18-02593-E

Debra Smetana
ktMINE
940 West Adams
Suite 100
Chicago, IL 60607

2/20/2018

U.S. Securities & Exchange Commission
Office of FOIA and Privacy Act Operations
100 F Street, NE
Mail Stop 2465
Washington, DC 20549-5100

Dear Sir or Madam:

Under the Freedom of Information Act (FOIA), please send the confidential portions (i.e. unredacted documents) corresponding to the expiration of the Confidential Treatment Order submitted under Rule 24b-2 of the following company

Exhibit 10.5 to the 6/30/11 10-Q, filed by Optimer Pharmaceuticals, Inc. on 8/4/2011

We authorize $0 for search and review fees, as these documents have been previously requested. Please contact me if search will require additional fees beyond the above mentioned. My daytime phone number is (312) 667-0267

Sincerely,

Debra Smetana

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

March 20, 2018

Ms. Debra Smetana
ktMine
940 West Adams, Suite 100
Chicago, IL 60607

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02593-E

Dear Ms. Smetana:

This letter is in response to your request, dated and received in this Office on February 20, 2018, for Exhibit 10.5 filed to the Form 10-Q by Optimer Pharmaceuticals, Inc. on August 4, 2011.

The search for responsive records has resulted in the retrieval of 69 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me directly at andersonc@sec.gov or (202) 551-8315. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

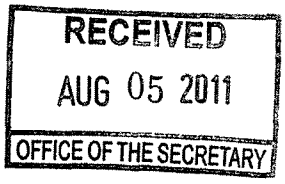
Sincerely,

Clarissa Anderson

Clarissa Anderson
FOIA Research Specialist

Enclosure

10.5



Manufacturing Services Agreement

June 1, 2011

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MANUFACTURING SERVICES AGREEMENT

THIS MANUFACTURING SERVICES AGREEMENT (the "Agreement") is made as of June 1, 2011 (the "**Effective Date**")

B E T W E E N:

PATHEON INC.,
a corporation existing under the laws of Canada,

("**Patheon**"),

- and -

OPTIMER PHARMACEUTICALS, 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 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;

"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 controlling interest of a party to this Agreement;

For this definition, "control" (with correlative meanings for the terms "controlling interest" and "controlled by") means the ownership of shares carrying at least a majority of the outstanding voting or equity interests or the ability to elect a majority of the board of directors or other managing authority of the entity or the other ability to manage and direct the business of the applicable entity.

"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 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);

"Applicable Laws" means the applicable provisions of any and all national, supranational, regional, state, provincial, county and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including marketing approvals) of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item;

"Authority" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether national, supranational, regional, state, provincial, county or local;

"Bill Back Items" means the reasonable expenses for all third party supplier fees for the purchase of columns, standards, tooling, PAPR or PPE suits (where applicable), RFID tags if requested by Client and supporting equipment, and other Product-specific items, in each case necessary for Patheon to perform the Manufacturing Services, and which are not included as Components;

"Business Day" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the Province of Ontario, Canada or the United States of America;

"cGMPs" means current good manufacturing practices as described in:

(a) Division 2 of Part C of the *Food and Drug Regulations* (Canada);

(b) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations; and

(c) EC Directive 2003/94/EC,

together with the latest Health Canada, FDA, and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time, and any foreign equivalents to any such regulations which may apply to the Manufacturing Site or be applicable to Products sold outside of the United States, Canada or the European Union;

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

"**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 dated June 25, 2004;

"**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);

"EMA" means the European Medicines Agency or any successor agency thereto which may regulate pharmaceutical products;

"**FDA**" means the United States Food and Drug Administration or any successor agency thereto which may regulate pharmaceutical products;

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

"First Firm Order" has the meaning specified in Section 5.1;

"**Force Majeure Event**" has the meaning specified in Section 13.7;

"**Health Canada**" means the section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate or any successor agency thereto which may regulate pharmaceutical products;

"Initial Manufacturing Month" has the meaning specified in Section 5.1;

"Initial Manufacturing Period" has the meaning specified in Section 5.1;

"Initial Set Exchange Rate" means 1.0:1.0 as of the Effective Date of the Agreement, being the initial exchange rate to convert one unit of the local currency where the Manufacturing Site is located to one unit of the billing currency, calculated as the average interbank exchange rate for conversion of one unit of the local currency where the Manufacturing Site is located to one unit of the billing currency during the 90-day period immediately preceding the Effective Date as published by OANDA.com "The Currency Site" under the heading "FxHistory: historical currency exchange rates" at http://www.oanda.com/convert/fxhistory, or such successor or other website or other heading as the parties may mutually agree;

"**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;

"**Information**" means any information, results, data, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique and 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;

"**Manufacturing Services**" means the process validation, manufacturing, quality control, quality assurance, stability testing, packaging, labelling and related services provided by Patheon with regard to Product pursuant to this Agreement;

"**Manufacturing Site**" means the facility or facilities owned and operated by Patheon and at which Patheon will be performing the Manufacturing Services under this Agreement, and that is/are located at 2100 Syntex Court, Mississauga, Ontario, Canada L5N 7K9 and at 977 Century Drive, Burlington, Ontario, Canada L7L 5J8.

"**Maximum Credit Value**" means the maximum value of Active Materials that may be credited by Patheon under this Agreement, as set forth on Schedule D;

"**Minimum Run Quantity**" means the minimum number of units 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 Client Intellectual Property;

"Price" means the price measured in US Dollars to be charged by Patheon for performing the Manufacturing Services, and includes, without limitation, 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**" means the product listed on Schedule A;

"Product Forecast" and **"Extended Product Forecast"** have the meanings specified in Section 5.1;

"**Quality Agreement**" means that certain [Quality Agreement] between the parties dated as of April 27, 2011 as amended in writing from time to time, setting out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client;

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

"Reset Date" means, with reference to any particular full calendar Year, the date on which Patheon is to provide Client with updated pricing for the Product for the next Year; which date will be not less than three months prior to the beginning of that Year;

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

"Second Source Facility" has the meaning specified in Section 2.1(j).

"Set Exchange Rate" means the exchange rate to convert one unit of Patheon facility local currency to one unit of the billing currency for each Year, calculated as the average interbank exchange rate for conversion of one unit of Patheon facility local currency to one unit of the billing currency during the three month period immediately preceding the Reset Date by one month as published by OANDA.com "The Currency Site" under the heading "FxHistory: historical currency exchange rates" at , or such successor or other website or other heading as the parties may mutually agree;

"**Specifications**" means the file, for the 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:

(d) specifications for Active Materials and Components;

(e) manufacturing specifications, directions, and processes;

(f) storage requirements;

(d) all environmental, health and safety information for 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;

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

"**Territory**" means the geographic area of North America and Europe;

"**Third Party Rights**" means the Intellectual Property of any party, other than Client or Patheon or an Affiliate of Client or Patheon;

"**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 in the last year of this Agreement, the period from January 1 of such calendar year until the date of termination or expiration of this Agreement, and will otherwise 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 as a whole and not to any particular part, Section or Schedule of this Agreement.

1.4 **Singular Terms; Including**.

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa, and all references to "includes" or "including" will mean "includes without limitation" or "including without limitation."

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 and Price
Schedule C	-	Annual Stability Testing and Annual Product Review
Schedule D	-	Active Materials and Active Materials Credit Value and Maximum Credit Value
Schedule E	-	Technical Dispute Resolution
Schedule F	-	Shipping Logistics Protocol
Schedule G	-	Monthly Active Materials Inventory Report
Schedule H	-	Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
Schedule I	-	Example of Price Adjustment due to Currency Fluctuation

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 and any additional countries outside the Territory subject to Section 4.5 for the fees specified in applicable amendments entered into by the parties. Schedule B sets forth a list of cost items that are included in the Price for Products. Patheon shall not perform any Manufacturing Services at any location other than at the Manufacturing Site located at 2100 Syntex Court, Mississauga, Ontario, Canada L5N 7K9 without the express written consent of Client, except that Patheon may perform certain analytical release and stability testing activities as agreed by the Parties at the Manufacturing Site located at 977 Century Drive, Burlington, Ontario, Canada L7L 5J8. Patheon shall perform the Manufacturing Services in strict compliance with this Agreement, the Specifications, the Quality Agreement, cGMP and Applicable Laws, Patheon may not change the Specifications, Manufacturing Site (including facility modification), site of stability testing or any other aspect of the manufacturing process used to perform the Manufacturing Services with respect to the Products without the prior written consent of Client, this consent not to be unreasonably withheld. If Manufacturing Services have not started within 12 months of the date of execution of this Agreement (other than as a result of Patheon's acts or omissions or a Force Majeure Event), Patheon may propose an amendment of the fees set out in Schedules B and C, which shall be subject to Client's approval. Patheon's right to manufacture Products offered for sale by Client in the Territory shall be non-exclusive. However, Client shall procure at least sixty-five percent (65%) of its annual Product requirements for the Territory from Patheon or its Affiliates. In performing the Manufacturing Services, Patheon and Client agree that:

(a) Conversion of Active Materials and Components. Patheon will use the Active Materials and Components to manufacture Products in accordance with this Agreement. Patheon shall not use Active Materials, or any Components or Bill Back Items supplied by or paid for or reimbursed by Client, for any other use or purpose.

(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, which Patheon will make available to Client for its review as reasonably requested by Client, and the Quality Agreement. Each time Patheon ships Products to Client or a designee of 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, the Quality Agreement, cGMPs and Applicable Laws. Client will have sole responsibility for the release of Products to the market. The batch documents, including, but not limited to, batch production records, lot packaging and labelling records, equipment set up control, operating parameters, and data printouts, raw material data, and analytical data and results regarding the Manufacture of Products (including any such information contained in laboratory notebooks) shall be the exclusive property of Client, provided, that any intellectual property comprised of the form and style of such batch documents are the exclusive property of Patheon, and provided further, that Patheon will not be obligated to disclose to Client confidential or proprietary information of third parties contained in any such lab notebooks that is unrelated to the Manufacturing Services performed pursuant to this Agreement. 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, if any) at Patheon's expense and as required by the Specifications and the Quality Agreement.

(d) Stability Testing. Patheon will conduct stability testing on the Products as part of the Manufacturing Services provided hereunder. Patheon will perform such testing in accordance with the protocols set out in the Specifications for the separate fees and during the time periods set out in Schedule C, if applicable. 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, or Applicable Laws. Patheon will give Client all stability test data and results (including a final approved report) at Client's request and promptly upon completion of such testing.

(e) Packaging. Patheon will package the Products as set out in the Specifications and the Quality Agreement. Client will be responsible for the cost of artwork development, as applicable. Patheon will determine and imprint the batch numbers and expiration dates for each Product shipped. Such expiration dates must be determined in accordance with the Specifications. 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 and Applicable Laws. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Those changes will be submitted by Client to all applicable Regulatory Authorities and other third parties responsible for issuing marketing approval of the Products. Client will be responsible for the cost of related Components which are no longer usable to package Products hereunder due to changes requested by Client, as contemplated in Section 4.3. Patheon's name will not appear on the label or anywhere else on the Products unless: (i) required by any Applicable Laws; or (ii) Client requests, and Patheon consents in writing to, the use of its name in such manner.

