, 2019 and 1.40 shares for each such Ordinary Share returning to the Plan on or after May 2, 2019.

(ii) Shares Not Available For Subsequent Issuance. If any Ordinary Shares subject to a Stock Award are not delivered to a Participant because the Stock Award is exercised through a reduction of Ordinary Shares subject to the Stock Award (i.e., “net exercised”), the number of Ordinary Shares that are not delivered to the Participant shall not remain available for issuance under the Plan. Also, any Ordinary Shares withheld by the Company pursuant to Section 8(f) or withheld or tendered as consideration for the exercise of an Option or purchase of any other Stock Award shall not again become available for issuance under the Plan.

(c) Source of Shares. The Ordinary Shares issuable under the Plan shall be authorized but unissued or reacquired Ordinary Shares, including Ordinary Shares redeemed or repurchased by the Company or any Affiliate on the open market or otherwise, in accordance with applicable Irish Law.

4. ELIGIBILITY.

Stock Awards may be granted to Non-employee Directors and Consultants as determined by the Board.

5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option or SAR shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. All Options shall be Nonstatutory Stock Options at the time of grant. The provisions of separate Options or SARs need not be identical; provided, however, that each Option Agreement or Stock Appreciation Right Agreement shall conform to (through incorporation of provisions hereof by reference in the applicable Award Agreement or otherwise) the substance of each of the following provisions:
(a) Term. No Option or SAR shall be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Award Agreement.

(b) Exercise Price. The exercise price (or strike price) of each Option or SAR shall be not less than one hundred percent (100%) of the Fair Market Value of the Ordinary Shares subject to the Option or SAR on the date the Option or SAR is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise price (or strike price) lower than one hundred percent (100%) of the Fair Market Value of the Ordinary Shares subject to the Option or SAR if such Option or SAR is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Sections 409A and, if applicable, 424(a) of the Code, provided that in all cases the exercise price is not less than the nominal value of an Ordinary Share. Each SAR will be denominated in Ordinary Shares equivalents.

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

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

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

(iii) by a “net exercise” arrangement pursuant to which the Company will reduce the number of Ordinary Shares issuable upon exercise by the largest whole number of Ordinary Shares with a Fair Market Value that does not exceed the aggregate exercise price; provided, however, that:

(1) the Company shall accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole Ordinary Shares to be issued;

(2) irrespective of whether a “net exercise” arrangement is used, the nominal value of each newly issued Ordinary Shares will be fully paid up in cash; and
Ordinary Shares will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) Ordinary Shares issuable upon exercise are reduced to pay the exercise price pursuant to the “net exercise,” (B) Ordinary Shares are delivered to the Participant as a result of such exercise, and (C) Ordinary Shares are withheld to satisfy tax withholding obligations; or

(iv) in any other form of legal consideration that may be acceptable to the Board and permissible under applicable law.

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

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

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

(ii) Domestic Relations Orders. Notwithstanding the foregoing, an Option or SAR may be transferred pursuant to a domestic relations order.

(iii) Beneficiary Designation. Notwithstanding the foregoing, the Participant may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company and any broker designated by the Company to effect Option exercises, designate a third party who, in the event of the death of the Participant, shall thereafter be entitled to exercise the Option or SAR and receive the Ordinary Shares or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant’s estate shall be entitled to exercise the Option or SAR and receive the Ordinary Shares or other consideration resulting from such exercise.
(f) Vesting Generally. The total number of Ordinary Shares subject to an Option or SAR may vest and therefore become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of Ordinary Shares as to which an Option or SAR may be exercised.

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

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

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

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

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARS.

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

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) services to the Company or an Affiliate or (C) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law, provided however, that where Ordinary Shares are issued pursuant to a Restricted Stock Award the nominal value of each newly issued Ordinary Share is fully paid up.

(ii) Vesting. Ordinary Shares awarded under a Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.
(iii) Termination of Participant's Continuous Service. If a Participant’s Continuous Service terminates, the Company or any Affiliate may receive through a forfeiture condition or a repurchase right any or all of the Ordinary Shares held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

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

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

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

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Ordinary Shares subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Ordinary Shares subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law, provided, however, that where Ordinary Shares are issued pursuant to a Restricted Stock Unit Award, the nominal value of each newly issued Ordinary Share is fully paid up.

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

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

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the Ordinary Shares (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.
(v) **Dividend Equivalents.** Dividend equivalents may be credited in respect of Ordinary Shares covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional Ordinary Shares covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional Ordinary Shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

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

(c) **Other Stock Awards.** Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Ordinary Shares, including the appreciation in value thereof (e.g., options or share rights with an exercise price or strike price less than 100% of the Fair Market Value of the Ordinary Shares at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Board shall have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of Ordinary Shares (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards; provided, however, that where Ordinary Shares are issued pursuant to any Other Stock Award, the nominal value of each newly issued Ordinary Share is fully paid up.

7. **COVENANTS OF THE COMPANY.**

(a) **Availability of Shares.** During the terms of the Stock Awards, the Company shall keep available at all times the authorized but unissued Ordinary Shares reasonably required to satisfy such Stock Awards.

(b) **Securities Law Compliance.** The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell Ordinary Shares upon exercise of the Stock Awards; provided, however, that this undertaking shall not require the Company to register under the Securities Act the Plan, any Stock Award or any Ordinary Shares issued or issuable pursuant to any such Stock Award. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Ordinary Shares under the Plan, the Company shall be relieved from any liability for failure to issue and sell Ordinary Shares upon exercise of such Stock Awards unless and until such authority is obtained. A Participant shall not be eligible for the grant of a Stock Award or the subsequent issuance of Ordinary Shares pursuant to the Stock Award if such grant or issuance would be in violation of any applicable securities law.
(c) **No Obligation to Notify or Minimize Taxes.** The Company and its Affiliates shall have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company and its Affiliates shall have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of a Stock Award or a possible period in which the Stock Award may not be exercised. The Company and its Affiliates have no duty or obligation to minimize the tax consequences of a Stock Award to the holder of such Stock Award.

8. **MISCELLANEOUS.**

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

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

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

   (d) **No Service Rights.** Nothing in the Plan, any Stock Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto shall confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Stock Award was granted or shall affect the right of the Company or an Affiliate to terminate (i) the service of a Consultant pursuant to the terms of such Consultant’s agreement with the Company or an Affiliate, or (ii) the service of a Non-employee Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate laws of the country or state in which the Company or the Affiliate is incorporated, as the case may be.

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

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

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

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

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

(i) the collection, use and processing of his Personal Data by the Company or any Subsidiary and the transfer of his Personal Data to any third party administrator of the Plan and any broker through whom Shares are to be sold on behalf of a Participant;

(ii) the Company, its Subsidiaries or any third party administrator of the Plan, transferring the Participant’s Personal Data amongst themselves for the purposes of implementing, administering and managing the Plan and the issue of Awards and the acquisition of Ordinary Shares pursuant to Awards;

(iii) the use of Personal Data by any such person for any such purposes; and

(iv) the transfer to and retention of Personal Data by third parties (including any situated outside the European Economic Area) for or in connection with such purposes.

