

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

**FORM 10-Q/A**  
(Amendment No. 1)

(MARK ONE)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2017

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 001-35238

**HORIZON PHARMA PUBLIC LIMITED COMPANY**

(Exact name of registrant as specified in its charter)

**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)

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

**Not Applicable**  
(Zip Code)

**011 353 1 772 2100**  
(Registrant's telephone number, including area code)

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

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

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

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

Number of registrant's ordinary shares, nominal value \$0.0001, outstanding as of July 28, 2017: 163,354,268.

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#### **EXPLANATORY NOTE**

Horizon Pharma Public Limited Company (the “Company”) is filing this Amendment No. 1 to Quarterly Report on Form 10-Q/A (this “Amendment”) to amend the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, as filed with the Securities and Exchange Commission (the “SEC”) on August 7, 2017 (the “10-Q”). This Amendment is being filed solely to re-file revised redacted versions of Exhibits 10.3 and 10.4 to the 10-Q (the “Exhibits”) to reflect changes to the Company’s confidential treatment request with respect to certain portions of the Exhibits, and in connection therewith, to amend and restate Part II, Item 6 of the 10-Q and to delete in its entirety the Index to Exhibits following the signature page in the 10-Q. In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by the Company’s principal executive officer and principal financial officer are filed as exhibits to this Amendment.

No attempt has been made in this Amendment to modify or update the other disclosures presented in the 10-Q. This Amendment does not reflect events occurring after the filing of the 10-Q or modify or update those disclosures that may be affected by subsequent events. Accordingly, this Amendment should be read in conjunction with the 10-Q and the Company’s other filings with the SEC.

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**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Document</b>
2.1(1)	<a href="#"><u>Transaction Agreement and Plan of Merger, dated March 18, 2014, by and among Horizon Pharma, Inc., Vidara Therapeutics Holdings LLC, Vidara Therapeutics International Ltd. (now known as Horizon Pharma Public Limited Company), Hamilton Holdings (USA), Inc. and Hamilton Merger Sub, Inc.†</u></a>
2.2(2)	<a href="#"><u>First Amendment to Transaction Agreement and Plan of Merger, dated June 12, 2014, by and between Horizon Pharma, Inc. and Vidara Therapeutics Holdings LLC.</u></a>
2.3(3)	<a href="#"><u>Agreement and Plan of Merger, dated March 29, 2015, by and among Horizon Pharma, Inc., Ghria Acquisition Inc. and Hyperion Therapeutics, Inc. †</u></a>
2.4(4)***	<a href="#"><u>Agreement and Plan of Merger, dated December 10, 2015, by and among Horizon Pharma USA, Inc., HZNP Limited, Criostail LLC, Crealta Holdings LLC and the other parties thereto.††</u></a>
2.5(5)	<a href="#"><u>Agreement and Plan of Merger, dated September 12, 2016, by and among Horizon Pharma Public Limited Company, Misneach Corporation and Raptor Pharmaceutical Corp.†</u></a>
3.1(6)	<a href="#"><u>Memorandum and Articles of Association of Horizon Pharma Public Limited Company, as amended.</u></a>
4.1(7)**	<a href="#"><u>Form of Warrant issued by Horizon Pharma, Inc. pursuant to the Securities Purchase Agreement, dated February 28, 2012, by and among Horizon Pharma, Inc. and the Purchasers and Warrant Holders listed therein.</u></a>
4.2(8)**	<a href="#"><u>Form of Warrant issued by Horizon Pharma, Inc. in Public Offering of Units.</u></a>
4.3(9)	<a href="#"><u>Indenture, dated March 13, 2015, by and among Horizon Pharma Public Limited Company, Horizon Pharma Investment Limited and U.S. Bank National Association.</u></a>
4.4(9)	<a href="#"><u>Form of 2.50% Exchangeable Senior Note due 2022 (included in Exhibit 4.3).</u></a>
4.5(10)	<a href="#"><u>Indenture, dated April 29, 2015, by and between Horizon Pharma Financing Inc. and U.S. Bank National Association.</u></a>
4.6(10)	<a href="#"><u>Form of 6.625% Senior Note due 2023 (included in Exhibit 4.5).</u></a>
4.7(11)	<a href="#"><u>First Supplemental Indenture, dated May 7, 2015, by and among Horizon Pharma Public Limited Company, certain subsidiaries of Horizon Pharma Public Limited Company and U.S. Bank National Association.</u></a>
4.8(12)	<a href="#"><u>Indenture, dated October 25, 2016, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and U.S. Bank National Association, as trustee.</u></a>
4.9(12)	<a href="#"><u>Form of 8.75% Senior Note due 2024 (included in Exhibit 4.8).</u></a>
10.1(13)	<a href="#"><u>Amendment No. 2, dated March 29, 2017, to Credit Agreement, dated May 7, 2015 (as amended by Amendment No. 1, dated October 25, 2016), by and among Horizon Pharma, Inc., as Borrower, Horizon Pharma USA, Inc., as an Additional Borrower, Horizon Pharma Public Limited Company, as Irish Holdco and a guarantor, the subsidiary guarantors party thereto, as subsidiary guarantors, the lenders party thereto and Citibank, N.A., as administrative agent and collateral agent.</u></a>
10.2(14)	<a href="#"><u>Transition services letter agreement, dated April 21, 2017, between Horizon Pharma plc and David Happel.</u></a>
10.3*	<a href="#"><u>Global Supply Agreement, dated June 30, 2017, by and between Horizon Pharma Ireland Limited and Boehringer Ingelheim Biopharmaceuticals GmbH.</u></a>
10.4*	<a href="#"><u>Amended and Restated License Agreement, dated May 31, 2017, by and between Horizon Orphan LLC and The Regents of the University of California.</u></a>
10.5(15)+	<a href="#"><u>Executive Employment Agreement, effective as of February 1, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Vikram Kamani.</u></a>
10.6(15)+	<a href="#"><u>Second Amendment to Amended and Restated Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D.</u></a>
10.7(15)+	<a href="#"><u>First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Paul W. Hoelscher.</u></a>
10.8(15)+	<a href="#"><u>First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Barry Moze.</u></a>

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10.9(15)+	<a href="#">First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Brian Beeler.</a>
10.10(15)+	<a href="#">First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and David A. Happel.</a>
10.11(15)+	<a href="#">First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and George P. Hampton.</a>
10.12(15)+	<a href="#">First Amendment to Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Robert F. Carey.</a>
10.13(15)+	<a href="#">Second Amendment to Amended and Restated Executive Employment Agreement, dated May 4, 2017, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Timothy P. Walbert.</a>
31.1(15)	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.</a>
31.2(15)	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.</a>
31.3	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.</a>
31.4	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.</a>
32.1(15)	<a href="#">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.</a>
32.2(15)	<a href="#">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.</a>
101.INS(15)	XBRL Instance Document
101.SCH(15)	XBRL Taxonomy Extension Schema Document
101.CAL(15)	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF(15)	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB(15)	XBRL Taxonomy Extension Label Linkbase Document
101.PRE(15)	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

† Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Horizon Pharma Public Limited Company undertakes to furnish supplemental copies of any of the omitted schedules upon request by the Securities and Exchange Commission.

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

\* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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

\*\*\* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(1) Incorporated by reference to Horizon Pharma, Inc.'s Current Report on Form 8-K, filed on March 20, 2014.

(2) Incorporated by reference to Horizon Pharma, Inc.'s Current Report on Form 8-K, filed on June 18, 2014.

(3) Incorporated by reference to Horizon Pharma Public Limited Company's Amendment No. 1 to Current Report on Form 8-K/A, filed on April 9, 2015.

(4) Incorporated by reference to Horizon Pharma Public Limited Company's Amendment No. 1 to Annual Report on Form 10-K/A, filed on May 26, 2017.

(5) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on September 12, 2016.

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- (6) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on May 4, 2017.
  - (7) Incorporated by reference to Horizon Pharma, Inc.'s Current Report on Form 8-K, filed on March 1, 2012.
  - (8) Incorporated by reference to Horizon Pharma, Inc.'s Current Report on Form 8-K, filed on September 20, 2012.
  - (9) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on March 13, 2015.
  - (10) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on April 29, 2015.
  - (11) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on May 11, 2015.
  - (12) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on October 25, 2016.
  - (13) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on March 30, 2017.
  - (14) Incorporated by reference to Horizon Pharma Public Limited Company's Current Report on Form 8-K, filed on April 21, 2017.
  - (15) Incorporated by reference to Horizon Pharma Public Limited Company's Quarterly Report on Form 10-Q, filed on August 7, 2017.

