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

FORM 8-K/A
(Amendment No. 1)

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **July 20, 2022**

JAGUAR HEALTH, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36714**	**46-2956775**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

200 Pine Street, Suite 400 **San Francisco, California** (Address of principal executive offices)	**94104** (Zip Code)

Registrant's telephone number, including area code: **(415) 371-8300**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.0001 Per Share	JAGX	The NASDAQ Capital Market

Explanatory Note

The purpose of this Amendment No. 1 (the "Amendment") on Form 8-K/A to Jaguar Health, Inc.'s (the "Company") Current Report on Form 8- K filed with the Securities and Exchange Commission on July 20, 2022 (the "Form 8-K") is to include Exhibit 10.1.

No other changes have been made to the Form 8-K. This Amendment speaks as of the original filing date of the Form 8-K, as amended, does not reflect events that may have occurred subsequent to the original filing date and does not modify or update in any way disclosures made in the Form 8-K, except as otherwise set forth above.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit

Exhibit No.	Description
10.1*#	Manufacturing Services Agreement, dated June 10, 2022, by and between Napo Pharmaceuticals, Inc. and Patheon Pharmaceuticals Inc.
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

* Filed herewith.

\# Portions of this exhibit have been omitted pursuant to Item 601 of Regulation S-K promulgated under the Securities Act because the information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

JAGUAR HEALTH, INC.

By: /s/ Lisa A. Conte
Name: Lisa A. Conte
Title: President and Chief Executive Officer

Date: August 24, 2022

Exhibit 10.1

Certain information marked as [****] has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Master Manufacturing Services Agreement
June 10, 2022

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MASTER MANUFACTURING SERVICES AGREEMENT

THIS MASTER MANUFACTURING SERVICES AGREEMENT (this "**Agreement**") is made as of June 10, 2022 (the "**Effective Date**")

BETWEEN

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

("**Patheon**"),

- and -

NAPO 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

STRUCTURE OF AGREEMENT AND INTERPRETATION

1.1. Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Patheon Affiliate may perform Manufacturing Services for Client or any Client Affiliate. This "master" form of agreement is intended to allow Client or any of its Affiliates to contract for the manufacture of multiple Products through Patheon's global network of Manufacturing Sites through the issuance of site specific Product Agreements without having to re-negotiate the terms and conditions contained herein.

1.2. Product Agreements.

This Agreement is structured so that a Product Agreement may be entered into by the parties for the manufacture of a particular Product or multiple Products at a Manufacturing Site. Each Product Agreement will be governed by, and subject to, the terms and conditions of this Agreement, except to the extent the parties agree to specifically modify the terms and conditions of this Agreement in the Product Agreement. The terms of this Agreement or a Product Agreement may be modified by the parties in accordance with Section 13.11 below. Unless otherwise agreed by the parties, each Product Agreement will be in the general form and contain the information set forth in **Appendix 1**.

1.3. Definitions.

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

"**Active Materials**", "**Active Pharmaceutical Ingredients**" or "**API**" means the materials listed and identified in Schedule D of a Product Agreement;

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

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

"**Affiliate**" of an entity means:

(a) a business entity which owns, directly or indirectly, a controlling interest in the entity; or

(b) a business entity which is controlled by the entity, either directly or indirectly; or

(c) a business entity, the controlling interest of which is owned, either directly or indirectly, by a person or entity that also owns, directly or indirectly, a controlling interest in the first entity;

For this definition, "control" means the ownership of equity carrying at least a majority of the votes for the election of the directors of a business entity.

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

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

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

"**Annual Volume Tier**" means one of the tiers set forth in Schedule B to a Product Agreement, showing the Price that would apply with respect to a given quantity of Product;

"**Applicable Laws**" means: (i) for Patheon, the Laws of the jurisdiction where the Manufacturing Site is located; and (ii) for Client and the Product, the Laws of all jurisdictions where Product is manufactured, distributed, and marketed;

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

"**Batch Order Quantity**" means the minimum number of batches of a Product to be produced during the same cycle of manufacturing as set forth in a Product Agreement on Schedule B thereto;

"**Bill Back Items**" means the documented and itemized expenses for all third party supplier fees for the purchase or use of columns, standards, tooling, non-standard pallets, powered air purifying respirator or personal protective equipment suits (where applicable), RFID tags and supporting equipment, and other project-specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Active Materials or Components;

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

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the United States or in the jurisdiction where the Manufacturing Site is located, and "**day**" means a calendar day;

"**cGMPs**" means, as applicable, 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 and Volume 4 of the European Commission's Rules governing medicinal products in the European Union,

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;

"**Client Indemnitees**" has the meaning specified in Section 10.3;

"**Client Intellectual Property**" means (a) Intellectual Property generated, discovered by, or developed by Client and (b) Product IP.

"**Client Property**" has the meaning specified in Section 8.4(d);

"**Components**" means, collectively, all packaging components, raw materials, ingredients, and other materials (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 and Bill Back Items;

"Confidentiality Terms" means the Non-Disclosure and Non-Use Terms and Conditions set forth in **Appendix 2**;

"**Confidential Information**" has the meaning set forth in **Appendix 2**;

"**Courts**" has the meaning specified in Section 13.20;

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

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

"**Disclosing Party**" has the meaning set forth in **Appendix *2***;

"**Dispute**" has the meaning set forth in Section 12.1;

"**DOL**" means the United States' Department of Labor

"**EMA**" means the European Medicines Agency and any successor Authority;

"**Excluded Lists**" means the Department of Health and Human Service's List of Excluded Individuals/Entities and the General Services Administration's Lists of Parties Excluded from Federal Procurement and Non-Procurement Programs;

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

"**FFDCA**" means the Federal Food, Drug, and Cosmetic Act, as amended;

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

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

"**Government Approval**" means any and all approvals, licenses, registrations or authorizations of Regulatory Authorities necessary for the manufacture of Product in the Territory or for distribution or sale in the Territory and the performance of the other activities contemplated in this Agreement;

"**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 and any successor Authorities;

"**Indemnification Claim Notice**" has the meaning specified in Section 10.5(a);

"**Indemnified Party**" has the meaning specified in Section 10.5(a);

"**Indemnifying Party**" has the meaning specified in Section 10.5(a);

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

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

"**Initial Set Exchange Rate**" means as of the effective date of a Product Agreement, the initial exchange rate set forth in the Product Agreement to convert one unit of the billing currency into the Manufacturing Site's local currency, calculated as the daily average interbank exchange rate for conversion of one unit of the billing currency into the Manufacturing Site's local currency during the 90 day period immediately preceding the effective date as published by OANDA.com, "The Currency Site" under the heading "Historical Exchange Rates" at www.OANDA.com/convert/fxhistory;

"**Intellectual Property**" means any and all intellectual property rights of whatever kind or nature and includes rights in patents, patent applications, formulae, trademarks, trademark applications, trade secrets, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

"**Invention**" means any innovation, improvement, development or discovery;

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

"**Joint Intellectual Property**" means Intellectual Property generated, discovered or developed jointly by Patheon and Client, excluding the Product IP;

"**Joint Invention Patents**" has the meaning specified in Section 13.1(d)(iii);

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

"**Losses**" has the meaning specified in Section 10.3;