9. **ADJUSTMENTS UPON CHANGES IN ORDINARY SHARES; OTHER CORPORATE EVENTS.**

(a) **Capitalization Adjustments.** In the event of a Capitalization Adjustment, the Board shall appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a)(i) and (ii) the class(es) and number of securities and price per Ordinary Share subject to outstanding Stock Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive.

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

(c) **Corporate Transaction.** The following provisions shall apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Stock Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of a Stock Award.
(i) **Stock Awards May Be Assumed.** In the event of a Corporate Transaction, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation’s parent company) may assume or continue any or all Stock Awards outstanding under the Plan or may substitute similar stock awards for Stock Awards outstanding under the Plan (including but not limited to, awards to acquire the same consideration paid to the shareholders of the Company pursuant to the Corporate Transaction), and any reacquisition or repurchase rights held by the Company in respect of Ordinary Shares issued pursuant to Stock Awards may be assigned by the Company to the successor of the Company (or the successor’s parent company, if any) in connection with such Corporate Transaction. A surviving corporation or acquiring corporation (or its parent) may choose to assume or continue only a portion of a Stock Award or substitute a similar stock award for only a portion of a Stock Award, or may choose to assume or continue the Stock Awards held by some, but not all Participants. The terms of any assumption, continuation or substitution shall be set by the Board.

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

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

(iv) **Payment for Stock Awards in Lieu of Exercise.** Notwithstanding the foregoing, in the event a Stock Award will terminate if not exercised prior to the effective time of a Corporate Transaction, the Board may provide, in its sole discretion, that the holder of such Stock Award may not exercise such Stock Award but will receive a payment, in such form as may be determined by the Board, equal in value, at the effective time, to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award (including, at the discretion of the Board, any unvested portion of such Stock Award), over (B) any exercise price payable by such holder in connection with such exercise.
(d) Change in Control. A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration shall occur.

10. TERMINATION OR SUSPENSION OF THE PLAN.

(a) Plan Term. The Board may suspend or terminate the Plan at any time. Unless terminated sooner by the Board, the Plan shall automatically terminate immediately after May 1, 2024. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

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

11. EFFECTIVE DATE OF PLAN.

The Plan originally became effective on the Effective Date. This amendment and restatement of the Plan document is effective on May 2, 2019, provided that this amendment and restatement of the Plan is approved by the Company’s shareholders at the annual general meeting of the shareholders of the Company held on such date.

12. CHOICE OF LAW.

The laws of the State of California shall govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state’s conflict of laws rules.

13. DEFINITIONS. As used in the Plan, the following definitions shall apply to the capitalized terms indicated below:

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

(b) "Award" means a Stock Award.

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

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

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

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

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the shareholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) the shareholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur, except for a liquidation into a parent corporation;
(iv) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by shareholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

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

For the avoidance of doubt, any one or more of the above events may be effected pursuant to (i) a compromise or arrangement sanctioned by the Irish courts under section 201 of the Companies Act 1963 (as may be amended, updated or replaced from time to time) (the “1963 Act”), or (ii) a scheme, contract or offer which has become binding on all shareholders pursuant to Section 204 of the 1963 Act., or (iii) a bid pursuant to Regulation 23 or 24 of the European Communities (Takeover Bids (Directive 2004/25/EC)) Regulations 2006.

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

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

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

(i) “Company” means Horizon Therapeutics Public Limited Company (formerly known as Horizon Pharma Public Limited Company), a company incorporated under the laws of Ireland.

(j) “Consultant” means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Non-employee Director, or payment of a fee for such service, shall not cause a Non-employee Director to be considered a “Consultant” for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company’s securities to such person.
(k) “Continuous Service” means that the Participant’s service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant’s service with the Company or an Affiliate, shall not terminate a Participant’s Continuous Service; provided, however, if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, in its sole discretion, such Participant’s Continuous Service shall be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company (or an Affiliate, if applicable), in that party’s sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer of the Company (or an Affiliate, if applicable), including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence shall be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company’s (or an Affiliate’s, if applicable) leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

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

(i) a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

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

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

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

(n) “Disability” means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than twelve (12) months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and shall be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.
(o) “Effective Date” means the effective date of this Plan, which is immediately prior to the effective time of the merger between Horizon Pharma, Inc. and Horizon Pharma Public Limited Company pursuant to the Transaction Agreement and Plan of Merger dated March 18, 2014.

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

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


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

(t) “Fair Market Value” means, as of any date, the value of the Ordinary Shares determined as follows:

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

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Ordinary Shares on the last market trading day prior to the day of determination, then the Fair Market Value shall be the closing selling price on the last preceding date for which such quotation exists.
(iii) In the absence of such markets for the Ordinary Shares, the Fair Market Value shall be determined by the Board in good faith and in a manner that complies with Sections 409A of the Code.

(u) “Non-Employee Director” means a Director who is not an Employee.

(v) “Nonstatutory Stock Option” means an Option not intended to qualify as an incentive stock option within the meaning of Section 422 of the Code and the regulations promulgated thereunder.

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

(x) “Option” means a Nonstatutory Stock Option to purchase Ordinary Shares granted pursuant to the Plan.

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

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

(aa) “Ordinary Shares” or “Shares” means the ordinary shares in the capital of the Company with a nominal value of US$0.0001 per share.

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

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

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

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

(ff) “Personal Data” has the same meaning as defined in the Data Protection Acts 1988 and 2003.

(ffc) “Plan” means this Horizon Therapeutics Public Limited Company 2014 Non-Employee Equity Plan.
(hh) “Restricted Stock Award” means an award of Ordinary Shares which is granted pursuant to the terms and conditions of Section 6(a).

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

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

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

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

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

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

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

(pp) “Stock Award” means any right to receive Ordinary Shares granted under the Plan, including a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, or any Other Stock Award.

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

(rr) “Subsidiary” means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%).
Pursuant to your Stock Option Grant Notice ("Grant Notice") and this Option Agreement (the "Agreement"), Horizon Therapeutics Public Limited Company (the "Company") has granted you an option under its 2014 Non-Employee Equity Plan (the "Plan") to purchase the number of the Company’s Ordinary Shares indicated in your Grant Notice at the exercise price indicated in your Grant Notice. Capitalized terms not explicitly defined in this Agreement but defined in the Plan shall have the same definitions as in the Plan.