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**SIGNATURES**

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

HORIZON PHARMA PLC

Date: September 28, 2017

By: /s/ Timothy P. Walbert

Timothy P. Walbert  
*Chairman, President and Chief Executive Officer*  
*(Principal Executive Officer)*

Date: September 28, 2017

By: /s/ Paul W. Hoelscher

Paul W. Hoelscher  
*Executive Vice President, Chief Financial Officer*  
*(Principal Financial Officer)*

**\*\*\*Text Omitted and Filed Separately  
with the Securities and Exchange Commission.  
Confidential Treatment Requested  
Under 17 C.F.R. Sections 200.80(b)(4)  
and 240.24b-2**

CONFIDENTIAL

CorA: 151373

GLOBAL SUPPLY AGREEMENT

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

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

(hereinafter referred to as “**HORIZON**”)

and

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

(hereinafter referred to as “**BI**”),

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



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**1. INTRODUCTION AND RECITALS**

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

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

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

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

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

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

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

**Whereas**, BII (as defined hereafter) had originally obtained exclusive licenses from GENENTECH to manufacture, use and sell INTERFERON GAMMA 1b in Europe and certain other territories under the trade-mark Imukin®, Immukin®, Imukine® and/or Immukine® (“**BI-**

**\*\*\* Confidential Treatment Requested**

**GENENTECH LICENSE AGREEMENTS**”). BII and HORIZON’s AFFILIATE HZNP Limited entered into an asset purchase agreement (“**ASSET PURCHASE AGREEMENT**”), effective as of May 18, 2016, as amended, under which HORIZON acquired all rights, title and interest from BII to INTERFERON GAMMA 1b, including the relevant confidential information and trademarks, in the BII territory.

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

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

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

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

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

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

**\*\*\* Confidential Treatment Requested**

## 2. DEFINITIONS

The following capitalized definitions will apply throughout this AGREEMENT:

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

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

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

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

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

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

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

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

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

**2.10 BI-GENENTECH LICENSE AGREEMENTS** has the same meaning as the "Genentech Agreements" as defined in 1.1.(ii) of the ASSET PURCHASE AGREEMENT.

**2.11 BII** means BI's AFFILIATE Boehringer Ingelheim International GmbH, Binger Straße 173, 55216 Ingelheim am Rhein, Germany.

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

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

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

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

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

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

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

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

**2.20 CMC** means the Chemistry, Manufacturing, and Controls content of a submission to a HEALTH AUTHORITY.

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

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

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

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

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

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

**2.27 CONTROLLED** means, with respect to any material, INFORMATION or INTELLECTUAL PROPERTY RIGHT possession of the ability by a Party to grant access, a license, or a sublicense to such material, INFORMATION or INTELLECTUAL PROPERTY RIGHT as provided for herein (a) without violating an agreement with a Third Party and (b) without obligation to make any payments to a Third Party as a result of such grant the other Party of such access, license or sublicense or the exercise thereof by such other Party unless such other

Party has agreed in writing to reimburse the granting Party for such payments. The granting Party, at the time such access, license or sublicense is required to be granted hereunder, will notify the other Party in writing of any payment obligation under subclause (b) above.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**2.44** [...\*\*\*...].

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

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

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

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MANUFACTURING PROCESS shall be HORIZON IMPROVEMENTS only to the extent that they directly relate to the DRUG SUBSTANCE and/or PRODUCT.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**2.76 SOPs** means standard operating procedures.

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

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

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

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

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

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

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

### **3. GENERAL**

#### **3.1 HORIZON's Tasks and Responsibilities**

##### **3.1.1 Support**

HORIZON shall timely send all documentation, and otherwise timely provide all information and other assistance, reasonably requested by BI for use under this AGREEMENT. HORIZON shall provide such reasonable technical support at its own expense, which support shall include

access to HORIZON's expert personnel upon reasonable notice and at such reasonable times as the Parties may agree.

### 3.1.2 Contact with Health Authorities

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

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

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

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

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

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

### 3.1.3 Shipment of Material by HORIZON

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

## 3.2 BI's Tasks and Responsibilities

### 3.2.1 Regulatory Support

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

3.2.1.2 The Parties shall consult with each other concerning the scope and content of all regulatory filings pertinent to BI's responsibilities for manufacture and supply of PRODUCT, and shall jointly define the requirements for the necessary PRODUCT registration with the applicable HEALTH AUTHORITIES so that BI shall be able to fulfill its obligations under this AGREEMENT with respect to the CMC portion of such PRODUCT registration. With respect to any part of the CMC portion which contains INFORMATION of BI and/or its AFFILIATES, BI shall be provided an opportunity of twenty (20) business days in accordance with Section 14.1.5 of the QAA, or such other period as the Parties may agree in writing (the "REVIEW PERIOD"), to review and approve in writing the CMC section(s) of any regulatory filing which contain any data generated by BI relating to the manufacture and testing of the Product at BI and / or the facility prior to submission of such filing by HORIZON to a HEALTH AUTHORITY, which approval shall not be unreasonably withheld, conditioned or delayed. If BI does not notify HORIZON in writing of any material objection to any CMC section(s) provided to BI in accordance with the preceding sentence within the REVIEW PERIOD, then BI shall be deemed to have approved such CMC section for provision to the applicable HEALTH AUTHORITIES. The foregoing BI review and prior approval shall not apply and a notification by HORIZON to BI shall be sufficient in the event that documents issued by BI for regulatory purposes are provided to any such Governmental Authority without further processing or changes by HORIZON. The Parties shall agree in good faith on the required time periods for such review and approval and for any compilation, review and approval of regulatory documents in general in the Quality Agreement or otherwise in writing.

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### 3.2.2 Format and Content of Documents

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

### 3.3 Harmonised MANUFACTURING PROCESS

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

## 4. MANUFACTURE AND SUPPLY

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

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

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

### 4.2 Scope Changes and Change Orders

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

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

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

#### **4.3 General Provisions for the Services**

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

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

4.3.3 All DRUG SUBSTANCE and PRODUCT manufactured for and/or supplied to HORIZON by BI hereunder shall be manufactured at the FACILITY in accordance with the DRUG SUBSTANCE SPECIFICATIONS and PRODUCT SPECIFICATIONS, respectively, the

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

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

#### 4.3.5 Supply of Excess Drug Substance

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

#### 4.3.6 Subcontracting

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

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HORIZON have entered into a written agreement with respect to ensuring such PERMITTED SUBCONTRACTOR's compliance with cGMP.

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

#### 4.4 Forecasts

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

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

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

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

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

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

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

4.4.6 HORIZON shall be obligated to buy and BI shall be obligated to sell only the quantities of EXCESS MATERIAL and/or PRODUCT which are subject to a purchase order accepted by BI; provided that BI shall accept sufficient purchase orders from HORIZON annually to meet its obligations pursuant to this Section 4.4 and in accordance with the rolling forecast model pursuant to Section 4.4. Any purchase order (or portion thereof) for which HORIZON has not received a written rejection from BI within [...\*\*\*...] of BI's receipt of such purchase order shall be deemed accepted by BI. With respect to PRODUCTS ordered by HORIZON for its clinical supply requirements, the number of vials supplied by BI shall not exceed the number of vials subject to the applicable purchase order submitted by HORIZON; provided, however, that if the number of vials BI is able to supply falls below the number of vials ordered by HORIZON in such purchase order and such lesser number is within a reasonable range of the number ordered by HORIZON, BI shall notify HORIZON in writing and inquire as to whether such lesser number of vials is acceptable and if not, whether BI should produce an additional BATCH of DRUG SUBSTANCE to produce enough vials to satisfy HORIZON's purchase order. If HORIZON notifies BI that such lesser number of vials is acceptable to HORIZON, then the applicable purchase order shall be deemed to be amended to

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4.4.7 provide for such lesser number of vials and BI shall be deemed to have accepted such purchase order in accordance with Section 4.4 and 4.5 (and HORIZON shall only be required to pay for the number of vials actually delivered). On the other hand, if HORIZON notifies BI that BI should manufacture an additional BATCH of DRUG SUBSTANCE to produce the number of vials ordered by HORIZON in its purchase order submitted to BI, then BI shall be obligated to produce the additional BATCH of DRUG SUBSTANCE, HORIZON shall be obligated to purchase any excess vials (above the amounts forecasted in accordance with Section 4.4) of PRODUCT from such additional BATCH of DRUG SUBSTANCE and the purchase order submitted to BI by HORIZON shall be deemed amended to account for any excess vials resulting from the additional BATCH of DRUG SUBSTANCE and such purchase order shall be deemed accepted by BI in accordance with Section 4.4 and 4.5. In the event HORIZON prefers to purchase any EXCESS MATERIAL of said additional BATCH, Section 4.3.5 shall apply.

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

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

#### **4.5 Purchase Orders**

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

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

#### **4.6 Shipment of Product and Material by BI**

4.6.1 DELIVERED MATERIAL and all material (e.g. samples) shall be shipped [...\*\*\*...] at the FACILITY and shipped to HORIZON or as directed by HORIZON, in accordance

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with [...\*\*\*...] and in accordance with the QUALITY ASSURANCE AGREEMENT. HORIZON's designated carrier shall be used to ship DELIVERED MATERIAL to the site designated by HORIZON. BI shall use commercially reasonable efforts to notify HORIZON in writing upon loading of the DELIVERED MATERIAL onto such designated carrier. The Parties acknowledge and agree that [...\*\*\*...] shall be responsible and bear the cost [...\*\*\*...] the DELIVERED MATERIAL onto the [...\*\*\*...] carrier such that [...\*\*\*...] onto the HORIZON designated carrier. Risk of loss in transit by [...\*\*\*...].