"**Manufacturing Services**" means the manufacturing, validation, quality control, quality assurance, stability testing, laboratory analysis, packaging, and related services, as set forth in this Agreement, required to manufacture and release Product or Products using the Active Materials, Components, and Bill Back Items;

"**Manufacturing Site**" means the facility owned and operated by Patheon where the Manufacturing Services are to be performed, as identified in the relevant Product Agreement;

"**Materials**" means all Components and Bill Back Items required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

"**Maximum Credit Value**" means the maximum value of Active Materials, established annually by Client, that may be credited by Patheon under a Product Agreement, as set forth in the Product Agreement on Schedule D thereto;

"**Patheon Competitor**" means a business that derives greater than 50% of its revenues from performing contract pharmaceutical development or commercial manufacturing services for third parties;

"**Patheon Indemnitees**" has the meaning specified in Section 10.4;

"**Patheon Intellectual Property**" means Intellectual Property (a) generated, discovered or developed by Patheon ***before*** performing any Manufacturing Services or receiving any Confidential Information from Client under this Agreement or (b) generated, discovered or developed by Patheon while or as a result of performing the Manufacturing Services, , and (c) excluding only for the purpose of this clause any Product IP and any Joint Intellectual Property;

"**PPI**" has the meaning specified in Section 4.2(a);

"**Product IP**" means Intellectual Property generated, discovered, or developed by Patheon, either alone or jointly with Client, while or as a result of performing the Manufacturing Services, that has particular application to, or is otherwise related to, the development, manufacture, use, marketing or sale of, or that is in any way dependent upon, any Active Material or Product;

"**Price**" or "**Pricing**", as the context requires, means the price measured in USD to be charged by Patheon for performing the Manufacturing Services under a particular Product Agreement, and includes the cost of Components, certain cost items as set forth on Schedule B to the relevant Product Agreement, and annual stability testing costs as set forth on Schedule C to the relevant Product Agreement;

"**Product Agreement**" means an agreement between Patheon and Client issued under this Agreement in the form set forth in **Appendix 1** (including Schedules A to D) under which Patheon is to perform Manufacturing Services at a particular Manufacturing Site;

"**Product**" means the products listed in a Product Agreement on Schedule A thereto;

"**Product Claims**" has the meaning specified in Section 6.3(c);

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

"**Quality Agreement**" means that certain agreement between Patheon and Client which is made a part of the applicable Product Agreement, setting forth the quality assurance standards for the Manufacturing Services to be performed under each Product Agreement;

"**Quantity Converted**" has the meaning specified in Section 2.2(a).

"**Quantity Dispensed**" has the meaning specified in Section 2.2(a).

"**Quantity Received**" has the meaning specified in Section 2.2(a).

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

"**Receiving Party**" has the meaning set forth in set forth in **Appendix *2***;

"**Regulatory Authority**" or "**Regulatory Authorities**" means the FDA, EMA, and Health Canada and any other Authority competent to regulate the manufacture, sale or marketing of pharmaceutical products, including the Products, in the Territory;

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

"**Representatives**" has the meaning set forth in set forth in **Appendix *2***;

"**Required Percentage**" has the meaning specified in Section 2.1;

"**Required Period**" has the meaning specified in Section 2.1;

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

"**Rolling Forecast**" has the meaning specified in Section 5.1(a).

"**Semi-Firm Commitment**" has the meaning specified in Section 5.1(b).

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

"**Set Exchange Rate**" means the exchange rate to convert one unit of the billing currency into the Manufacturing Site local currency for each Year, calculated as the average daily interbank exchange rate for conversion of one unit of the billing currency into the Manufacturing Site local currency during the full year period (October 1st [preceding year] to September 30th), as published by OANDA.com "The Currency Site" under the heading "Fx History: historical currency exchange rates" at www.OANDA.com/convert/fxhistory;

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

"**Specifications**" means the file, for each Product, which is given by Client or an Affiliate of Client to Patheon in accordance with the procedures listed in a Product Agreement on Schedule A thereto and which contains documents relating to each Product, including**:**

(a) specifications for Active Materials and Components;

(b) manufacturing specifications, directions, and processes;

(c) storage requirements;

(d) all environmental, health and safety information for each 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 and the applicable Product Agreement;

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

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

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

"**Territory**" means the countries comprising the geographic area described in a Product Agreement where Products manufactured by Patheon are to be distributed, marketed and otherwise exploited by, or on behalf of, Client;

"**Third Party Claims**" has the meaning specified in Section 10.3;

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

"**United States**" means the United States of America, including its territories and possessions, including the District of Columbia and Puerto Rico;

"USD" means United States Dollars.

"**Year**" means each consecutive period of 12 consecutive calendar months commencing on January 1 and ending on December 31, except that the first Year of the Term will be the period from the Effective Date up to and including December 31 of the same calendar year, and the last Year of the Term will commence on January 1 of the calendar year in which the Term ends and end on the last day of the Term.

1.4. **Interpretation**.

The division of this Agreement into Articles, Sections, Subsections, Appendices. Exhibits and Schedules, and the insertion of headings, are for convenience of reference only and will not affect the interpretation of this Agreement. Any Appendices and Exhibits referenced in this Agreement are, by such reference, incorporated into this Agreement and made a part hereof. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix, Exhibit or Schedule refers to the specified Section, Appendix, Exhibit or Schedule to this Agreement. In this Agreement, the term "**this Agreement**" and similar expressions refer to this Agreement as a whole and not to any part, Section, Appendix, Exhibit or Schedule of this Agreement. Unless otherwise expressly provided in this Agreement or the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which these words appear, (c) words using the singular include the plural, and vice versa, (d) the words "includes" and "including" will be considered to be followed by the phrase "but not limited to", "without limitation" or words of similar import, and (e) the words "will" or "must" have the same meaning and effect as the mandatory or obligatory sense of the word "shall". If a payment under this Agreement is due on a day which is not a Business Day, the due date for that payment will be the next Business Day. Terms other than those defined in this Agreement will be given their plain English meaning and those terms, acronyms and phrases known in the pharmaceutical/ healthcare industry will be interpreted in accordance with their generally accepted meanings.

1.5. Currency.

Unless otherwise agreed in a Product Agreement, monetary amounts expressed in this Agreement are in USD.