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

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

3. **Method of Payment.** Payment of the applicable exercise price is due in full upon exercise of all or any part of your option. All amounts due are payable in United States dollars based, if applicable, upon the local currency to United States dollar exchange rate published in the West Coast edition of The Wall Street Journal on the date of exercise of your option (or, if the date of exercise is not a business day in the United States, the preceding business day in the United States). You may not exercise your option, and no obligation shall arise upon the Company to procure the issue or transfer of the Ordinary Shares, unless and until the Company and/or any Affiliate are satisfied in their absolute discretion that you have fully paid up in cash (or by check) the nominal value of each Ordinary Share subject to the exercised portion of the option. You may elect to make payment of the remaining portion of the option exercise price by remittance for the amount payable or in any other manner permitted by your Grant Notice, which may include one or more of the following:

   a. Provided that at the time of exercise the Ordinary Shares are publicly traded and quoted regularly in a source the Board deems reliable, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Ordinary Shares, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds.

   b. Subject to the consent of the Company at the time of exercise, by a “net exercise” arrangement pursuant to which the Company will reduce the number of Ordinary Shares issuable upon exercise of your option by the largest whole number of Ordinary Shares with a Fair Market Value that does not exceed the aggregate exercise price; provided, however, that:
1) the Company shall accept a cash or other payment from you to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole Ordinary Shares to be issued;

2) Ordinary Shares will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) Ordinary Shares issuable upon exercise are reduced to pay the exercise price pursuant to the "net exercise," (B) Ordinary Shares are delivered to you as a result of such exercise, and (C) Ordinary Shares are withheld to satisfy tax withholding obligations.

4. WHOLE SHARES. You may exercise your option only for whole Ordinary Shares.

5. SECURITIES LAW COMPLIANCE. Notwithstanding anything to the contrary contained herein, you may not exercise your option unless the Ordinary Shares issuable upon such exercise are then registered under the Securities Act or, if such Ordinary Shares are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with other applicable laws and regulations governing your option, including, without limitation, the laws and regulations of the United States and your country of residence, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations.

6. TERM. You may not exercise your option before the commencement of its term or after its term expires. The term of your option commences on the Date of Grant and expires upon the earliest of the following:

   a. three (3) months after the termination of your Continuous Service for any reason other than Cause, Disability or death, provided that if during any part of such three (3)-month period you may not exercise your option solely because of the condition set forth in the preceding paragraph relating to “Securities Law Compliance,” your option shall not expire until the earlier of the Expiration Date or until it shall have been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service;

   b. twelve (12) months after the termination of your Continuous Service due to your Disability;

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

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

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

7. EXERCISE.

   a. You may exercise the vested portion of your option (and the unvested portion of your option if your Grant Notice so permits) during its term by following the option
exercise instructions specified in your StockCross Financial Services brokerage account including adequate provision for payment of the option exercise price to the Company together with such additional documents as the Company may then require.

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

c. By exercising your option you agree that, as a condition to any exercise of your option, you must pay the nominal value of the Ordinary Shares by cash or check. The option will not be exercised, and the Ordinary Shares will not be issued to you until you pay the nominal value of the Ordinary Shares by cash or check.

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

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

10. Withholding Obligations.

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

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

c. You may not exercise your option and no obligation shall arise upon the Company to procure the issue or transfer of the Ordinary Shares unless and until the Company and/or any Affiliate are satisfied in their absolute discretion that either (i) you have made payment, or have made arrangements satisfactory to the Company and/or any Affiliate for the payment to it of such sum as is sufficient to meet any withholding liability to Taxation (defined below) in any jurisdiction which is or would be recoverable from you following exercise of your option and/or the issue of Ordinary Shares by the Company arising from such exercise, and in respect of which the Company and/or any Affiliate is liable to account in any jurisdiction; or (ii) you have entered into an agreement with the Company and/or an Affiliate (in a form satisfactory to the Company or such Affiliate) to ensure that such a payment is made by you including, without limitation, amounts in respect of any employers’ social security (or the local law equivalent thereof) or other forms of Taxation. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company shall have no obligation to issue a certificate for such Ordinary Shares or release such Ordinary Shares from any escrow provided for herein unless such obligations are satisfied. “Taxation” shall include all forms of taxation including employees’ and employers’ social security, income tax and any other taxes of whatever nature in any jurisdiction together with any amount payable by an Affiliate in respect of which the Affiliate has a duty to account as a result of any laws of any jurisdiction relating to taxation.

11. PERSONAL DATA. You understand that the Company, and/or its Affiliates hold certain personal information about you. This information include your name, home address, telephone number, date of birth, social security or equivalent tax identification number, salary, nationality, job title, and details of your option grant and all Ordinary Shares subject to such grant that have been granted, cancelled, vested, unvested, or are outstanding (the “Personal Data”).

You hereby declare your express consent to allowing the Company and/or its Affiliates to transfer your Personal Data (name, home address, telephone number, date of birth, salary, nationality, job title, and details of the option grant and all Ordinary Shares subject to such grant) outside the country in which you are retained to its Affiliates, Horizon Pharma, Inc. and Horizon Pharma USA, Inc. which are located in the United States and their parent entity, Horizon Therapeutics Public Limited Company (together such entities are the “Company Group”). The legal persons for whom such Personal Data are intended are: Horizon Therapeutics Public Limited Company, Horizon Pharma, Inc., Horizon Pharma USA, Inc., StockCross Financial Services and any other third party entity providing option and/or Plan administration services to the Company and for the sole purpose of facilitating the transactions contemplated by this Stock Agreement. You have the right to access and correct your Personal Data by applying to the Company representative identified on the Grant Notice (the “Representative”). You have the right to revoke this consent at any time with future effect towards the Company Group by providing written notice to the Representative of such revocation (the “Revocation Notice”). You may also elect to exercise
your option, to the extent such option is vested, by following the option exercise instructions specified in your StockCross Financial Services brokerage account and making provision for payment of the applicable option exercise price to the Company concurrently with your Revocation Notice, in which case your consent revocation will become effective as soon as administratively practicable following the execution of your option exercise election and the issuance of the Ordinary Shares subject to the option to you. If you do not follow the option exercise instructions specified in your StockCross Financial Services brokerage account or provide for payment of the option exercise price along with your Revocation Notice, or to the extent your option is unvested at the time you elect to provide a Revocation Notice, then as soon as administratively practicable following the Representative’s receipt of the Revocation Notice your consent revocation will become effective and your option shall automatically immediately terminate and be forfeited, and you will not receive any Ordinary Shares or any other consideration in respect of such forfeited option.