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

#### 4.7 Testing and Rejection

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

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

4.7.3 Notwithstanding the above, any and all remedies for Non-CONFORMING PRODUCT pursuant to this Section 4.7 shall be time-barred following expiration of the RESIDUAL SHELF LIFE of such PRODUCT. BI's warranties under Section 4.3.3 with respect to such PRODUCT shall expire upon expiration of the RESIDUAL SHELF LIFE of such

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PRODUCT, and BI shall have no liability under Section 11.1 with respect any product liability due to the use of any PRODUCT following the expiration of its RESIDUAL SHELF LIFE.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### **4.8 Risk Management and Business Continuity Plan**

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

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

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

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

#### **4.9 Continuity of Supply**

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

4.9.2 BI shall supply the ordered quantities of DRUG SUBSTANCE to HORIZON in accordance with the respective HORIZON order. In the event of a MATERIAL SUPPLY BREACH, the matter of second source manufacture of DRUG SUBSTANCE and/or PRODUCT

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and any potential next steps shall be discussed in good faith by the Parties' executive officers, subject to the remainder of this Section 4.9.

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

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

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

#### **4.10 Material Supply Breach**

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

4.10.2 Upon BI's receipt of such notice the Parties shall agree in writing upon a timetable and activity plan to cure such MATERIAL SUPPLY BREACH as promptly as possible (the "CURE PLAN"). If the Parties fail to agree upon such a CURE PLAN within [...\*\*\*...] from the date of notice of such MATERIAL SUPPLY BREACH, or if BI fails to comply with such CURE PLAN, or if despite BI's compliance with the CURE PLAN, BI cannot cure the MATERIAL SUPPLY BREACH, then HORIZON shall have the right to purchase from a second source manufacturer, to be agreed upon within the STEERING COMMITTEE in accordance with Section 7.4, such amounts of PRODUCT as necessary to offset BI's shortfall in fulfilling HORIZON's purchase orders for such PRODUCT (or the anticipated shortfall).

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4.10.3 BI shall evaluate its capabilities and, as applicable, promptly nominate a BI AFFILIATE as a second source manufacturer and, if such BI AFFILIATE is approved by HORIZON, shall use its commercially reasonable efforts to qualify such BI AFFILIATE as promptly as possible. In the event that:

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

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

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

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

#### **4.11 Manufacturing [...\*\*\*...] Commitment**

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

#### **4.12 Extension of Territory**

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

## 5. PRICES AND PAYMENT

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

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

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

**5.4** All payments owed to BI by HORIZON on the basis of accounts rendered shall be made in such a way that [...\*\*\*...] shall [...\*\*\*...] on such [...\*\*\*...]. In the event of a default in payment for whatever reason, default interest at a rate of [...\*\*\*...] p.a. shall be payable on the outstanding amount due. BI

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reserves the right to claim any damage exceeding such amount that shall have been caused by such delay, subject to Section 12.1.

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

## **6. QUALITY ASSURANCE AND COMPLIANCE WITH LAW**

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

### **6.2 Manufacturing Facilities**

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

### **6.3 Compliance with Law**

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

6.3.2 All costs in connection with maintaining BI's compliance with all applicable regulatory requirements applicable to a biopharmaceutical manufacturer in [...\*\*\*...] and cGMP in performing under this AGREEMENT, including but not limited to the maintenance and upgrading of technical facilities and infrastructure and the training of personnel, shall be borne by [...\*\*\*...]. [...\*\*\*...]

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[...\*\*\*...]. All costs in connection with any requirements by (i) HORIZON or a (ii) HEALTH AUTHORITY which relate specifically and solely to the PRODUCT shall be [...\*\*\*...], provided that to the extent that such requirements arise due to the manufacture, use, sale or other disposition of IMUKIN PRODUCT [...\*\*\*...] prior to the Closing Date (as defined in the ASSET PURCHASE AGREEMENT), [...\*\*\*...].

6.3.3 If a HEALTH AUTHORITY requests or requires that a change be made to the DRUG SUBSTANCE SPECIFICATIONS, PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS, then BI shall make such changes in accordance with the QUALITY ASSURANCE AGREEMENT and SOPs (i.e., change control procedures) agreed in writing by HORIZON and BI. Those changes are subject to written approval of each Party, which approval shall not be unreasonably withheld, delayed or conditioned. In case that a request from a HEALTH AUTHORITY may be challenged by either Party, HORIZON and/or BI shall use commercially reasonable efforts to challenge the requests of the HEALTH AUTHORITY and shall assist each other in its communication with the pertinent HEALTH AUTHORITY requesting such a change. The costs for such a change shall be allocated between the Parties according to Section 6.3.2.

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

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

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

6.3.4.3 BI shall make changes as described in this Section 6.3.4 in accordance with timelines agreed to by the Parties, except that BI shall have no obligation to make any such change where doing so, (i) in BI's reasonable judgment after due consultation with legal counsel having experience in such matters, which shall be communicated in writing to HORIZON, would violate

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any applicable law or regulations, or (ii) has a material adverse effect upon any regulatory filings for other products of BI or (iii) would be incompatible with BI's established operations for biopharmaceuticals. For all changes requested by HORIZON, BI shall cooperate with HORIZON in good faith to implement all agreed upon changes to DRUG SUBSTANCE SPECIFICATIONS, PRODUCT SPECIFICATIONS or the MANUFACTURING PROCESS in accordance with the timelines agreed to by the Parties according to this Section 6.3.4.3.

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

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

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

6.3.8 HORIZON shall bear the costs for HEALTH AUTHORITY regulatory inspections

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

#### **6.4 Environmental**

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

#### **6.5 Person-in-Plant**

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

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

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

The PIP at the FACILITY shall at all times:

- be accompanied by BI's personnel for safety and confidentiality reasons; and

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- observe BI's house rules, regulations, confidentiality rules and requirements, standard procedures, safety requirements and security procedures, to the extent previously disclosed in writing by BI to HORIZON; and
- operate in a manner as not to adversely interfere with operations at the FACILITY or at the premises, and not give any instruction to BI or personnel; and
- respect any instructions provided by BI regarding presence in the FACILITY and overall use of BI's premises and EQUIPMENT at the FACILITY.

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

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

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

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

### **7.1 PROJECT LEADER**

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

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

## **7.2 JOINT PROJECT TEAM**

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

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

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

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

7.2.5 In the event that the JOINT PROJECT TEAM is unable to reach agreement on any issue and is unable to make decisions arising out of operational and scientific issues within [...\*\*\*...], each PARTY may call in an expert of its own choice to render advice to the JOINT PROJECT TEAM. Based on the advice of such expert(s) and the team members' know-how, the JOINT PROJECT TEAM will try to resolve such issue. In the event that the PROJECT TEAM fails to reach agreement on an issue within [...\*\*\*...] of first undertaking resolution of such issue, such issue shall then be referred to the STEERING COMMITTEE for immediate resolution.

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7.2.6 The JOINT PROJECT TEAM shall have no authority to amend this Agreement, including any Appendix or CHANGE ORDER. The JOINT PROJECT TEAM shall recommend to the STEERING COMMITTEE for approval changes to any planned activities that are expected to result in increased costs to HORIZON, but shall have no authority itself to approve such activities.

### 7.3 PRODUCT Team

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

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

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

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

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

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

#### **7.4 Steering Committee**

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

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

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

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

#### **7.5 Limitation of Powers**

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

#### **8. INTELLECTUAL PROPERTY AND LICENSES**

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

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

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

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

**8.5** BI hereby grants to HORIZON a non-exclusive, perpetual (subject to Horizon's payment of all undisputed amounts under this AGREEMENT), sublicenseable (through multiple tiers), royalty free license under the BI IMPROVEMENTS and BI BACKGROUND IP (i) to the extent necessary to develop, use, import, offer for sale and sell products containing INTERFERON GAMMA 1b in the name and on the account of HORIZON (or its successor in interest) throughout the world, and (ii) in the event HORIZON is entitled to request a TECHNOLOGY TRANSFER in accordance with Section 14.4.1, to make and have made products containing INTERFERON GAMMA 1b in the name and on account of HORIZON (or

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its successor in interest) throughout the world, whereby in each case HORIZON shall assume the costs to be paid by BI for awards to inventors of BI IMPROVEMENTS, as such awards are set forth in written agreements between BI and such inventor or in an applicable industry labor contract or mandatory by applicable laws, but solely to the extent that BI has given HORIZON written notice of such costs and inventors.

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

## **9. COMPLAINTS; ADVERSE EVENTS; RECALLS**

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

### **9.2 Recalls**

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

### **9.3 Insurance**

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

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

## 10. REPRESENTATIONS AND WARRANTIES

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

### 10.2 BI Warranties

10.2.1 BI represents and warrants (*gewährleistet*):

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

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

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

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

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

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

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

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

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

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

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

#### **10.7 HORIZON Warranties**

10.7.1 HORIZON represents and warrants (*gewährleistet*):

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

10.7.1.2 [...\*\*\*...].