1.6. Appendices and Exhibits.

The following Appendices and Exhibits are attached to, incorporated into, and form an integral part of this Agreement:

Appendix 1	-	Form of Product Agreement (including Schedules A to D)
Appendix 2	-	Non-Disclosure and Non-Use Terms and Conditions
Exhibit A	-	Quarterly Active Materials Inventory Report
Exhibit B	-	Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
Exhibit C	-	Example of Price Adjustment Due to Currency Fluctuation

ARTICLE 2

PATHEON'S MANUFACTURING SERVICES

2.1. Manufacturing Services.

Patheon will perform the Manufacturing Services for Products to be distributed and sold by Client in the Territory for the fees specified in Schedules B and C to the relevant Product Agreement. Schedule B to each Product Agreement sets forth a list of cost items that are included in the Price for Products; all cost items that are not included in this list are excluded from the Price and are subject to additional fees to be paid by Client. Patheon may amend the fees set out in Schedules B and C to a Product Agreement as set forth in Article 4. Patheon will perform the Manufacturing Services solely at the designated Manufacturing Site, unless otherwise agreed in writing by Client. If the parties agree that Patheon will supply, and Client will purchase, at least a specified minimum percentage of Client's requirements for a Product under a Product Agreement (the "**Required Percentage"**), then the applicable Product Agreement will set forth the Required Percentage and the time period during which the obligation will apply (the "**Required Period**"). But this obligation (if any) will cease to apply to Client with respect to the Product if Patheon fails to remain in material compliance with its obligations under this Agreement or the applicable Product Agreement, or Patheon suspends performance under this Agreement or the applicable Product Agreement in connection with a Force Majeure Event or where Patheon is or will be prevented from supplying the Product as a result of the action of a Regulatory Authority. Subject to its obligation (if any) to purchase the Required Percentage of a Product during the Required Period, Client may, at any time, obtain Product from a third party or may, at any time, qualify a third party to perform Manufacturing Services for the Product. In performing the Manufacturing Services, Patheon and Client agree that:

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

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the applicable Quality Agreement. Batch review and release to Client will be the responsibility of Patheon's quality assurance group. Patheon will perform its batch review and release responsibilities in accordance with Patheon's standard operating procedures. Each time Patheon delivers Products to Client, it will give Client a certificate of analysis and certificate of compliance, in form and substance previously agreed between Patheon and Client, including a statement that the batch has been manufactured and tested in accordance with Specifications and cGMPs, together with any other documents that are required by the applicable Quality Agreement or are necessary for the distribution or sale of the Products in the Territory. Client will have sole responsibility for the release of Products to the market. The form and style of batch documents, including batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks will be the exclusive property of Patheon**;** provided, however, that all Product-related information contained in those batch documents will be Client Intellectual Property and will be made available to Client for review, and inspection upon reasonable request. Additionally, if Client reasonably requests copies, Patheon will provide copies.

(c) Components. Patheon will purchase all Components at Patheon's expense and as required by the Specifications. Patheon will inspect and test all Components as required by the Specifications.

(d) Stability Testing. Patheon will conduct stability testing on the Products in accordance with the protocols set out in the Specifications for the separate fees and during the time periods set out in Schedule C to the relevant Product Agreement. 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, the Quality Agreement, cGMPs, Applicable Laws, and other requirements specified herein. Patheon will give Client all stability test data and results at Client's request.

(e) Packaging. Patheon will package the Products as set out in the Specifications and Quality Agreement. Client will be responsible for the cost of artwork development. Patheon will determine and imprint the batch numbers, expiration dates and serialization information for each Product delivered. 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 Authorities and other third parties responsible for the approval of the Products. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4(c). Patheon's name will not appear on the label or anywhere else on the Products, except that Patheon hereby consents to the use of its name or the name of the appropriate Patheon Affiliate and the appropriate Manufacturing Site, together with required location and contact information, on labels that are applied to primary and secondary packaging, as required by Applicable Laws.

(f) Active Materials. At least 45 days before the scheduled production date for a Product, Client will deliver the Active Materials to the Manufacturing Site DDP (Incoterms 2020), at no cost to Patheon, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If Client fails to deliver the API or Client-supplied Components within the agreed time period and, making commercially reasonable efforts, Patheon is unable to manufacture Product on the scheduled date because of the delay, the Firm Order will be considered cancelled by Client and Section 5.2(e) will apply. All shipments of Active Materials will be accompanied by certificates of analysis from the Active Material manufacturer, as applicable, confirming the identity and purity of the Active Materials and its compliance with the Active Material specifications. The Active Materials will remain the property of Client. Patheon will inspect and test all Active Materials as required by the Specifications.

(g) Use of Active Materials. Patheon will use the Active Materials solely for manufacturing Product for Client and for related activities in accordance with the terms of this Agreement and the applicable Product Agreement and for no other purpose.

(h) Storage of Active Materials. Patheon will store the Active Materials exclusively at the applicable Manufacturing Site, in a physically secure area under conditions that maintain their stability, integrity, and effectiveness and in accordance with the storage instructions provided therefor by Client. Patheon will ensure that all Active Materials will be free from damage, contamination, deterioration, and adulteration and protected against theft. Patheon will store all Active Materials by lot number and all Active Materials will be physically segregated from other goods and materials stored in the applicable Manufacturing Site. Patheon will use all Active Materials on a first expired, first-out basis, and Patheon will not use any Active Materials after the applicable retest date thereof.

(i) Notifications. Patheon will promptly notify Client if any Active Materials are damaged, contaminated, adulterated, lost, or stolen, deteriorated, or are otherwise rendered unusable after delivery to Patheon (whether before or after incorporation into work in progress). If this occurs, the loss of Active Materials will be addressed under Section 2.2.

(j) Bill Back Items. Bill Back Items will be acquired by Patheon as required to perform the Manufacturing Services and charged to Client at Patheon's cost plus a 10% handling fee.

(k) Product Rejection for Finished Product Specification Failure. If the parties agree, after a full quality investigation by the parties in accordance with cGMP requirements, Applicable Laws, and the applicable Quality Agreement, that Patheon manufactured Product in accordance with the Specifications, the batch production record, Patheon's standard operating procedures for manufacturing, cGMPs, Applicable Laws, the applicable Quality Agreement and the other terms and conditions of this Agreement, and the batch or partial batch of Product does not meet a Specification, Client will pay Patheon 75% of the Component cost and 75% of the manufacturing labor cost directly incurred from manufacturing the non-conforming Product. The API in the non-conforming Product will be included in the "Quantity Converted" for purposes of calculating the "Actual Annual Yield" under Section 2.2(a).

2.2. Active Material Yield.

(a) Reporting. Within 15 Business Days after the end of each quarter of each Year, Patheon will give Client a quarterly inventory report of the Active Materials held by Patheon using the inventory report form set out in **Exhibit A**, which will contain the following information for the quarter:

"**Quantity Received**": The total quantity of Active Materials that complies with the Specifications and was received at the applicable Manufacturing Site during the applicable quarter.

"**Quantity Dispensed**": The total quantity of Active Materials dispensed at the applicable Manufacturing Site during the applicable quarter. The Quantity Dispensed for each applicable quarter is calculated by adding the Quantity Received during the applicable quarter to the inventory of Active Materials that complied with the Specifications held at the beginning of the applicable quarter, less the inventory of Active Materials that complied with the Specifications held at the end of the quarter. The Quantity Dispensed during each applicable quarter will only include Active Materials received and dispensed in commercial manufacturing of Products and will not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or dispensed in technical transfer activities or development activities during the applicable quarter, including any regulatory, stability, validation or test batches manufactured during the applicable quarter.

"**Quantity Converted**": The total amount of Active Materials contained in the Products manufactured with the Quantity Dispensed during the applicable quarter (including any additional Products produced in accordance with Section 6.3(a) or 6.3(b)), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 because of Patheon's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Within 30 days after the end of each Year, Patheon will give Client an annual reconciliation of Active Materials on the reconciliation report form set forth in Exhibit B, including the calculation of the "**Actual Annual Yield**" or "**AAY**" for the Product at the applicable Manufacturing Site during the Year, which will be the percentage of the Quantity Dispensed that was converted to Products and will be 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 15 successful commercial production batches of Product at the applicable Manufacturing Site and has produced commercial production batches for at least six months at the applicable Manufacturing Site (collectively, the "**Target Yield Determination Batches**"), the parties will agree in writing on the target yield for the Product at the applicable Manufacturing Site (each, a "**Target Yield**"). The Target Yield will be revised annually to reflect the actual manufacturing experience as agreed to by the parties.