12. ADDITIONAL ACKNOWLEDGEMENTS. You hereby consent and acknowledge that:

a. Participation in the Plan is voluntary and therefore you must accept the terms and conditions of the Plan and this option as a condition to participating in the Plan and receipt of this option.

b. The Plan is discretionary in nature and the Company can amend, cancel, or terminate it at any time.

c. This option and any other options under the Plan are voluntary and occasional and do not create any contractual or other right to receive future options or other benefits in lieu of future options, even if similar options have been granted repeatedly in the past.

d. All determinations with respect to any such future options, including, but not limited to, the time or times when such options are made, the number of Ordinary Shares, and performance and other conditions applied to the options, will be at the sole discretion of the Company.

e. The value of the Ordinary Shares and this option is an extraordinary item of compensation, which is outside the scope of your service contract or consulting agreement, if any. This option shall not form part of any past, current or future entitlement to remuneration or benefits which you may have under any service contract with the Company nor form any part of any such service contract between you and the Company.

f. The Ordinary Shares, this option, or any income derived therefrom are a potential bonus payment not paid in lieu of any cash compensation and not part of normal or expected compensation for any purposes, including, but not limited to, calculating any termination, severance, resignation, redundancy, end of service payments, bonuses, long-service awards, life or accident insurance benefits, pension or retirement benefits or similar payments.

g. In the event of the involuntary termination of your Continuous Service, your eligibility to receive Ordinary Shares or payments under the option or the Plan, if any, will terminate effective as of the date that you are no longer actively retained regardless of any reasonable notice period mandated under local law, except as expressly provided in the option.
h. The future value of the Ordinary Shares is unknown and cannot be predicted with certainty. You do not have, and will not assert, any claim or entitlement to compensation, indemnity or damages arising from the termination of this option or diminution in value of the Ordinary Shares and you irrevocably release the Company, its Affiliates and, if applicable, the entity to which you provide services, if different from the Company, from any such claim that may arise.

i. The Plan and this option set forth the entire understanding between you, the Company and any Affiliate regarding the acquisition of the Ordinary Shares and supersedes all prior oral and written agreements pertaining to this option.

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

14. **OTHER DOCUMENTS.** You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company’s policy permitting officers, directors and other specified individuals to sell shares only during certain “window” periods and the Company’s insider trading policy, in effect from time to time.

15. **NOTICES.** Any notices provided for in your option or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting the option you consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

16. **MISCELLANEOUS.**

   a. The rights and obligations of the Company under your option shall be transferable to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by the Company’s successors and assigns. Your rights and obligations under your option may only be assigned with the prior written consent of the Company.
b. You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your option.

c. You acknowledge and agree that you have reviewed your option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your option, and fully understand all provisions of your option.

d. This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

e. All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

17. GOVERNING PLAN DOCUMENT. Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of your option and those of the Plan, the provisions of the Plan shall control. In addition, your option (and any compensation paid or shares issued under your option) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

18. SEVERABILITY. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

19. EFFECT ON OTHER BENEFIT PLANS. The value of the option subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company’s or any Affiliate’s benefit plans.

20. AMENDMENT. This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that no such amendment adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this
Agreement in any way it may deem necessary or advisable to carry out the purpose of the grant as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the option which is then subject to restrictions as provided herein.
Horizon Therapeutics Public Limited Company (the “Company”), pursuant to its 2014 Non-Employee Equity Plan (the “Plan”), hereby grants to you a non-statutory stock option (the “Option”) to purchase the Company’s Ordinary Shares. The following specific terms of the Option can be obtained by logging on to your StockCross brokerage account: [Optionholder, Date of Grant, Vesting Commencement Date, Number of Ordinary Shares Subject to Option, Exercise Price (Per Share), Total Exercise Price, Expiration Date, Exercise Schedule, Vesting Schedule and Payment]. These specific terms are incorporated by reference into this Grant Notice. This Option is subject to all of the terms and conditions as set forth herein and in the Option Agreement and the Plan, all of which are available on the StockCross website.

Additional Terms/Acknowledgements: You must electronically accept the Option by logging into your StockCross account. If you have not set-up your StockCross brokerage account, the following information provided below will assist you in this process. Failure to do so may result in forfeiture of the Option. By electronically accepting the Option, you acknowledge receipt of, and understand and agree to, this Stock Option Grant Notice, the Option Agreement and the Plan. You further acknowledge that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between you and the Company regarding the acquisition of shares in the Company and supersede all prior oral and written agreements on that subject with the exception of awards previously granted and delivered to you under the Plan.

STOCKCROSS FINANCIAL SERVICES BROKERAGE ACCOUNT

The Company currently utilizes StockCross Financial Services as our online broker. StockCross Financial Services offers an internet website for viewing option data and for buying or selling stock your stock options. To open your brokerage account, you can do so by visiting the StockCross website at www.stockcross.com, select the red “Employee Stock Plans” menu item. Under the “Get Started” window, select the blue menu button “Open an Account.” Additionally, under the New Account Application screen, select “Employee Stock Option Plan ESOP” button to proceed with the brokerage application.

If you have any questions or comments completing the brokerage application, please contact the StockCross New Accounts team at 800-225-6196.

OPTION ACCEPTANCE (via StockCross after completing your brokerage application)

Please follow steps 1 through 7 to electronically accept your Option.

1. Login to www.stockcross.com
2. Select the red menu item “Employee Stock Plans.”
3. In the Get Started screen, enter “HZNP” for the Company’s stock ticker symbol.
4. Under the StockCross Customer Account Login screen, enter your StockCross account number and password.
5. Once logged into your StockCross account, select the menu item “Employee Stock Plan.” This will bring you into another window screen which provides a summary of your equity grants. Please note that to view this information, you will need to disable popup blockers.
6. Select “My Portfolio.” This will show you all equity grants that you have been granted. For your new equity grant, in the last column, click on the “View” hyperlink.
7. Selecting “View” in step 7 will take you to an electronic acceptance window. For your reference, the Stock Option Agreement applicable to the Option is provided for your reference. If you agree with the terms and conditions of your equity grant, select the green “Accept” button.

IMPORTANT REMINDER: In order to avoid forfeiture of your Option, you must electronically accept your Option 30 days prior to your first vesting date.

Contact Horizon Therapeutics plc’s Senior Manager, Accounting and Global Equity Plan Administrator Garry Devine at 224-383-3037 or email gdevine@horizontherapeutics.com with any further questions regarding your awards.
Pursuant to the Restricted Stock Unit Grant Notice (the “Grant Notice”) and this Restricted Stock Unit Agreement (the “Agreement”) and in consideration of your services, Horizon Therapeutics Public Limited Company (the “Company”) has granted you a Restricted Stock Unit Award (the “Award”) under its 2014 Non-Employee Equity Plan (the “Plan”) for the number of restricted stock units referenced in the Grant Notice. Capitalized terms not explicitly defined in this Agreement shall have the same meanings given to them in the Plan or the Grant Notice, as applicable. Except as otherwise explicitly provided herein, in the event of any conflict between the terms in this Agreement and the Plan, the terms of the Plan shall control.

The details of your Award, in addition to those set forth in the Grant Notice and the Plan, are as follows.

1. **Grant of the Award.** This Award represents your right to be issued on a future date the number of Ordinary Shares that is equal to the number of restricted stock units indicated in the Grant Notice (the “Stock Units”) at the Purchase Price per Ordinary Share specified in your Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the “Account”) the number of Stock Units subject to the Award.