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

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

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

## 11. LIABILITY/INDEMNIFICATION

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

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

**11.3** Subject to Section 11.4 and 12, HORIZON shall indemnify, defend and hold harmless (*freistellen*) BI and its AFFILIATES and their respective officers, directors, employees and agents from and against all LIABILITIES arising out of or resulting from (a) any willful or negligent act or omission by HORIZON relating to the subject matter of this AGREEMENT, (b) the use by or administration to any person of DELIVERED MATERIAL manufactured by BI in performance of its obligations under this AGREEMENT or (c) any breach of this AGREEMENT by HORIZON for which HORIZON is responsible in accordance with Section 276 BGB (except in each case to the extent such LIABILITIES arose or resulted from any negligent act or omission by BI, its AFFILIATES or subcontractors, or any failure to deliver DELIVERED MATERIAL in accordance with BI's warranties, or any breach of any other provision of this AGREEMENT for which BI is responsible in accordance with Section 276 BGB). For clarity, any indemnification of BI by HORIZON according to this Section 11.3 shall not extend to any LIABILITIES if and to the extent arising from any action or omission described in Section 11.2(a), (b) or (c) above.



**11.4** A Party and its AFFILIATES and their respective directors, officers, employees and agents which intends to claim indemnification under this Section 11 (each, an “INDEMNITEE”) shall promptly notify the other Party (the “INDEMNITOR”) in writing of any action, claim or other matter in respect of which the INDEMNITEE intend to claim such indemnification; *provided, however*, that the failure to provide such notice within a reasonable period of time shall not relieve the INDEMNITOR of any of its obligations hereunder except to the extent that the INDEMNITOR is prejudiced by such failure. The INDEMNITEE shall permit the INDEMNITOR at its discretion to settle any such action, claim or other matter, and the INDEMNITEE agrees to the complete control of such defense or settlement by the INDEMNITOR. Notwithstanding the foregoing, the INDEMNITOR shall not enter into any settlement that would adversely affect the INDEMNITEE’s rights hereunder, or impose any obligations on the INDEMNITEE in addition to those set forth herein in order for it to exercise such rights, without INDEMNITEE’s prior written consent, which shall not be unreasonably withheld or delayed. No such action, claim or other matter shall be settled without the prior written consent of the INDEMNITOR, which shall not be unreasonably withheld or delayed. The INDEMNITOR shall not be responsible for any attorneys’ fees or other costs incurred other than as provided herein. The INDEMNITEE shall cooperate fully with the INDEMNITOR and its legal representatives in the investigation and defense of any action, claim or other matter covered by the indemnification obligations of this Section 11. The INDEMNITEE shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

## **12. LIMITATIONS ON LIABILITY**

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

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

## **13. CONFIDENTIALITY**

**13.1** Each Party shall treat confidentially all CONFIDENTIAL INFORMATION of the other Party, and shall not use or disclose such CONFIDENTIAL INFORMATION other than it is expressly permitted under this AGREEMENT. Each Party will take steps to protect the other Party’s CONFIDENTIAL INFORMATION that are at least as stringent as the steps such Party uses to protect its own CONFIDENTIAL INFORMATION, but in no event shall be less than reasonable. Each Party may disclose the other Party’s CONFIDENTIAL INFORMATION to employees (including those of its AFFILIATES), (sub)contractors, advisors, agents and potential

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or actual merger, acquisition or other business partners who reasonably need to know that CONFIDENTIAL INFORMATION provided that (i) they are bound by written obligations of confidentiality and non-use consistent with those set forth in this AGREEMENT or (ii) that they enter into a legally binding agreement with the disclosing PARTY pursuant to which they agree to observe confidentiality provisions which are substantially similar to those set out in this Section 13 or are bound by confidentiality obligations under applicable laws and/or rules of professional conduct. BI may disclose CONFIDENTIAL INFORMATION for corporate reporting purposes to its AFFILIATES.

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

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

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

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

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

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disclosing THIRD PARTY or with respect to any Confidential Information of GENENTECH disclosed to BI or its Affiliates by or on behalf of HORIZON.

## 14. DURATION AND TERMINATION

### 14.1 Duration

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

### 14.2 Termination for Cause

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

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

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

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

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

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

#### **14.3 Effect of Termination**

14.3.1 In the event of any termination of this AGREEMENT (other than for BI's material breach or negligence or willful misconduct by BI), HORIZON shall also do one of the following (at HORIZON's option): (i) HORIZON shall purchase (in which case BI shall sell) PRODUCT [...\*\*\*...]; or (ii) HORIZON shall pay to BI an amount equal to [...\*\*\*...] of the unit price of the PRODUCT then in effect for the PRODUCT [...\*\*\*...]; provided, however, that with regard to any [...\*\*\*...] by BI at the time of termination, [...\*\*\*...] and (B) [...\*\*\*...] for any non-cancellable costs incurred by BI for COMPONENTS which were purchased by BI at HORIZON's request to the extent that HORIZON has not yet paid for such COMPONENTS; and (C) [...\*\*\*...]. Notwithstanding the foregoing, in the event of termination by HORIZON under Section 14.2.3 (prevention by HEALTH AUTHORITIES), Section 14.2.3 shall govern and this Section 14.3.1 shall not apply.

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14.3.2 In the event of any termination or expiration of this AGREEMENT, at the request of HORIZON, BI shall either (i) destroy all material, including but not limited to samples and all documentation received from HORIZON under this AGREEMENT, the CONSOLIDATED SUPPLY AGREEMENT, the ORIGINAL SUPPLY AGREEMENT or the RESTATED SUPPLY AGREEMENT, or (ii) deliver the same to HORIZON or a party nominated by HORIZON, at HORIZON's cost (except in the case of termination by HORIZON for BI's material breach, in which case such destruction or delivery shall be at BI's cost).

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

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

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

#### **14.4 Technology Transfer**

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

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

- (i) Provide reasonable support and assistance to HORIZON with [...\*\*\*...] of the then current MANUFACTURING PROCESS of the DRUG SUBSTANCE and/or PRODUCT from BI to HORIZON or such secondary source manufacturer during a period of [...\*\*\*...] from HORIZON's written notice of determination of such different second source manufacturer with a total capacity of [...\*\*\*...] at an hourly rate of [...\*\*\*...] for upstream, downstream, quality control, quality assurance and analytics (the "TRANSFER SUPPORT"), and/ or
- (ii) deliver to HORIZON the PROCESS PACKAGE (as defined in Section 2) consisting of the most current version of the documentation and materials set forth below, always to the extent not already in HORIZON's possession:
  - A. MASTER BATCH RECORD (including MASTER BATCH RECORDS for buffers, sampling plans);
  - B. MANUFACTURER'S RELEASE SPECIFICATIONS;
  - C. Analytical procedures for in-process control (IPC), release and stability, as applicable;
  - D. Bill of materials and raw materials specifications;
  - E. Storage specifications and instructions for DRUG SUBSTANCE and PRODUCT, as applicable, and other materials;
  - F. Executed BATCH records (i.e. the filled-in MASTER BATCH RECORD) from the most recent three (3) BATCHES;
  - G. Analytical records from the most recent three (3) BATCHES;
  - H. Stability protocols and reports, as applicable;
  - I. Process validation protocols and reports;
  - J. Method validation protocols and reports;
  - K. HORIZON material including but not limited to the reference standards, WCB, reagents, and retained DRUG SUBSTANCE and PRODUCT samples, as applicable, including in-process samples, and other than samples a or applicable laws and regulations in the jurisdictions in which such retention of material occurs; and

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- L. Any other documents, data or materials that the Parties mutually agree are necessary or reasonably required for HORIZON and/ or its Affiliates or HORIZON's designee(s) to manufacture DRUG SUBSTANCE and PRODUCT, as applicable, using the MANUFACTURING PROCESS and support APPROVALS for the PRODUCT, which documents, data and materials may be reflected in a list to be mutually agreed by the Parties, with such agreement not to be unreasonably withheld, delayed or conditioned.

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

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

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

## 15. MISCELLANEOUS

### 15.1 Performance by Affiliates

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

### 15.2 Force Majeure

Neither Party shall be liable for any failure or delay in performance or non-performance caused by circumstances beyond the reasonable control of such Party, including but not limited to explosion, fire, flood, labour strike or labour disturbances, sabotage, order or decree of any court or action of any governmental authority (except where such order, decree or action is a direct result of BI's breach of its obligations hereunder), or other causes, whether similar or dissimilar to those specified which cannot reasonably be controlled by the Party who failed to perform

(each such event, a “**FORCE MAJEURE EVENT**”). A Party affected by a FORCE MAJEURE EVENT shall give notice of such to the other Party as soon as is reasonably possible, and shall resume performance hereunder as soon as is reasonably possible. Each Party shall have the right to terminate this AGREEMENT in the event that a FORCE MAJEURE EVENT continues for more than thirty (30) business days upon written notice thereof.