(b) Shortfall Calculation. If the Actual Annual Yield falls more than 5% below the applicable Target Yield for a Product in a Year, then the shortfall for the Year (the "**Shortfall**") will be calculated as follows:

Shortfall = [(Target Yield – 5%) – 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 Shortfall no later than 60 days after the end of the Year.

Each Shortfall and credit owed Client under this Section 2.2(c) will be summarized on the reconciliation report form set forth in Exhibit B. Upon expiration or termination of a Product Agreement, any remaining credit owing under this Section 2.2, related to the Product Agreement, will be paid to Client. The Annual 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 in a Year under any Product Agreement will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D to the applicable Product Agreement

(e) No Material Breach. The parties agree that, if the Actual Annual Yield is less than the Target Yield for a given Year, this fact will not by itself constitute a material breach of this Agreement by Patheon.

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1. Payment.

Client will pay Patheon for performing the Manufacturing Services according to the Prices specified in Schedules B and C to each Product Agreement. Client will also pay Patheon for any Bill Back Items in accordance with Section 2.1(j)).

3.2. Active Materials and Qualification of Additional Sources of Supply.

Client will, at its sole cost and expense, deliver the Active Materials to Patheon (in accordance with Section 2.1(f)) sufficient for Patheon to manufacture the desired quantities of Product. Patheon and Client will reasonably cooperate to permit the import of the Active Materials to the applicable Manufacturing Site. Client's obligation will include obtaining the proper release of the Active Materials from the applicable customs agency and Regulatory Authority, as applicable. Client or Client's designated agent will be the "Importer of Record" for Active Materials imported to the applicable Manufacturing Site.

If Client asks Patheon to qualify an additional source for the Active Material or any Component, Patheon will cooperate with Client to evaluate the Active Material or Component to be supplied by the additional source to determine if it is suitable for use in the Product. The parties will agree on the scope of work to be performed by Patheon at Client's cost. For an Active Material, this work at a minimum will include:

(a) laboratory testing to confirm the Active Material meets existing Specifications;

(b) manufacture of a GMP qualification batch of Product that will be placed at a minimum on three months accelerated stability;

(c) If applicable, manufacture of three full-scale validation batches that will be placed on concurrent stability (one batch may be the registration batch if manufactured at full scale).

Section 2.1(k) will apply to all Product manufactured using the newly approved Active Material or Component because of the limited material characterization that is performed on additional sources of supply.

ARTICLE 4

INITIAL PRICING AND ADJUSTMENTS

4.1. Initial Pricing.

The tiered Price and annual stability Price for the Products for the first Year are listed in Schedules B and C to the relevant Product Agreement and are subject to the adjustments set forth in Sections 4.2 and 4.3.

4.2. Price Adjustments.

After the first Year of a Product Agreement, Patheon may adjust the Price for the Product Agreement effective January 1st of each Year as follows:

(a) Manufacturing and Stability Testing Costs. For Products manufactured in the United States, Patheon may adjust that portion of the Price attributable to Manufacturing Services (and not to Components) for inflation, based upon the preliminary number for any increase in the Producer Price Index pcu325412325412 for Pharmaceutical Preparation Manufacturing ("**PPI**") published by the DOL Bureau of Labor Statistics 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. On or about November 1st of each Year, 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. For Products manufactured outside the United States, Patheon may similarly adjust the Price for inflation using an inflation index to be agreed by the parties in the Product Agreement. The maximum Price adjustment under this Section 4.2(a) will not exceed ***the lesser of*** (i) the PPI (as published by the DOL in August of the preceding Year compared to the final number for the same month of the Year prior to that, as may be otherwise agreed to by the parties) and (ii) 5%.

(b) Component Costs. If Patheon incurs an increase in Component costs during the Year, it may increase the Price for the next Year to pass through the additional Component costs. If Patheon's Component costs decrease during a Year, Patheon will decrease the Price for the next Year to pass through the reduced Component costs. On or about November 1st of each Year, Patheon will give Client information about any increase or decrease in Component costs, which will be applied to the calculation of the Price for the next Year, which information, in the case of a cost increase, will reasonably demonstrate that the Price increase is justified. If the price increase is less than 5%, Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers**;** however, if the price increase is 5% or more, then Patheon will provide Client with copies of invoices (which may be reasonably redacted by Patheon) issued to Patheon by those suppliers that have increased their respective prices. Disclosure by Patheon of the invoices is subject to **Appendix 2**.

(c) Pricing Basis. Client acknowledges that the Price in any Year is quoted based upon the Batch Order Quantity and Annual Volume Tiers specified in Schedule B to the relevant Product Agreement. The Price may be subject to change if the specified Batch Order Quantity changes or the quantity specified in the lowest specified Annual Volume Tier is not ordered in a Year. If Patheon and Client agree that the Batch Order Quantity or lowest Annual Volume Tier will not be ordered in a Year, whether as a result of a decrease in Client's forecasts or otherwise, and, as a result of the reduction, Patheon demonstrates to Client that its costs to perform the Manufacturing Services or to acquire the Components for the Product will increase on a per-unit basis, and the amount of the increase, then Patheon may increase the Price by an amount sufficient to absorb the documented 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 (if any) for the next Year. If the price increase is less than 5%, Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers**;** however, if the price increase is 5% or more, then Patheon will provide Client with copies of invoices (which may be reasonably redacted by Patheon) issued to Patheon by those suppliers that have increased their respective prices. Disclosure by Patheon of the invoices is subject to **Appendix 2**.

(d) Adjustments Due to Currency Fluctuations. If the parties agree in a Product Agreement to invoice in a currency other than the local currency for the Manufacturing Site, Patheon will adjust the Price to reflect currency fluctuations. The adjustment will be calculated after all other annual Price adjustments under this Section 4.2 have been made. 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 (for a Canadian Manufacturing Site invoiced in USD) is set forth in **Exhibit C**.

(e) Tier Pricing (if applicable). The Pricing in Schedule B to a Product Agreement is set forth in Annual Volume Tiers based upon Client's volume forecasts under Section 5.1. Client will be invoiced during the Year at the unit Price set forth in the applicable Annual Volume Tier based on the 18 month forecast provided in September of the previous Year. Within 30 days after the end of each Year or of the termination of the Product Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by the Client during the Year with the applicable Pricing tiers. If Client has overpaid during the Year, Patheon will issue a credit or refund to the Client for the amount of the overpayment within 45 days after ***the earlier of*** (i) the end of the then-current Year or (ii) termination of the Product Agreement. If Client has underpaid during the Year, Patheon will issue an invoice to the Client under Section 5.5 for the amount of the underpayment within 45 days after ***the earlier of*** (i) the end of the then-current Year or (ii) termination of the Product Agreement. If Client disagrees with the reconciliation, the parties will work in good faith to resolve the disagreement amicably. If the parties are unable to resolve the disagreement within 30 days of Client's notification to Patheon of its disagreement, the matter will be resolved in accordance with Section 12.1.