2. **Vesting.** Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service. Upon such termination of your Continuous Service, the Stock Units credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in such Stock Units or the Ordinary Shares to be issued in respect of such portion of the Award.

3. **Method of Payment.** On or before the time you receive a distribution of the Ordinary Shares in settlement of your Stock Units, you hereby authorize the Company or any Affiliate to satisfy the payment of the Purchase Price per Ordinary Share with respect to such Ordinary Shares by withholding such payment from any other cash amounts otherwise payable to you. If no cash amounts are otherwise payable to you by the Company and available for such deduction, you must provide timely payment of the applicable Purchase Price to the Company via cash or check and no obligation shall arise upon the Company to procure the issue or transfer of the Ordinary Shares unless and until the Company and/or any Affiliate are satisfied in their absolute discretion that you have satisfied such payment requirement. All amounts due are payable in United States dollars based, if applicable, upon the local currency to United States dollar exchange rate published in the West Coast edition of The Wall Street Journal on the applicable payment date (or, if such date is not a business day in the United States, the preceding business day in the United States).
4. NUMBER OF STOCK UNITS, ORDINARY SHARES AND PURCHASE PRICE.

a. The number of Stock Units subject to your Award and the Purchase Price per Ordinary Share may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Furthermore, the Purchase Price per Ordinary Share will be automatically adjusted from time to time, as applicable, such that it shall at all times be equal to the nominal value per Ordinary Share as then in effect. In no event will the Purchase Price per Ordinary Share be less than the nominal value per Ordinary Share.

b. Any additional Stock Units that become subject to the Award pursuant to this Section 4, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Stock Units covered by your Award.

c. Notwithstanding the provisions of this Section 4, no fractional shares or rights for fractional Ordinary Shares shall be created pursuant to this Section 4. The Board shall, in its discretion, determine an equivalent benefit for any fractional shares or fractional shares that might be created by the adjustments referred to in this Section 4.

5. SECURITIES LAW COMPLIANCE. You may not be issued any shares in respect of your Award unless either (i) the shares are registered under the Securities Act; or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award also must comply with other applicable laws and regulations governing the Award, including, without limitation, the laws and regulations of the United States and your country of residence, and you will not receive such shares if the Company determines that such receipt would not be in material compliance with such laws and regulations.

6. TRANSFER RESTRICTIONS. Your Award is not transferable, except by will or by the laws of descent and distribution. In addition to any other limitation on transfer created by applicable securities laws, you agree not to assign, hypothecate, donate, encumber or otherwise dispose of any interest in any of the Ordinary Shares subject to the Award until the shares are issued to you in accordance with Section 7 of this Agreement. After the shares have been issued to you, you are free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such shares provided that any such actions are in compliance with the provisions herein, any applicable Company policies (including, but not limited to, insider trading and window period policies) and applicable securities laws. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, shall thereafter be entitled to receive any distribution of Ordinary Shares to which you were entitled at the time of your death pursuant to this Agreement.

7. DATE OF ISSUANCE.

a. To the extent the Award is exempt from application of Section 409A of the Code and any state law of similar effect (collectively “Section 409A”), the Company will deliver to you a number of Ordinary Shares equal to the number of vested Stock Units subject to your Award, including any additional Stock Units received pursuant to Section 4 above that relate to those vested Stock Units, on the applicable vesting date(s). However, if a scheduled
delivery date falls on a date that is not a business day, such delivery date shall instead fall on the next following business day. Notwithstanding the foregoing, in the event that (i) any shares covered by your Award are scheduled to be delivered on a day (the “Original Distribution Date”) that does not occur: (A) during an open “window period” applicable to you under the Company’s policy permitting officers, directors and other designated individuals to sell shares only during certain “window” periods, in effect from time to time (the “Policy”), (B) on a day on which you are permitted to sell Ordinary Shares pursuant to a written plan that meets the requirements of Rule 10b5-1 under the Exchange Act, as determined by the Company in accordance with the Policy, or (C) on a date when you are otherwise permitted to sell Ordinary Shares on the open market, and (ii) the Company elects not to satisfy its tax withholding obligations by withholding shares from your distribution or withholding from other compensation otherwise payable to you by the Company, then such shares shall not be delivered on such Original Distribution Date and shall instead be delivered on the first business day of the next occurring open “window period” applicable to you pursuant to such Policy (regardless of whether you are still providing continuous services at such time) or the next business day when you are not prohibited from selling Ordinary Shares in the open market, but in no event later than the fifteenth (15th) day of the third calendar month of the calendar year following the calendar year in which the shares covered by the Award vest. Delivery of the shares pursuant to the provisions of this Section 7(a) is intended to comply with the requirements for the short-term deferral exemption available under Treasury Regulations Section 1.409A-1(b)(4) and shall be construed and administered in such manner. The form of such delivery of the shares (e.g., a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

b. The provisions of Appendix A to this Agreement will apply to the extent the Award is subject to, and not exempt from, application of Section 409A (a “Non-Exempt Award”).

8. DIVIDENDS. You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment as provided in the Plan; provided, however, that this sentence shall not apply with respect to any Ordinary Shares that are delivered to you in connection with your Award after such shares have been delivered to you.

9. RESTRICTIVE LEGENDS. The shares issued in respect of your Award shall be endorsed with appropriate legends determined by the Company.

10. AWARD NOT A SERVICE CONTRACT.

a. Your Continuous Service with the Company or an Affiliate is not for any specified term and may be terminated by you or by the Company or an Affiliate at any time, for any reason, with or without cause and with or without notice. Nothing in this Agreement (including, but not limited to, the vesting of your Award pursuant to the schedule set forth in the Grant Notice or the issuance of the shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other
term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

b. By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice is earned only by continuing as an employee, director or consultant at the will of the Company (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a “reorganization”). You further acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee, director or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with your right or the Company’s right to terminate your Continuous Service at any time, with or without cause and with or without notice.

11. WITHHOLDING OBLIGATIONS.

a. On or before the time you receive a distribution of the shares subject to your Award, or at any time thereafter as requested by the Company, you hereby authorize any required withholding from the Ordinary Shares issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate which arise in connection with your Award (the “Withholding Taxes”). Additionally, the Company may, in its sole discretion, satisfy all or any portion of the Withholding Taxes obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company; (ii) causing you to tender a cash payment, (iii) permitting or requiring you to enter into a “same day sale” commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a “FINRA Dealer”) whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Restricted Stock Units to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company and/or its Affiliates; or (iv) withholding Ordinary Shares from the Ordinary Shares issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date Ordinary Shares are issued pursuant to Section 7) equal to the amount of such Withholding Taxes; provided, however, that the number of such Ordinary Shares so withheld shall not exceed the amount necessary to satisfy the Company’s required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income; and provided further, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, such share withholding procedure shall be subject to the express prior approval of the Company’s Compensation Committee.
b. Unless the tax withholding obligations of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to deliver to you any Ordinary Shares pursuant to this Award.