### 15.3 Assignment

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

### 15.4 Notices

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

**If to HORIZON:**

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

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**If to BI:**

Boehringer Ingelheim Biopharmaceuticals GmbH  
Birkendorfer Straße 65  
88397 Biberach an der Riss  
Germany  
Attention: Head of B&C  
Fax: +49/ 7351/54 - 4845  
Phone: +49/ 7351/54 - 96145

With a copy to:  
Boehringer Ingelheim Biopharmaceuticals GmbH  
Binger Straße 173  
55216 Ingelheim am Rhein  
Germany  
Attention: Corporate Legal  
Fax: +49/ 6132 77-4080  
Phone: +49/ 6132 77-2106

**15.5 Dispute Resolution; Governing Law**

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

15.5.2 Any controversy or claim arising out of, relating to or in connection with any provision of this AGREEMENT, or the rights or obligations of the Parties hereunder, and not resolved by executive mediation in accordance with Section 15.5.1 hereof, shall be referred to and finally settled by binding arbitration, in accordance with the Rules of Arbitration of the International Chamber of Commerce in force on the date the demand for arbitration is filed, which Rules are deemed to be incorporated by reference into this section. [...\*\*\*...]

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[...\*\*\*...]. The language to be used in the arbitral proceedings shall be English. The place of arbitration shall be [...\*\*\*...]. Any determination by such arbitration shall be final and conclusively binding. Judgment on the arbitral award may be entered in any court having jurisdiction thereof. [...\*\*\*...].

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

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

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

#### **15.6 Independent Contractor**

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

#### **15.7 Waiver**

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

#### **15.8 Severability**

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

#### **15.9 Entire Agreement**

This AGREEMENT, the QUALITY ASSURANCE AGREEMENT, the TERMINATION AGREEMENT and the Exhibits set forth the entire agreement between the Parties, and supersede all previous agreements (including but not limited to the RESTATED SUPPLY AGREEMENT), negotiation and understanding, written or oral, regarding the subject matter

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hereof, excluding, however the LYOPHILISATION DEVELOPMENT AGREEMENT. This AGREEMENT may be modified or amended only by an instrument in writing duly executed on behalf of the Parties. For the avoidance of doubt, this AGREEMENT does not supersede the TERMINATION AGREEMENT entered into by the Parties on June 6, 2007.

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

#### **15.10 Headings**

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

#### **15.11 Interpretation**

In this AGREEMENT, unless the context otherwise requires

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

#### **15.12 Priority of Documents**

In the event of a conflict or ambiguity between any term of the ASSET PURCHASE AGREEMENT, this AGREEMENT and its Exhibits and any purchase order or the like, the following order of precedence shall apply (1= highest priority) except where explicitly provided otherwise. The document with the higher priority shall prevail over the document with the lower priority.

1. The ASSET PURCHASE AGREEMENT, except for the event that a provision of this AGREEMENT expressly and specifically states the intent to supersede a specific provision of the ASSET PURCHASE AGREEMENT
2. This AGREEMENT and its Exhibits
4. The QAA and its Exhibits, except for the event that a provision of the QAA expressly and specifically states the intent to supersede a specific provision of this AGREEMENT
5. Any purchase order or the like

**15.13 Ambiguities**

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

**15.14 Counterparts**

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

**15.15 English Language**

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

**[REMAINDER OF PAGE IS INTENTIONALLY BLANK.**

**THE SIGNATURE PAGE FOLLOWS.]**

**In Witness Whereof**, the Parties hereto have caused this AGREEMENT to be executed by their duly authorized representatives as of the EFFECTIVE DATE.

Biberach an der Riss, Germany

Dublin, Ireland

**BOEHRINGER INGELHEIM  
BIOPHARMACEUTICALS GMBH**

**HORIZON PHARMA IRELAND LIMITED**

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

**By:** /s/ David G. Kelly  
**Name:** David G. Kelly  
**Title:** Director  
**Date:** June 29, 2017

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

**List of Exhibits:**

Exhibit 1: Product Specifications

Exhibit 2: Drug Substance Specifications

Exhibit 3: Certificate of Analysis (COA)

Exhibit 4: Certificate of Compliance (COC)

Exhibit 5: DNA sequence of Interferon Gamma lb

Exhibit 6: Product

Exhibit 7 a, b and c: Manufacturing Processes for DRUG SUBSTANCE of Imukin, Actimmune and harmonised process thereof

Exhibit 8: Governance: Product Manager, Product Team and Steering Committee

Exhibit 9: Billing plan for additional services

Exhibit 10: Price

Exhibit 11: Rolling Forecast for Product

Exhibit 12: Territory

Exhibit 13: Permitted Subcontractors

Exhibit 14: Costs of Regulatory Inspections for PRODUCT

Exhibit 15: BCP

Exhibit 16: Manufacturing Process for PRODUCT of Imukin, Actimmune and harmonised process thereof

Exhibit 17: Additional Scope of Services for Process Harmonisation

**Exhibit 1: Product Specifications**

[...\*\*\*...]

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[...\*\*\*...]

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**Exhibit 2: Drug Substance Specifications**

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[...\*\*\*...]

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[...\*\*\*...]

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**Exhibit 3: Certificate of Analysis (COA):**

[...\*\*\*...]

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**Exhibit 4: Certificate of Compliance (COC)**

[...\*\*\*...]

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**Exhibit 5: DNA sequence of Interferon Gamma 1b**

[...\*\*\*...]

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**Exhibit 6: PRODUCT**

[...\*\*\*...]

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**Exhibit 7 a, b and c: MANUFACTURING PROCESSES**

[...\*\*\*...]

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**Exhibit 7 a: MANUFACTURING PROCESS for ACTIMMUNE:**

[...\*\*\*...]

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[...\*\*\*...]

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[...\*\*\*...]

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[...\*\*\*...]

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[...\*\*\*...]

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**Exhibit 7 b: MANUFACTURING PROCESS for IMUKIN PRODUCT:**

[...\*\*\*...]

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[...\*\*\*...]

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[...\*\*\*...]

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[...\*\*\*...]

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[...\*\*\*...]

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**Exhibit 7 c: Harmonised MANUFACTURING PROCESS for ACTIMMUNE and IMUKIN PRODUCT [...\*\*\*...]:**

[...\*\*\*...]

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[...\*\*\*...]

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[...\*\*\*...]

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**Exhibit 8: Governance**

[...\*\*\*...]

**\*\*\*Confidential Treatment Requested**

**Exhibit 9: Billing plan for additional services**

[...\*\*\*...]

**\*\*\*Confidential Treatment Requested**

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**Exhibit 10: Price**

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**Exhibit 11: Rolling Forecast for DP**

[...\*\*\*...]

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**Exhibit 12: Territory**

[...\*\*\*...]

**\*\*\*Confidential Treatment Requested**

**Exhibit 13: Permitted subcontractors**

[...\*\*\*...]

**\*\*\*Confidential Treatment Requested**

**Exhibit 14: Costs of Regulatory Inspections for Product**

[...\*\*\*...]

**\*\*\*Confidential Treatment Requested**

**Exhibit 15: Generic Business Continuity Plan (BCP)**

[...\*\*\*...]

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[...\*\*\*...]

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

[...\*\*\*...]

**\*\*\*Confidential Treatment Requested**

**Exhibit 17: Additional Scope of Services for Process Harmonization**

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**\*\*\*Text Omitted and Filed Separately with  
the Securities and Exchange Commission.  
Confidential Treatment Requested Under  
17 C.F.R. Sections 200.80(b)(4) and 240.24b-2.**

**AMENDED AND RESTATED  
LICENSE AGREEMENT  
BETWEEN  
HORIZON ORPHAN LLC  
AND  
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA  
FOR  
CASE NOS. SD2006-092, SD2017-110, SD2017-113 AND SD2017-236**

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**AMENDED AND RESTATED LICENSE AGREEMENT**

This agreement ("Agreement") is made by and between Horizon Orphan LLC, as successor in interest to Raptor Pharmaceuticals, Inc. (f/k/a Encode Pharmaceuticals, Inc.), a Delaware limited liability company having an address at 150 South Saunders Road, Lake Forest, Illinois 60045 ("LICENSEE") and The Regents of the University of California, a California corporation having its statewide administrative offices at 1111 Franklin Street, Oakland, California 94607-5200 ("UNIVERSITY"), represented by its San Diego campus having an address at University of California, San Diego, Office of Innovation and Commercialization, Mail Code 0910, 9500 Gilman Drive, La Jolla, California 92093-0910 ("UCSD"). This Agreement is being entered into as of the date of last signature below ("Execution Date") and is deemed effective as of October 31, 2007 ("Effective Date").

**RECITALS**

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

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

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

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

*NOW, THEREFORE*, the parties agree:

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## ARTICLE 1. DEFINITIONS

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

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

1.2 "Commercially Reasonable Efforts" means, as the case may be, exerting such efforts and employing such resources as would normally and objectively be exerted or employed by [...\*\*\*...], taking into account the competitiveness of the relevant marketplace, the patent, intellectual property and development positions of third parties, the applicable regulatory situation, the pricing/reimbursement situation, the commercial viability of the product and [...\*\*\*...].

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

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

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

1.6 "HD Indication" means the diagnosis, prevention or treatment of Huntington's Disease.