(f) Active Materials and Client-Supplied Components Importing. At least forty-five (45) days before the scheduled production date, Client will deliver the Active Materials to the Manufacturing Site where the Manufacturing Services are to be performed, DDP (Incoterms 2010), in quantity 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 at least forty-five (45) days before the scheduled production date, Patheon will use all reasonable efforts to meet the scheduled production date nonetheless; provided, however, that if Patheon is unable to meet the scheduled production date despite using all reasonable efforts to do so, it may delay the shipment of Product by up to the same number of days as the delay in receipt of the Active Materials. 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 if agreed to by the parties. All shipments of Active Materials will be accompanied by certificate(s) of analysis from the Active Materials manufacturer or the Client, confirming the identity and purity of the Active Materials and their compliance with the Active Materials specifications. Patheon will inspect and test the Active Materials at the Manufacturing Site prior to manufacturing Product using such Active Materials, and will notify Client in the event any

Active Materials do not comply with the Active Materials specifications, each in accordance with the Quality Agreement.

(g) Bill Back Items. Bill Back Items acquired by Patheon will be charged to Client at Patheon's actual and reasonable cost plus a 10% handling fee; provided, however, that the prior written approval of Client shall be required for all Bill Back Items valued above $1000.00. All Bill Back Items shall be the sole and exclusive property of Client.

(h) Validation Activities. At Client's written request, Patheon may assist in the development and approval of the validation protocols for analytical methods and manufacturing procedures (including packaging procedures) for the Products. The fees associated with Patheon's assistance in providing validation development assistance are set out in Schedule C.

(i) Internal process specifications. Internal process specifications will be defined and mutually agreed upon by the parties.

(j) Second Source Facility. Within twelve (12) months after Client provides notice to Patheon requesting that Patheon commence qualification and validation of an additional manufacturing facility, Patheon shall, at Client's expense, qualify and validate, and thereafter keep qualified and validated, an additional manufacturing facility at Patheon's manufacturing site located at 111 Consumers Drive, Whitby, Ontario, Canada L1N 5Z5 (a "Second Source Facility"), in addition to the existing Manufacturing Site, for the manufacture of Product to ensure a second source of supply of Product to Client. The Second Source Facility must be a second facility operated by Patheon with quality and reliability in manufacturing comparable to the Manufacturing Site and shall comply with all obligations and limitations of this Agreement to the same extent as Manufacturing Site. Without limiting the generality of the foregoing, such Second Source Facility must be approved by the FDA, EMA and other relevant Regulatory Authorities such that the Product manufactured by the Second Source Facility may be commercialized by Client under the applicable Regulatory Approvals for Product.

2.2 Active Materials Yield.

(a) Reporting. Patheon will give Client a monthly inventory report of the Active Materials held by Patheon using the inventory report form set out in Schedule G, which will contain the following information for the month:

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 when received and that is held by Patheon at the beginning of the applicable period, less the inventory of Active Materials that complies with the Specifications when received and that is held by Patheon at the end of the period. The Quantity Dispensed will not include any (i) Active Materials that must be retained by Patheon as samples in accordance with this Agreement, (ii) Active Materials contained in Product that must be retained as samples in accordance with this Agreement, (iii) Active Materials used in testing (if applicable) in accordance with this Agreement, 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, but excluding Mishandled Active Materials, as defined below.

Within 60 days after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials on the reconciliation report form set forth in Schedule H 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 3 commercial production batches of Product (which shall include any validation production batches) and has produced commercial production batches (including validation production batches) for at least six months at the Manufacturing Site (collectively, the "**Target Yield Determination Batches**"), the parties will mutually agree in good faith on the target yield for the Product at the Manufacturing Site which, (i) for the first 5 batches following the first 3 commercial production batches of Product referenced above shall be equal to the average yield of the first 3 commercial production batches of Product referenced above; and (ii) for all remaining batches, shall be equal to the average yield of the 5 commercial production batches following the first 3 commercial batches of Product referenced above; provided, in each case, that such determination shall exclude any batch(es) which have yield(s) that the parties mutually agree are abnormally low or high (such average, in each case, as applicable, the "**Target Yield**"); provided, further, that within 30 days following January 1st of each Year the Parties shall calculate the average yield of the 5 commercial production batches immediately preceding such date and if such average yield is greater than the then-current Target Yield, the Target Yield shall be increased to equal such average yield effective as of such January 1st; and provided, further, that for all batches of Product produced prior to calculation of the first Target Yield pursuant to this paragraph, the Target Yield shall be 85%.

(b) Shortfall Calculation. If the Actual Annual Yield falls more than three percent below the applicable Target Yield in a Year, then the shortfall for the Year (the "**Shortfall**") will be calculated as follows:

Shortfall = [(Target Yield – 3%) – AAY] * Active Materials Credit Value * Quantity Dispensed

(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 60 days after the end of the Year.

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

(d) Maximum Credit. Patheon's liability for Active Materials calculated in accordance with this Section 2.2 for any Product, including Mishandled Active Material, in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D.

(e) Material Breach. Without limiting any of Client's other rights or remedies under this Agreement, it will be considered a material breach of this Agreement by Patheon under Section 8.2(a) if, for any Year, Actual Annual Yield is less than 75% of the applicable Target Yield.

(f) Mishandled Active Material. In each report provided by Patheon pursuant to Section 2.2(a), Patheon will include, if applicable, the amount of Active Material that were lost, destroyed or damaged by Patheon after receipt at the Manufacturing Site including, without limitation, as a result of Patheon's failure to comply with the storage and handling obligations set forth in the Quality Agreement ("Mishandled Active Material"). No later than 60 days after the end of the Year, Patheon will reimburse Client for all costs incurred by Client in purchasing and shipping the Active Material that became Mishandled Active Material that Year subject to the aggregate Maximum Credit Value.

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 Payment.

Client will pay Patheon for Product manufactured as a result of performing the Manufacturing Services in accordance with this Agreement, cGMP, the Specifications and Applicable Laws and delivered in accordance with this Agreement, according to the Prices specified in Schedules B and C. These Prices may be subject to adjustment under Section 4.2 and Section 4.3 of this Agreement. Client will also pay Patheon for any Bill Back Items purchased and provided by Patheon in accordance with this Agreement.

3.2 Active Materials, Components and Bill Back Items.

The Active Materials, Components and Bill Back Items will be held by Patheon on behalf of Client as set forth in this Agreement. All Active Materials, Components and Bill Back Items will at all times remain the property of Client and will at all times be free and clear of any and all encumbrances, liens, or other third party claims. Any Active Materials, Components and Bill Back Items 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 are listed in Schedules B and C. The Prices for Products are subject to the adjustments set forth in Sections 4.2, 4.3, 4.4 and 4.5.

4.2 Price Adjustments – Subsequent Years' Pricing.

After December 31, 2011, Patheon or Client may adjust the Price for the Products effective January 1st of each subsequent Year as follows:

(a) Manufacturing Costs. Patheon or Client may adjust the Price for inflation, based upon the preliminary number for any increase or decrease in the Producer Price Index pcu325412325412 for Pharmaceutical Preparation Manufacturing published by the United States Department of Labor, Bureau of Labor Statistics ("PPI") in August of the preceding Year compared to the final number for the same month of the Year prior to that, unless the parties otherwise agree in writing. If the PPI for a given Year reflects a change from the PPI on the Effective Date, then the adjustment to be made pursuant to this Section 4.2(a) will proportionately reflect the increase or decrease, if any, compared to the PPI on the Effective Date, as the case may be. On or about November 1st of each Year starting with 2012, Patheon will give Client a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year; provided, that Client shall have the right to dispute any such calculation in good faith, and for the duration of such dispute the existing Prices shall continue to apply.

(b) Component Costs. If Patheon incurs an increase (as adjusted for inflation) in costs for Components during the Year due to Client's direction or other factors outside of Patheon's reasonable control, it may increase the Price for the next Year to pass through the additional Component costs; provided, however, that the Price increase shall be no greater than the actual additional Component costs incurred, as adjusted for inflation. On or before November 1st of each Year starting with 2011, Patheon will give Client detailed information about and support for the increase in Component costs which will be applied to the calculation of the Price for the next Year to reasonably demonstrate that the Price increase is justified, but Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers. However, at the Client's request, Patheon shall allow an independent third party auditor to review the information supporting the increase in Component costs and confirm that such information reasonably demonstrates that the Price increase is justified.

(c) Pricing Basis. Client acknowledges that the Price in any Year is quoted based upon the Minimum Run Quantity specified in Schedule B. The Price is subject to change if the specified Minimum Run Quantity changes. For greater certainty, if Patheon and Client agree that the Minimum Run Quantity will be reduced, whether as a result of a decrease in estimated annual volume or otherwise and, as a result of the reduction, Patheon demonstrates to Client's reasonable satisfaction that its costs to perform the Manufacturing Services for the Product will increase on a per unit basis (including the amount of the increase), then Patheon may increase the Price for the following Year by an amount sufficient to absorb the demonstrated increased costs. On or about

November 1st of each Year Patheon will give Client a statement setting forth the information to be applied in calculating those cost increases for the next Year, but Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers. However, at the Client's request, Patheon shall allow an independent third party auditor to review the information supporting the increase in Component costs and confirm that such information reasonably demonstrates that the Price increase is justified. If Client places orders for quantities permitting Patheon to manufacture in larger production runs, then the parties shall review the then-current fees for Manufacturing Services for such Product in accordance with Section 4.2(d) below, and Patheon shall reduce such fees on a per-unit basis by a reasonable amount to reflect savings in Patheon's costs relating to such Product as a result of such increase, if any.

(d) Adjustments Due to Currency Fluctuations. The Price for Product that is manufactured outside the United States or Puerto Rico shall be adjusted once per year to reflect currency fluctuations in accordance with this Section 4.2(d). The adjustment will be calculated after all other annual Price adjustments under this Section 4.2 have been made. In the event the Set Exchange Rate for a given Year has changed the adjustment will proportionately reflect the increase or decrease, if any, in the Set Exchange Rate compared to the Set Exchange Rate established for the prior Year or the Initial Set Exchange Rate, as the case may be. An example of the calculation of the price adjustment is set forth in Schedule I.

(e) Audit Costs. If Client requests that an auditor review information supporting an increase in Price pursuant to Section 4.2(b) or (c) or pursuant to Section 4.3 below, such review shall be at the expense of Client unless the auditor determines that Patheon's reported cost increase is greater than the actual cost increase by an amount equal to five percent (5%) or more of the prior cost of such Component or Manufacturing Services, as applicable, in which case (i) all costs related to the auditor's review shall be paid by Patheon, (ii) the Prices shall automatically revert to the price determined by Client in accordance with the auditor's findings with respect to such cost increases (or, if based on the auditor's findings, Client determines that no Price increase should have occurred, the Price shall revert to the prior level), and (iii) Patheon shall promptly refund to Client any excess amounts paid by Client based on such incorrect cost increase.

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or about November 1st of each Year suggested revisions to Schedule B based upon this Section 4.2 to be effective for the next Year, which revised Schedule B must be approved in writing by Client before it becomes binding on either party.

4.3 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 the cost on which the current fee is based, then Patheon will be entitled to an adjustment to the Price for any affected Product to compensate it for these increased Component costs; provided, however, that in no event shall

Patheon be permitted to increase the Price by an amount equal to fifteen percent (15%) or more of the current Price pursuant to this Section 4.3. Changes materially greater than the cost on which the current fee is based will have occurred if: (i) the cost of a Component increases by 10% of the cost for that Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases by 5% of the total Component costs for the Product upon which the most recent fee quote was based. 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.

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, but Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. However, at the Client's request, Patheon shall allow an independent third party auditor to review the information supporting the increase in Component costs and confirm that such information reasonably demonstrates that the Price increase is justified. The revised Price will be effective for any Product delivered on or after the first day of the month following Client's receipt of the revised Schedule B.

