HORIZON PHARMA PLC

FORM 10-Q/A
(Amended Quarterly Report)

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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 September 30, 2016

OR

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

For the transition period from to

Commission File Number 001-35238

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

Ireland	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Connaught House, 1st Floor 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland	**Not Applicable**
(Address of principal executive offices)	**(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	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
Emerging growth company	☐		

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

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

Number of registrant’s ordinary shares, nominal value $0.0001, outstanding as of November 2, 2016: 161,257,419.

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 September 30, 2016, as filed with the Securities and Exchange Commission (the "SEC") on November 7, 2016 (the "10-Q"). This Amendment is being filed solely to re-file a revised redacted version of Exhibit 10.5 to the 10-Q, reflecting changes to the Company's confidential treatment request with respect to certain portions of such exhibit. 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 registrant's other filings with the SEC.

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: May 26, 2017

By: /s/ Timothy P. Walbert

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

Date: May 26, 2017

By: /s/ Paul W. Hoelscher

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

INDEX TO EXHIBITS

Exhibit Number	Description of Document
10.5*	Manufacturing Services Agreement, dated November 15, 2010, by and among Patheon Pharmaceuticals Inc., Horizon Orphan LLC (as successor in interest to Raptor Therapeutics Inc.) and Horizon Pharma Europe B.V. (as successor in interest to Raptor Pharmaceuticals Europe B.V.), as amended April 5, 2012 and June 21, 2013.
31.3	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
31.4	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.

* 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.

*****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.

Manufacturing Services Agreement

November 15, 2010

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MANUFACTURING SERVICES AGREEMENT

THIS MANUFACTURING SERVICES AGREEMENT (the " **Agreement** ") is made as of November 15, 2010 (the " **Effective Date** ")

BETWEEN:

PATHEON PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware

(" **Patheon** "),

- and -

RAPTOR THERAPEUTICS, INC.,
a corporation existing under the laws of the State of Delaware

(" **Client** ")

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

INTERPRETATION

1.1 Definitions .

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

" **Active Materials** ", " **Active Pharmaceutical Ingredients** " or " **API** " means the materials listed on Schedule D;

" **Active Materials Credit Value** " means the value of the Active Materials for certain purposes of this Agreement, as set forth on Schedule D;

" **Actual Annual Yield** " or " **AAY** " has the meaning specified in Section 2.2(a);

" **Affiliate** " means

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity. the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement;

For this definition, " **control** " means the ownership of shares carrying at least a majority of the votes for the election of the directors of a corporation.

" **Annual Product Review Report** " means the annual product review report prepared by Patheon as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

" **Annual Report** " means the annual report to the FDA prepared by Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

" **Annual Volume** " means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B;

" **Applicable Laws** " means (i) for Patheon, all the Laws of State of Ohio and all other state and federal laws applicable to the manufacture of the Products; and (ii) for Client and the Products. the Laws of all jurisdictions where the Products are manufactured, distributed, and marketed as these are agreed and understood by the parties in this Agreement;

" **Authority** " means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

[…***…];

" **Breach Notice** " will have the meaning specified in Section 8.2(a);

" **Business Day** " means a day other than a Saturday, Sunday or a day that is a statutory holiday in the State of Ohio or the State of California;

" **cGMPs** " means current good manufacturing practices as described in Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations together with the latest FDA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

" **Client Intellectual Property** " means Intellectual Property generated or derived by Client before entering into this Agreement, or by Patheon while performing any Manufacturing Services or otherwise generated or derived by Patheon in its business which Intellectual Property is specific to, or dependent upon, Client's Active Material or Product;

" **Client Property** " will have the meaning specified in Section 8.4(f);

" **CMC** " has the meaning specified in Section 7.8(c);

" **Components** " means, collectively, all packaging components, raw materials, and ingredients (including labels, product inserts and other labelling for the Products),

required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

" **Confidentiality Agreement** " means the agreement about the non-disclosure of confidential information between Patheon and Client (formerly know as Bennu Pharmaceuticals, Inc.) […***…];

" **Deficiency** " has the meaning specified in Section 7.8(d);

" **Deficiency Notice** " has the meaning specified in Section 6.1(a);

" **Delivery Date** " means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(e);

[" **Equipment** " will have the meaning ascribed to it in {the Capital Equipment Agreement related to this MSA if any}]

" **FDA** " means the United States Food and Drug Administration;

" **Firm Orders** " has the meaning specified in Section 5.1(c);

" **First Firm Order** " has the meaning specified in Section 5.1(b);

" **Force Majeure** " will have the meaning specified in Section 13.7;

" **Initial Manufacturing Month** " has the meaning specified in Section 5.1(b);

" **Initial Manufacturing Period** " has the meaning specified in Section 5.1(b);

" **Initial Term** " has the meaning specified in Section 8.1;

" **Intellectual Property** " includes, without limitation, rights in patents, patent applications, formulae: trade-marks, trade-mark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

" **Invention** " means information about any innovation, improvement, development, discovery, computer program, device. trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

" **Inventory** " means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the Active Materials;

" **Late Delivery** " has the meaning specified in Section 5.5:

" **Laws** " means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

" **Manufacturing Services** " means the manufacturing, quality control, quality assurance, stability testing, packaging, and related services, set forth in this Agreement, required to manufacture Product or Products from Active Materials and Components;

" **Manufacturing Site** " means the facility owned and operated by Patheon that is located at 2110 East Galbraith Road, Cincinnati, OH 45237-1625;

" **Materials** " means all Components, […***…], and other materials used to manufacture the Product other than Active Materials;

[…***…];

" **Minimum Run Quantity** " means the minimum number of batches of a Product to be produced during the same cycle of manufacturing as set forth in Schedule B;

" **Patheon Intellectual Property** " means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, Intellectual Property developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business which Intellectual Property is not specific to, or dependent upon. Client's Active Material or Product including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products, drug product dosage forms or drug delivery systems unrelated to the specific requirements of the Product(s);

" **Price** " means the price measured in US Dollars to be charged by Patheon for performing the Manufacturing Services, and includes the cost of Components. certain cost items as set forth in Schedule B, and annual stability testing costs as set forth in Schedule C.

" **Product(s)** " means the product(s) listed on Schedule A;

" **Quality Agreement** " means the agreement (the form of which is set forth in Schedule F) between the parties setting out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client;

" **Recall** " has the meaning specified in Section 6.2(a);

" **Regulatory Authority** " means the FDA and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products including the Products in the Territory;

" **RFID** " means Radio Frequency Identification Devices which (at present or in the future) may be affixed to Products or Materials to assist in inventory control, tracking, and identification;

" **Remediation Period** " has the meaning specified in Section 8.2(a);

" **Shortfall** " has the meaning specified in Section 2.2(b);

" **Specifications** " means the file, for each Product, which is given by Client to Patheon in accordance with the procedures listed in Schedule A and which contains documents relating to each Product, including, without limitation:

(a) specifications for Active Materials and Components;

(b) manufacturing specifications, directions, and processes;

(c) storage requirements;

(d) all environmental, health and safety information for each the Product including material safety data sheets; and

(e) the finished Product specifications, packaging specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

" **Target Yield** " has the meaning specified in Section 2 2(a);

" **Target Yield Determination Batches** " has the meaning specified in Section 2.2(a);

" **Technical Dispute** " has the meaning specified in Section 12.2;

" **Territory** " means […***…];

" **Third Party Rights** " means the Intellectual Property of any third party;

" **Year** " means in the first year of this Agreement the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year.

1.2 Currency .

Unless otherwise indicated. all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.

1.3 Sections and Headings .

The division of this Agreement into Articles, Sections, Subsections, and Schedules and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section or Schedule refers to the specified Section or Schedule to this Agreement. In this Agreement, the terms **''this Agreement** " **,** " **hereof',** " **herein** " **,** " **hereunder** " and similar expressions refer to this Agreement and not to any particular part, Section or Schedule of this Agreement.

1.4 Singular Terms .

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

1.5 Schedules .

The following Schedules are attached to, incorporated in, and form part of this Agreement:

Schedule A -	Product List and Specifications
Schedule B -	Minimum Run Quantity, Annual Volume, and Price
Schedule C -	Annual Stability Testing
Schedule D -	Active Materials, Active Materials Credit Value, and [...***...]
Schedule E -	Technical Dispute Resolution
Schedule F -	Commercial Quality Agreement
Schedule G -	(Reserved)
Schedule H -	Quarterly Active Materials Inventory Report
Schedule I -	Report of Annual Active Materials inventory Reconciliation and Calculation of Actual Annual Yield
Schedule J -	(Reserved)
[Schedule K -	Capital Equipment Agreement]

ARTICLE 2

PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services for the Territory for the fees specified in Schedules B and C to manufacture Products for Client in accordance with Specifications and requirements in the Quality Agreement agreed to by the parties. Unless specifically agreed to by Client, Price for Products will include costs items. Schedule B sets forth a list of cost items that are included in the Price for Products. If any cost items are to be excluded from the Price, Patheon will provide a list of the excluded items to Client in advance for approval. Client agrees to pay additional fees for the excluded items approved in advance by Client. Patheon may change the Manufacturing Site for the Products only with the prior written consent of Client, this consent not to be unreasonably withheld. If Manufacturing Services have not started within […***…] of the date of execution of this Agreement, Patheon may amend the fees set out in Schedules B and C. As long as Patheon is in compliance with the terms and conditions of this Agreement, Client will utilize Patheon to manufacture […***…].