c. No obligation shall arise upon the Company to procure the issue or transfer of the Ordinary Shares unless and until the Company and/or any Affiliate are satisfied in their absolute discretion that either (i) you have made payment, or have made arrangements satisfactory to the Company and/or any Affiliate for the payment to it of such sum as is sufficient to meet any withholding liability to Taxation (defined below) in any jurisdiction which is or would be recoverable from you in connection with the vesting or the Award or the issuance of Ordinary Shares by the Company in settlement of the Award, and in respect of which the Company and/or any Affiliate is liable to account in any jurisdiction; or (ii) you have entered into an agreement with the Company and/or an Affiliate (in a form satisfactory to the Company or such Affiliate) to ensure that such a payment is made by you including, without limitation, amounts in respect of any employers’ social security (or the local law equivalent thereof) or other forms of Taxation. Accordingly, the Company shall have no obligation to issue a certificate for such Ordinary Shares or release such Ordinary Shares from any escrow provided for herein unless such obligations are satisfied. “Taxation” shall include all forms of taxation including employees’ social security, income tax and any other taxes of whatever nature in any jurisdiction together with any amount payable by an Affiliate in respect of which the Affiliate has a duty to account as a result of any laws of any jurisdiction relating to taxation.

12. PERSONAL DATA. You understand that the Company and/or its Affiliates hold certain personal information about you. This information include your name, home address, telephone number, date of birth, social security or equivalent tax identification number, salary, nationality, job title, and details of your Award and all Ordinary Shares subject to your Award that have been granted, cancelled, vested, unvested, or are outstanding (the “Personal Data”).

You hereby declare your express consent to allowing the Company to transfer your Personal Data (name, home address, telephone number, date of birth, salary, nationality, job title, and details of the Award and all Ordinary Shares subject to such grant) outside the country in which you are retained to its Affiliates, Horizon Pharma, Inc. and Horizon Pharma USA, Inc. which are located in the United States and their parent entity, Horizon Therapeutics Public Limited Company (together such entities are the “Company Group”). The legal persons for whom such Personal Data are intended are: Horizon Therapeutics Public Limited Company, Horizon Pharma, Inc., Horizon Pharma USA, Inc., StockCross Financial Services and any other third party entity providing equity award and/or Plan administration services to the Company and for the sole purpose of facilitating the transactions contemplated by this Agreement. You have the right to access and correct your Personal Data by applying to the Company representative identified on the Grant Notice (the “Representative”). You have the right to revoke this consent at any time with future effect towards the Company Group by providing written notice to the Representative of such revocation (the “Revocation Notice”) and as soon as administratively practicable following the Representative’s receipt of the Revocation Notice your consent revocation will become effective and your Award shall automatically immediately terminate and be forfeited, and you will not receive any Ordinary Shares or any other consideration in respect of such forfeited Award.
13. ADDITIONAL ACKNOWLEDGEMENTS. You hereby consent and acknowledge that:

a. Participation in the Plan is voluntary and therefore you must accept the terms and conditions of the Plan and this Award as a condition to participating in the Plan and receipt of the Award.

b. The Plan is discretionary in nature and the Company can amend, cancel, or terminate it at any time.

c. This Award and any other equity awards granted under the Plan are voluntary and occasional and do not create any contractual or other right to receive future awards or other benefits in lieu of future awards, even if similar awards have been granted repeatedly in the past.

d. All determinations with respect to any such future awards, including, but not limited to, the time or times when such awards are granted, the number of Ordinary Shares, and performance and other conditions applied to the awards, will be at the sole discretion of the Company.

e. The value of the Ordinary Shares and this Award is an extraordinary item of compensation, which is outside the scope of your service contract or consulting agreement, if any. This Award shall not form part of any past, current or future entitlement to remuneration or benefits which you may have under any service contract with the Company nor form any part of any such contract between you and the Company.

f. The Ordinary Shares, this Award, or any income derived therefrom are a potential bonus payment not paid in lieu of any cash salary compensation and not part of normal or expected compensation or salary for any purposes, including, but not limited to, calculating any termination, severance, resignation, redundancy, end of service payments, bonuses, long-service awards, life or accident insurance benefits, pension or retirement benefits or similar payments.

g. In the event of the involuntary termination of your Continuous Service, your eligibility to receive Ordinary Shares or payments under the Award or the Plan, if any, will terminate effective as of the date that you are no longer actively employed or retained regardless of any reasonable notice period mandated under local law, except as expressly provided in the Agreement.

h. The future value of the Ordinary Shares is unknown and cannot be predicted with certainty. You do not have, and will not assert, any claim or entitlement to compensation, indemnity or damages arising from the termination of this award or diminution in value of the Ordinary Shares and you irrevocably release the Company, its Affiliates and, if applicable, your employer, if different from the Company, from any such claim that may arise.
14. **Unsecured Obligation.** Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company’s obligation, if any, to issue shares pursuant to this Agreement. You shall not have voting or any other rights as a shareholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 7 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a shareholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

15. **Other Documents.** You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company’s policy permitting officers, directors and other specified individuals to sell shares only during certain “window” periods and the Company’s insider trading policy, in effect from time to time.

16. **Notices.** Any notices provided for in your Award or the Plan shall be given in writing (including electronically) and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award you consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

17. **Miscellaneous.**

   a. The rights and obligations of the Company under your Award shall be transferable to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by the Company’s successors and assigns. Your rights and obligations under your Award may only be assigned with the prior written consent of the Company.

   b. You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

   c. You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award, and fully understand all provisions of your Award.
This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

18. GOVERNING PLAN DOCUMENT. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Except as expressly provided in this Agreement, in the event of any conflict between the provisions of your Award and those of the Plan, the provisions of the Plan shall control. In addition, your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

19. SEVERABILITY. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

20. EFFECT ON OTHER BENEFIT PLANS. The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's benefit plans.

21. AMENDMENT. This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that no such amendment adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the grant as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.
22. NO OBLIGATION TO MINIMIZE TAXES. The Company has no duty or obligation to minimize the tax consequences to you of this Award and will not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so.
Appendix A

The provisions set forth on this Appendix A shall apply to the extent the Award is a Non-Exempt Award and shall supersede any provisions to the contrary set forth in the Plan or in any other section of the Agreement to which this Appendix A is attached.