4.4 **Adjustments Due to Technical Changes**.

Material 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 (if any) 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. Upon receiving notice of a request by Client for any such amendments, Patheon shall promptly advise Client in writing of any scheduling adjustments, any cost increases or decreases or other changes that may result from such change, and (a) will use its best efforts to make any change identified in such Client request that is in response to a regulatory or safety issue pertaining to the Product, and (b) will use commercially reasonable efforts to implement any other change identified in a Client request by the date requested by Client, or as soon thereafter as it is commercially reasonable. If Client accepts a proposed Price change (if any) in response to such Client-proposed material amendment, the proposed change in the Specifications or the Quality Agreement will be implemented, and the Price change (if any) will become effective, only for those orders of Products that are manufactured under the revised Specifications or revised Quality Agreement. In addition, Client agrees to purchase, at Patheon's actual cost (including all reasonable costs incurred by Patheon for the purchase and handling of the Inventory), all Inventory used under the "old" Specifications and purchased or maintained by Patheon and necessary in order to fill Firm Orders or under Section 5.2, solely to the extent the Inventory can no longer be used under the revised Specifications or be returned to the vendor for a refund or credit. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers and necessary 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, at Client's sole discretion, either (i) assigned to and satisfied by Client, or (ii) cancelled by Patheon, and Client will reimburse Patheon for the penalty it incurs as a result of such cancellation.

4.5 Multi-Country Packaging Requirements.

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside North America (other than Manufacturing Services for bulk tablet Product which is unpackaged and unlabeled), then Client will inform Patheon of the packaging requirements for each such 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 18 Month Forecast. When this Agreement is executed, Client will give Patheon a non-binding 18 month forecast of the volume of Product that Client expects to order in the first 18 months of commercial manufacture of the Product. This forecast will then be routinely updated by Client on or before the 10th day of each month on a rolling forward basis and will be known as the Product Forecast. Client will update the Product Forecast forthwith if it determines that the volumes estimated in the most recent Product Forecast have changed by more than 20%. The most recent 18 month Product Forecast will prevail.

(b) Firm Orders for Initial Manufacturing Month. Client will update the Product Forecast for the first three months of manufacture of the Product (the "**Initial Manufacturing Period**"). The first month of this updated Product 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 sixty (60) days 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 more than thirty (30) days but fewer than sixty (60) days before the scheduled Delivery Date under the First Firm Order, but Client will pay Patheon $15,000 for each cancelled batch. 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 be Patheon's sole and exclusive remedy for such cancellation, and will not be considered a penalty. If the First Firm Order is changed or adjusted as described above, then the initial Product Forecast will also be adjusted as necessary. The cancellation rights in this section are subject to Client retaining responsibility for any reasonable, documented costs or expenses actually incurred or irrevocably committed by Patheon in accordance with this Agreement and related to such cancelled Batches before it received notice of the cancellation.

(c) Firm Orders Thereafter. After the Initial Manufacturing Month, on a rolling basis during the term of this Agreement, and on or before the 10th day of each month, Client will issue an updated Product Forecast and the first three months of that updated forecast will constitute a firm written 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 three months from the first day of the month 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. Upon Patheon's acceptance of a Firm Order, the quantities of Products ordered will be firm and binding on Client and Patheon and may not be reduced by Client or Patheon (unless the parties mutually agree otherwise in writing).

(d) Three Year Forecast. On or before the 10th day of June of each Year, Client will give Patheon a written non-binding three-year forecast, broken down by quarters for the second and third years of the forecast, of the volume of each Product Client then anticipates will be required to be manufactured and delivered to Client during the three-year period (the "Extended Product Forecast"). For clarification, the Extended Product Forecast shall in no event be binding on Client.

(e) Acceptance of Firm Order. Patheon shall accept all Firm Orders that are placed by Client in accordance with Client's obligations under this Section 5.1. Patheon will accept Firm Orders by sending an acknowledgement to Client within five Business Days 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 written agreement of the parties or as set forth in Sections 2.1(f) or 5.1(b).

5.2 Reliance by Patheon.

(a) Client understands and acknowledges that Patheon will use the Firm Orders and Product Forecasts submitted under Sections 5.1(a), (b), and (c) in reasonably ordering the Components required to meet the Firm Orders (recognizing that Product Forecasts other than Firm Orders are non-binding). In addition, Client understands that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in reasonable 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 in quantities needed to satisfy the Manufacturing Services requirements for Products for the first six months contemplated in the most recent Product Forecast. Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods only if agreed to in advance in writing by the parties. 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. Patheon will use a FIFO (First-In-First-Out) method with regard to the Components it uses to manufacture Products. If Components ordered by Patheon under Firm Orders or this Section 5.2 are not included in finished Products manufactured for Client within twelve (12) months 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). If these Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will promptly, in Client's discretion, either (i) receive credit for any costs of those Components previously paid to Patheon by Client, or (ii) receive a full refund from Patheon in an amount equal to costs of those Components previously paid to Patheon by Client.

(b) If Client fails to take possession or arrange for the destruction of Components reasonably purchased by Patheon pursuant to Section 5.2(a) above or fails to take possession or arrange for the

destruction of Active Materials within 12 months of purchase or, in the case of finished Product, within three months of manufacture, Client will pay Patheon $100.00 per pallet, per month thereafter for storing the Components, Active Materials or finished Product. Storage fees for Components, Active Materials or Product which contain controlled substances or require refrigeration will be charged at $200.00 per pallet per month. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship finished Product held by it longer than 3 months to the Client at Client's expense on 14 days advance written notice to the Client. Additional storage requirements for Components, Active Materials and Products shall be specified in the Quality Agreement or otherwise specified in writing by Client.

5.3 Minimum Orders; Annual Volume.

Client may only order Manufacturing Services for batches of Products in multiples of the Minimum Run Quantities as set out in Schedule B. For clarification, Client will in no event be obligated to order any minimum annual volume of Products unless and until the FDA grants marketing approval of the Product.

5.4 Shipments.

Shipments of Products will be made EXW (INCOTERMS 2010) Patheon's shipping point unless otherwise mutually agreed by the parties in writing. Risk of loss or of damage to Products will remain with Patheon until Patheon loads the Products onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. 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 shall deliver Product ordered under a Firm Order on the applicable Delivery Date. The parties agree that they will work together closely to expedite deliveries of Product, including, without limitation, any samples of Product and Product for initial launch, 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 five percent (5%) of the Price of the quantities of Product not delivered by Patheon under the Firm Order on the Delivery Date (i.e., Client Credit = [Quantity Ordered in the Firm Order – Actual Delivery Quantities of Product] * Price * 5%). This credit shall not limit any other rights or remedies that Client may have under this Agreement or otherwise for such Late Delivery.

(c) Without limiting Client's other rights or remedies in this Agreement, (i) a late delivery by more than thirty (30) days, and (ii) three (3) or more Late Deliveries within a six (6) month period, regardless of the number of days by which any such Late Delivery is late, will, in each case, be a material breach of this Agreement by Patheon for the purposes of Section 8.2, provided that Client shall deliver a Breach Notice to Patheon as soon as practicable but in any case within 14 days of the occurrence of the breach, and provided further that a breach under (i) above shall be subject to remediation within a thirty (30) day Remediation Period for the purposes of Section 8.2,

whereas a breach under (ii) above shall be deemed to be not remediable and therefore the Remediation Period shall not apply. For clarity, a Late Delivery will not include any delay in shipment of Product caused by a Force Majeure Event, which may include a delay in delivery of Active Materials, a delay in Product release approval from Client, receipt of non-conforming API or Components supplied by Client or any market driven delays in deliveries from Client-approved vendors, in each case not within Patheon's reasonable control, in which case the provisions of Section 13.7 shall apply. Notwithstanding anything to the contrary in this Agreement, a delay in shipment of Product due to a Product quality investigation in accordance with the Quality Agreement and due to product non-conformance shall not be deemed to be a Late Delivery, unless the investigation determines that the quality problem was as a result of Patheon's breach of this Agreement.

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 for shipment. 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 invoices within 30 days of the date thereof. Interest on accounts that are past due for longer than thirty (30) days will accrue at 1.0% per month which is equal to an annual rate of 18% (or at the highest percentage allowed by Applicable Laws, whichever is less). 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 45 days 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 shipment of Products or portion thereof that deviates from the warranties set forth in Section 9.3 below ("Defective Product"). Client will inspect the Products supplied by Patheon upon receipt and will give Patheon written notice (a "**Deficiency Notice**") of all claims for Defective Products based on such inspection within 30 days after Client's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within 30 days after discovery by Client or its Affiliate or licensee, or any third party consumer, but not after the expiration date of the Product). Should Client fail to give Patheon the Deficiency Notice within the applicable 30 day period, then the delivery will be deemed to have been accepted by Client on the 30th day 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 30 day period.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon will have ten days 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 ten days after Patheon's notice to Client as to whether any Products identified in the Deficiency Notice are Defective Products, then the parties will mutually select an

independent laboratory to evaluate if the Products are Defective Products. This evaluation will be binding on the parties. If the independent laboratory determines that any Products are Defective Products, 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 independent laboratory determines that the Products are not Defective Products, then Client will be deemed to have accepted delivery of the Products on the date of such final determination by the laboratory 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. For clarification, this Section 6.1(c) shall not limit any other rights or remedies of the parties under this Agreement or otherwise.

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 by telephone (to be confirmed in writing) 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 and/or its Affiliates or licensees to recover title to or possession or stop distribution, prescription or consumption 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 Client or its Affiliates or licensees 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 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.

(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. Subject to Section 6.3(c), if Client rejects Products under Section 6.1, Client shall not be required to pay for such Product under Section 3.1. Patheon will promptly, at Client's election, either: (i) refund the amount paid for the defective Products, if Client previously paid for such Products, and the cost incurred by Client for the Bill Back Items, and Client-supplied Components used in such Products; (ii) offset the amount paid for the defective Products, if Client previously paid for such Products, and the cost incurred by Client for the Bill Back Items, and Client-supplied Components used in such Products, against other amounts due to Patheon hereunder; or (iii) at Patheon's sole expense (excluding expense to incur replacement Active Materials, but including the replacement of Client-supplied Components and Bill Back Items), replace the Products with conforming Products as promptly as practical 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

clarification, any refund of the amount paid by Client for the defective Products that is paid by Patheon pursuant to this Section 6.3(a) shall not be considered a liability under, and shall therefore not be subject to, Section 10.2(a).

(b) Recalled Product. If a Recall or return of Product results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the terms of this Agreement, including warranties set forth in Section 9.3 or 9.4, or other negligence or willful misconduct of Patheon, Patheon will be responsible for all costs and documented out-of-pocket expenses of the Recall or return of Product and will promptly, at the election of Client, either: (i) refund the amount paid for the Recalled or returned Products and the cost incurred by Client for the Bill Back Items, Active Materials and Client-supplied Components used in such Products; (ii) offset the amount paid for the Recalled or returned Products and the cost incurred by Client for the Bill Back Items, Active Materials and Client-supplied Components used in such Products, against other amounts due to Patheon hereunder; or (iii) replace the Recalled or returned Products with conforming Products, at Patheon's sole expense (including the expense to obtain replacement Active Materials, Bill Back Items and Client-supplied Components), as promptly as practical 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. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense. For clarification, any refund of the amount paid by Client for the defective Products that is paid by Patheon pursuant to this Section 6.3(b) shall not be considered a liability under, and shall therefore not be subject to, Section 10.2(a).