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

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

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

1.10 “Net Sales” means [...\*\*\*...].

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

1.12 “Patent Rights” means [...\*\*\*...].

The “Patent Rights” in which UNIVERSITY has rights as of the Execution Date are set forth in Exhibit A, which are all such patent applications or patents described in this Paragraph 1.12 as of the Execution Date.

1.13 “Regulatory Authority” means (a) the FDA in the United States or (b) any equivalent agency or governmental authority in any country or other jurisdiction outside the United States that has responsibility for granting any licenses or approvals necessary for the marketing and/or sale of a Licensed Product in such country or other jurisdiction (including, without limitation, any supra-national agency such as the “European Medicines Agency” (EMA)).

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1.14 “Royalty Term” means, with respect to each Licensed Product, the period beginning on the date of the first commercial sale of such Licensed Product and ending on the last to occur of: (i) the expiration of the last-to-expire Patent Rights in the applicable country that covers the making, sale, offer for sale or import of such Licensed Product in such country; and (ii) the twentieth (20th) anniversary of the first commercial sale of such Licensed Product.

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

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

- (i) any royalty payments;
- (ii) payments for equity or debt securities of LICENSEE (except to the extent such payments exceed the fair market value of such securities upon date of receipt, in which case such premiums over fair market value shall be deemed to be “Sublicense Fees”);
- (iii) research or development funding to be applied directly to the future research and/or development of Licensed Products; and
- (iv) payments and reimbursement of Patent Costs paid to UNIVERSITY by LICENSEE with respect to the filing, preparation, prosecution or maintenance of the Patent Rights.

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

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

1.19 “Territory” means world-wide.

## **ARTICLE 2. GRANTS**

2.1 **License.** Subject to the limitations set forth in this Agreement, UNIVERSITY hereby grants to LICENSEE, and LICENSEE hereby accepts, a license under Patent Rights to make and have made, to use and have used, to sell and have sold, to offer for sale, and to import and have imported Licensed Products and to practice Licensed Methods and to use Technology, in the Field within the Territory. The license granted herein is exclusive for Patent Rights and non-exclusive for Technology. Upon expiration of the Royalty Term and provided that all royalty

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

**2.2 Sublicense.**

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

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

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

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

(iii) within [...\*\*\*...] of the execution of the Sublicense agreement, provide UNIVERSITY with a copy of each Sublicense issued; and

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

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

**2.3 Reservation of Rights.** UNIVERSITY reserves the right to:

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

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

### ARTICLE 3. CONSIDERATION

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

(a) a **license issue fee** of fifty thousand dollars (US\$50,000), within thirty (30) days after the Effective Date (it being understood that LICENSEE has fully performed this obligation as of the Execution Date);

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

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

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

<u>Amount</u>	<u>Date or Event</u>
(i) For each orphan indication, the following amounts will be paid: [...***...]	

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[...\*\*\*...]

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

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

[...\*\*\*...]

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

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(e) during the Royalty Term, an **earned royalty** of[...\*\*\*...].

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

[...\*\*\*...];

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

(h) beginning the calendar year of commercial sales of the first Licensed Product by LICENSEE, its Sublicensee, or an Affiliate and if the total earned royalties paid by

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LICENSEE under Paragraphs 3.1(e) and (g) to UNIVERSITY in any such year cumulatively amounts to less than:

a. [...\*\*\*...]

b. [...\*\*\*...]

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

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

**3.3 Patent Costs.** LICENSEE shall reimburse UNIVERSITY all past (prior to the Execution Date) and future (on or after the Execution Date) Patent Costs within [...\*\*\*...] following the date an itemized invoice is sent from UNIVERSITY to LICENSEE. In UNIVERSITY’s discretion, for Patent Costs anticipated to exceed [...\*\*\*...] (“Anticipated Costs”), UNIVERSITY will inform LICENSEE no less than [...\*\*\*...] prior to the date when Anticipated Costs are incurred. UNIVERSITY may, at its discretion and in accordance with Paragraph 5.1(c), require full advance payment of Anticipated Costs at least [...\*\*\*...] before required filing dates (“Advance Payment Deadline”). [...\*\*\*...]. In the event that the Anticipated Costs paid by LICENSEE are greater than the actual cost, the excess amount is creditable against future Patent Costs. In the event that the actual costs exceed the Anticipated Costs paid in advance by LICENSEE, LICENSEE shall pay such excess costs within [...\*\*\*...] following the date an itemized invoice is sent as set forth in Paragraph 4.3.

**3.4 Due Diligence.**

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

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

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[...\*\*\*...]. Except as provided in this Paragraph 3.4(b), LICENSEE shall have no other diligence obligations with respect to the development, commercialization or other exploitation of any Licensed Product for the HD Indication.

**(c) NASH Indication.**

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

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

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

(A) [...\*\*\*...]: and

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

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

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

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

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

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attendees, LICENSEE shall be responsible for [...\*\*\*...] of UNIVERSITY representatives incurred for participation in attending such meetings of the NASH Working Group, as arranged by LICENSEE or otherwise approved in advance by LICENSEE.

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

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

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

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

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

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

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

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

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

#### ARTICLE 4. REPORTS, RECORDS AND PAYMENTS

##### 4.1 Reports and Periodic Meetings.

###### (a) Progress Reports and Periodic Meetings.

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

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

(b) **Royalty Reports.** After the first commercial sale of a Licensed Product anywhere in the world, LICENSEE shall submit to UNIVERSITY quarterly royalty reports on or before each March 31, June 30, September 30 and December 31 of each year. Each royalty report shall cover LICENSEE’s (and each Affiliate’s and Sublicensee’s) most recently completed calendar quarter (until the expiration or termination of such period or the earlier expiration or termination of this Agreement) and shall show:

- (i) the date of first commercial sale of a Licensed Product in each country;
- (ii) the gross sales, deductions as provided in Paragraph 1.12 and Net Sales during the most recently completed calendar quarter and the royalties, in US dollars, payable with respect thereto;
- (iii) the applicable Indication for each type of Licensed Product sold;
- (iv) the number of each type of Licensed Product sold;
- (v) Sublicense Fees and royalties received during the most recently completed calendar quarter in US dollars, payable with respect thereto;
- (vi) the method used to calculate the royalties; and
- (vii) the exchange rates used.

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

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

#### **4.2 Records & Audits.**

(a) LICENSEE shall keep, and shall require its Affiliates and Sublicensees to keep, accurate and correct records of all Licensed Products manufactured, used, and sold, and

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Sublicense Fees received under this Agreement. Such records shall be retained by LICENSEE for at least five (5) years following a given reporting period.

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

#### 4.3 Payments.

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

#### (b) Royalty Payments.

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

(ii) LICENSEE shall pay to UNIVERSITY earned royalties within [...] after the end of each previously stated [...] noted in Paragraph 4.1(b). Each such payment shall be for earned royalties accrued within such preceding [...].

(iii) Royalties earned on sales occurring or under Sublicense granted pursuant to this Agreement in any country outside the United States shall not be reduced by LICENSEE for any taxes, fees, or other charges imposed by the government of such country on the payment of royalty income, except that all payments made by LICENSEE in fulfillment of UNIVERSITY's tax liability in any particular country may be credited against earned royalties or fees due UNIVERSITY for that country. LICENSEE shall pay all bank charges resulting from the transfer of such royalty payments.

(iv) If at any time legal restrictions prevent the prompt remittance of part or all royalties by LICENSEE with respect to any country where a Licensed Product is sold or a

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Sublicense is granted pursuant to this Agreement, LICENSEE shall convert the amount owed to UNIVERSITY into US currency and shall pay UNIVERSITY directly from its US sources of fund for as long as the legal restrictions apply.

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

(vi) Royalty payments under Article 3, recoveries and settlements under Article 5, and royalty reports under 4.1(b) shall be rendered for any and all Licensed Products even if due after expiration of the Agreement (in each case with respect to the Net Sales for Licensed Products sold, and settlements entered into and recoveries received (as applicable) during the Term).

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

## ARTICLE 5. PATENT MATTERS

### 5.1 Patent Prosecution and Maintenance.

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

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

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

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

## 5.2 Patent Infringement.

(a) In the event that UNIVERSITY (to the extent of the actual knowledge of the licensing professional responsible for the administration of this Agreement) or LICENSEE learns of infringement of potential commercial significance of any patent licensed under this Agreement, the knowledgeable party will provide the other (i) with written notice of such infringement and (ii) with any evidence of such infringement available to it (the "Infringement Notice"). During the period in which, and in the jurisdiction where, LICENSEE has any exclusive rights under Patent Rights licensed under this Agreement (including with respect to any indication in the Field), neither party will notify a third party (including the infringer) of infringement or put such third party on written notice of the infringement of any Patent Rights without first obtaining consent of the other party.