1. The provisions of this Section 1 are intended to apply to the extent your Award is a Non-Exempt Award because of the terms of a severance arrangement or other agreement between you and the Company, if any, that provide for acceleration of vesting of your Award and issuance of the shares in respect of the Award upon your termination of employment or separation from service (as such term is defined in Section 409A(a)(2)(A)(i) of the Code (and without regard to any alternative definition thereunder) (“Separation from Service”) and such severance benefit does not satisfy the requirements for an exemption from application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(4) or 1.409A-1(b)(9) (“Non-Exempt Severance Arrangement”). To the extent your Award is a Non-Exempt Award due to application of a Non-Exempt Severance Arrangement, the following provisions in this Section 1 of Appendix A shall supersede anything to the contrary in Section 6(a) of the Award Agreement.

   a. If your Award vests in the ordinary course during your Continuous Service in accordance with the vesting schedule set forth in the Grant Notice, without accelerating vesting under the terms of a Non-Exempt Severance Arrangement, in no event will the shares be issued in respect of your Award any later than the later of: (i) December 31st of the calendar year that includes the applicable vesting date and (ii) the 60th day that follows the applicable vesting date.

   b. If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were in effect as of the date of grant of your Award and, therefore, are part of the terms of your Award as of the date of grant, then the shares will be earlier issued in respect of your Award upon your Separation from Service in accordance with the terms of the Non-Exempt Severance Arrangement, but in no event later than the 60th day that follows the date of your Separation from Service. However, if at the time the shares would otherwise be issued you are subject to the distribution limitations contained in Section 409A applicable to “specified employees,” as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six (6) months following the date of your Separation from Service, or, if earlier, the date of your death that occurs within such six month period.

   c. If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were not in effect as of the date of grant of the Award and, therefore, are not a part of the terms of your Award on the date of grant, then such acceleration of vesting of your Award shall not accelerate the issuance date of the shares, but the shares shall instead be issued on the same schedule as set forth in the Grant Notice as if they had vested in the ordinary course during your Continuous Service, notwithstanding the vesting acceleration of the Award. Such issuance schedule is intended to satisfy the requirements of payment on a specified date or pursuant to a fixed schedule, as provided under Treasury Regulations Section 1.409A-3(a)(4).
2. Permitted Treatment of Non-Exempt Awards Upon a Corporate Transaction for Employees and Consultants. The provisions in this Section 2 shall apply and shall supersede anything to the contrary that may be set forth in the Plan with respect to the permitted treatment of your Non-Exempt Award in connection with a Corporate Transaction if you were either an Employee or Consultant upon the applicable date of grant of your Non-Exempt Award.

a. **Vested Non-Exempt Awards.** To the extent your Non-Exempt Award has vested in accordance with its terms upon or prior to the date of a Corporate Transaction (such portion of your Non-Exempt Award is a “**Vested Non-Exempt Award**”), then the following provisions shall apply.

1) If the Corporate Transaction is also a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company’s assets, as described in Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A-3(i)(5) (a “**409A Change of Control**”), then the surviving or acquiring corporation (or its parent company) (the “**Acquiring Entity**”) may not assume, continue or substitute your Vested Non-Exempt Award. Upon the 409A Change of Control the settlement of your Vested Non-Exempt Award will automatically be accelerated and the shares will be immediately issued in respect of your Vested Non-Exempt Award. Alternatively, the Company may instead provide that you will receive a cash settlement equal to the Fair Market Value of the shares that would otherwise be issued to you upon the 409A Change of Control.

2) If the Corporate Transaction is not also a 409A Change of Control, then the Acquiring Entity must either assume, continue or substitute your Vested Non-Exempt Award. The shares to be issued in respect of your Vested Non-Exempt Award shall be issued to you by the Acquiring Entity on the same schedule that the shares would have been issued to you if the Corporate Transaction had not occurred. In the Acquiring Entity’s discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to you on such issuance dates, with the determination of the Fair Market Value of the shares made on the date of the Corporate Transaction.

b. **Unvested Non-Exempt Awards.** To the extent your Non-Exempt Award has not vested in accordance with its terms upon or prior to the date of any Corporate Transaction, (such portion of your Non-Exempt Award is an “**Unvested Non-Exempt Award**”), then the following provisions shall apply.

1) If the Acquiring Entity will not assume, substitute or continue your Unvested Non-Exempt Award, then such Award shall automatically terminate and be forfeited upon the Corporate Transaction with no consideration payable to you in respect of your forfeited Unvested Non-Exempt Award. Notwithstanding the foregoing, to the extent permitted and in compliance with the requirements of Section 409A, the Company may in its discretion determine to elect to accelerate the vesting and settlement of the Unvested Non-Exempt Award upon the Corporate Transaction, or instead substitute a cash payment equal to the Fair Market Value of such shares that would otherwise be issued to you, as further provided in Section 4(b) below. In the absence of such discretionary election by the Company, your Unvested Non-Exempt Award shall be forfeited without payment of any consideration to you if the Acquiring Entity will not assume, substitute or continue your Unvested Non-Exempt Award in connection with the Corporate Transaction.
2) The foregoing treatment shall apply with respect to all Unvested Non-Exempt Awards upon any Corporate Transaction, and regardless of whether or not such Corporate Transaction is also a 409A Change of Control.

3. Permitted Treatment of Non-Exempt Awards Upon a Corporate Transaction for Non-Employee Directors. If you were a Director but not an Employee on the applicable grant date of your Non-Exempt Award and ("Non-Exempt Director Award"), the following provisions shall apply and shall supersede anything to the contrary that may be set forth in the Plan with respect to the permitted treatment of your Non-Exempt Director Award in connection with a Corporate Transaction.

   a. If the Corporate Transaction is also a 409A Change of Control then the Acquiring Entity may not assume, continue or substitute your Non-Exempt Director Award. Upon the 409A Change of Control the vesting and settlement of your Non-Exempt Director Award will automatically be accelerated and the shares will be immediately issued to you in respect of the Non-Exempt Director Award. Alternatively, the Company may provide that you will instead receive a cash settlement equal to the Fair Market Value of the shares that would otherwise be issued to you upon the 409A Change of Control pursuant to the preceding provision.

   b. If the Corporate Transaction is not also a 409A Change of Control, then the Acquiring Entity must either assume, continue or substitute your Non-Exempt Director Award. Unless otherwise determined by the Board, your Non-Exempt Director Award will remain subject to the same vesting and forfeiture restrictions that were applicable to the Award prior to the Corporate Transaction. The shares to be issued in respect of your Non-Exempt Director Award shall be issued to you by the Acquiring Entity on the same schedule that the shares would have been issued to you if the Corporate Transaction had not occurred. In the Acquiring Entity’s discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to you on such issuance dates, with the determination of Fair Market Value made on the date of the Corporate Transaction.