(a) Conversion of Active Materials and Components . Patheon will convert Active Materials and Components into Products.

(b) Quality Control and Quality Assurance . Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon's quality assurance group. Patheon will perform its batch review and release responsibilities in accordance with Patheon's standard operating procedures. Each time Patheon ships Products to Client, it will give Client a certificate of analysis and certificate of compliance including a statement that the batch has been manufactured and tested in accordance with Specifications and cGMPs. Client will have sole responsibility for the release of Products to the market. The form and style of batch documents, including, but not limited to, batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of Patheon. Specific Product related information contained in those batch documents is Client property.

(c) Components . Patheon will purchase and test all Components (with the exception of those that are supplied by Client) at Patheon's expense and as required by the Specifications.

(d) Stability Testing . Patheon will conduct stability testing on the Products in accordance with the protocols set out in the Specifications for the separate fees and during the time periods set out in Schedule C. Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs. Patheon will notify Client within one Business Day, after which Patheon and Client will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure, including which party will bear the cost of the investigation. Patheon will not be liable for these costs unless it has failed to perform the Manufacturing

Services in accordance with the Specifications, cGMPs, and Applicable Laws. Patheon will give Client all stability test data and results at Client's request.

(e) Packaging . Patheon will package the Products as set out in the Specifications. Client will be responsible for the cost of artwork development. Patheon will determine and imprint the batch numbers and expiration dates for each Product shipped. The batch numbers and expiration dates will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon's name will not appear on the label or anywhere else on the Products unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name.

(f) Active Materials and Client Supplied Components Importing . At least […***…] before the scheduled production date, Client will deliver the Active Materials to the Manufacturing Site [...***...] sufficient for Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If the Active Materials are not received […***…] before the scheduled production date, the Firm Order may not be cancelled but Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials. There will be no penalty to Client under these circumstances. But if Patheon is unable to manufacture Product to meet this new shipment date due to prior third party production commitments, Patheon may delay the shipment until a later date as agreed to by the parties. All shipments of Active Material will be accompanied by certificate(s) of analysis from the Active Material manufacturer and the Client, confirming the identity and purity of the Active Materials and its compliance with the Active Material specifications.

(g) […***…]

(h) Product Rejection for Finished Product Specification Failure . Internal process specifications will be defined and mutually agreed upon. If Patheon manufactures Product in accordance with the agreed upon process specifications and a batch or portion of batch of Product does not meet a Finished Product Specification, […***…]. If Client previously paid for the non-conforming Product, Patheon will promptly, at Clients election, either: (i) refund the labor and overhead costs associated with such non-conforming Product; or (ii) offset such costs against other amounts due to Patheon hereunder.

2.2 Active Material Yield .

(a) Reporting . Patheon will give Client a […***…] inventory report of the Active Materials held by Patheon using the inventory report form set out in Schedule H, which will contain the following information for the quarter:

Quantity Received: The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

Quantity Dispensed: The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications held at the beginning of the applicable period, less the inventory of Active Materials that complies with the Specifications held at the end of the period. The Quantity Dispensed will only include Active Materials received and dispensed in commercial manufacturing of Products and, for certainty, will not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or dispensed in technical transfer activities or development activities during the applicable period, including without limitation, any regulatory, stability, validation or test batches manufactured during the applicable period.

Quantity Converted: The total amount of Active Materials contained in the Products manufactured with the Quantity Dispensed (including any additional Products produced in accordance with Section 6.1 or 6_2), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 because of Patheon's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Within […***…] after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials on the reconciliation report form set forth in Schedule I including the calculation of the " **Actual Annual Yield** " or " **AAY** " for the Product at the Manufacturing Site during the Year AAY is the percentage of the Quantity Dispensed that was converted to Products and is calculated as follows:

$$\frac{\text{Quantity Converted during the Year}}{\text{Quantity Dispensed during the Year}} \times 100\%$$

After Patheon has produced a minimum of […***…] successful commercial production batches of Product or has produced commercial production batches for at least […***…] at the Manufacturing Site (collectively, the " **Target Yield Determination Batches** "), the Parties will mutually agree on the target yield for the Product at the Manufacturing Site (each, a " **Target Yield** "); The Target Yield will be revised […***…] to reflect the actual manufacturing experience as agreed to by the parties.

(b) Shortfall Calculation . If the Actual Annual Yield falls more than […***…] below the respective Target Yield in a […***…], then the shortfall for the […***…] (the " **Shortfall** ") will be calculated as follows.

[…***…]

(c) Credit for Shortfall . If there is a Shortfall for a Product in a Year, then Patheon will credit Client's account for the amount of the Shortfall not later than […***…] after the end of the Year

Each credit under this Section 2.2(c) will be summarized on the reconciliation report form set forth in Schedule I. Upon expiration or termination of this Agreement, any remaining credit owing under this Section 2.2 will be paid to Client. The Annual Shortfall, if any, will be disclosed by Patheon on the reconciliation report form.

(d) […***…]

(e) No Material Breach . It will not be a material breach of this Agreement by Patheon under Section 8.2(a) if the Actual Annual Yield is less than the Target Yield.

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 Payment .

Client will pay Patheon for performing the Manufacturing Services according to the Prices specified in Schedules B and C. These prices may be subject to adjustment under other parts of this Agreement. […***…] Notwithstanding anything to the contrary, Patheon will not purchase nor will Client be obligated to reimburse Patheon for any cost items not included in Schedule B, […***…], without the prior written approval of Client.

3.2 Active Materials .

Client will […***…], deliver the Active Materials to Patheon (in accordance with Section 2.1(f)) sufficient for Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If applicable, Patheon and the Client will reasonably cooperate to permit the import of the Active Materials into the United States. Client's obligation will include obtaining the proper release of the Active Materials from U.S. Customs and the FDA. Client or Client's designated broker will be the "Importer of Record" for Active Materials imported into the United States. The Active Materials will be held by Patheon on behalf of Client as set forth in this Agreement. Title to the Active Materials will at all times remain the property of Client. Any Active Materials received by Patheon will only be used by Patheon to perform the Manufacturing Services.

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing .

The […***…] Price and annual stability Price for the Products for the first Year are listed in Schedules B and C and are subject to the adjustments set forth in Sections 4.2 and 4.3.

4.2 Price Adjustments — Subsequent Years' Pricing .

[…***…], Patheon may adjust the Price effective […***…] as follows:

(a) Manufacturing Costs . Patheon may adjust the Price […***…]. On or about […***…], Patheon will give Client a statement setting forth the […***…] in calculating the Price […***…] provided that no Prices may be increased until at least […***…] after completion of all validation and test batches of the Products.

(b) Component Costs . If Patheon incurs an increase in Component costs […***…], it may increase the Price for the next […***…] to pass through the additional Component costs. On or about […***…], Patheon will give Client information about the increase in Component costs which will be applied to the calculation of the Price for the next Year to demonstrate that the Price increase is justified. Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers, provided that Patheon demonstrates using non-confidential means that the Price increase is justified.

(c) […***…]

[…***…]

(d) […***…]

[…***…]

4.3 Price Adjustments — Current Year Pricing

During any Year of this Agreement, the Prices set out in Schedule B will be adjusted as follows:

Extraordinary Increases in Component Costs . If, at any time, market conditions result in Patheon's cost of Components being materially greater than normal forecasted increases, then Patheon will be entitled to an adjustment to the Price for any affected Product to compensate it for the increased Component costs. Changes materially greater than normal forecasted increases will have occurred if: […***…]. If Component costs have been previously adjusted to reflect an increase in the cost of one or more Components, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Components. Notwithstanding the foregoing, no Prices may be increased until [...***...].

For a Price adjustment under this Section 4.3, Patheon will deliver to Client a revised Schedule B and budgetary pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. The revised Price will be effective for any Product delivered on or after the […***…] following Client's receipt of the revised Schedule B.

4.4 Adjustments Due to Technical Changes

Amendments to the Specifications or the Quality Agreement requested by Client will only be implemented following a technical and cost review by Patheon and are subject to Client and Patheon reaching agreement on Price changes required because of the amendment. Amendments to the Specifications, the Quality Agreement, or the Manufacturing Site requested by Patheon will only be implemented following the written approval of Client, the approval not to be unreasonably withheld. If Client accepts a proposed Price change, the proposed change in the Specifications will be implemented. and the Price change will become effective, only for those orders of Products that are manufactured under the revised Specifications. […***…] Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 will be cancelled where possible and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Client if the Components cannot be used by other Patheon customers.

4.5 Multi-Country Packaging Requirements .

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional Component costs and the change over fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts .

(a) Rolling [… *** …] Forecast . When this Agreement is executed, Client will give Patheon a non-binding […***…] forecast of the volume of Product that Client expects to order in the first [...***...] of commercial manufacture of the Product. This forecast will then be updated by Client on or before the […***…] on a rolling forward basis. Client will update the forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than […***…]. The most recent […***…] forecast will prevail.