(c) 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**"), to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Products manufactured in accordance with this Agreement and conforming to the Specifications or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications or as otherwise this Agreement, (iii) results from a defect in the Active Materials or Components supplied by Client that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications or as otherwise set forth in this Agreement, (iv) is caused by actions of third parties occurring after the Product is shipped by Patheon under Section 5.4, (v) is due to packaging design or labelling defects or omissions not attributable to Patheon or its Affiliates or its or their employees, agents or subcontractors, or (vi) is due to any breach by Client of its obligations under this Agreement.

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, which shall not be unreasonably withheld or delayed. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition (including any applicable storage fees) for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.1 or 6.3. In all other circumstances, Client will bear the cost of disposition, including all applicable fees for Manufacturing Services, for any damaged, defective, returned, or Recalled Products.

6.5 Healthcare Provider or Patient Questions and Complaints.

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client's (and its Affiliate's and licensee's) customers, 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 and any other assistance reasonably requested by Client. In addition, Patheon will promptly 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. Client shall bear costs incurred under this Section 6.5 except to the extent the complaint resulted from a failure by Patheon to perform the Manufacturing Services in accordance with this Agreement, in which case all costs incurred under this Section 6.5 will be borne by Patheon.

6.6 Sole Remedy.

Except for the indemnity set forth in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2 (or as expressly set forth in this Agreement), the remedies described in this Article 6 will be Client's sole remedy for any failure by Patheon to supply Products in accordance with the warranties set forth in Section 9.3.

ARTICLE 7

CO-OPERATION

7.1 Quarterly 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 quarterly 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, Patheon may communicate with any Regulatory Authority, including but not limited to governmental agencies responsible for granting regulatory approval for the Products, regarding the Products only if, (i) in the opinion of Patheon's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any Applicable Laws and (ii) a representative of Client is present for such communication, in the event of a verbal communication, or has reviewed and approved such communication, in the event of a written communication. Patheon shall notify Client immediately upon and in any event within 24 hours after receiving any request from a Regulatory Authority for communication related to a Product.

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 applicable manufacturing regulatory requirements, 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 Applicable Law, 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 or a third party on behalf of 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. In addition, Client shall have the right to have its representatives visit the Manufacturing Site with reasonable advance notice during normal business hours to audit Patheon's manufacturing operations as relating to the manufacture, packaging, labelling, shipping and storage of Product, including to assess Patheon's compliance with this Agreement and the Quality Agreement (which will include the right to audit financial records related thereto in order to confirm compliance with the calculations set forth in this Agreement, provided that such audit is conducted by an independent third party), and to discuss any related issues with Patheon's manufacturing and management personnel as relating to the manufacture and supply of Products.

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 one cGMP-type audit, lasting no more than two (2) Business Days per Manufacturing Site, and involving no more than two auditors; provided, that if such audit becomes a For Cause Audit as a result of issues discovered during such audit, then the limits set forth herein with respect to such audit shall not apply. 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 $5,000 for each additional audit day and $1,000 per audit day for each additional auditor. However, in the event any of the following circumstances arise, Client may elect and Patheon shall permit Client to conduct additional audits (each, a "For Cause Audit") in a timely manner: (i) where there is the occurrence of a condition or event relating to the API or any Product which constitutes a serious health risk; (ii) where either party has received correspondence or a report from a Regulatory Authority pointing out a deficiency by or on behalf of Patheon; (iii) where the Specifications have not been complied with or there is otherwise evidence that compliance with the Specifications is at risk; or (iv) in the event of a Recall related to the Product. The right of access set forth in this Section 7.5 will not include a right to access or inspect Patheon's financial records. In addition, upon the request of any Regulatory Authority having jurisdiction over the manufacture of Product hereunder, such Regulatory Authority shall have access to observe, audit and inspect any Manufacturing Site and Patheon's procedures used for the manufacture, release and stability testing, and/or warehousing of Product and to audit such facilities and procedures for compliance with cGMP and/or other regulatory requirements. Patheon specifically agrees to cooperate with any inspection by a Regulatory Authority, whether prior to or after Regulatory Approval of a Product, and to provide Client a copy of any inspection or audit report resulting from any such inspection.

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 or Patheon's ability to manufacture and supply to Client the Products. Within one (1) Business Day of receipt, Patheon will provide Client with a reasonable description of any such notifications and inspections and all supporting documentation, including, as applicable, all form 483's and warning letters or similar warning or objection of the applicable Regulatory Authority, which may be redacted to protect the confidential information of third parties. Patheon shall discuss with Client and consider in good faith any comments provided by Client on the proposed

response. Patheon shall in any event use best efforts to address and rectify any issues or problems in its manufacturing facility or procedures and any objections or warnings raised by Regulatory Authorities, as soon as practicable and such that Patheon may continue to manufacture and supply to Client, in compliance with all Applicable Laws and the terms of this Agreement, the Products ordered by Client. After the filing of a response with the FDA or other Regulatory Authority, Patheon shall notify Client of any further contacts with such Regulatory Authority relating to the subject matter of the response.

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 or other Regulatory Authority in the relevant jurisdiction. 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 or other Regulatory Authority requirements will be subject to an additional fee to be agreed upon between Patheon and the Client.

7.8 Regulatory Filings.

(a) Regulatory Authority. Client will have the sole right and 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 manufacture, import, distribution, marketing and sale 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 15 days prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon or describe processes performed 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. Patheon agrees to review and provide feedback, as requested by Client, within 10 days of receipt of draft regulatory submissions. Notwithstanding the foregoing, in the event that Client has prepared documents in response to an urgent request from a Regulatory Authority, Client may provide such document for Patheon's review within 24 hours prior to filing. Such documents shall be Confidential Information of Client.

(c) Deficiencies. If, in Patheon's sole discretion, acting reasonably, Patheon determines that any of the information given by Client under clause (b) above is materially inaccurate or deficient in any manner whatsoever (the "**Deficiencies**"), Patheon will notify Client in writing of the Deficiencies within 24 hours of discovery of such Deficiencies by Patheon, but in any case, within the time limit set forth in clause (b) above. The parties will work together to have the Deficiencies resolved prior to any filing or pre-approval inspection, as applicable.

(d) 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.

7.9 Quality Agreement. For clarification, in the event of any conflict between the terms and conditions of this Agreement, including this Article 7, and the terms and conditions of the Quality Agreement, the terms and conditions of the Quality Agreement shall control with regard to topics related to quality and compliance only.

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, 2016 (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 twelve (12) months prior to the end of the then current term, and unless otherwise terminated early as permitted under this Article 8. The Initial Term and all successive terms (if any) shall be referred to herein as the "**Term**."

8.2 Termination for Cause.

(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 60 days 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) the other party makes an assignment for the benefit of creditors.

(c) Client may terminate this Agreement as to any Product upon 30 days' 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 Client (or its Affiliate or licensee) determines that for safety or efficacy reasons Client is not going to continue to develop or commercialize such Product. But if this occurs, Client will still fulfill all of its obligations under Section 8.4 below.

(d) Without limiting Client's other rights or remedies under this Agreement, Client may immediately terminate this Agreement upon written notice, but without prior advance notice, to Patheon if (i) any Authority takes any enforcement action regarding the Manufacturing Site, and such enforcement action relates to the Product or could reasonably be expected to adversely affect the ability of Patheon to supply the Product; or (ii) for any two calendar quarters during any continuous four calendar quarter period, Patheon is unable to deliver or supply any Firm Order in accordance with this Agreement.

8.3 Product Discontinuation or Non-Approval.

During the Term, Client will give at least six months' advance notice if it intends to no longer order Manufacturing Services for a Product due to this Product's discontinuance in the market. Upon expiration of the applicable six-month notice period, this Agreement shall terminate with respect to

such Product or, if such Product is the only Product subject to this Agreement, this Agreement shall terminate in its entirety.

8.4 Further Termination rights of Client.

Client shall have the right to terminate this Agreement immediately upon written notice to Patheon (a) in accordance with Section 9.4 of this Agreement, (b) in the event the Product is not approved by the FDA for marketing in the United States by January 1, 2012, or (c) if at any time the Target Yield falls below 85%.

8.5 Obligations on Termination.

If this Agreement is completed, expires, or is terminated in whole or in part for any reason (other than by Client pursuant to Section 8.2), then:

(a) Client will take delivery of and pay for all undelivered conforming Products that are manufactured and/or packaged under a Firm Order, at the Price in effect at the time the Firm Order was placed.

(b) Client will purchase, at Patheon's actual 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 and maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2.

(c) Client will reimburse Patheon the purchase price actually paid by Patheon under Patheon's non-cancellable orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2; and

Patheon will, at Client's option, either return to Client all unused Active Materials (with shipping and related expenses, if any, to be borne by Client) or destroy all unused Active Materials in accordance with Client's directions and at Client's expense; and

Client acknowledges that no contract manufacturer that is a direct competitor of Patheon will be permitted access to the Manufacturing Site unless otherwise agreed in writing by the parties.

(d) Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within 30 Business Days, all of Client's Components, Inventory and Active Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control ("**Client Property**"). If Client fails to remove the Client Property within 30 Business Days following the completion, termination, or expiration of the Agreement Client will pay Patheon $100.00 per pallet, per month, one pallet minimum ($200 per pallet, per month, one pallet minimum, for any of the Client Property that contains controlled substances or requires refrigeration) thereafter for storing the Client Property and will assume any reasonable, documented 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.

In addition, upon any expiration or termination of this Agreement, Patheon will immediately cease all Manufacturing Services (unless otherwise instructed by Client) and return to Client all Confidential Information, unused Active Materials, Client-supplied Components and Bill Back Items (with reasonable shipping and related expenses, if any, to be borne by Client).

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. For greater certainty, expiration or termination of this Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 10, 11 and 12 and Sections 5.4, 5.5(a), 5.6, 7.3, 7.4, 8.5, 13.1, 13.2, 13.3, 13.11, 13.15 and 13.16, all of which survive any expiration or termination.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 **Authority**.

Each party covenants, represents, and warrants to the other party that, as of the Effective Date, (a) it has the full right and authority to enter into this Agreement and to perform its obligations hereunder and has taken all necessary action on its part to authorize the performance of such obligations; (b) the execution and delivery of this Agreement and the performance of such party's obligations hereunder (i) do not conflict with or violate any requirement of Applicable Laws or regulations and (ii) do not conflict with, or constitute a default or require any consent under, any contractual obligation of such party; (c) it is duly organized, validly existing and in good standing under the laws of the state or country in which it is organized; and (d) this Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation, enforceable against such party in accordance with its terms.

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 generated or derived by Client before entering into this Agreement or independent of this Agreement that is necessary for Patheon to perform the Manufacturing Services according to the Specifications (A) is Client's or its Affiliate's unencumbered property or is otherwise controlled by Client or its Affiliate (by license or otherwise), (B) may be lawfully used by Patheon as directed by Client, and (C) does not infringe and will not infringe any Third Party Rights in relation to the Products or their manufacture; and

(iii) as of the Effective Date, there are no actions or other legal proceedings to which Client is a party or of which Client is aware, concerning the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials

and the Components supplied by Client, or the sale, use, or other disposition of any Product made in accordance with the Specifications; and

(iv) on the date of shipment to the Manufacturing Site, the Active Materials will conform to the specifications for the Active Materials that Client has given to Patheon (provided, however, that Patheon acknowledges that it is obligated to test Active Materials in accordance with the Quality Agreement before beginning manufacture of Products using such Active Material).