4. General Superseding Provisions. The provisions in this Section 4 shall apply and supersede anything to the contrary that may be set forth in the Plan, the Grant Notice or in any other section of the Agreement with respect to the permitted treatment of your Non-Exempt Award:

   a. Any exercise by the Board of discretion to accelerate the vesting of your Non-Exempt Award shall not result in any acceleration of the scheduled issuance dates for the shares in respect of the Non-Exempt Award unless earlier issuance of the shares upon the applicable vesting dates would be in compliance with the requirements of Section 409A.

   b. The Company explicitly reserves the right to earlier settle your Non-Exempt Award to the extent permitted and in compliance with the requirements of Section 409A, including pursuant to any of the exemptions available in Treasury Regulations Section 1.409A-3(j)(4)(ix).
c. To the extent the terms of your Non-Exempt Award provide that it will be settled upon a Change in Control or Corporate Transaction, to the extent it is required for compliance with the requirements of Section 409A, the Change in Control or Corporate Transaction event triggering settlement must also constitute a 409A Change of Control. To the extent the terms of your Non-Exempt Award provides that it will be settled upon a termination of employment or termination of Continuous Service, to the extent it is required for compliance with the requirements of Section 409A, the termination event triggering settlement must also constitute a Separation From Service. However, if at the time the shares would otherwise be issued to you in connection with your “separation from service” you are subject to the distribution limitations contained in Section 409A applicable to “specified employees,” as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six (6) months following the date of your Separation From Service, or, if earlier, the date of your death that occurs within such six month period.

5. **Section 409A Compliance.** The provisions in this Agreement for delivery of the shares in respect of the Non-Exempt Award are intended to comply with the requirements of Section 409A so that the delivery of the shares to you in respect of your Non-Exempt Award will not trigger the additional tax imposed under Section 409A, and any ambiguities herein will be so interpreted.
Horizon Therapeutics Public Limited Company (the “Company”), pursuant to its 2014 Non-Employee Equity Plan (the “Plan”), hereby grants you a restricted stock unit award (the “Award”) to purchase the Company’s Ordinary Shares. The following specific terms of the Award can be obtained by logging on to your StockCross brokerage account: [Participant, Date of Grant, Vesting Commencement Date, Number of Restricted Stock Units, Purchase Price per Ordinary Share, Vesting Schedule and Issuance Schedule]. These specific terms are incorporated by reference into this Grant Notice. This Award is subject to all of the terms and conditions as set forth herein and in the Restricted Stock Unit Agreement (the “Award Agreement”) and the Plan, all of which are available on the StockCross website. Capitalized terms are defined in the Plan or the Award Agreement shall have the meanings set forth in the Plan or the Award Agreement. The Purchase Price per Ordinary Share that may be issued in settlement of your Award is equal to the nominal value per Ordinary Share as of the Date of Grant and is subject to adjustment as provided in Section 4 of the Award Agreement.

Additional Terms/Acknowledgements: You must electronically accept the Award by logging into your StockCross account. If you have not set-up your StockCross brokerage account, the following information provided below will assist you in this process. Failure to do so may result in forfeiture of the Award. By electronically accepting the Award, you acknowledge receipt of, and understand and agree to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. You further acknowledge that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement, and the Plan set forth the entire understanding between you and the Company regarding the acquisition of shares in the Company and supersede all prior oral and written agreements on that subject with the exception of: (i) any written employment or severance arrangement that would provide for vesting acceleration of the Award upon the terms and conditions set forth therein, or (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law. By accepting this Award, the Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

STOCKCROSS FINANCIAL SERVICES BROKERAGE ACCOUNT

The Company currently utilizes StockCross Financial Services as our online broker. StockCross Financial Services offers an internet website for viewing Award data and for buying or selling stock subject to your stock Awards. To open your brokerage account, you can do so by visiting the StockCross website at www.stockcross.com, select the red “Employee Stock Plans” menu item. Under the “Get Started” window, select the blue menu button “Open an Account.” Additionally, under the New Account Application screen, select “Employee Stock Award Plan ESOP” button to proceed with the brokerage application.

If you have any questions or comments completing the brokerage application, please contact the StockCross New Accounts team at 800-225-6196.

AWARD ACCEPTANCE (via StockCross after completing your brokerage application)

Please follow steps 1 through 7 to electronically accept your Award.

1. Login to www.stockcross.com
2. Select the red menu item “Employee Stock Plans.”
3. In the Get Started screen, enter “HZNP” for the Company’s stock ticker symbol.
4. Under the StockCross Customer Account Login screen, enter your StockCross account number and password.
5. Once logged into your StockCross account, select the menu item “Employee Stock Plan.” This will bring you into another window screen which provides a summary of your equity grants. Please note that to view this information, you will need to disable popup blockers.
6. Select “My Portfolio.” This will show you all equity grants that you have been granted. For your new equity grant, in the last column, click on the “View” hyperlink.

7. Selecting “View” in step 7 will take you to an electronic acceptance window. For your reference, the Award Agreement applicable to the Award is provided for your reference. If you agree with the terms and conditions of your equity grant, select the green “Accept” button.

**IMPORTANT REMINDER:** In order to avoid forfeiture of your Award, you must electronically accept your Award 30 days prior to your first vesting date.

Contact Horizon Therapeutics plc’s Senior Manager, Accounting and Global Equity Plan Administrator Garry Devine at 224-383-3037 or email gdevine@horizontherapeutics.com with any further questions regarding your awards.
May 8, 2019

Board of Directors of
Horizon Therapeutics plc
Connaught House, 1st Floor
1 Burlington Road, Dublin 4, D04 C5Y6, Ireland

Dear Directors:

We are providing this letter to you for inclusion as an exhibit to Horizon Therapeutics plc’s (the “Company”) Quarterly Report on Form 10-Q for the period ended March 31, 2019 (the “Form 10-Q”) pursuant to Item 601 of Regulation S-K.

We have been provided a copy of the Company’s Form 10-Q. Note 1 therein describes a change in accounting principle for recording the fair value of intangible assets and related third-party contingent royalties acquired through business combinations under ASC 805 from separately recording the fair value of acquired intangible assets and contingent royalties to third-parties other than the sellers to accounting for the intangible assets and these contingent royalties on a net basis. It should be understood that the preferability of one acceptable method of accounting over another for recording the fair value of acquired intangible assets and related third-party contingent royalties has not been addressed in any authoritative accounting literature, and in expressing our concurrence below we have relied on management’s determination that this change in accounting principle is preferable. Based on our reading of management’s stated reasons and justification for this change in accounting principle in the Form 10-Q, and our discussions with management as to their judgment about the relevant business planning factors relating to the change, we concur with management that such change represents, in the Company’s circumstances, a change to a preferable accounting principle in conformity with Accounting Standards Codification 250, Accounting Changes and Error Corrections.

We have not audited any financial statements of the Company as of any date or for any period subsequent to December 31, 2018. Accordingly, our comments are subject to change upon completion of an audit of the financial statements covering the period of the accounting change.

Very truly yours,

/s/ PricewaterhouseCoopers LLP
I, Timothy P. Walbert, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Horizon Therapeutics 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: May 8, 2019

/s/ Timothy P. Walbert
Timothy P. Walbert
Chairman, President and Chief Executive Officer
(Principal Executive Officer)
I, Paul W. Hoelscher, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Horizon Therapeutics 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: May 8, 2019

/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 Therapeutics 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 March 31, 2019 (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: May 8, 2019

/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 Therapeutics 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 March 31, 2019 (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: May 8, 2019

/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.