(b) Firm Orders for Initial Manufacturing [… *** …] . At least […***…] before the start of commercial manufacture of the Product, Client will update the rolling forecast for the first […***…] of manufacture of the Product (the " **Initial Manufacturing Period** "). The […***…] of this updated forecast (" **Initial Manufacturing Month** ") will constitute a firm written order in the form of a purchase order or otherwise (" **First Firm Order** ") by Client to purchase and,

when accepted by Patheon, for Patheon to manufacture the quantity of the Product. If manufacturing has not started, Client may cancel any Batches from the First Firm Order at no cost if notice of cancellation is received by Patheon […***…] or more before the scheduled Delivery Date under the First Firm Order. If manufacturing has not started, Client may cancel any Batches from the First Firm Order if notice of cancellation is received by Patheon […***…] before the scheduled Delivery Date under the First Firm Order, […***…]. The parties agree that this payment will be considered liquidated damages for Patheon's loss of manufacturing capacity due to the Client's cancellation of manufacturing and will not be considered a penalty. If the First Firm Order is changed or adjusted as described above then the initial rolling […***…] forecast will also be adjusted as necessary.

(c) Firm Orders Thereafter . Before and during the Initial Manufacturing Period, and on a rolling basis during the term of this Agreement, Client will issue an updated […***…] forecast on or before […***…]. The first […***…] of this updated forecast will be a firm order in the form of a purchase order or otherwise (" **Firm Order** ") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Products on a date not less than […***…] from the […***…] immediately following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client's Manufacturing Services purchase order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. The quantities of Products ordered in those written orders will be firm and binding on Client and may not be reduced by Client unless otherwise provided in this Agreement.

(d) [… *** …] Forecast . On or before the […***…], Client will give Patheon a written non-binding [...***...] forecast, broken down by […***…] for the […***…] of the forecast, of the volume of each Product Client then anticipates will be required to be manufactured and delivered to Client during the […***…].

(e) Acceptance of Firm Order . Patheon will accept Firm Orders by sending an acknowledgement to Client within […***…] of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from the Client, the Delivery Date for the Product ordered. The Delivery Date may be amended by agreement of the Parties or as set forth in Sections 2.1(f) or 5.1(b). Patheon will accept all Firm Orders submitted by Client up to […***…] of the quantities specified in the most recent forecast submitted by Client for the applicable period subject to the availability of Materials and API.

5.2 Reliance by Patheon .

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Sections 5.1(a), (b), and (c) in ordering the Components required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in sufficient volumes to meet the production requirements for Products during part or all of the forecasted

periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components to satisfy the Manufacturing Services requirements for Products for the first […***…] contemplated in the most recent forecast given by Client under Section 5.1(a). Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties The Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon. If Components ordered by Patheon under Firm Orders or this Section 5.2 are not included in finished Products manufactured for Client, or in any third party products manufactured by Patheon, […***…] after the forecasted month for which the purchases have been made (or for a longer period as the parties may agree) or if the Components have expired during the period, then Client will pay to Patheon its costs therefor (including all costs incurred by Patheon for the purchase and handling of the Components) But if these Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

(b) If Client fails to take possession or arrange for the destruction of Components within […***…] of purchase or, in the case of finished Product, within […***…] of manufacture, Client will pay Patheon $[…***…] thereafter for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at $[…***…]. Storage fees are subject to a […***…] minimum charge […***…]. Patheon may ship finished Product held by it longer than […***…] to the Client at Client's expense on […***…] written notice to the Client.

5.3 Minimum Orders .

Client may only order Manufacturing Services for batches of Products in multiples of the Minimum Run Quantities as set out in Schedule B.

5.4 Shipments .

Shipments of Products will be made […***…] Patheon's shipping point unless otherwise mutually agreed. Risk of loss or of damage to Products will remain with Patheon until […***…]. Patheon will, in accordance with Client's instructions and as agent for Client, (i) arrange for shipping to be paid by Client and (ii) at Client's risk and expense, obtain any export licence or other official authorization necessary to export the Products. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications.

5.5 On Time Delivery .

(a) Patheon and the Client understand that there may be uncertainties and necessary adjustments in production schedules during the initial Manufacturing Period. The parties agree that they will work together closely to expedite deliveries and manage the scheduling of the initial Product launch.

(b) If after the Initial Manufacturing Period, Patheon is unable to deliver the quantity of Product ordered under a Firm Order on the Delivery Date due to an act or omission by Patheon (a " **Late Delivery** "), Client will receive a credit from Patheon for the Late Delivery that will be applied against the purchase price under the next Firm Order The credit will be […***…].

(c) A Late Delivery will not be a material breach of this Agreement by Patheon for the purposes of Section 8.2 unless the Products are delivered more than […***…] after the Delivery Date.

(d) For clarity, a Late Delivery will not include any delay in shipment of Product caused by events outside of Patheon's reasonable control, such as […***…].

(e) Patheon will not ship Products to Client or its agents in advance of a scheduled delivery date, without Client's prior approval.

(f) No shipment will be deemed complete until all ordered Product SKUs have been delivered in accordance with Client's instructions and a certificate of compliance has been issued by Patheon Partial shipment must be authorized by Client.

5.6 Invoices and Payment .

Invoices will be sent by fax or email to the fax number or email address given by Client to Patheon in writing. Invoices will be sent when the Product is manufactured and released by Patheon to the Client. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all undisputed invoices for accepted Products within […***…] of the date thereof. No payment or other obligations of Client will accrue on partial or incomplete shipments. Interest on past due accounts will accrue at […***…]. The Late Delivery credits set forth in this Section 5 are only available to Client if all outstanding undisputed invoices have been paid in full or are within […***…] outstanding from the invoice date when the Late Delivery arose.

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.

(a) Product Claims . Client has the right to reject any portion of any shipment of Products that deviates from the Specifications, cGMPs, or Applicable Laws without invalidating any remainder of the shipment. Client will inspect the Products manufactured by Patheon upon receipt and will give Patheon written notice (a " **Deficiency Notice** ") of all claims for Products that deviate from the Specifications, cGMPs, or Applicable Laws within […***…] after Clients

receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within […***…] after discovery by Client, […***…]). Should Client fail to give Patheon the Deficiency Notice within the applicable […***…], then the delivery will be deemed to have been accepted by Client on the […***…] after delivery or discovery, as applicable. Except as set out in Section 6.3, Patheon will have no liability for any deviations for which it has not received notice within the applicable […***…] period.

(b) Determination of Deficiency . Upon receipt of a Deficiency Notice, Patheon will have […***…] to advise Client by notice in writing that it disagrees with the contents of the Deficiency Notice. If Client and Patheon fail to agree within […***…] after Patheon's notice to Client as to whether any Products identified in the Deficiency Notice deviate from the Specifications, cGMPs, or Applicable Laws, then the parties will mutually select an independent laboratory to evaluate if the Products deviate from the Specifications, cGMPs, or Applicable Laws. This evaluation will be binding on the parties. If the evaluation certifies that any Products deviate from the Specifications, cGMPs, or Applicable Laws, Client may reject those Products in the manner contemplated in this Section 6.1 and Patheon will be responsible for the cost of the evaluation. If the evaluation does not so certify for any of the Products, then Client will be deemed to have accepted delivery of the Products on the […***…] after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the […***…] after discovery thereof by Client, but not after the expiration date of the Product) and Client will be responsible for the cost of the evaluation.

(c) Shortages . Claims for shortages in the amount of Products shipped by Patheon will be dealt with by reasonable agreement of the parties.

6.2 Product Recalls and Returns .

(a) Records and Notice . Patheon and Client will each maintain records necessary to permit a Recall of any Products delivered to Client or customers of Client. Each party will promptly notify the other of any information which might affect the marketability, safety or effectiveness of the Products or which might result in the Recall or seizure of the Products. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Products in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. " **Recall** " will mean any action (i) by Client to recover title to or possession of quantities of the Products sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any regulatory authorities to detain or destroy any of the Products. Recall will also include any action by either Party to refrain from selling or shipping quantities of the Products to third parties which would have been subject to a Recall if sold or shipped.

(b) Recalls . If (i) any governmental or regulatory authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a "Dear Doctor" letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by Client, having regard to all applicable laws and regulations.

(c) Product Returns . Client will have the responsibility for handling customer returns of the Products. Patheon will give Client any assistance that Client may reasonably require to handle the returns.

6.3 Patheon's Responsibility for Defective and Recalled Products .

(a) Defective Product . If Client rejects Products under Section 6.1 and the deviation is determined to have arisen from Patheon's failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws. Patheon will credit Client's account for Patheon's invoice price for the defective Products. If Client previously paid for the defective Products, Patheon will promptly, at Client's election, either: (i) refund the invoice price for the defective Products; (ii) offset the amount paid against other amounts due to Patheon hereunder; or (iii) replace the Products with conforming Products without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all Active Materials required for the manufacture of the replacement Products. For greater certainty, Patheon's responsibility for any loss of Active Materials in defective Product will be captured and calculated in the Active Materials Yield under Section 2.2.

(b) Recalled Product . If a Recall or return results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will be responsible for the documented out-of-pocket expenses of the Recall or return and will use its commercially reasonable efforts to replace the Recalled or returned Products with new Products as soon as possible, contingent upon the receipt from Client of all Active Materials required for the manufacture of the replacement Products. For greater certainty, Patheon's responsibility for any loss of Active Materials in Recalled Product will be captured and calculated in the Active Materials Yield under Section 2.2. If Patheon is unable to replace the Recalled or returned Products (except where this inability results from a failure to receive the required Active Materials), then Client may request Patheon to reimburse Client for the price that Client paid to Patheon for Manufacturing Services for the affected Products. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense.