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or about November 1st of each Year a revised Schedule B to each Product Agreement to be effective for Product delivered under the Product Agreement on or after the first day of the next Year.

4.3. Price Adjustments – Current Year Pricing. During any Year, the Prices set out in Schedule B of a Product Agreement will be adjusted as follows:

(a) Extraordinary Increases in Component Costs. If, at any time, market conditions result in Patheon's cost of Components being materially greater than normal forecasted increases, then Patheon will be entitled to an adjustment to the then-applicable Price for any affected Product to compensate Patheon for the increased Component costs. Changes materially greater than normal forecasted increases 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.

(b) For a Price adjustment proposed under this Section 4.3, Patheon will deliver to Client a revised Schedule B to the Product Agreement and budgetary Pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. But, if requested by Client, Patheon will use commercially reasonable efforts to obtain permission to disclose these documents to Client or will provide these documents with appropriate redactions. The revised Price will be effective for any Product with a date of manufacture on or after the first day of the month following Client’s receipt of the revised Schedule B to the Product Agreement and the supporting documentation.

4.4. Adjustments Due to Technical Changes.

(a) Amendments to Specifications Required by Applicable Laws. If an amendment to the Specifications is required by Applicable Laws, Client may amend the Specifications unilaterally and in its sole discretion. If this amendment will result in increased or decreased costs incurred by Patheon, then the parties will negotiate in good faith an appropriate adjustment to the Price on commercially reasonable terms to reflect the increased or decreased cost to Patheon. If the parties are not able to mutually agree to the Price changes within 30 days (or for a longer period as the parties may agree) and Patheon does not agree to implement the amendment at no increase or decrease in Price, then the dispute will be resolved in accordance with Section 12.1.

(b) Other Amendments. Amendments to the Specifications or the Quality Agreement requested by Client, other than those addressed in Section 4.4(a), will only be implemented following a technical and cost review. If this amendment will result in increased or decreased costs incurred by Patheon, then the parties will negotiate in good faith an appropriate adjustment to the Price on commercially reasonable terms to reflect the increased or decreased cost to Patheon. If the parties are not able to mutually agree to the Price adjustment within 30 days (or for a longer period as the parties may agree) and Patheon does not agree to implement the amendment at no increase or decrease in Price, Client at its option may either (i) determine not to implement the amendment and there will be no adjustment to the Price, or (ii) terminate this Agreement or the applicable Product Agreement. Client will notify Patheon of its election within five Business Days after the end of the 30-day period (or for a longer period as the parties may agree). If Client elects to terminate this Agreement or a Product Agreement as set forth above in this Section 4(b), the termination will be effective ten days after Client gives Patheon written notice of its election to terminate.

(c) Obsolete Inventory. Client agrees to purchase, at the price paid by Patheon (including documented out-of-pocket costs incurred by Patheon for the purchase and handling of the Inventory), all Inventory used under the previous Specifications or Quality Agreement and purchased or maintained by Patheon in order to fill current Firm Orders, if the Inventory can no longer be used to manufacture Product under the amended Specifications or Quality Agreement and if the revisions to the Specifications or the Quality Agreement were proposed by Client. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill current Firm Orders will be cancelled where possible, and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Client, unless these Components may be used by Patheon for some other purpose.

(d) Patheon-Requested Amendments. Amendments to the Specifications, the Quality Agreement, or the applicable Manufacturing Site requested by Patheon will only be implemented following the written approval of Client.

4.5. Multi-Country Packaging Requirements.

If Client requests that Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional costs for Components and Bill-Back Items and the change-over fees for the Product destined for each new country. If Client agrees to, and accepts, Patheon's quotation, then the agreed additional packaging requirements and related packaging costs will be set out in a written amendment to the applicable Product Agreement.

4.6. Audits.

Client will have the right to have an independent accounting firm of nationally recognized standing, provided with access to, and cooperation by, Patheon during normal business hours, and upon reasonable prior written notice, to examine only those records of Patheon (and, if applicable, its Affiliates) as may be reasonably necessary to determine, with respect to any Year ending not more than three Years prior to Client's request, the correctness of any Price increase taken by Patheon. These examinations may not be conducted more than once in any Year (unless a previous audit during that Year revealed an overpayment by Client with respect to the period or an incorrect statement submitted by Patheon during the period). Results of the audit will (a) be (i) limited to information related to the Products, (ii) made available to both parties in writing, and (iii) subject to Article 11 and (b) not reveal any specific information of Patheon to Client other than (i) whether statements submitted by Patheon with respect to any increase in Price are true and correct, as the case may be, and (ii) the amount of any excess payment reimbursable to Client or any correction to statements submitted by Patheon under this Agreement, as the case may be. The determination of the accounting firm will be final and binding as between the parties. The cost of the examination will be borne by Client, unless the audit reveals a variance of more than 10% from the reported amounts for the period under examination, in which case Patheon will bear the cost of the audit. If the audit concludes that excess payments were made by Client during the period under examination, then Patheon will reimburse to Client the amount of the excess payment within 60 days after the date on which the auditor's written report is delivered to the parties.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1. Orders and Forecasts.

(a) Rolling 18 Month Forecast. When each Product 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 under the Product Agreement ("**Rolling Forecast**"). .

(b) Firm Orders. Unless otherwise agreed in a Product Agreement, Client will issue on a rolling basis during the term of the Product Agreement, an updated Rolling Forecast on or before the 15th day of each month (or, at Client's discretion, at any time from the 8th day of the month up to and including the 22nd day of the month), which updated Rolling Forecast will be non-binding except as set forth in this Section 5.1(b). Each updated Rolling Forecast will start on the first day of the next month. The first three months of each updated forecast will be considered binding. Thus, concurrent with each updated Rolling Forecast, Client will issue a new firm written purchase order ("**Firm Order**") for Client to purchase the quantity of Product forecasted for the third month of the updated Rolling Forecast, and, when the new Firm Order is accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Product. The Delivery Date will not be less than 90 days following the date that the Firm Order is submitted. The following nine months of the Rolling Forecast will be 80% binding (the "**Semi-Firm Commitment**"). For example, of the Semi-Firm Commitment, if a forecast states ten batches in month 12 then Client may adjust the number of batches to no less than eight or no more than twelve in each of the following nine months until each month becomes part of the Firm Commitment. The following six months of the Rolling Forecast will be non-binding, good-faith estimates to facilitate Patheon's production scheduling. Patheon will review each Rolling Forecast and notify Client within ten business days if Patheon is unable to accept any portion of the Rolling Forecast. Firm Orders submitted to Patheon will specify, at a minimum, Client's purchase order number, quantities by Product type, monthly shipment schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. The quantities of Products ordered in Client's Firm Orders, once accepted by Patheon, will be firm and binding on Client and may not be reduced by Client.

(c) Three Year Forecast. On or before the tenth day of June of each Year while a Product Agreement is in effect, 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 under each Product Agreement during the three-Year period.