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) all Product delivered hereunder shall (i) conform to the applicable Specifications; (ii) be free and clear of any and all encumbrances, liens, or other third party claims; (iii) be manufactured, packaged, labelled and delivered in compliance with the Quality Agreement and applicable cGMP, all regulatory approvals for the Product, and Applicable Laws and in accordance with manufacturing procedures described in the applicable master batch records for such Product; (iv) not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act, as amended, and any regulations promulgated thereunder, or any analogous law or regulation in the applicable jurisdiction (the "Act"); (v) not be articles that, under the provisions of the Act, may not be introduced into interstate commerce and (vi) subject to Client's representation in Section 9.2(a)(ii)(C), the manufacture of the Product in accordance with this Agreement will not infringe any Third Party Rights;

(b) (i) it will perform the Manufacturing Services in accordance with the Specifications, cGMPs, all regulatory approvals for the Product and Applicable Laws, and (ii) the Components, Active Materials and the Bill Back Items will at all times be free and clear of any and all encumbrances, liens, or other third party claims; and

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

9.4 Debarred Persons.

Patheon covenants 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) or any analogous provision under any other applicable jurisdiction. 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 Act. In the event that Patheon or any officer, employee or agent of Patheon: (a) becomes debarred; or (b) receives notice of action or threat of action with respect to its debarment, during the Term of this Agreement, Patheon agrees to notify Client immediately. In the event that Patheon or any of its officers, employees or agents becomes debarred as set forth in clause (a) above or receives notice of

action or threat of action as set forth in clause (b) above, Client shall have the right to terminate this Agreement upon written notice to Patheon.

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 in accordance with this Agreement.

9.6 No Warranty.

EACH PARTY MAKES NO WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY FOR THE PRODUCTS MANUFACTURED BY PATHEON IN ACCORDANCE WITH THIS AGREEMENT.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages.

Except for liability for breach by Patheon of its obligations under 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; provided, however, that this shall not be deemed to limit either party's indemnification obligations under this Article 10.

10.2 Limitation of Liability.

(a) Active Materials. Except as expressly set forth in Section 2.2 and Article 6, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials, except to the extent resulting from Patheon's negligence or willful misconduct or failure to comply with this Agreement or the Quality Agreement. Patheon's maximum responsibility per Year for loss or damage to the Active Materials will not exceed the Maximum Credit Value set forth in Schedule D.

(b) Maximum Liability. Subject to 10.2(c), and except for any liability arising under Section 10.3, Patheon's maximum liability to Client per Year under this Agreement for any reason whatsoever, including, without limitation, any liability arising under Article 6 hereof or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement will not exceed twenty-two and one half percent (22.5%) of Patheon's revenues under this Agreement in the aggregate per Year.

(c) Death, Personal Injury and Fraudulent Misrepresentation. Nothing contained in this Agreement shall act to exclude or limit either party's liability for personal injury, death or fraudulent misrepresentation.

10.3 Indemnification by Patheon.

Patheon agrees to defend, indemnify, and hold Client, its Affiliates and licensees, and each of their respective directors, officers, employees, and agents ("Client Indemnitees") harmless against any and all losses, damages, costs, liabilities, fees and expenses (including reasonable attorneys' fees) (collectively, "Losses") resulting from any suit, claim, demand, judgment or action brought by a third party (excluding Affiliates) (each, a "Claim") including, without limitation, any Claim of personal injury or property damage, to the extent that such Loss is the result of (a) a failure by Patheon or any other Patheon Indemnitee to perform the Manufacturing Services in accordance with the Specifications, cGMPs or Applicable Laws, (b) Patheon's breach of any of its obligations, representations or warranties under this Agreement, or (c) the negligence or willful misconduct of any Patheon Indemnitee, except to the extent that the Losses are due to the negligence or willful misconduct of any Client Indemnitee.

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 defence of the Claim; and (d) permit Patheon to control the defence and settlement of the Claim, all at Patheon's cost and expense. Notwithstanding the foregoing, Patheon shall not compromise or settle any Claim for any damages other than monetary damages without Client's prior written consent, which shall not be unreasonably withheld.

10.4 Indemnification by Client.

Client agrees to defend, indemnify, and hold Patheon, its Affiliates and each of their respective directors, officers, employees, and agents ("Patheon Indemnitees") harmless against any and all Losses resulting from any Claim of infringement or alleged infringement of any Third Party Rights in the Products, or any portion thereof, or any Claim of personal injury or property damage, each to the extent that the Loss is the result of a breach of this Agreement by Client, including, without limitation, a breach by Client of any representation or warranty contained herein, or the negligence or willful misconduct of any Client Indemnitee, except to the extent that the Losses are due to the negligence or willful misconduct of any Patheon Indemnitee.

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 defence of the Claim; and (d) permit Client to control the defence and settlement of the Claim, all at Client's cost and expense. Notwithstanding the foregoing, Client shall not compromise or settle any Claim for any damages other than monetary damages without Patheon's prior written consent, which shall not be unreasonably withheld.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidentiality Obligation.

During the Term of this Agreement and for a period of ten (10) years thereafter, Patheon will maintain all Confidential Information (as defined below) as confidential and will not disclose any Confidential Information or use any Confidential Information for any purpose, except (a) as expressly authorized by this Agreement, (b) as permitted by Section 11.3, or (c) to its employees, Affiliates and Client-approved subcontractors who require access to such information to accomplish the purposes of this Agreement so long as such persons and entities are under obligations regarding the confidentiality of the Confidential Information that are consistent with and no less protective to Client than the terms of this Agreement. Patheon may use the Confidential Information only to the extent required to accomplish the purposes of this Agreement. Patheon will use at least the same standard of care as it uses to protect its own confidential information to ensure that its employees, Affiliates and Client-approved subcontractors do not disclose or make any unauthorized use of the Confidential Information. Patheon shall be responsible for any breach of this Agreement by any of its employees, Affiliates or subcontractors. Patheon will promptly notify Client upon discovery of any unauthorized use or disclosure of the Confidential Information.

11.2 Definition.

For purpose of this Agreement, "***Confidential Information***" means all information provided by or on behalf of Client to Patheon pursuant to this Agreement or the Confidentiality Agreement, and all Information and Client Intellectual Property, whether in oral, written, graphic or electronic form. Notwithstanding the foregoing, Confidential Information will not include any information which Patheon can demonstrate by competent written evidence: (a) is or becomes publicly known other than as a result of any breach of this Agreement by Patheon; (b) is disclosed to Patheon on a non-confidential basis by a third party who rightfully possesses the information and is not under an obligation of confidentiality with respect thereto; or (c) was known to Patheon prior to its first receipt from Client (whether such first receipt occurred before or during the term of this Agreement), except in the case of Information and Client Intellectual Property, which shall not be subject to the exception in this clause (c). For purposes of clause (a) of this Section 11.2, no combination of elements within the Confidential Information shall be deemed to be publicly known merely because the individual elements of such combination are publicly known, unless the entire combination itself, or the entire principle of use or operation of such combination (if any), is publicly known. In addition, no element within the Confidential Information shall be deemed to be publicly known merely because it is embraced by more general information or data that is publicly known.

11.3 Authorized Disclosure.

Notwithstanding the provisions of Section 11.1, Patheon may disclose Confidential Information, without violating its obligations under this Agreement, to the extent the disclosure is required by a valid order of a court or other governmental body having jurisdiction or is otherwise required by law or regulation, *provided* that Patheon shall reasonable prior written notice to Client of such required disclosure and, at Client's request and expense, shall cooperate with Client's efforts to contest such requirement, to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the order was issued or the law or regulation required, or to obtain other confidential treatment of such Confidential Information.

11.4 Third Party Confidential Information.

Patheon shall not disclose to Client any confidential or proprietary information that belongs to any third party during its performance under this Agreement.

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 ten Business Days from receipt of the notice of dispute, a single representative having full power and authority to resolve 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 ten Business Day period set forth above, the dispute will immediately be referred to the Chief Operating Officer (or another officer as he/she may designate) of Patheon and the Chief Executive Officer of Client 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 ten Business Days 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 30 Business Days 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, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license under the Client Intellectual Property solely to the extent necessary to perform the Manufacturing Services in accordance with this Agreement, and for no other purpose.

(b) All Information generated or derived by Patheon while performing the Manufacturing Services, to the extent it relates specifically to the development, manufacture, use, and sale of Product that is the subject of the Manufacturing Services, and all Client Intellectual Property, will be the exclusive property of Client. Patheon agrees to assign and hereby does assign all of its right, title and interest in and to all such Information and Client Intellectual Property to Client and agrees to take all further acts reasonably required to evidence and/or perfect such assignment to Client, at Client's expense. Patheon shall notify Client in writing, as promptly as practicable, of all Information and any Client Intellectual Property made, created, discovered, generated or derived by Patheon in the course of performing the Manufacturing Services. Patheon may retain one copy of records relating to Client Intellectual Property to the extent required under Applicable Laws.

(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, transferable license to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services to enable Client to research, develop, make, have made, use, sell, offer for sale, import and otherwise commercialize the Product(s).

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

13.2 Intellectual Property.

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 or expressly set forth herein. 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 commercial general liability 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 three years thereafter. This insurance will have policy limits of not less than (i) $5,000,000 for each occurrence for personal injury or property damage liability; and (ii) $5,000,000 in the aggregate per annum for product and completed operations liability. 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 30 days' written notice to the insured of a cancellation of the insurance, except that for cancellation due to non-payment, a minimum of 10 days' written notice to the insured will be provided. 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.

13.6 Assignment.

(a) Patheon may not assign this Agreement or any of its rights or obligations hereunder, or subcontract any of its rights or obligations hereunder, without the written consent of Client, this consent not to be unreasonably withheld; provided, that Patheon may arrange for subcontractors to perform specific testing services arising under this Agreement without the written consent of Client to the extent such subcontractors are specifically named and agreed in the Quality Agreement.

(b) Client may assign this Agreement or any of its rights or obligations hereunder without approval from Patheon. Client will give Patheon written notice of any assignment, and any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement.

(c) Despite the foregoing provisions of this Section 13.6, either party may assign this Agreement to any of its Affiliates or to a successor or purchaser of all or substantially all of its business to which this Agreement relates, 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 labour disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, 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. If the performance of any obligation under this Agreement is delayed due to for a Force Majeure Event for a continuous period of more than 60 days, the other party may terminate this Agreement without penalty upon written notice to the other party under such event.

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 electronic mail 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:

Optimer Pharmaceuticals, Inc.
10110 Sorrento Valley Rd., Suite C
San Diego, CA 92121
Attention: Chief Operating Officer and Vice President of Manufacturing
Telecopier No.: 858.909.0737

If to Patheon:

Patheon Inc.
2100 Syntex Court
Mississauga, Ontario L5N 7K9
Canada
Attention: Law Department
Telecopier No.: 905.812.6613

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

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, 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, or one Business Day after being sent by overnight courier.

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 all Schedules hereto, and the Quality Agreement, constitute 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, including, without limitation, the Confidentiality Agreement as it relates to 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 first and the Quality Agreement second.

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 New York. 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 INC.

by /s/ Eric Evans

by_____

OPTIMER PHARMACEUTICALS, INC.

by /s/ John D. Prunty

by_____

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

Fidamoxicin 200 mg Tablets (the "Product")

Bottling:

- Fidaxomicin 200mg Tablets, 20 count
- Fidaxomicin 200mg Tablets, 60 count

Blistering:

- Fidaxomicin 200mg Tablets, 2x10
- Fidaxomicin 200mg Tablets, 10x10

Specifications

To the extent practicable, prior to the start of commercial manufacturing of Product under this Agreement Client will give Patheon the originally executed copies of the FDA approved Specifications, or such Specifications as have been most recently filed with the FDA. Client will have the right to amend the Specifications in its sole and absolute discretion without having to amend this Agreement. If the Specifications received are subsequently amended, then Client will give Patheon the revised and originally executed copies of the revised Specifications. Upon receipt of the revised Specifications, Patheon will give Client a signed and dated receipt indicating Patheon's receipt of the revised Specifications.