(c) Except as set forth in Sections 6.3(a) and (b) above, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it, (collectively, " **Product Claims** "). For greater certainty, Patheon will have no obligation for any Product Claims to the extent the Product Claim […***…].

6.4 Disposition of Defective or Recalled Products .

Client will not dispose of any damaged, defective, returned, or Recalled Products for which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.3. […***…]

6.5 Healthcare Provider or Patient Questions and Complaints .

Client will have the sole responsibility for responding to questions and complaints from its customers Questions or complaints received by Patheon from Clients customer's, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations. including testing. In addition, Patheon will give Client all mutually agreed upon information that will enable Client to respond properly to questions or complaints about the Products as set forth in the Quality Agreement. Unless it is determined that the cause of the complaint resulted from a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, all costs incurred under this Section 6.5 will be borne by Client.

6.6 […*…]**

[…***…]

ARTICLE 7

CO-OPERATION

7.1 [… * …] Review .**

Each party will forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet not less than […***…] to review the current status of the business relationship and manage any issues that have arisen.

7.2 Governmental Agencies .

Subject to Section 7.8, each party may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Products, regarding the Products if, in the opinion of that party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any law, governmental order or regulation. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a party will permit the other party to accompany and take part in any communications with the agency, and to receive copies of all communications from the agency.

7.3 Records and Accounting by Patheon .

Patheon will keep records of the manufacture, testing, and shipping of the Products, and retain samples of the Products as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for a period of one year following the date of Product expiry, or longer if required by law or the Quality Agreement, at which time Client will be contacted concerning the delivery and destruction of the documents and/or samples of Products. Client is responsible for retaining samples of the Products necessary to comply with the legal/regulatory requirements applicable to Client.

7.4 Inspection .

Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice. but a Patheon representative must be present during the inspection.

7.5 Access .

Patheon will give Client reasonable access at mutually agreeable times to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws. But, with the exception of "for-cause" audits, Client will be limited each Year to […***…], lasting no more than […***…], and involving no more than […***…] auditors. Client may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of a fee of […***…]. The right of access set forth in this Section 7.5 will not include a right to access or inspect Patheon's financial records.

7.6 Notification of Regulatory Inspections .

Patheon will notify Client within one Business Day of any inspections by any governmental agency specifically involving the Products. Patheon will also notify Client of receipt of any form 483's or warning letters or any other significant regulatory action which Patheon's quality assurance group determines could impact the regulatory status of the Products.

7.7 Reports .

Patheon will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA. At the Client's request, Patheon will provide a copy of the Annual Product Review Report to the Client at no additional cost. Any additional report requested by Client beyond the scope of cGMPs and customary FDA requirements will be subject to an additional fee to be agreed upon between Patheon and the Client.

7.8 FDA Filings .

(a) Regulatory Authority . Client will have the sole responsibility for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture of the Products. Patheon will assist Client, to the extent consistent with Patheon's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible.

(b) Verification of Data . At least […***…] prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, Client will give Patheon a copy of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and regulatory validity of those documents as they relate to Patheon generated data

(c) Verification of CMC . At least […***…] prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA's Chemistry and Manufacturing Controls (" **CMC** ") related to any Marketing Authorization, such as a New Drug Application or Abbreviated New Drug Application, Client will give Patheon a copy of the CMC as well as all supporting documents which have been relied upon to prepare the CMC This disclosure will permit Patheon to verify that the CMC accurately describes the work that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Client will give Patheon copies of all FDA filings at the time of submission which contain CMC information regarding the Product

(d) Deficiencies . If, in Patheon's sole discretion, acting reasonably, Patheon determines that any of the information given by Client under clauses (b) and (c) above is inaccurate or deficient in any manner whatsoever (the " **Deficiencies** "), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to any pre-approval inspection.

(e) Client Responsibility . For clarity, the parties agree that in reviewing the documents referred to in clause (b) above, Patheon's role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Patheon. Subject to the foregoing, Patheon will not assume any responsibility for the accuracy of any application for receipt of an approval by a regulatory authority. The Client is solely responsibility for the preparation and filing of the application for approval by the regulatory authorities and any relevant costs will be borne by the Client.

(f) Inspection by Regulatory Authorities . If Client does not give Patheon the documents requested under clause (b) above within the time specified and if Patheon reasonably believes that Patheon's standing with a regulatory authority may be jeopardized, Patheon may, in its sole discretion. delay or postpone any inspection by the regulatory authority until Patheon has reviewed the requested documents and is satisfied with their contents.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term

This Agreement will become effective as of the Effective Date and will continue until December 31, 2017 (the " **Initial Term** "), unless terminated earlier by one of the parties in accordance herewith This Agreement will automatically continue after the Initial Term for successive terms of two years each unless either party gives written notice to the other party of its intention to terminate this Agreement at least 18 months prior to the end of the then current term.

8.2 Termination for Cause; Client Termination .

(a) Either party at its sole option may terminate this Agreement upon written notice where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement within […***…] following receipt of a written notice (the " **Remediation Period** ") of the breach that expressly states that it is a notice under this Section 8.2(a) (a " **Breach Notice** ").

(b) Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice. to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction: (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate this Agreement as to any Product upon […***…] prior written notice if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product or if Client is unable to secure a license for Patheon to manufacture the Product without infringing third party rights in the Product. But if this occurs, Client will still fulfill all of its obligations under Section 8.4 below [and under any Capital Equipment Agreement regarding this Product].

(d) Patheon may terminate this Agreement upon […***…] prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement to an assignee that, in the opinion of Patheon acting reasonably, is: (i) not a credit worthy substitute for Client; or (ii) a competitor of Patheon; or (iii) an entity with whom Patheon has had prior unsatisfactory business relations.

(e) Client may terminate this Agreement upon […***…] prior written notice to Patheon if Client enters into a strategic arrangement with a third party that does not compete with Patheon by principally providing contract manufacturing services to third parties, and if the written notice of termination to Patheon is made within […***…] after the Effective Date of this Agreement.

8.3 Product Discontinuation .

Client may terminate this agreement with at least […***…] advance notice to Patheon if it intends to no longer order Manufacturing Services for a Product due to (i) Client's

termination of sales of the Product in the Territory, or (ii) termination of clinical trials for the Product.

8.4 Obligations on Termination .

If this Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

(a) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged under a Firm Order according to the terms of this Agreement, at the price in effect at the time the Firm Order was placed;

(b) Client will purchase, at Patheon's cost (including all costs incurred by Patheon for the purchase and handling of the Inventory). the Inventory applicable to the Products which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders;

(c) Client will satisfy the purchase price payable under Patheon's orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders;

(d) Patheon will return to Client all unused Active Materials (with shipping and related expenses, if any, to be borne by Client); and

(e) Client acknowledges that no competitor of Patheon will be permitted access to the Manufacturing Site.

(f) Patheon will, at its own expense. remove from Patheon site(s) and deliver to Client, within [...***...], all of Client's Components, Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, [E]equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control (" **Client Property** "). If Client requests that the Client Property be stored at Patheon, following the completion, termination, or expiration of the Agreement Client will pay Patheon […***…] thereafter for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.6 of this Agreement.

Any termination or expiration of this Agreement will not affect any outstanding obligations or payments due hereunder prior to the termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement [or any related Capital Equipment Agreement]. For greater certainty, termination of this Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 10 and 11 and Sections 5.4, 5.6, 8.4, 13.1, 13.2, 13.3, and 13.15, all of which survive any termination.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority .

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

9.2 Client Warranties .

Client covenants, represents, and warrants that:

(a) Non-Infringement .

(i) the Specifications for each of the Products are its or its Affiliate's property and that Client may lawfully disclose the Specifications to Patheon;

(ii) any Client Intellectual Property, used by Patheon in performing the Manufacturing Services according to the Specifications (A) is Clients or its Affiliates unencumbered property, (B) may be lawfully used as directed by Client, and (C) to the knowledge of Client, does not infringe and will not infringe any Third Party Rights;

(iii) to the knowledge of Client, the performance of the Manufacturing Services by Patheon for any Product under this Agreement or the use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement does not and will not infringe any Third Party Rights;

(iv) there are no actions or other legal proceedings, concerning the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Components, or the sale, use, or other disposition of any Product made in accordance with the Specifications;

(b) Quality and Compliance .

(i) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws;

(ii) on the date of shipment, the API will conform to the specifications for the API that Client has given to Patheon and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container;

(iii) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets the Products after separate approval, and (ii) to the knowledge of Client, will be safe for human consumption.

9.3 Patheon Warranties .

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in a professional and workmanlike manner and in accordance with the Specifications, cGMPs, and Applicable Laws,

(b) Patheon and its personnel performing the Manufacturing Services have the requisite experience, skills, knowledge, and expertise necessary to perform the Manufacturing Services in a competent manner;

(c) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliates unencumbered property, (ii) may be lawfully used by Patheon, and (iii) to the knowledge of Patheon, does not infringe and will not infringe any Third Party Rights; and

(d) the Products will be delivered free of all liens and encumbrances

9.4 Debarred Persons .

Patheon represents and warrants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b), Patheon represents that it does not currently have, and covenants that it will not hire. as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the Federal Food, Drug, and Cosmetic Act (United States).