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

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the approval of the UC Board of Regents and a response to the LICENSEE's request for such consent to be provided as promptly as possible. If, in a suit initiated by LICENSEE, UNIVERSITY is involuntarily joined other than by LICENSEE, LICENSEE will pay any costs incurred by UNIVERSITY arising out of such suit, including but not limited to, any legal fees of counsel that UNIVERSITY selects and retains to represent it in the suit. In the event that, in a given country in which a Licensed Product is sold, there is infringing activity of potential commercial significance in such country with respect to Patent Rights in such country that cover the Licensed Product in the Field, which has not been abated and UNIVERSITY does not agree to join as a party in a suit proposed by LICENSEE to enforce Patent Rights against such infringement in such country, then the parties will meet and discuss a modification to LICENSEE's obligation to pay royalties with respect to such Licensed Product in such country under this Agreement.

(c) If within a [...] following the date the Infringement Notice takes effect, infringing activity of potential commercial significance by the infringer has not been abated and if LICENSEE has not brought suit against the infringer and is not otherwise engaged in reasonable efforts to cause such infringement to be abated, UNIVERSITY may institute suit for patent infringement against the infringer upon [...] prior written notice to LICENSEE; provided that, at the request of LICENSEE, UNIVERSITY will first meet with LICENSEE and consider in good faith any reasons that LICENSEE believes that such a suit by UNIVERSITY may have an adverse effect. If UNIVERSITY institutes such suit, LICENSEE may not join such suit without UNIVERSITY's consent and may not thereafter commence suit against the infringer for the acts of infringement that are the subject of UNIVERSITY's suit or any judgment rendered in that suit, and UNIVERSITY will control such patent infringement suit, and also will control any counterclaims and defenses in connection with such suit; provided however that, in the event LICENSEE did not bring suit against the infringer because of UNIVERSITY's refusal to consent to be joined in a suit brought by LICENSEE, UNIVERSITY will not bring a suit against the infringer unless it allows LICENSEE, at LICENSEE's expense, to join and share control of such suit ("UNIVERSITY Refusal Suit").

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

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

(e) Any monetary recovery or settlement received in connection with any suit covered by this Paragraph 5.2 will first be shared by UNIVERSITY and LICENSEE equally to cover the litigation costs each incurred, and next shall be paid to UNIVERSITY or LICENSEE to cover any litigation costs it incurred in excess of the litigation costs of the other. In any suit initiated by LICENSEE under Paragraphs 5.2(b) or (d), any recovery in excess of litigation costs will be shared between LICENSEE and UNIVERSITY as follows: (i) for any recovery other than amounts paid for willful infringement: (A) UNIVERSITY will receive [...\*\*\*...] of the recovery if UNIVERSITY was not a party in the litigation and did not incur any litigation costs; (B) UNIVERSITY will receive [...\*\*\*...] of the recovery if UNIVERSITY was a party in the litigation, but did not incur any litigation costs, including the provisions of Paragraph 5.2(b) above, or (C) UNIVERSITY will receive [...\*\*\*...] of the recovery if UNIVERSITY incurred any litigation costs in connection with the litigation; and (ii) for any recovery for willful infringement, UNIVERSITY will receive [...\*\*\*...] of the recovery. In any suit initiated by UNIVERSITY in accordance with the terms of this Agreement, any recovery in excess of litigation costs will belong to UNIVERSITY, except that in any UNIVERSITY Refusal Suit as defined in Paragraph 5.2(c), any recovery in excess of litigation costs will be shared [...\*\*\*...] by UNIVERSITY and [...\*\*\*...] by LICENSEE.

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

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

#### **5.4 Related Provisions.**

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

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

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

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

### **ARTICLE 6. GOVERNMENTAL MATTERS**

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

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

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## ARTICLE 7. TERMINATION OR EXPIRATION OF THE AGREEMENT

### 7.1 Term and Termination by UNIVERSITY.

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

(b) Subject to Paragraph 7.1(d), if LICENSEE breaches its material obligations under this Agreement, then UNIVERSITY may give written notice of default (“Notice of Default”) to LICENSEE. If LICENSEE fails to cure the material breach within ninety (90) days of the Notice of Default, then (i) in the case of any Notice of Default based on LICENSEE’s material breach of its diligence obligations specified in Paragraphs 3.4(a), (b) or (c) with respect to a Cystinosis Indication, NASH Indication or HD Indication, as applicable, UNIVERSITY shall have the right and option, solely with respect to the applicable indication, to either terminate the license granted herein to such indication (in which case, the Field will exclude that terminated indication) or convert LICENSEE’s exclusive license to such indication to a nonexclusive license, and (ii) in the case of any other such material breach, UNIVERSITY may terminate this Agreement and the license granted herein. UNIVERSITY may exercise any such right to terminate or convert the license (in the case of clause (i), solely with respect to the applicable indication) by providing to LICENSEE a second written notice (in the case of a termination, a “Notice of Termination” and in the case of a license conversion, a “Notice of License Conversion”) to LICENSEE. If either such notice is sent to LICENSEE, this Agreement (or in the case of clause (i), the license solely with respect to the applicable indication) shall automatically terminate or the license shall convert to a non-exclusive license with respect to the subject indication, as applicable, on the effective date of that notice. Termination of this Agreement in its entirety or termination of the license granted herein with respect to any indication shall not relieve LICENSEE of its obligation to pay any fees owed at the time of termination and shall not impair any accrued right of UNIVERSITY. During the term of any such Notice of Default or period to cure, to the extent the default at issue is a failure to pay past or ongoing Patent Costs as provided for under this Agreement as provided in Paragraph 3.3, UNIVERSITY shall have no obligation to incur any new Patent Costs under this Agreement and shall have no obligation to further prosecute Patent Rights or file any new patents under Patent Rights.

(c) This Agreement will terminate immediately, without the obligation to provide ninety (90) days’ notice as set forth in Paragraph 7.1(b), if LICENSEE files a claim including in any way the assertion that any portion of UNIVERSITY’s Patent Rights is invalid or unenforceable where the filing is by the LICENSEE, a third party on behalf of the LICENSEE, or a third party at the written urging of the LICENSEE.

### 7.2 Termination by LICENSEE.

(a) LICENSEE shall have the right at any time and for any reason, upon a ninety (90) day written notice to UNIVERSITY, either to terminate this Agreement in its entirety or to terminate the licensed granted herein with respect to any one or more indication(s) (in which case, the Field will exclude that terminated indication(s)). Said notice shall state LICENSEE’s reason for terminating this Agreement.



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(b) Any termination under Paragraph 7.2(a) shall not relieve LICENSEE of any obligation or liability accrued under this Agreement prior to termination or rescind any payment made to UNIVERSITY or action by LICENSEE prior to the time termination becomes effective. Termination shall not affect in any manner any rights of UNIVERSITY arising under this Agreement prior to termination.

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

- (a) Paragraph 2.2(c);
- (b) Article 4 (Reports, Records and Payments);
- (c) Paragraph 7.3 (Survival on Termination or Expiration);
- (d) Paragraph 7.5 (Disposition of Licensed Products on Hand);
- (e) Article 8 (Limited Warranty and Indemnification);
- (f) Article 9 (Use Of Names and Trademarks);
- (g) Paragraph 10.2 hereof (Secrecy);
- (h) Paragraph 10.5 (Failure to Perform); and
- (i) Paragraph 10.6 (Governing Law).

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

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

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the effective date of such termination provided that the sale of such Licensed Product by LICENSEE, its Sublicensees, or Affiliates shall be subject to the terms of this Agreement, including but not limited to the rendering of reports and payment of royalties required under this Agreement.

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

## **ARTICLE 8. LIMITED WARRANTY AND INDEMNIFICATION**

### **8.1 Limited Warranty.**

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

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

(c) EXCEPT WITH RESPECT TO A BREACH OF PARAGRAPH 8.1(a) ABOVE, A BREACH OF CONFIDENTIALITY UNDER PARAGRAPH 10.2 OR, IN THE CASE OF LICENSEE, LICENSEE'S DUTIES FOR CLAIMS OF THIRD PARTIES UNDER PARAGRAPH 8.2, NEITHER PARTY WILL BE LIABLE FOR ANY LOST PROFITS, COSTS OF PROCURING SUBSTITUTE GOODS OR SERVICES, LOST BUSINESS, ENHANCED DAMAGES FOR INTELLECTUAL PROPERTY INFRINGEMENT, OR FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, OR OTHER SPECIAL DAMAGES SUFFERED BY THE OTHER PARTY, SUBLICENSEES, JOINT VENTURES, OR AFFILIATES ARISING OUT OF OR RELATED TO THIS AGREEMENT FOR ALL CAUSES OF ACTION OF ANY KIND (INCLUDING TORT, CONTRACT, NEGLIGENCE, STRICT LIABILITY AND BREACH OF WARRANTY) EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

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

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- (i) a warranty or representation by UNIVERSITY as to the validity or scope of any Patent Rights;
  - (ii) a warranty or representation that anything made, used, sold or otherwise disposed of under any license granted in this Agreement is or shall be free from infringement of patents of third parties;
  - (iii) an obligation to bring or prosecute actions or suits against third parties for patent infringement except as provided in Paragraph 5.2 hereof;
  - (iv) conferring by implication, estoppel or otherwise any license or rights under any patents of UNIVERSITY other than Patent Rights as defined in this Agreement, regardless of whether those patents are dominant or subordinate to Patent Rights; or
  - (v) an obligation to furnish any know-how not provided in Patent Rights and Technology; or
  - (vi) an obligation to update Technology.