Specifications for Fidaxomicin Drug Substance (API)	MM-AD-11-010, Rev.01
Bulk Fidaxomicin Drug Product	MM-AD-11-009, Rev.03
Specifications for Packaged Fidaxomicin Drug Product	MM-AD-11-011, Rev.01

OPTIMER PHARMACEUTICALS, INC.

Memorandum

Date:	25 February 2011
To:	File, Patheon, Inc.
From:	Elena Korobetskaya, Ph.D., Manager, Analytical Development
Subject:	Specifications for Fidaxomicin Drug Substance
Memo Number:	MM-AD-11-010, Rev. 01
Project:	Fidaxomicin (OPT-80)
File:	☒ Memorandum ☐ Other _____

25 Feb 2011

This memorandum is to provide Patheon, Inc. with the specifications for the fidaxomicin drug substance release.

The following testing and criteria are proposed for the fidaxomicin drug substance specification:

Attribute	**Method**	**Acceptance Criteria**
Description	Visual	White to off-white powder, free of foreign matter
Identification:		
Test 1	TM-0022 (Patheon CTMLP-2512)	Conforms to the RT of Reference Standard
Test 2	TM-0016	To be taken from manufacturer's release COA
Assay	TM-0022 (Patheon CTMLP-2512)	93.0 to 103.0%
Related Substances and Process Impurities:		

Attribute	Method	Acceptance Criteria
Specified		
Identified:		Identified:
OP-1405 (Lipiarmycin A4)		0.2 to 3.0%
OP-1801		NMT 1.0%
OP-1802		NMT 1.0%
OP-1417		NMT 1.0%
OP-1799		NMT 1.0%
OP-1435		NMT 1.0%
OP-1833		NMT 0.5%
OP-1858		NMT 0.5%
OP-1859	TM-0024	NMT 0.5%
OP-1854		NMT 0.5%
OP-1853		NMT 0.5%
OP-1855		NMT 0.5%
RRT 1.07		NMT 1.5%
Unidentified:[1]		Unidentified:[1]
RRT 0.85		NMT 1.0%
RRT 0.97		NMT 0.5%
[1] Nominal RRTs are provided		
Individual Unspecified		NMT 0.10%
Total		NMT 5.0%
Residual Solvents:		
Methanol Acetonitrile Ethyl Acetate Isopropanol n-Heptane	TM-0003 (GC)	To be taken from manufacturer's release COA
Acetic Acid	TM-0015 (HPLC)	To be taken from manufacturer's release COA
Residue on Ignition (Sulphated Ash)	USP <281> PhEur 2.4.14	To be taken from manufacturer's release COA
Heavy Metals	USP <231>, Method II PhEur 2.4.8, Method C	To be taken from manufacturer's release COA
Particle Size Distribution	TM-0005 (Patheon CTMLP-1937)	D(10) NLT 0.5 µm D(50) NMT 50 µm

Attribute	Method	Acceptance Criteria
		D(90) NMT 100 µm
Microbial Enumeration	Harmonized USP <61>/ PhEur 2.6.12	Total Aerobic Microbial Count (TAMC): NMT 1000 cfu/g Total Yeast and Mould Count (TYMC): NMT 100 cfu/g
Test for Specified Microorganisms	Harmonized USP <62>/ PhEur 2.6.13	*Escherichia coli*: absent *Salmonella* spp: absent *Pseudomonas aeruginosa*: absent *Candida albicans*: absent Bile tolerant gram negative bacteria: absent
Specific Optical Rotation $[\alpha]_D^{25}$, (D = 589 nm) in DMSO	USP <781S> PhEur 2.2.7	To be taken from manufacturer's release COA

Memo Approved by:

Michael Hui 25 Feb 2011

Name: Michael Hui Date

Title V.P., QA

OPTIMER PHARMACEUTICALS, INC.

Memorandum

Date: 13 April 2011

To: File, Patheon, Inc.

From: Elena Korobetskaya, Ph.D., Manager, Analytical Development 13 Apr 2011

Subject: Specifications for Bulk Fidaxomicin Drug Product

Memo Number: MM-AD-11-009, Rev. 03

Project: Fidaxomicin (OPT-80)

File: ☒ Memorandum
☐ Other _____

This memorandum is to inform Patheon, Inc. of the commercial specifications for bulk fidaxomicin drug product. The revision concerns the change to the Dissolution test acceptance criteria.

The following testing and criteria are proposed to the regulatory agencies as commercial specifications for bulk fidaxomicin drug product:

Attribute	Test Method	Acceptance Criteria
Description	Visual	White to off-white film-coated modified capsule shaped tablet debossed with "FDX" on one side and "200" on the other side
Identification:		
Test 1	TM-0023 (Patheon CTMLP-2510)	Conforms to the RT of Reference Standard
Test 2		Conforms to the UV spectrum of Reference Standard
Assay		Release: 95.0 to 105.0% Stability: 90.0 to 105.0%
Degradation Products:		
Specified Identified: OP-1858 OP-1832 OP-1859 OP-1854 OP-1853 OP-1800	TM-0025 (Patheon CTMLP-2511)	 NMT 0.5% NMT 0.5% NMT 0.5% NMT 0.5% NMT 0.5% NMT 0.5%

Attribute	Test Method	Acceptance Criteria
OP-1833 Unidentified:[1] RRT 0.79 RRT 0.91 RRT 0.92		NMT 0.5% NMT 0.5% NMT 0.5% NMT 0.5%
Individual Unspecified Impurities		NMT 0.2%
Total Impurities		NMT 5.0 %
Uniformity of Content	USP <905>, by HPLC; PhEur 2.9.40 by HPLC	Meets USP <905> and PhEur 2.9.40 criteria
Dissolution	TM-0009 (Patheon CTMLP-1929)	Q=75 in 45 min
Residual Solvent: Methanol	TM-0011 (Patheon CTMLP-1879)	NMT 3000 ppm
Disintegration	USP <701> PhEur 2.9.1 Test A	NMT 15 min
BHT Assay	TM-0010 (Patheon CTMLP-1880)	Release: 0.18 to 0.32 mg/tablet Stability: NLT 0.10 mg/tablet
Water Content	USP<921>, Ia PhEur 2.5.12, Method A	NMT 5.0%
Microbial Enumeration	Harmonized USP <61>/ PhEur 2.6.12	Total Aerobic Microbial Count (TAMC): NMT 1000 cfu/g Total Yeast and Mold Count (TYMC): NMT 100 cfu/g
Test for Specified Microorganisms	Harmonized USP <62>/ PhEur 2.6.13	*Escherichia coli*: absent *Salmonella* spp: absent *Pseudomonas aeruginosa*: absent

[1] Nominal RRTs are provided

Memo Approved by:

Anita L Hissem 13 Apr 2011

Name: Anita L Hissem Date

Title Senior Manager Quality Assurance

OPTIMER PHARMACEUTICALS, INC.

Memorandum

Date:	30 March 2011
To:	File, Patheon, Inc.
From:	Elena Korobetskaya, Ph.D., Manager, Analytical Development
Subject:	Specifications for Packaged Fidaxomicin Drug Product
Memo Number:	MM-AD-11-011, Rev. 01
Project:	Fidaxomicin (OPT-80)
File:	☒ Memorandum
	☐ Other _____

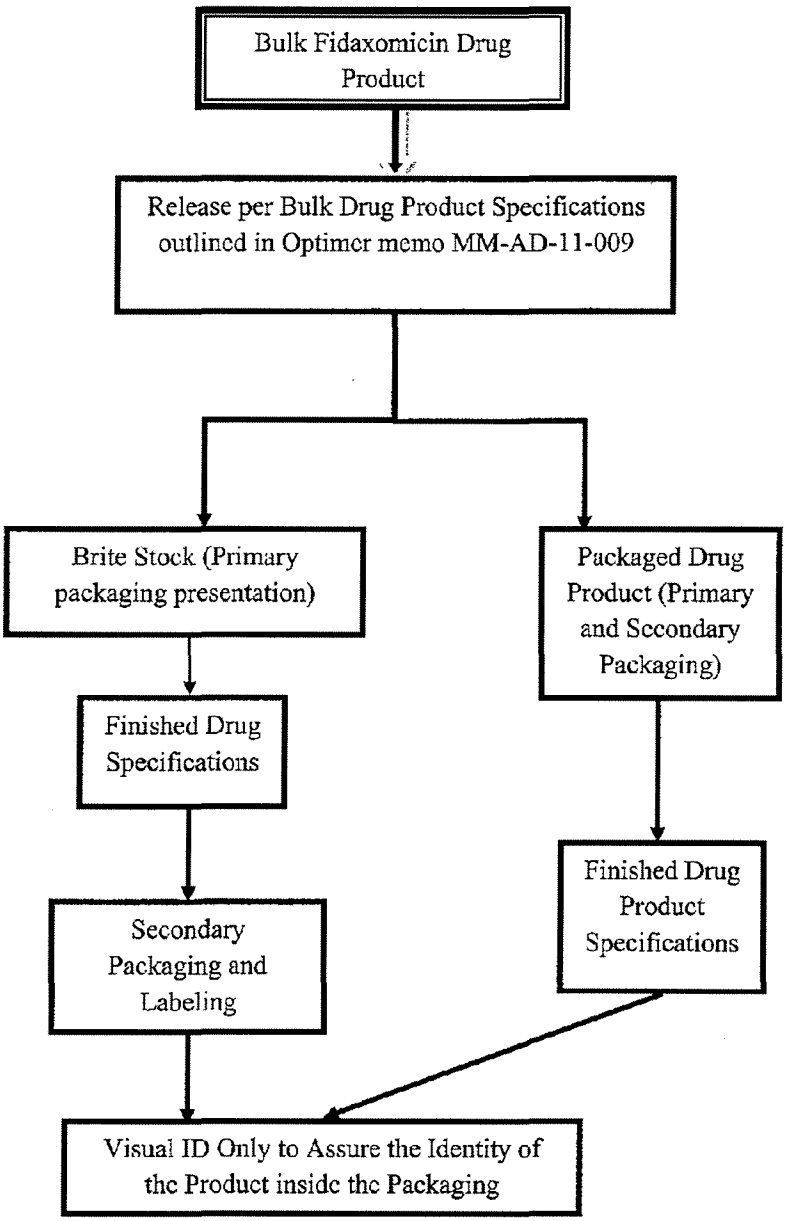
30 Mar 2011

This memorandum is to inform Patheon, Inc. of the commercial specifications for packaged fidaxomicin drug product. Activities related to initiation of packaging and stability studies of packaged fidaxomicin product will be guided by the appropriate Patheon SOPs.

The tests and criteria outlined in the table below are proposed as the commercial specifications for the release of the final fidaxomicin drug product (primary and secondary packaging presentation).

In case if the drug product in its primary packaging presentation is not labeled and/or packaged into the secondary packaging presentation within 30 days it will be considered Brite Stock and released per the table and the flow chart below.