9.5 Permits .

Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

Patheon will maintain at all relevant times all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

9.6 No Warranty .

NEITHER PATHEON NOR CLIENT MAKE ANY WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. NEITHER PATHEON NOR CLIENT MAKES ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY FOR THE PRODUCTS.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages .

Except for a party's indemnification obligations under this Agreement, or due to a breach of Article 11, under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

10.2 Limitation of Liability .

(a) Active Materials . Except as expressly set forth in Section 2 2, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials. […***…]

(b) […***…]

10.3 Patheon .

Patheon agrees to defend, indemnify, and hold Client, its officers, employees, and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to […***…].

If a claim occurs, Client will: (a) promptly notify Patheon of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim, (c) reasonably cooperate with Patheon in the defense of the claim: and (d) permit Patheon to control the defense and settlement of the claim, all at Patheon's cost and expense.

10.4 Client .

Client agrees to defend, indemnify, and hold Patheon, its officers, employees, and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any […***…]

[…***…].

If a claim occurs, Patheon will: (a) promptly notify Client of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Client in the defense of the claim; and (d) permit Client to control the defense and settlement of the claim, all at Client's cost and expense.

10.5 Reasonable Allocation of Risk .

This Agreement (including, without limitation, this Article 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Products. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Products because Client has developed and holds the marketing approval for the Products, Client requires Patheon to manufacture and label the Products strictly in accordance with the Specifications, and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Products.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidentiality .

The Confidentiality Agreement will apply to all confidential information disclosed by the parties under this Agreement. If the Confidentiality Agreement expires or is terminated prior to the expiration or termination of this Agreement, the terms of the Confidentiality Agreement will continue to govern the parties' obligations of confidentiality for any confidential or proprietary information disclosed by the parties hereunder, for the term of this Agreement, as though the Confidentiality Agreement remained in full force and effect.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Disputes .

If any dispute arises out of this Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined herein), the parties will first try to resolve it amicably In that regard, any party may send a notice of dispute to the other, and each party will appoint, within […***…] from receipt of the notice of dispute, a single representative having full power and authority to solve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within one month from their appointment, or if a party fails to appoint a representative within the […***…] period set forth above, the dispute will immediately be referred to the Chief Operating Officer (or another officer as he/she may designate) of each party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the parties fail to reach a resolution

under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.15.

12.2 Technical Dispute Resolution .

If a dispute arises (other than disputes under Sections 6.1(b) or 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage. or other activities under this Agreement (a " **Technical Dispute** "), the parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, senior representatives of each party will, as soon as practicable and in any event no later than […***…] after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within […***…] of the written request, the Technical Dispute will, at the request of either party, be referred for determination to an expert in accordance with Schedule E. If the parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Schedule E) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

ARTICLE 13

MISCELLANEOUS

13.1 Inventions .

(a) For the term of this Agreement, Client hereby grants to Patheon a limited, non-exclusive, paid-up, royalty-free, non-transferable, non-sublicensable license of Client's Intellectual Property which Patheon must use in order to perform the Manufacturing Services solely for use by Patheon in performing the Manufacturing Services.

(b) All Intellectual Property generated or derived by Patheon while performing the Manufacturing Services, to the extent it is specific to the development, manufacture, use, and sale of Client's Product that is the subject of the Manufacturing Services, will be the exclusive property of Client, and Patheon hereby assigns all of its right, title, and interest in and to such Intellectual Property to Client.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, sublicensable, transferable license to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services or otherwise incorporated into the Products to make, use, sell, offer for sale, import, export, distribute, create derivative works of, and otherwise use the Product(s) in any manner as contemplated under this Agreement.

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

(e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Products or processes or technology owned or otherwise controlled by the party.

13.2 Intellectual Property .

Subject to Section 13.1, all Client Intellectual Property will be owned by Client and all Patheon Intellectual Property will be owned by Patheon. Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13.3 Insurance .

Each party will maintain […***…] insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of [...***...] thereafter. This insurance will have policy limits of not less than […***…]. If requested each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of […***…] written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will forthwith notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors .

The parties are independent contractors and this Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.5 No Waiver .

Either party's failure to require the other party to comply with any provision of this Agreement will not be deemed a waiver of the provision or any other provision of this Agreement, with the exception of Sections 6.1 and 8.2.

13.6 Assignment .

(a) Patheon may not assign this Agreement or any of its rights or obligations hereunder without the written consent of Client, this consent not to be unreasonably withheld. But Patheon may arrange for subcontractors to perform specific testing services arising under this Agreement without the consent of Client.

(b) Subject to Section 8.2(d), Client may assign this Agreement or any of its rights or obligations hereunder without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement, and Client will remain liable hereunder. Any partial assignment will be subject to Patheon's cost review of the assigned Products and Patheon may terminate this Agreement or any assigned part thereof, on […***…] written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time.

(c) Despite the foregoing provisions of this Section 13.6, and notwithstanding Section 8.2(d), either party may assign this Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound hereunder.

13.7 Force Majeure .

Neither party will be liable for the failure to perform its obligations under this Agreement if the failure is caused by an event beyond that party's reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within colour of right (a " **Force Majeure Event** ") A party claiming a right to excused performance under this Section 13.7 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement.

13.8 Additional Product .

Additional products may be added to this Agreement and the additional products will be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by amendments to Schedules A, B, and C as applicable.

13.9 Notices .

Any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery, by telecopy, facsimile communication, or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses, telecopy or facsimile numbers or electronic mail addresses set forth below:

If to Client:

●

Attention: ●

Telecopier No.: ●

Email address:

If to Patheon:

Patheon Pharmaceuticals Inc.
2110 East Galbraith Road
Cincinnati, OH 45237-1625
Attention. Director of Legal Services
Telecopier No 513-948-6927

Email address: [Frank.McCune@patheon.com]

With a copy to:

Patheon Inc.
4721 Emperor Boulevard
Research Triangle Park,
NC 27703
Attention: General Counsel
Telecopier No.: 919-474-2269

Email address: [Doaa.Fathallah@patheon.com]

or to any other addresses, telecopy or facsimile numbers or electronic mail addresses given to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery, telecopy, facsimile, or electronic mail will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner.

13.10 Severability .

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions hereof, because each provision is separate, severable, and distinct.

13.11 Entire Agreement .

This Agreement, together with the Quality Agreement and the Confidentiality Agreement, constitutes the full, complete, final and integrated agreement between the parties

relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Quality Agreement, and the Confidentiality Agreement.

13.12 Other Terms .

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement and is signed by both parties.

13.13 No Third Party Benefit or Right .

For greater certainty, nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement.

13.14 Execution in Counterparts .

This Agreement may be executed in two or more counterparts, by original or facsimile signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.15 Use of Client Name .

Patheon will not make any use of Client's name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client, which consent will not be unreasonably withheld. Despite this, Client agrees that Patheon may include Client's name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon's Manufacturing Services.

13.16 Governing Law .

This Agreement will be construed and enforced in accordance with the laws of the State of Ohio and the laws of the United States of America applicable therein and subject to the exclusive jurisdiction of the courts thereof. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the date first written above.

PATHEON PHARMACEUTICALS INC.

By: /s/ Eric Evans
Name: Eric Evans
Title: Chief Financial Officer

RAPTOR THERAPEUTICS, INC.

By: /s/ Thomas E. Daley
Name: Thomas E. Daley
Title: President

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

[…***…]

***Confidential Treatment Requested

SCHEDULE B

MINIMUM RUN QUANTITY, ANNUAL VOLUME, AND PRICE

[…***…]

***Confidential Treatment Requested

SCHEDULE C

ANNUAL STABILITY TESTING

[…***…]

***Confidential Treatment Requested

SCHEDULE D

[…***…]

***Confidential Treatment Requested

SCHEDULE E

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 will be resolved in the following manner

1. **Appointment of Expert** . Within […***…] after a party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the parties are unable to so agree within the […***…] period, or in the event of disclosure of a conflict by an expert under Paragraph 2 hereof which results in the parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association

2. **Conflicts of Interest** . Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the parties will, after the disclosure, have confirmed his appointment.

3. **Not Arbitrator** . No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Schedule E.

4. **Procedure** . Where an expert is appointed

(a) Timing . The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and that he issues the authorizations to the parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within […***…] (or another other date as the parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.

(b) Disclosure of Evidence . The parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within […***…] of a written request from the relevant expert to do so.

(c) Advisors . Each party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the parties will co-operate and seek to narrow and limit the issues to be determined.

(d) Appointment of New Expert . If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment,

a new expert may (at the request of either party) be appointed and the appointment of the existing expert will thereupon cease for the purposes of determining the matter at issue between the parties save this if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.

(e) Final and Binding . The determination of the expert will, except for fraud or manifest error be final and binding upon the parties.

(f) Costs . Each party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

For greater certainty, the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Schedule E) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

SCHEDULE F

COMMERCIAL QUALITY AGREEMENT

Q UALITY A GREEMENT
Commercial Product

Between
Raptor Therapeutics Inc.