## 8.2 Indemnification.

(a) LICENSEE will, and will require Sublicensees to, indemnify, hold harmless, and defend UNIVERSITY and its officers, employees, and agents; the sponsors of the research that led to the Invention; and the inventors of patents or patent applications under Patent Rights, and their employers; against any and all claims, suits, losses, damages, costs, fees, and expenses resulting from, or arising out of, the exercise of this license or any Sublicense, except to the extent arising out of or related to Patent Rights to the extent assigned, or otherwise licensed, by UNIVERSITY's inventors to third parties. This indemnification will include, but will not be limited to, any product liability.

(b) From and after the Execution Date, LICENSEE, at its sole cost and expense, shall insure its activities in connection with the work under this Agreement and obtain, keep in force and maintain insurance or an equivalent program of self-insurance as follows:

(i) comprehensive or commercial general liability insurance (contractual liability included) with limits of at least: (A) each occurrence, five million dollars (US\$5,000,000); (B) products/completed operations aggregate, ten million dollars (US\$10,000,000); (C) personal and advertising injury, five million dollars (US\$5,000,000); and (D) general aggregate (commercial form only), ten million dollars (US\$10,000,000); Worker's Compensation as legally required in the jurisdiction in which the LICENSEE is doing business;

(ii) the coverage and limits referred to above shall not in any way limit the liability of LICENSEE; and

(iii) If the above insurance is written on a claims-made form, it shall continue for three (3) years following termination or expiration of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the Effective Date.

(c) Upon request, LICENSEE shall furnish UNIVERSITY with certificates of insurance showing compliance with all requirements. Such certificates shall: (i) indicate that UNIVERSITY has been endorsed as an additional insured party under the coverage referred to above; and (ii) include a provision that the coverage shall be primary and shall not participate with nor shall be excess over any valid and collectable insurance or program of self-insurance carried or maintained by UNIVERSITY. LICENSEE shall provide [...\*\*\*...] advance written notice to the UNIVERSITY of any policy modification with respect to the matters addressed in clause (i) or (ii) of this Paragraph 8.2(c).

(d) UNIVERSITY shall notify LICENSEE in writing of any claim or suit brought against UNIVERSITY in respect of which UNIVERSITY intends to invoke the provisions of this Article. LICENSEE shall keep UNIVERSITY informed on a current basis of its defense of any claims under this Article.

#### ARTICLE 9. USE OF NAMES AND TRADEMARKS

9.1 Nothing contained in this Agreement confers any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of either party hereto (including contraction, abbreviation or simulation of any of the foregoing). Unless required by law, the use by LICENSEE of the name, "The Regents of the University of California" or the name of any campus of the University Of California is prohibited, without the express written consent of UNIVERSITY.

9.2 UNIVERSITY may disclose to the Inventors the terms and conditions of this Agreement upon their request. If such disclosure is made, UNIVERSITY shall request the Inventors not disclose such terms and conditions to others.

9.3 UNIVERSITY may acknowledge the existence of this Agreement and the extent of the grant in Article 2 to third parties, but UNIVERSITY shall not disclose the financial terms of this Agreement to third parties, except where UNIVERSITY is required by law to do so, such as under the California Public Records Act. LICENSEE hereby grants permission for UNIVERSITY (including UCSD) to include LICENSEE's name and a link to LICENSEE's website in UNIVERSITY's and UCSD's annual reports and on UNIVERSITY's (including UCSD's) websites that showcase technology transfer-related stories.

#### ARTICLE 10. MISCELLANEOUS PROVISIONS

10.1 **Correspondence.** Any notice or payment required to be given to either party under this Agreement shall be deemed to have been properly given and effective:

(a) on the date of delivery if delivered in person, or

(b) five (5) days after mailing if mailed by first-class or certified mail, postage paid, to the respective addresses given below, or to such other address as is designated by written notice given to the other party.

If sent to LICENSEE:  
Horizon Orphan LLC

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150 South Saunders Road  
Lake Forest, Illinois 60045  
Attention: General Counsel  
Phone: +1 224-393-3233 (direct)  
Fax: +1-847-572-1631  
Attention:

If sent to UNIVERSITY by mail:  
University of California, San Diego  
Office of Innovation and Commercialization  
9500 Gilman Drive  
Mail Code 0910  
La Jolla, CA 92093-0910  
Attention: Director of Commercialization

If sent to UNIVERSITY by courier:  
University of California, San Diego  
Office of Innovation and Commercialization  
10300 North Torrey Pines Road  
Torrey Pines Center North, Third Floor La Jolla, CA 92037  
Attention: Director of Commercialization

#### 10.2 **Secrecy.**

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

(b) Each party and its employees and agents shall:

(i) use the Confidential Information for the sole purpose of performing under the terms of this Agreement;

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(ii) safeguard Confidential Information against disclosure to others with the same degree of care as it exercises with its own data of a similar nature;

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

(A) the receiving party can demonstrate by written records was previously known to it;

(B) is now, or becomes in the future, public knowledge other than through acts or omissions of the receiving party or its employees or agents;

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

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

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

(c) The secrecy obligations provided in this Paragraph 10.2 with respect to Confidential Information of the disclosing party shall continue for a period ending [\*...\*\*\*...] from the expiration or termination date of this Agreement.

**10.3 Assignability.** This Agreement is binding upon and inures to the benefit of UNIVERSITY, its successors and assigns. But it is personal to LICENSEE and assignable by LICENSEE only with the written consent of UNIVERSITY. Notwithstanding the foregoing, the consent of UNIVERSITY will not be required if the assignment is in conjunction with the transfer of all or substantially all of the business of LICENSEE to which this Agreement relates or is to an Affiliate of LICENSEE.

**10.4 No Waiver.** No waiver by either party of any breach or default of any covenant or agreement set forth in this Agreement shall be deemed a waiver as to any subsequent and/or similar breach or default.

**10.5 Failure to Perform.** In the event of a failure of performance due under this Agreement and if it becomes necessary for either party to undertake legal action against the other on account thereof, then the prevailing party shall be entitled to reasonable attorney's fees in addition to costs and necessary disbursements.

**10.6 Governing Laws.** THIS AGREEMENT SHALL BE INTERPRETED AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CALIFORNIA, but

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the scope and validity of any patent or patent application shall be governed by the applicable laws of the country of the patent or patent application.

10.7 **Force Majeure.** A party to this Agreement may be excused from any performance required herein if such performance is rendered impossible or unfeasible due to any catastrophe or other major event beyond its reasonable control, including, without limitation, war, riot, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and floods, fires, explosions, or other natural disasters. When such events have abated, the non-performing party's obligations herein shall resume.

10.8 **Headings.** The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

10.9 **Entire Agreement.** This Agreement embodies the entire understanding of the parties and supersedes all previous communications, representations or understandings, either oral or written, between the parties relating to the subject matter hereof, including the Prior Agreement.

10.10 **Amendments.** No amendment or modification of this Agreement shall be valid or binding on the parties unless made in writing and signed on behalf of each party.

10.11 **Severability.** In the event that any of the provisions contained in this Agreement is held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if the invalid, illegal, or unenforceable provisions had never been contained in it.

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*IN WITNESS WHEREOF*, both UNIVERSITY and LICENSEE have executed this Agreement, in duplicate originals, by their respective and duly authorized officers on the day and year written.

**HORIZON ORPHAN LLC:**

By: /s/ Brian K. Beeler  
Name: Brian K. Beeler  
Title: Executive Vice President  
General Counsel

Date: 5/19/17

**THE REGENTS OF THE  
UNIVERSITY OF CALIFORNIA:**

By: /s/ Ruben Flores  
Name: Ruben Flores  
Title: Director, Office of Innovation  
and Commercialization

Date: 5/31/17



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**THE REGENTS OF THE  
UNIVERSITY OF CALIFORNIA:**

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

Date: May 31, 2017

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EXHIBIT A

Patent Rights

<u>Title</u>	<u>Territory</u>	<u>Date of Filing</u>	<u>Application No.</u>	<u>Publication No.</u>	<u>Patent No.</u>	<u>Status</u>	<u>Comment</u>	<u>Owner</u>
[...***...]								

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(1) [...\*\*\*...].

(2) [...\*\*\*...].

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*Certification of Principal Executive Officer*

I, Timothy P. Walbert, certify that:

1. I have reviewed this Amendment No. 1 to the quarterly report on Form 10-Q/A of Horizon Pharma plc; and
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.

Date: September 28, 2017

/s/ Timothy P. Walbert

Timothy P. Walbert

Chairman, President and Chief Executive Officer  
(Principal Executive Officer)



*Certification of Principal Financial Officer*

I, Paul W. Hoelscher, certify that:

1. I have reviewed this Amendment No. 1 to the quarterly report on Form 10-Q/A of Horizon Pharma plc; and
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.

Date: September 28, 2017

/s/ Paul W. Hoelscher

Paul W. Hoelscher

Executive Vice President, Chief Financial Officer

(Principal Financial Officer)