Attribute	Test Method	Acceptance Criteria
Description	Visual	White to off-white film-coated modified capsule shaped tablet debossed with "FDX" on one side and "200" on the other side
Identification:		
Test 1	TM-0023 (Patheon CTMLP-2510)	Conforms to the RT of Reference Standard
Test 2		Conforms to the UV spectrum of Reference Standard
Microbial Enumeration	Harmonized USP <61>/ PhEur 2.6.12	Total Aerobic Microbial Count (TAMC): NMT 1000 cfu/g Total Yeast and Mold Count (TYMC): NMT 100 cfu/g
Test for Specified Microorganisms	Harmonized USP <62>/ PhEur 2.6.13	*Escherichia coli*: absent *Salmonella* spp: absent *Pseudomonas aeruginosa*: absent



Memo Approved by:

Name: Susanne Dunham, QA - Manager
Title

30 Mar 2011
Date

SCHEDULE B

MINIMUM RUN QUANTITY AND PRICE

Validation Pricing Summary

	Fidaxomicin 200 mg Tablets (OPT-80)			
Units	**Bottles of 20 tablets**			
Pkg Format	**Brite Stock (primary pkg on 1 lot)**	**Brite Stock (primary pkg on 2 lots, run back to back)**	**Secondary Pkg – (secondary pkg on 2 lots, run back to back)**	**Full Service (primary and secondary packaging run back to back, on 1 lot)**
Minimum Run Qty (20 count)	10,584	21,168	10,584	10,584
Price per Unit	**$5.54**	**$4.84**	**$1.55**	**$6.28**

Commercial Product Pricing Summary

Fidaxomicin 200 mg Tablets (OPT-80)					
Format	Bottles		Blisters		Bulk Tablets
Units	20 count	60 count	2x10	10x10	1,000s
Product Code	4000001285	4000001286	4000001271	4000001164	TBD
Campaign Length (Batches)	1	1	1	1	1

Minimum Run Quantity (units)	10,584	3,528	10,368	2,074	212
Price per Unit	$6.28	$13.88	$8.08	$29.58	$162.76

Key Technical Assumptions

Manufacturing Assumptions

1. The manufacturing process at Patheon will closely follow the process information and experience to-date at the site.

2. The API, Fidaxomicin, has been evaluated as a Toxicity Category 2 compound at Patheon and can be handled safely using existing equipment and facility at the site.

3. The core tablet weight and manufacturing batch size for Fidaxomicin Tablets, 1 strength, proposed by Patheon are summarized in the following table:

Strength	Core Tablet Weight	Core Batch Size	Theoretical Yield
200 mg	350 mg	84 kg	240,000 Tablets

4. The theoretical coated batch size will be 86.4 kg.

5. Manufacturing is a wet process which involves high shear mixing, high shear granulating, milling, FBD, milling, final blending, compressing and aqueous film coating.

6. The following manufacturing equipment train is being utilized:

   - PMA400 High Shear Granulator
   - Fitzmill
   - S6 FBD

- GEI Gallay Blender with 650L Tote
- Stokes 30B Tablet Press
- 48" Accela Cota

7. Patheon assumes the current cleaning procedure is adequate and full cleaning occurs after each campaign.

8. A manufacturing yield of 90% is assumed.

Packaging Assumptions - Bottling

1. Bottling will utilize the following equipment:
   - Bottle Unscramble/ Blower
   - Desiccant Dispenser
   - Cremer Filler
   - Capper
   - Induction Sealer
   - Re-Torquer
   - Labeller
   - Automatic Cartoning

2. The proposed packaging configurations will be as follows:

20's Bottle in Carton	**60's Bottle in Carton**
• 20 tabs per 30cc HDPE bottle • 1 desiccant canister per bottle • 1 24/400 CR cap with induction seal per bottle • 1 label per bottle • 1 bottle per carton • 1 insert per carton • 80 cartons per shipper	• 60 tabs per 60cc HDPE bottle • 1 desiccant canister per bottle • 1 33/400 CR cap with induction seal per bottle • 1 label per bottle • 1 bottle per carton • 1 insert per carton • 32 cartons per shipper

Note: Insert common between 20's and 60's pkg skus

3. A 98% bottling yield is assumed.

Packaging Assumptions – Blistering

1. Blistering will utilize the following equipment:
   - IMA TR-100 Blister Machine
   - Manual Cartoning

2. The proposed packaging configurations will be as follows:

2x10's Blisters in Carton	**10x10's Blisters in Carton**
• 10 tablets per blister • 2 blisters per carton • 2 inserts per carton • 78 cartons per shipper	• 10 tablets per blister • 10 blisters per carton • 10 inserts per carton • 24 cartons per shipper

Note: Insert common between 2x10's and 10x10's pkg skus

3. A 96% blistering yield is assumed.

Testing Assumptions

Testing will be completed as per Client direction:

- Drug Substance – refer to memo MM-AD-11-010, Rev 1
- Bulk Specifications – refer to memo MM-AD-11-009, Rev 3
- Finished Product Specifications – refer to memo MM-AD-11-011, Rev 1

The following cost items are included in the Price for the Products:

- Product manufactured and packaged under the Agreement
- Standard certificate of analysis ("COA")
- Standard certificate of compliance ("COC")

- GMP required retention samples
- Copies of deviation reports
- Batch Production Records ("BPR")/Lot Packaging Records ("LPR") copies for validation batches, first ten commercial batches, and one commercial batch per Year thereafter
- One label copy change per Year
- BPR/LPR changes (one change per Year)
- Common HPLC/GC columns, reagents, and lab supplies
- Copy of the Annual Product Review Report
- Product Approval Inspection ("PAI") and copy of FDA Report
- Simple, routine statistical review
- Storage of Production Test Record ("PTR") batches and other experimental batches for three months
- Storage of registration batches and other experimental batches for two years or until Product approval, whichever comes first
- Routine sampling and analysis as part of Product manufacture and release
- Warehousing of equipment, raw materials, API, and finished goods for normal commercial supply

SCHEDULE C

ANNUAL STABILITY TESTING & ANNUAL PRODUCT REVIEW

2012 Commercial Annual Stability Pricing

Patheon will place 1 lot of commercial Fidaxomicin Tablets, for each packaging sku (20 count bottles, 60 count bottles, 2x10 blisters or 10x10 blisters), on stability to meet the 2012 commercial stability requirements.

Testing requirements include:

- Storage Condition: 25C/60%RH
- Timepoints: T= 3, 6, 9 and 18 months.
- Required Testing: Description, Assay, Moisture Content, Degradation Products, Dissolution, BHT Assay, and Disintegration

- Storage Condition: 25C/60%RH
- Timepoints: T= 0*, 12, 24, 36, 36** and 48 months.
- Required Testing: Description, Assay, Moisture Content, Degradation Products, Dissolution, BHT Assay, Disintegration, and Microbial Enumeration and Testing for Specified Microorganisms

- Optional : Storage Condition: 40C /75% R.H.
- Timepoint: T= 3 months.
- Required Testing: Description, Assay, Degradation Products, Dissolution, BHT Assay, and Disintegration

- Optional: Storage Condition: 40C /75% R.H.
- Timepoint: T= 6 months.
- Required Testing: Description, Assay, Degradation Products, Dissolution, BHT Assay, Disintegration, and Microbial Enumeration and Testing for Specified Microorganisms.

Storage Condition: 30C/65%RH:

Patheon will retain and store samples under these conditions as a contingency, in the event of poor product stability at the 40C/75% RH conditions. Testing of samples stored at 30C/65% RH is not included in the stability pricing below. If required by Client, a separate proposal will be issued to reflect the cost of the additional testing for the 30C/65% RH samples.

STABILITY - COMMERCIAL												USD
Number of Lots 3												
Protocol Generation							$791					
Pullpoint Month	T = 0*	T = 1	T = 2	T = 3	T = 6	T = 9	T = 12	T = 18	T = 24	T = 36	T = 36**	T = 48
25°C / 60% RH	x			x	x	x	x	x	x	x	x	x
Samples per pullpoint	3			3	3	3	3	3	3	3	3	3
Microbiology	x						x		x	x	x	x
Cost per pullpoint (Milestone Price)	$14,616	$0	$0	$13,311	$13,311	$13,311	$14,616	$13,311	$14,616	$14,616	$14,616	$14,616
GRAND TOTAL										$141,731		

STABILITY - COMMERCIAL					
Number of Lots 3					
Pullpoint Month	T = 0*	T = 1	T = 2	T = 3	T = 6
40°C / 75% RH				x	x
Samples per pullpoint				**3**	**3**
Microbiology					***x***
Cost per pullpoint (Milestone Price)	$0	$0	$0	$13,311	$14,616
GRAND TOTAL					**$27,927**

Total Budget Stability Summary $169,658

* T=0 costing to be applied only if new initial testing to be performed for T=0. This will only apply if samples are placed in the stability chambers greater than 30 days from the date of manufacture. Otherwise, the results from release testing will be reported as T=0.

** If the expiry date does not coincide with one of the routine test points, then an additional time point may be added to the stability schedule and billed accordingly.

2011-2012 Annual Product Review Pricing

If Client is not generating the Annual Product Review ("APR"), Patheon's Quality Assurance department will complete a comprehensive review which Client will use to file an Annual Product Report. Patheon offers three levels of APR depending on the client requirements.

The following table outlines charges that will be billed to Client, depending on the Level of APR agreed upon.

	Level 1		**Level 2**		**Level 3**	
	Base	**Next 10 Lots**	**Base**	**Next 10 Lots**	**Base**	**Next 10 Lots**
Hours for APR	125	10	90	8	70	6
Price Rate	$100	$100	$100	$100	$100	$100
Price of APR	$12,500	$1000	$9000	$800	$7000	$600

		Level 1	Level 2	Level 3
Deviations		X	X	X
	Manufacturing Out of Specifications	X	X	X
	Analytical Out of Specifications	X	X	X
	Evaluation of CAPA on previous review	X		
Change Controls				
	Initiated during the review period	X	X	X
	Changes still open	X	X	X
Validation Studies		X	X	X
	Cleaning Protocols during the review period	X	X	X
	Process Study's during the review period	X	X	X
	Main Equipment and studies during the review period	X		
	Facility status for HVAC, Water etc.	X		
Complaints		X	X	X
	Any received and analysed during the review period	X	X	X
Recalls		X	X	X
	Any reported during the review period	X	X	X
Stability Studies		X	X	X
	Following packaged product stability protocols and monitored during the review period	X	X	X
	OOS Stability raised during the review period	X	X	X
Retain Samples Evaluation		X	X	X
Conclusions		X		
	Evaluation based on data collected on batches produced during the review period	X		
	Yields	X		
	Analytical data	X		
	Deviations	X		
	Change controls	X		
	Validation	X		
	Complaints	X		
	Recalls	X		
	Stability	X		
Recommendations		X		
	On the basis of the evaluation performed further action recommendations	X		

APR/PQR Information Levels

	Level 1	Level 2	Level 3
Product Description	X	X	X
Product Codes	X	X	X
Standard Yields	X	X	X
Variance	X	X	X
Quality Agreement revision number and approval date	X	X	X
Shelf Life	X	X	X
Client Identification	X	X	X
Manufacturing Information	X	X	X
Master Batch Records	X	X	X
In place during review	X	X	X
Description	X	X	X
Revision history and change control references	X	X	X
Copies of batch records	X	X	X
List of Batches manufactured and packaged during the reporting period	X	X	X
Disposition	X	X	X
Date of Manufacture	X	X	X
Theoretical Batch size	X	X	X
In process and final Yield summaries	X	X	
Comments on Yields and suggestions for improvements	X		
Quality of Manufacturing Variation Trending to Cp and Cpk, using control charts +/- 3 sigma	X		
Rejected Batches	X	X	X
Reworked Batches	X	X	X
Analytical Data	X	X	X
Specifications	X	X	X
Analytical Data/Results (summaries)	X	X	
Copies of testing results for each batch			X
Comments on analytical data including suggestions for im mprovements	X		
Quality of Analytical Data Variation Trending to Cp and Cpk, using contro charts +/- 3 sigma	X		
Analytical Methods	X	X	X
Raw Materials (Excipients and Packaging Materials)	X	X	X
In place during review period	X	X	X
Description	X	X	X
Revision history and change control references	X	X	X
Active Pharmaceutical Ingredient (API)	X	X	X
Finished Product	X	X	X

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
Fidaxomicin (OPT-80) Drug Substance	Biocon Limited 20th KM, Hosur Road, Electronics City, Bangalore 56-100

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
Fidaxomicin 200mg Tablets	Fidaxomicin (OPT-80) Drug Substance	Client's actual cost for Active Materials

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Agreement for any Product in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
Fidaxomicin	Twelve and a half percent (12.5%) of Patheon's revenues under this Agreement, in the aggregate per Year.