(d) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within ten Business Days of its receipt of the Firm Order. If no acknowledgement is sent by Patheon in the specified period, the Firm Order will be considered to have been accepted by Patheon. Patheon will be required to accept any Firm Order submitted by Client in accordance with Section 5.1(b). But Patheon will not be required to accept a Firm Order submitted by Client under Section 5.1(b) if the quantity of Product specified in the Firm Order exceeds 100% of the quantity specified in the most recent Rolling Forecast for the period to which the Firm Order relates. Patheon will use commercially reasonable efforts to accept Firm Orders up to 125% of the quantity specified in the most recent Rolling Forecast for the period to which the Firm Order relates. The acknowledgement will include, subject to confirmation from the Client, the Delivery Date for the Product ordered, and Patheon will be required to deliver the Product on the Delivery Date, subject to the following sentence. The Delivery Date may be amended by agreement of the parties or as set forth in Section 2.1(f).

5.2. Reliance by Patheon.

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and Rolling Forecasts submitted under Sections 5.1(a), and (b), in ordering the Components required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in sufficient volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Section 5.1(a) and (b) or to meet the production requirements of any longer period agreed to by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components to satisfy the Manufacturing Services requirements for Products for the first six months contemplated in the most recent forecast given by Client under Section 5.1(a) or (b), as the case may be. Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties.

(b) If Client requests that Patheon manufacture launch quantities of a Product for which purchase of Components is not provided for by Section 5.2(a), then Client will give Patheon written authorization to order the necessary Components and, once the written authorization is accepted by Patheon, Components ordered in this manner will be considered to be properly ordered by Patheon as though they were ordered under Section 5.2(a).

(c) If Components properly ordered by Patheon under Firm Orders for use in finished Products, as set forth in Sections 5.2(a) or (b), are not included in finished Products manufactured for Client within six months after the forecasted month for which the purchases have been made (or for a longer period as the parties may agree), then Client will pay to Patheon its costs therefor (including all costs incurred by Patheon for the purchase and handling of the Components). But if these Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

(d) If Client fails to take possession or arrange for the destruction of Components within 6 months after purchase in quantities and on a schedule as contemplated by Section 5.2(a), within 30 days of receipt of written notice from Patheon identifying the obsolete Components or of finished Product within one month of batch release of finished Product to Client pursuant to a Firm Order, Patheon will notify Client, and Client will pay Patheon $300 per pallet, per month thereafter for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at $600 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 three months following batch release of the Finished Product to Client or Client’s agent pursuant to a Firm Order to the Client at Client's expense on 14 days' prior written notice to the Client.

(e) Cancellation or Postponement. Patheon will determine, in accordance with Client's Rolling Forecast, the manufacturing schedule of all Product covered by Firm Orders. If Client cancels or reduces a Firm Order, or wishes to postpone the applicable Delivery Date (subject to Section 5.1(d)), Client will remain liable to pay Patheon 100% of the Price for the Firm Order.

5.3. Batch Order Quantities.

Client may only order Manufacturing Services for batches of Products in multiples of the Batch Order Quantities as set out in Schedule B to a Product Agreement, unless otherwise agreed by the parties.

5.4. Delivery.

Shipments of Products will be made EXW (Incoterms 2020) Patheon's Manufacturing Site or other shipping point as the parties may agree in writing and specify in the relevant Product Agreement. Risk of loss or of damage to Products will remain with Patheon until the Products are loaded 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, (a) arrange for shipping, to be paid by Client and at Client's risk, and (b) at Client's expense, obtain any export license or other official authorization necessary to export the Products. Client will arrange for insurance and will select the freight carrier to be used by Patheon to ship Products and Client may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications. Patheon will cooperate and help Client or Client's designee for purposes of obtaining any license or approval required for the import of Products into a country in the Territory.

5.5. Invoices and Payment.

(a) Invoices will be sent by email to **[****]**

(b) ╪. Invoices will be sent and dated when the Product is manufactured and released by Patheon to Client. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment. Patheon will also give Client an invoice covering storage of any Product under Section 5.2(d) 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 to the local address set forth in the Product Agreement, and the total amount to be paid by Client. Client will pay the Manufacturing Site all undisputed invoices within 30 days of the date thereof. Interest on undisputed past due accounts will accrue at 1% per month, which is equal to an annual rate of 12%. Patheon agrees that, so long as Client remits payment in accordance with the "Payment Details" stated in each invoice issued pursuant to a Product Agreement, such payment will constitute payment under this Agreement.

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1. Product Claims.

(a) Product Claims. Client has the right to reject any portion of any shipment of Products that deviates from the Specifications, cGMPs, Applicable Laws or other warranties or requirements set forth herein without invalidating any remainder of the shipment. Client will inspect the Products manufactured by Patheon upon receipt and will give Patheon written notice (a "**Deficiency Notice**") of all claims for Products that deviate from the Specifications, cGMPs, Applicable Laws or other warranties or requirements set forth herein within 45 days after Client's receipt of the Product and full batch records therefor (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within 45 days after discovery by Client, but not after the expiration date of the Product). If Client fails to give Patheon the Deficiency Notice within the applicable 45-day period, then the delivery will be considered to have been accepted by Client on the 45th day after delivery or discovery, as applicable. Patheon will not be liable under Section 6.3(a) for any deviations for which it has not received notice within the applicable 45-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. Should Patheon fail to object to the Deficiency Notice on a timely basis, Patheon will be considered to have accepted and agreed with the Deficiency Notice. If Client and Patheon fail to agree within ten days after any Patheon notice to Client objecting to a Deficiency Notice as to whether any Products identified in the Deficiency Notice deviate from the Specifications, cGMPs, Applicable Laws or other warranties or requirements set forth herein, then, on the tenth (10^{th}) day after receipt of the Deficiency Notice, the parties will mutually select an independent laboratory that is properly qualified to make the relevant determination to determine whether the Products deviate from the Specifications, cGMPs, Applicable Laws or other warranties or requirements set forth herein. The determination of the independent laboratory will be binding on the parties. If the independent laboratory determines that any Products deviate from the Specifications, cGMPs, Applicable Laws, or other warranties or requirements set forth herein, 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 finds that none of the Products deviates from the Specifications, cGMPs, Applicable Laws or other warranties or requirements set forth herein, then (i) Client will be considered to have accepted delivery of the Products on or before the 45th day after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on or before the 45th day after discovery thereof by Client), (ii) the invoice for the Product will be considered to be dated as of the date when the finding is made, and (iii) Client will be responsible for the cost of the evaluation.

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

6.2. Product Recalls and Returns.

(a) Records and Notice. Patheon and Client will each maintain records necessary to permit a Recall of any Products delivered to Client or to 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 to recover title to or possession of quantities of the Products sold or shipped to third parties (including the voluntary withdrawal of Products from the market); or (ii) by any Authorities to detain or destroy any of the Products. Recall will also include any action by either party to refrain from selling or shipping quantities of the Products to third parties which would have been subject to a Recall if sold or shipped.

(b) Recalls. If (i) any 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. If Client rejects Products under Section 6.1 and the deviation is determined to have arisen from Patheon's failure to provide the Manufacturing Services or Products in accordance with the Specifications, cGMPs, Applicable Laws, or other warranties or requirements set forth herein, Patheon will credit Client's account for Patheon's invoice Price for the defective Products and for any reasonable costs that Client may have incurred to store and ship the defective Product. If Client previously paid for the defective Products, Patheon will promptly, at Client's election: (i) refund the invoice Price for the defective Products; (ii) offset the amount paid against other amounts due to Patheon hereunder; or (iii) replace the Products with conforming Products without Client being liable for payment therefor, contingent upon Patheon's receipt from Client, of all Active Materials required for the manufacture of the replacement Products. Patheon's responsibility for any loss of Active Materials in defective Product will be captured and calculated in the Active Materials Yield under Section 2.2.