9 Commercial Blvd., Suite 200 Novato, CA 94949
a corporation existing under the laws of Delaware(“ **Client** ”)

-and-

P ATHEON P HARMACEUTICALS I NC .,
a corporation existing under the laws of Delaware,

Specific sites covered by this Agreement:
2110 E. Galbraith Rd. Cincinnati OH 45237-1625
(“ **Patheon** ”)

Effective Date:

Version: QG01-05-T001-01

TABLE OF CONTENTS

SECTION 1: BACKGROUND AND AGREEMENT

BACKGROUND . Under a manufacturing services agreement ("MSA") that will be effective November 15, 2010 between Patheon and the Client, Patheon agreed to perform pharmaceutical manufacturing services (" **Manufacturing Services** ") for certain Products (as described in Appendix A hereto) and the Client is required to give certain information ("Specifications") to Patheon in order for Patheon to perform the Manufacturing Services. Under the MSA, Patheon is required to operate within the Specifications. The parties desire to allocate the responsibility for procedures and Specifications impacting on the identity, strength, quality, and purity of the Products.

AGREEMENT . NOW THEREFORE in consideration of rights conferred and the obligations assumed under the MSA and herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound, the parties agree as follows:

SECTION 2: RESPONSIBILITIES TABLE

Patheon will be responsible for all the operations that are marked with “X” in the column titled “Patheon” and the Client will be responsible for all the operations that are marked with “X” in the column titled “Client”. If marked with “(X)”, cooperation is required from the designated party.

Section No.	Subject / Terms	Client	Patheon
4.1 Quality Management			
4.1.1	GMP, Health and Safety Compliance	X	X
4.1.2	Client Audit Rights	X	
4.1.3	Subcontracting		X
4.1.4	Self-Inspection		X
4.2 Regulatory Requirements			
4.2.1	Permits	X	X
4.2.2	Regulatory Filing / Registration Change Control	X	(X)
4.2.3	Regulatory Compliance		X
4.2.4	Government Agency Inspections, Communications and Requisitions	(X)	X
4.3 Material Control			
4.3.1	Test Methods and Specifications	X	
4.3.2	Material Destruction	(X)	X
4.3.3	Vendor Audit Responsibility	X	X
4.3.4	Client Furnished Materials	X	
4.3.5	Incoming Material Release		X
4.4 Building, Facilities, Utilities and Equipment			
4.4.1	General		X
4.4.2	Equipment, Calibration and Preventative Maintenance		X
4.4.3	Environmental Monitoring Program		
4.5 Product Controls			
4.5.1	Master Batch Record	(X)	X
4.5.2	Reprocessing and Rework	(X)	X
4.5.3	Personnel Training		X
4.6 Packaging, Labeling and Printed Materials			
4.6.1	Master Batch Packaging Records	(X)	X
4.6.2	Content of Printed Material and Artwork	X	
4.6.3	Test Methods and Method Validation	(X)	X
4.7 Exception Reports (Deviations / Investigations)			
4.7.1	Manufacturing Instruction Deviations		X
4.7.2	Packaging Instructions Deviations		X
4.7.3	Notification of Deviations		X

4.8 Release of Product			
4.8.1	Test Methods and Specifications	X	X
4.8.2	Batch Release for Shipment		X
4.8.3	Certificate of Compliance		X
4.8.4	Product Release	X	
4.9 Validation			
4.9.1	Master Validation Plan	(X)	X
4.9.2	Cleaning Validation Program	(X)	X
4.9.3	Analytical Method and Procedure Validation	X	(X)
4.10 Change Control			
4.10.1	General	X	X
4.11 Documentation			
4.11.1	Record Retention		X
4.11.2	Batch Document Requisition		X
4.12 Laboratory Controls			
4.12.1	Specifications and Test Methods	X	X
4.12.2	Out of Specifications (OOS) / Out of Trend (OOT)		X
4.13 Stability			
4.13.1	Sample Storage		X
4.13.2	Stability Studies and Protocol	X	X
4.13.3	Stability Failures		X
4.13.4	Termination of MSA		X
4.14 Annual Product Review			
4.14.1	General		
4.15 Storage and Distribution			
4.15.1	General		X
4.15.2	Product Storage and Shipment Changes	(X)	X
4.15.3	Product Quarantine		X
4.16 Product Complaints			
4.16.1	Complaint Investigation		
4.17 Product Recall			
4.17.1	Product Recall Notification	X	(X)
4.17.2	Government Agency Notification	X	(X)
4.18 Reference and Retention Samples			
4.18.1	Excipient and Active Ingredient Reference Sample		X
4.18.2	Finished Product Retention Sample	X	X

SECTION 3: GENERAL

3.1 Any communications about the subject matter of this Agreement will be directed, in the first instance, to the person(s) identified in Appendix B.

3.2 Capitalized terms not otherwise defined herein will have the meaning specified in the MSA.

3.3 If any provision of this Agreement should be or found invalid, or unenforceable by law, the rest of the Agreement will remain valid and binding and the parties will negotiate a valid provision which meets as close as possible the objective of the invalid provision.

3.4 If this Agreement requires modification so that the party affected cannot be reasonably expected to continue to perform under this Agreement, then the parties will negotiate and revise the Agreement accordingly.

3.5 Any amendment of this Agreement will be made in writing and signed by both parties.

3.6 This Agreement will start on the Effective Date that is set forth on the cover page of this Agreement and will remain valid until all Quality obligations under all applicable MSAs have been fulfilled.

3.7 If there is any conflict between the terms of this Agreement and the MSA, the MSA will control except for any specific quality issue.

3.8 The “Background” provisions of Section 1 are incorporated into this Agreement.

SECTION 4: DESCRIPTION OF RESPONSIBILITIES

4.1 QUALITY MANAGEMENT

4.1.1 GMP, Health and Safety Compliance

Patheon will conduct operations in compliance with applicable environmental, occupational health and safety laws, and cGMP regulations.

4.1.2 Client Audit Rights

Patheon will permit audits by the Client, on reasonable prior written notice, of all relevant premises, procedures, and documentation that relate to Client's Product. Client audits are limited to one audit per calendar year unless for cause.

4.1.3 Subcontracting

Patheon will not subcontract tasks to a third party without Client's consent. Patheon may subcontract raw material testing to other Patheon facilities and to other qualified third party laboratories.

4.1.4 Self-Inspection

Patheon will perform self-inspections of its premises, facilities, and processes used to manufacture, package, test, and store the Client's starting, intermediate, and/or finished products in accordance with Patheon's written standard operating procedures (" **SOPs** ") to ensure compliance with cGMP and this Agreement.

4.2 REGULATORY REQUIREMENTS

4.2.1 Permits

The Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

Patheon will obtain and maintain the appropriate manufacturing license(s) to allow for the Manufacturing Services.

4.2.2 Regulatory Filing / Registration Change Control

The Client will determine whether changes to the Product or related to the Product will impact a regulatory filing and will apply for and receive approval for any required manufacturing amendment, change or addition to their Product marketing authorization. Upon request, Patheon will assist in the preparation and review of pertinent sections of new or supplemental regulatory applications before filing. The Client will give Patheon copies of sections of product registration/regulatory submissions that are relevant to

the manufacture of the Product. The Client is responsible for all communications with Regulatory Authorities as well as for the approval, maintenance, and updating of marketing approval in a timely manner.

4.2.3 Regulatory Compliance

Patheon will ensure that Product(s) are manufactured and tested in strict compliance with current US Federal and EC regulatory and statutory requirements relating to Good Manufacturing Practices (GMP) (US 21 CFR parts 21O and 211 and EU Directive 2003/94/EC for the manufacture of finished medicinal product) as applicable, regulatory approvals and local laws and regulations applicable at the site(s) of manufacture and/or testing.

4.2.4 Government Agency Inspections, Communication and Requisitions

Patheon will permit all relevant inspections by regulatory authorities of premises, procedures, and documentation.

Patheon will notify the Client within one Business Day of receipt of any notice of inspection from a regulatory authority and within one Business Day of any regulatory authority request for Product samples, batch documentation, or other information related to the Product. The Client reserves the right to be present on site for PRODUCT pre-approval inspections.

Patheon will notify the Client within one Business Day of receipt of a Form 483s, warning letter, or the like, from any regulatory agency that relates to the Product; or if the supply of Product will be affected, or if the facilities used to produce, test or package the Product will be affected. A redacted copy will be provided to the Client within five Business Days.

The responses from Patheon related to the Product will be reviewed and approved by the Client before submission to the regulatory agency. But Patheon reserves the right to respond to the regulatory agency without approval, if, in the reasonable opinion of Patheon's Legal counsel, it is required to do so.

4.3 MATERIAL CONTROL

4.3.1 Test Methods and Specifications

The Client will give Patheon a copy of the Specifications and test methods used if the Client issues raw material Specifications.

4.3.2 Material Destruction

Patheon has the right to either return to the Client or dispose of any outdated or rejected material. If the material is disposed of, disposal will be consistent with the nature of the material and sent to a permitted waste

disposal facility. Before disposal:

(i.) Patheon will send notice to the Client of Patheon's intent to dispose of the material. If no direction is received from the Client, Patheon will dispose of the material no sooner than 90 days after the date of the notice.

(ii.) The materials will be disposed and destroyed in compliance with local environmental regulations and performed in a secure and legal manner that prevent unauthorized use or diversion.