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 ten Business Days 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 ten Business Day 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 ADR Chambers who will be a retired judge of the Ontario Superior Court of Justice or 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 *Arbitration Act* (Ontario) 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 15 Business Days (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 five Business Days 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

[FORM OF] SHIPPING LOGISTICS PROTOCOL

[NTD: regional variations in the instructions etc. may be necessary while maintaining the EXWorks principle and the export principles outlined below]

Shipping will be carried out under the following terms and conditions:

[NOTE TO DRAFT: Use this section if we are only shipping within the country of manufacture.]

Shipping terms will be EXW (INCOTERMS 2000), the Manufacturing Site.

[NOTE TO DRAFT: Use this section if we are exporting to the US]

Exports of Products from Canada to the United States

1. Shipping terms will be EXW (INCOTERMS 2000), the Manufacturing Site.
2. Client, as the importer of record into the United States, will advise Patheon prior to export of the Products from Canada of Client's designated customs broker and freight forwarder to enable Patheon to complete all applicable shipping documentation.

[NOTE TO DRAFT: Use this section if we are exporting outside of North America]

International Exports of Products from Canada (other than to the United States)

[NOTE TO DRAFT: Use next 3 clauses if we are exporting EXW to outside of North America. We can only ship EXW to outside of North America if Client has a Canadian affiliate that can act as the "exporter of record" from Canada. Many Clients do not have Canadian affiliates, in which case export to outside of North America must be FCA.]

EX WORKS

1. Shipping terms will be EXW (INCOTERMS 2000), the Manufacturing Site.
2. Client will designate its Canadian affiliate as the exporter of record from Canada and will advise Patheon of the name and address of that affiliate.
3. Client will instruct its Canadian affiliate to advise Patheon prior to export of the Products from Canada of the affiliate's designated customs broker and freight forwarder to enable Patheon to complete all applicable shipping documentation.

[NOTE TO DRAFT: Use this section if we are exporting outside of North America and if the shipment is not EXW – see prior note to draft. In most cases, we will use FCA so the following 3 clauses will apply rather than the prior 3 clauses.]

FCA

1. Shipping terms will be FCA (INCOTERMS 2000), Manufacturing Site.
2. Patheon, as the exporter of record from Canada, will carry out all customs formalities necessary to export the Products including declaring the value of the Products being exported from Canada by completing a B-13 Export Declaration form which will be completed showing Patheon as the exporter of record of the Products with a value equivalent to Patheon's selling price of the Products to Client plus assists. The assist value will be calculated in a manner consistent with the method of calculation used in calculating the values provided under Section 2.1(f) of the

Agreement and as may be specified in the instructions of Canada Revenue Agency at time of export. For the purposes hereof, "assists" means (a) materials, components, parts, and other goods incorporated in the Products; (b) tools, dies, moulds, and other goods utilised in the production of the Products; (c) any materials consumed in the productions of the Products; (d) engineering, development work, art work, plans and sketches undertaken by Patheon for the production of the Products.

3. Patheon will report exports directly to Canada Revenue Agency and Statistics Canada at the time of shipment from the Manufacturing Site.

[CLIENT LETTERHEAD]

Form of Logistics Routing Guide

Patheon Inc.
[INSERT ADDRESS]

Attention: _____, A/M

1. Routine Routing/Shipping Instructions

The following lists the recommended agents and procedures for shipments of **[PRODUCT NAME]** from Patheon's manufacturing site at **[INSERT SITE ADDRESS]**, Ontario, Canada to **[INSERT DESTINATION NAME AND ADDRESS].**

AGENTS:

- Freight forwarder Contact: PH: ( )
- Customs broker Contact: PH: ( )

Questions concerning transport logistics should be directed to **[CLIENT CONTACT INFO].**

The following documents must be provided to the carrier for transport and customs purposes:

- Proforma Invoice
- Bill of Lading (**"B/L"**)
- Applicable Permits/Declarations
- Packing List
- If eligible, NAFTA Certificate of Origin will be provided in blanket form yearly to **[INSERT CLIENT'S NAME]** or **[INSERT CLIENT'S NAME]** broker.

Upon shipment departure from Patheon, a full set of documents must also be faxed to the following individuals:

- **[INSERT CLIENT CONTACT FAX OR EMAIL]**

Freight is shipped to:

[INSERT DESTINATION NAME AND ADDRESS]

Information to be provided on Proforma Invoice.

- Net Quantity
- Patheon Code & Lot Number
- Client Lot Number/ Purchase Order (**"PO"**)Number
- $ / Unit Including Assist Value (Active Materials Usage) & Toll Manufacturing Charge
- HTS (Harmonize Tariff Schedule)#
- NDC/IND/ANDA
- FDA Product Code
- Ship Date
- Patheon Bill of Lading Number
- Gross Weight

- Number of Pallets

Assist Values:

- **[INSERT ACTIVE MATERIALS NAME]** $/kg.

Note: [INSERT CLIENT NAME] will provide updated values during the first month of each calendar year. If a change occurs throughout the year, Patheon will be notified within 30 days. Method of valuation for API will be provided in writing to Patheon Inc.

Information to be provided on Bill of Lading:

- B/L Number
- Carrier
- Origin Point
- Shipper Information
- Consignee
- Consignee Address
- Ship Date
- Number of Pallets
- Gross Weight
- PO Number for each Product/Lot
- Description of Goods Indication PC, Lot Number Quantity
- Seal Number
- Freight Terms (EXW or FCA)
- Carrier Signature

Information to be provided on Packing List:

- Ship date
- Bill of Lading Number
- Number of Pallets
- Weight
- Product Description
- Patheon Code Number, if applicable
- Patheon Lot Number, if applicable
- Number of Full Cartons (drums if bulk) x Quantity Per Carton
- Number of Partial Cartons (drums if bulk) x Quantity Per Carton
- Total Number of Cartons with Total Quantity Shipped

2. ***Non-Routine Routing/Shipping Instructions***

As non-standard shipments are unique, the specific situations are to be discussed and agreed to by both Patheon and **[INSERT CLIENT NAME]** prior to shipment. Examples of non-standard shipments are shipping study samples, clinical/development batches, etc.

Yours truly,

_____

AUTHORIZED SIGNATORY
CLIENT NAME

SCHEDULE G

MONTHLY ACTIVE MATERIALS INVENTORY REPORT

TO: Optimer Pharmaceuticals, Inc.

FROM: PATHEON INC.

RE: Active Materials quarterly inventory report under Section 2.2(a) of the Manufacturing Services Agreement dated • (the "Agreement")

Reporting quarter: _____

Active Materials on hand
at beginning of month: _____ kg (A)

Active Materials on hand
at end of month: _____ kg (B)

Quantity Received during month: _____ kg (C)

Quantity Dispensed[1] during month: _____ kg
(A + C – B)

Quantity Converted during month: _____ kg
(total Active Materials in Products produced
and not rejected, recalled or returned)

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

PATHEON INC. DATE:_____

Per: _____
Name:
Title:

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[1] Excludes 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 consumed in technical transfer activities or development activities, including, without limitation, any regulatory, stability, validation, or test batches manufactured during the month.

SCHEDULE H

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

TO: Optimer Pharmaceuticals, Inc.

FROM: PATHEON INC.

RE: Active Materials annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.2(a) of the Manufacturing Services Agreement dated • (the "Agreement")

Reporting Year ending: _____

Active Materials on hand at beginning of Year: _____ kg (A)

Active Materials on hand at end of Year: _____ kg (B)

Quantity Received during Year: _____ kg (C)

Quantity Dispensed[1] during Year: _____ kg (D)
(A + C - B)

Quantity Converted during Year: _____ kg (E)
(total Active Materials in Products produced and not rejected, recalled or returned)

Active Materials Credit Value: $_____ / kg (F)

Target Yield: _____ % (G)

Actual Annual Yield: _____ % (H)
((E/D) * 100)

Shortfall: $_____ (I)
(((G – 5) - H)/100) * F * D (if a negative number, insert zero)

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[1] Excludes 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 consumed in technical transfer activities or development activities, including, without limitation, any regulatory, stability, validation, or test batches manufactured during the Year.

Based on the foregoing reimbursement calculation Patheon will reimburse Client the amount of $_____ _____.

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

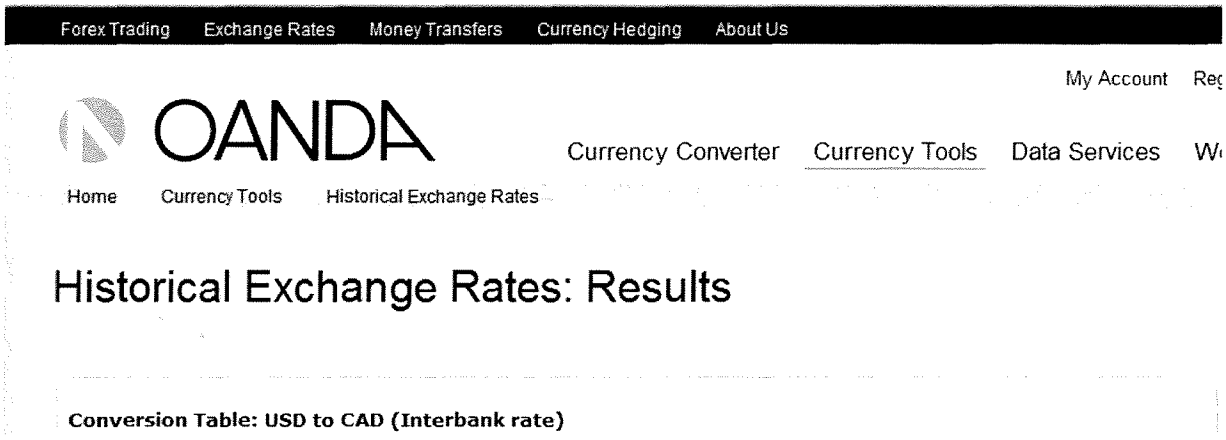
DATE: _____

PATHEON INC.

Per: _____
Name:
Title:

SCHEDULE I

EXAMPLE OF PRICE ADJUSTMENT DUE TO CURRENCY FLUCTUATION
Section 4.2(d)



SAMPLE EXCHANGE CALCULATION

Initial Exchange Rate: 1.00000 CAD/USD
Set Exchange Rate: 1.18007 CAD/USD

Initial Price: 5.25
Revised Price (FX): 5.30 (Material price and PPI adjustments)

Calculation:

[Revised Price (After FX)] = [Revised Price (Before FX)] X [Initial Exchange Rate] / [Set Exchange Rate]

= 5.30 X 1.00000 / 1.18007

= 4.49