(b) Recalled Product. If a Recall, return or other corrective action for the Products results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, Applicable Laws, or other warranties or requirements set forth herein, Patheon will (i) be responsible for all documented out-of-pocket expenses (including attorneys' fees and amounts paid to Authorities) of Client and customers of Client of the Recall, return or other corrective action, and (ii) promptly, at Client's election: (A) refund the invoice Price for the Products that are subject to the Recall, return or other corrective action and the reasonable costs that Client incurred to insure, store and ship the Products; (B) offset the amount paid for the Products that are subject to the Recall, return or other corrective action against other amounts due to Patheon hereunder; or (C) replace the Products that are subject to the Recall, return or other corrective action with conforming Products without Client being liable for payment therefor, contingent upon Patheon's receipt from Client, at Patheon’s expense, of all Active Materials required for the manufacture of the replacement Products. Patheon's responsibility for any loss of Active Materials in Products that are subject to a Recall, return or other corrective action will be captured and calculated in the Active Materials Yield under Section 2.2. In all circumstances other than those addressed in this Section 6.3(b), Recalls, returns, or other corrective actions will be made at Client's cost and expense.

(c) Product Claims. 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 Patheon (collectively, "**Product Claims**") to the extent the Product Claim (i) is caused by deficiencies in the Specifications or Client's marketing or distribution of the Products, (ii) results from a defect in the Active Materials or Components supplied by Client that (x) is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, and (y) has not resulted from Patheon's storage or handling of the Active Materials or Components, (iii) is caused by actions of third parties occurring after the Product is shipped by Patheon in accordance with Section 5.4, (iv) is due to packaging design or labelling defects or omissions for which Patheon has no responsibility, (v) is determined, by agreement of the parties, after a full quality investigation by the parties in accordance with cGMP requirements, Applicable Laws, and the applicable Quality Agreement, to be due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Specifications, the batch production record, Patheon's standard operating procedures for manufacturing, cGMPs, Applicable Laws, and the other terms and conditions of this Agreement, or (vi) is due to any breach by Client of its manufacturing obligations, under this Agreement.

(d) Notice by Patheon. Patheon immediately will notify Client if at any time Patheon discovers that any Product delivered hereunder does not conform to the Specifications, cGMPs, Applicable Laws, or other warranties or requirements set forth herein.

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. Any storage of this Product (including at Client's facilities) will be at Patheon's cost and expense. Alternatively, Patheon may instruct Client to return any damaged, defective, returned or Recalled Products to Patheon. Patheon will bear the cost of storage, return and disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 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, healthcare providers, and patients. Questions or complaints received by Patheon from Client's customers, healthcare providers or patients will be promptly referred to Client in accordance with the terms of the applicable Quality Agreement. Patheon will co-operate as reasonably requested to allow Client to determine the cause of, and resolve, any questions and complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will promptly give Client all agreed upon information to enable Client to respond properly and timely to questions or complaints about the Products as set forth in the applicable Quality Agreement. Unless it is determined that the cause of the complaint resulted from a failure by Patheon to provide the Manufacturing Services and Products in accordance with the Specifications, cGMPs, Applicable Laws or other warranties or requirements set forth herein, all costs incurred under this Section 6.5 will be borne by Client.

6.6. Remedies.

Client's exercise of its rights and remedies under this Article 6 will not limit its exercise of other rights or remedies to which Client is entitled by the terms of this Agreement.

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. Commencing on the Effective Date, the relationship managers will make commercially reasonable efforts to meet on a quarterly basis to review the current status of the business relationship and manage any issues that have arisen.

7.2. Authorities.

Subject to Section 7.8, each party may communicate with any Authority with regard to the activities described in this Agreement, including Regulatory Authorities responsible for granting regulatory approval for the Products, if, in the opinion of that party's regulatory counsel, the communication is necessary to allow that party to comply with the terms of this Agreement or the requirements of any Applicable Laws. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a party will (a) notify the other party of its intention to make these communications prior to making them to any Authority, (b) permit the other party to accompany and take part in any relevant communications with the Authority, (c) provide the other party with the contents of the proposed communication on a schedule designed to afford the receiving party an opportunity to review and comment thereon, and (d) provide the other party with copies of all communications with the Authority.

7.3. Records and Accounting by Patheon.

(a) Patheon will generate, retain, and maintain:

(i) all records necessary to comply with cGMPs and all other Applicable Laws relating to the manufacture of the Products or any component or intermediate thereof. Without limiting the foregoing, records will be made concurrently with the performance of each step in the manufacture of Products and in a way so that at any time successive steps in the manufacture and distribution of any batch may be traced by an inspector. These records will be legible and indelible, will identify the person immediately responsible, will include dates of the various steps and be as detailed as necessary for a clear understanding of each step by an individual experienced in the manufacture of pharmaceutical products;

(ii) all manufacturing records, standard operating procedures, equipment log books, batch manufacturing records, laboratory notebooks and all raw data relating to the manufacturing of Products and any Component or intermediate thereof;

(iii) samples of each batch of Product and of Active Materials and Components. Samples will include a quantity of representative material of each batch, Active Materials and Components sufficient to perform at least full duplicate quality control testing and will specify the dates of manufacture and packaging thereof. These retained samples will be selected at random from either final container material or from bulk and final containers and must include at least one final container as a final package, or package-equivalent of the filling of each batch. Each sample will be stored at temperatures and under conditions which will maintain the identity and integrity of the relevant sample; and

(iv) any other records and samples that Client reasonably may require to ensure compliance by Patheon with the terms of this Agreement and Applicable Laws.

(b) Patheon will diligently complete the master batch record for each Product during the manufacture of the Product.

(c) Copies of the records and samples will be retained for one year following the date of Product expiry, or longer if required by Applicable Laws, at which time Client will be contacted concerning the delivery to Client or the destruction of the documents or samples of Products. Patheon will not destroy any samples or records without Client's prior written consent. Without limiting the preceding sentence, following the expiration of Patheon's obligation to retain samples, Client will be responsible for retaining samples of the Products necessary to comply with the legal/regulatory requirements applicable to Client.

7.4. Inspection.

Client may inspect Patheon's reports and records relating to this Agreement and Product Agreements, and may request copies of the reports and records (with the exception of standard operating procedures), at Client's expense, during normal business hours and with reasonable advance notice, but a Patheon representative must be present during the inspection. Standard operating procedures (as referenced in 7.3(a)(ii) may be viewed by Client during on-site visits at the relevant Manufacturing Site. On an exception-only basis, Patheon may agree to allow for standard operating procedures to be viewed by Client as long as Client agrees to refrain from recording or taking any screen snapshot of th video audit/visit and to notify Patheon promptly if any video or photograph has been taken and is used or disclosed in violation of the terms of this Agreement. Violation of this provision will be considered a material breach.