Patheon will maintain destruction records in accordance with Patheon SOPs.

4.3.3 Vendor Audit Responsibility

4.3.3.1 Excipient and API Vendors:

(i.) If the Client stipulates an excipient or API vendor, the Client will audit and approve the vendor and ensure cGMP compliance in accordance with Section 4.3.4 of this Agreement. The Client stipulated vendor(s) will be included on the Client's approved vendor list (Appendix D).

(ii.) If Patheon stipulates the excipient vendor, Patheon will audit and approve the vendor and ensure cGMP compliance in accordance with Patheon's SOPs. The Patheon stipulated vendor(s) will be included on Patheon's approved vendor list (Appendix C).

4.3.3.2 Packaging Component Vendors:

(i.) If the Client stipulates a packaging component vendor, the Client will audit and approve the manufacturer and ensure cGMP compliance. The Client stipulated vendor(s) will be included on the approved vendor list (Appendix D).

(ii.) If Patheon stipulates the packaging component vendor, Patheon will audit and approve the vendor and ensure cGMP compliance in accordance with Patheon's SOP. The Patheon stipulated vendor(s) will be included on the approved supplier list (Appendix C).

4.3.4 Client Furnished Materials

The Client is responsible for vendor qualification of Client furnished materials and for providing a certificate of compliance confirming the following:

(i.) That the materials are compliant with the provisions outlined in the "Note for Guidance on minimizing the risk of transmitting spongiform

encephalopathy agents via human and veterinary medicinal products" (EMEA/410/01 , Rev.2 or update); and

(ii.) A residual solvent certificate confirming that there is no potential for specific toxic solvents listed in the EP / USP / ICH residual solvents Class I, Class II or Class III to be present and the material, if tested, will comply with established IEP / USP / ICH requirements. If any of the solvents listed in the EP / USP / ICH residual solvents Class I, Class II or Class III are used in the manufacture or are generated in the manufacturing process, solvents of concern will be indicated.

4.3.5 In-Coming Material Release

Before its use in the manufacture of any Product, all material(s) will be inspected, tested, and released by Patheon against the Specification approved by the Client.

4.4 BUILDING, FACILITIES, UTILITIES, AND EQUIPMENT

4.4.1 General

All buildings and facilities used in the manufacturing, packaging, testing and storage of any materials and/or Product will be of suitable size, construction and location to facilitate cleaning, and will be maintained in a good state of repair. Maintenance and cleaning records will be kept in accordance with Patheon SOPs.

4.4.2 Equipment, Calibration and Preventative Maintenance

All equipment used in the manufacturing, packaging, testing, and storage of any materials and/or Product will be suitable for its intended use and appropriately located to allow for cleaning and maintenance. Calibration and maintenance records will be kept according to Patheon SOPs for all critical equipment. Patheon will calibrate instrumentation and qualify computer systems and all equipment used in the manufacture and testing of the Product in accordance with Patheon SOPs.

4.4.3 Environmental Monitoring Program

Patheon will perform and maintain an environmental monitoring program. The collected data will be reviewed and interpreted by the responsible person within Patheon's quality unit. Any out of limit results will be managed appropriately in accordance with Patheon SOPs.

4.5 PRODUCTION CONTROLS

4.5.1 Master Batch Record

The Client will give Patheon the Specifications and Patheon will manufacture Product in accordance with the Specifications.

Patheon is responsible for preparing the master batch records for the Product. The Client is responsible for reviewing and approving the master batch records before the manufacture of the Product.

Patheon will not make changes to master batch records except through the established Patheon change control system, and all master document revisions will be approved by the Client's quality unit. Any changes made to issued batch records (before master revisions) must be reviewed and approved by the Client's quality unit before implementation unless otherwise agreed to in writing.

4.5.2 Reprocessing and Rework

Patheon will not reprocess or rework the Product without the prior written consent from the Client.

Reprocessing is defined as the introduction of material back into the process and repeating a step, (e.g. redrying, remilling) using the same equipment and techniques of the established manufacturing process.

Rework is defined as the introduction of material to one or more processing steps that are different from the established manufacturing process.

4.5.3 Personnel Training

Patheon will give appropriate training to its employees. Each person engaged in the manufacture, packaging, testing, storage, and shipping of the Product will have the education, training, and experience necessary, consistent with current GMP and safety training requirements.

4.6 PACKAGING, LABELING AND PRINTED MATERIALS

4.6.1 Master Batch Packaging Records

The Client will approve the Specifications for all packaging components. Patheon will create, control, issue, and execute in accordance with the master batch packaging record and the Specifications.

Patheon will not make changes to master batch packaging records except through the established Patheon change control system, and all master document revisions will be approved by the Client's quality unit. Any changes made to issued batch records (before Master revisions) must be reviewed and approved by the Client's quality unit before implementation unless otherwise agreed to in writing.

4.6.2 Printed Material and Artwork

The Client will give Patheon the Specifications for artwork and labelling text (blister, carton, leaflet, label etc.). The labelling proofs must be reviewed and approved by the Client.

4.6.3 Test Methods and Method Validation

The Client will give Patheon the test methods and method validation for packaging components. Where applicable, Patheon will provide test methods and validation for packaging components purchased from vendors on the Patheon approved vendor list only (Appendix C).

4.7 EXCEPTION REPORTS (DEVIATIONS / INVESTIGATIONS)

4.7.1 Manufacturing Instruction Deviations

Patheon will document, investigate, and resolve deviations from approved manufacturing instructions or Specifications in accordance with Patheon's SOPs. Patheon will report and obtain approval from the Client's responsible person for deviation report (" **DR** ") type deviations where there is a potential to affect Product quality. This Client approval will not be unreasonably withheld. Patheon will give the Client copies of all DR's as part of the executed batch record.

4.7.2 Packaging Instructions Deviations

Patheon will document, investigate, and resolve any deviation from approved packaging instructions or Specifications according to Patheon SOPs. Patheon will report and obtain approval from the Client's responsible person for DR type deviations where there is a potential to affect Product quality. This Client approval will not be unreasonably withheld. Patheon will give the Client copies of all DRs as part of the executed batch packaging record.

4.7.3 Notification of Deviations

Patheon will notify the Client within one Business Day if any significant deviation occurs during manufacture, testing or storage of the Product, where the deviation affects the quality, efficacy or availability of the Product.

4.8 RELEASE OF PRODUCT

4.8.1 Test Methods and Specifications

The Client will give Patheon the finished Product Specifications . Patheon will validate the test methods used with assistance from the Client.

4.8.2 Batch Release for Shipment

Batch review and release for shipment to the Client will be the responsibility of Patheon's Quality Assurance department who will act in accordance with Patheon's SOPs.

4.8.3 Batch release documentation

For each batch released by Patheon for shipment to the Client, the following documentation will be provided.

- Copy of the executed Batch Record
- Copy of the executed Packaging Record
- Certificate of Analysis (CoA)
- Certificate of Manufacturing (CoM)*
- Copy of any Critical or Major deviations. Minor deviations will be noted on the CoM and available upon request.

*CoC or CoM to include a statement that the batch has been manufactured in accordance with cGMPs and the Specifications.

4.8.4 Product Release

The Client will have sole responsibility for release of the Product to the market. When Patheon qualified person (" **QP** ") services are employed, Patheon QP may release the Product for distribution on behalf of the Client.

4.9 VALIDATION

4.9.1 Master Validation Plan

Patheon will establish applicable master validation plans and maintain a validation program for the Product. The Client will review and approve the master validation plan, performance qualification and process validation protocols and reports for the Product.

4.9.2 Cleaning Validation Program

The Client will give Patheon the toxicological information to be used in the development of a cleaning program. Patheon will maintain an appropriate cleaning and cleaning validation program.

4.9.3 Analytical Method and Procedure Validation

The Client must ensure that its analytical methods and manufacturing procedures (including packaging procedures) are validated. If the methods and procedures are not validated by the Client, then Patheon may assist in validation development at Client's cost.

4.10 CHANGE CONTROL

4.10.1 General

Patheon will notify and obtain approval from the Client before implementing any proposed changes to the process, materials, testing, equipment or premises, where the changes may directly affect the Product or regulatory submission. This Client approval will not to be unreasonably withheld.

The Client will be responsible for determining whether or not to initiate registration variation procedures and for maintaining adequate control over the quality commitments of the marketing authorization made to the regulatory authorities by the Client for the Products.

Following validation of a process change, Patheon will deliver a copy of the related validation report to the Client and the associated stability data, if applicable, as it becomes available.

4.11 DOCUMENTATION

4.11.1 Record Retention

Patheon will maintain all batch records for a minimum of one year past Product expiry date and supply all these records to the Client upon request.

Patheon will maintain records and evidence on the testing of raw materials and packaging/labeling materials for five years after the materials were last used in the manufacture or packaging/labeling of the Product.

At the end of the above noted retention period, the Client will be contacted concerning the future storage or destruction of the documents.

4.11.2 Batch Document Requisition

At the request of the Client, Patheon will give the Client a copy of any of the executed batch documents relating to Products within five Business Days of the request.

4.12 LABORATORY CONTROLS

4.12.1 Specifications and Test Methods

Patheon will test and approve starting material, intermediate, and the finished Product in accordance with the approved Specifications, analytical methods, and Patheon's SOPs.

The Client will give Patheon the Active Material Specifications including a CoA.

The Client will give Patheon the test methods for Active Material (if non -compendial). The Client is responsible for validating non-compendial testing methods. If these methods are not validated by the Client, then Patheon may assist in validation development at Client's cost.

4.12.2 Out of Specifications (OOS) / Out of Trend (OOT)
Patheon will notify Client's quality unit of confirmed out-of-Specification (" **OOS** ") or out-of-trend (" **OOT** ") results within one Business Day. Patheon will generate a DR type deviation as per Patheon SOPs and obtain approval of the DR from the Client's responsible person within their quality unit. This Client approval will not be unreasonably withheld.

4.13 STABILITY

4.13.1 Sample Storage
Patheon will store stability samples as required.

4.13.2 Stability Studies and Protocol
The Client will develop and validate stability indicating assay(s) before process validation. If required, Patheon may assist at Client's cost.

If applicable, Patheon will conduct stability studies in accordance with the agreed and validated stability testing analytical methods at the agreed upon testing points in accordance with the approved stability protocol.

Patheon will perform the stability testing described in a stability protocol agreed to by both Patheon and the Client. Patheon will give the Client the stability data on an ongoing basis as agreed to by both parties.

4.13.3 Stability Failures
Patheon will notify the Client of any stability failure for Product supplied to the Client within two Business Days If a result indicates that a Product has failed to remain within stability Specifications, Patheon will notify the Client within one Business Day.

4.13.4 Termination of MSA
If the MSA is terminated, Patheon will continue to give the Client the stability data supporting the acceptability of the Product until all Product distributed by the Client has reached the end of its shelf-life.

4.14 ANNUAL PRODUCT REVIEW

4.14.1 General

The Client will complete the annual product review in accordance with regulatory requirements of the Product marketed authorization. Patheon will give the Client copies of all information and correspondence necessary to support the annual product reviews upon request..

4.15 STORAGE AND DISTRIBUTION

4.15.1 General

Patheon will ship Product in accordance with the agreed qualified transportation requirements provided by the Client to Patheon.

4.15.2 Product Storage and Shipment Changes

Patheon will communicate any proposed changes in storage or shipping to the Client for review and approval. . The Client approval will not be unreasonably withheld.

4.15.3 Product Quarantine

Patheon will have a system in place for assuring that unreleased Product is not shipped unless authorized by the Client's quality unit.

4.16 PRODUCT COMPLAINTS

4.16.1 Complaint Investigation

The Client will investigate and resolve all medical and non-medical Product complaints. Patheon will investigate all Patheon manufacturing and packaging-type Product complaints related to the Manufacturing Services. The Client will retrieve complaint sample(s) and forward them to Patheon in a timely manner to aid a complete and comprehensive investigation.

4.17 PRODUCT RECALL

4.17.1 Product Recall Notification

The Client will notify Patheon about a Product recall or other regulatory type product notification (e.g. field alert) as soon as possible, but, in any event, before informing the appropriate regulatory authorities. The Client will be responsible for all related recall activities.

4.17.2 Government Agency Notification

The Client will perform the Product recall and will inform the appropriate regulatory authorities. Where legislated, Patheon reserves the right to

notify regulatory authorities of Product quality issues. Patheon will inform the Client before notifying the regulatory authorities.

4.18 REFERENCE AND RETENTION SAMPLES

4.18.1 Excipient and Active Ingredient Reference Sample

Patheon will keep a reference sample of each material received by Patheon and used to manufacture the Product. The reference sample will consist of at least two times the necessary quantity for all Quality Control tests required to determine whether the materials meet required Specifications.

The reference samples will be stored by Patheon under controlled conditions in accordance with GMP storage requirements for one year beyond the expiration date of the last batch of the product containing the materials. The reference samples will be made available by Patheon to the Client, if requested

4.18.2 Finished Product Retention Sample

Retention samples of finished Product will be retained by Patheon for one year past Product expiry or for a longer period as required by law. Where applicable, the legal sample(s) of finished Product must be retained by the Client.

* * *

IN WITNESS WHEREOF, the parties have caused their duly authorized officer to execute and deliver this Quality Agreement as of the Effective Date identified on the first page:

RAPTOR THERAPEUTICS INC.

By: _____ Date: _____

Erica Kraynack
Director, Program Management

PATHEON PHARMACEUTICALS INC.

By: _____ Date: _____

David J. Leuck
Quality Operations Director

SECTION 5: APPENDICES

- Appendix A: Product(s)
- Appendix B: Quality Contacts
- Appendix C: Patheon Approved Supplier List
- Appendix D: Client Approved Supplier List
- Appendix E: Patheon Approved Contract Laboratories List

SCHEDULE G (Reserved)

SCHEDULE H

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

[…***…]

***Confidential Treatment Requested

SCHEDULE I

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL ANNUAL YIELD

[…***…]

***Confidential Treatment Requested

SCHEDULE J (Reserved)

Amendment to Manufacturing Services Agreement

between Patheon Pharmaceuticals Inc., and Raptor Therapeutics, Inc.

Background : Patheon Pharmaceuticals Inc., (" **Patheon** ") and Raptor Therapeutics, Inc., (" **Raptor** ") entered into a Manufacturing Services Agreement dated November 15, 2010 (the " **Agreement** "). Patheon and Raptor wish to amend the Agreement to revise Schedule B.

NOW THEREFORE in consideration of the premises hereof and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, the parties agree to amend the Agreement as follows:

1. Amendment to Agreement:

Schedule B to the Agreement is deleted in its entirety and is replaced with a new Schedule B as attached to this Amendment.

2. No Other Modifications . The " **Background** " section of this document is incorporated into the Amendment. Except as modified by this Amendment, the terms and conditions of the Agreement remain unchanged.

IN WITNESS WHEREOF, the parties have caused this Amendment to be duly executed by their authorized representatives, effective as of April 5, 2012.

RAPTOR THERAPEUTICS, INC.

By: */s/ Thomas E. Daley*
Name: Thomas E. Daley
Title: President

PATHEON PHARMACEUTICALS INC.

By: */s/ Francis P. McCune*
Name: Francis P. McCune
Title: Secretary

APPROVED BY LEGAL

FPM 4-13-12
Initials Date

SCHEDULE B

(as revised by the Amendment to the Agreement effective April 5, 2012)

MINIMUM RUN QUANTITY, ANNUAL VOLUME, AND PRICE

[…***…]

***Confidential Treatment Requested

Second Amendment to Manufacturing Services Agreement

between Patheon Pharmaceuticals Inc., and Raptor Pharmaceuticals Inc.

Background : Patheon Pharmaceuticals Inc., (" **Patheon** ") and Raptor Pharmaceuticals Inc., (formerly known as Raptor Therapeutics, Inc.), (" **Raptor** ") entered into a Manufacturing Services Agreement dated November 15, 2010, as amended on April 5, 2012 (the " **Agreement** "). Patheon and Raptor wish to further amend the Agreement to add Raptor Pharmaceuticals Europe B.V., a wholly owned subsidiary of RPTP European Holdings C.V. (a wholly-owned subsidiary of Raptor) as an additional party to the Agreement and to update the Pricing in Schedule B.

NOW THEREFORE in consideration of the premises hereof and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the parties, the parties agree to amend the Agreement as follows:

1. **Second Amendment to Agreement:**

   (a) Raptor Pharmaceuticals Europe B.V. located at Naritaweg 165, Telestone-Teleport, 1043 BW Amsterdam, the Netherlands, is hereby added as a party to the Agreement and will thereupon have all the rights and obligations of the "Client" thereunder. All references to "Client" in the Agreement shall refer to Raptor and/or Raptor Pharmaceuticals Europe B.V., as applicable.

   (b) Schedule B to the Agreement is deleted in its entirety and is replaced in its entirety with the Schedule B attached to this Second Amendment.

2. **No Other Modifications** . The " **Background** " section of this document is incorporated into this Second Amendment. Except as expressly amended by this Second Amendment, the terms and conditions of the Agreement shall remain in full force and effect.

3. **Counterparts** . This Second Amendment may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument.

[Signature page to follow]

IN WITNESS WHEREOF, the parties have caused this Second Amendment to be duly executed by their authorized representatives, effective as of June 21, 2013.

RAPTOR PHARIVI ACEUTICALS INC.

By: /s/ Julie Smith
Name: Julie Smith
Title: EVP Strategy & COO

RAPTOR PHARMACEUTICALS EUROPE B.V.

By: /s/ Kim R. Tsuchimoto
Name: Kim R. Tsuchimoto
Title: Director A

RAPTOR PHARMACEUTICALS EUROPE B.V.

By: /s/ Henk Doude van Troostwijk
Name: Henk Doude van Troostwijk
Title: Director B

PATHEON PHARMACEUTICALS INC.

By: /s/ Francis P. McCune
Name: Francis P. McCune
Title: Secretary

APPROVED BY LEGAL

FPM 4-13-12
Initials Date

SCHEDULE B

(as revised by the Second Amendment to the Agreement effective June 21, 2013)

MINIMUM ORDERING QUANTITY AND PRICE

[…***…]

***Confidential Treatment Requested

Exhibit 31.3

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: May 26, 2017

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

Exhibit 31.4

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: May 26, 2017

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