7.5. Access.

Patheon will give Client reasonable access at agreed times to the areas of the applicable Manufacturing Site in which all phases of the Manufacturing Services are performed to permit Client to observe manufacturing of the Product and to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, Applicable Laws and other warranties and requirements set forth herein. With the exception of "for-cause" audits, Client will be limited each Year to one cGMP-type audit and one inventory observation audit, each lasting no more than two days and involving no more than two auditors, which auditors may be Client's employees or designated agents. At Client's request, Patheon will grant additional cGMP-type audits, additional inventory observation 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. The right of access set forth in this Section 7.5 will not include a right to access or inspect Patheon's financial records.

7.6. Notification of Regulatory Inspections.

(a) Patheon will notify Client by telephone within 24 hours, and in writing within two Business Days, after learning of any proposed visit to, or inspection of, a Manufacturing Site by any Regulatory Authority, and immediately by telephone after learning of any unannounced visit to, or inspection of, a Manufacturing Site by any Regulatory Authority if the visit or inspection primarily relates to the Manufacturing Site's compliance with cGMPs or the manufacture of the Product.

(b) In the case of any visit or inspection that relates to the Manufacturing Site's compliance with cGMPs in respect of the manufacture of the Product or directly to the manufacture of the Product, Patheon will permit Client or its agents to be present at the Manufacturing Site during the visit or inspection.

(c) Patheon will provide to Client a copy of (i) any report and other written communication (or the relevant portions thereof) received from a Regulatory Authority in connection with a visit to or inspection of the Manufacturing Site that relates to compliance with cGMPs in respect of the manufacture of the Product or directly to the manufacture of the Product; (ii) any warning letters or similar communications from a Regulatory Authority in respect of the Manufacturing Site; and (iii) any written communications received from a Regulatory Authority relating to the Manufacturing Site's compliance with cGMPs in respect of the manufacture of the Product or directly to the manufacture of the Product or any component or intermediate thereof or any equipment or manufacturing process used in connection with the manufacture of Product or any component or intermediate thereof, in each case within three Business Days after receipt thereof. Patheon will consult with Client concerning the response of Patheon to each communication. Patheon will provide Client with a copy of all draft responses for comment as soon as possible and all final responses for review and approval, at least five Business Days prior to submission thereof.

7.7. Reports.

Patheon will, at its cost, supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA. At Client's request, Patheon will promptly (in no event later than March 31 each Year) provide a copy of the Annual Product Review Report to Client at no additional cost. Patheon will also promptly provide any additional reports that Client may reasonably request, but any additional reports requested by Client beyond the scope of cGMPs and customary FDA requirements will be subject to an additional fee to be agreed upon between Patheon and Client.

7.8. Regulatory Filings.

Except as otherwise contemplated by Sections 9.3 and 9.5(b), Client will have the sole responsibility and authority for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt or maintenance of Regulatory Authority approval for the commercial manufacture of the Products. Client will be responsible for ensuring the accuracy of the documents provided to the Regulatory Authorities by Client for the Products, and will ensure through use of the change control process that Patheon is provided with the currently filed, active Specifications for Products and the information needed to enable Patheon to comply with the applicable requirements of the Product marketing authorizations. Patheon will assist Client to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible. Without limiting the foregoing, Patheon will cooperate with any reasonable requests for assistance from Client with respect to obtaining and maintaining any and all regulatory approvals required in connection with the sourcing of Product by Client hereunder and the sale of Product in the Territory, including by:

(a) at Client's cost, making its employees, consultants and other staff available upon reasonable notice during normal business hours to attend meetings with Regulatory Authorities concerning Product or any component or intermediate thereof; and

(b) at Patheon's cost, disclosing and making available to Client, in whatever form Client may reasonably request, all manufacturing and quality control data, CMC data and other information related to Product or any component or intermediate thereof and the manufacturing process therefor as is reasonably necessary or desirable to prepare, file, obtain and maintain any regulatory approval required in connection with the sourcing of Product by Client hereunder and the sale of Product in the Territory.

ARTICLE 8

TERM AND TERMINATION

8.1. Initial Agreement Term.

This Agreement will become effective as of the Effective Date and will continue until January 31, 2027 (the "**Initial Agreement Term**"). Unless sooner terminated as set forth below, this Agreement will automatically renew after the Initial Agreement 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 (a) 18 months prior to the end of the then current term (the Initial Agreement Term, together with any renewal periods, the "**Agreement Term"**). In any event, this Agreement will continue to govern any Product Agreement in effect as provided in Section 1.2. Each Product Agreement will have an initial term of five Years from the effective date of the Product Agreement unless the parties agree to a different initial term in the applicable Product Agreement (each, an "**Initial Product Term**"). Unless otherwise agreed in the applicable Product Agreement, Product Agreements will automatically renew after the Initial Product Term for successive terms of two Years each unless either party gives written notice to the other party of its intention to terminate the Product Agreement at least 18 months prior to the end of the then current term (the Initial Product Term, together with any renewal periods, the "**Product Term**"). Notwithstanding the foregoing, this Agreement and any Product Agreement may be terminated in accordance with the provisions of Section 8.2.

8.2. Termination for Cause.

(a) Either party at its sole option may terminate this Agreement or a Product 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 or the Product Agreement within 60 days following receipt of a written notice (the "**Remediation Period**") of the breach from the aggrieved party that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved party's right to terminate this Agreement or a Product Agreement under this Section 8.2(a) may only be exercised for 60 days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be considered to have waived the breach of the representation, warranty, or obligation in the instance described in the Breach Notice.

(b) Either party may terminate this Agreement immediately upon notice to the other party if the other party (i) files in any court or agency under any statute or regulation of any state, country or jurisdiction a petition in bankruptcy or insolvency or for reorganization or for arrangement or for the appointment of a receiver or trustee of that party or its assets; (ii) is served with an involuntary petition against it, filed in any insolvency proceeding, and this petition is not dismissed within 60 days after the filing thereof; (iii) becomes a party to any dissolution or liquidation; (iv) makes an assignment for the benefit of its creditors; or (v) admits in writing its inability generally to pay its debts as they become due in the general course.

(c) Client may terminate a Product Agreement immediately if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product or Client withdraws the relevant Product from the market, but Client will still be required to fulfill all of its obligations under Section 8.4 below.

(d) Patheon may terminate this Agreement or a Product Agreement upon six months' prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement or a Product Agreement to an assignee that, in the opinion of Patheon acting reasonably, is: (i) not a creditworthy substitute for Client; or (ii) a Patheon Competitor.

8.3. Product Discontinuation.

Except if a Product is withdrawn for the reasons specified in Section 8.2(c), 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.

8.4. Obligations on Termination.

If this Agreement is terminated for any reason, then:

(a) Client will take delivery of and pay for all undelivered Products that have been manufactured 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 documented cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), the Inventory that was purchased, produced or maintained by Patheon for use in then-current Firm Orders and prior to the notice of termination being given;

(c) Client acknowledges that Patheon will not be required to permit a Patheon Competitor to access the Manufacturing Site; and

(d) Client will make commercially reasonable efforts, at its own expense, to remove from the Manufacturing Site, within 30 days after termination or within such longer time as the parties may agree, all unused Active Material, all applicable Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Product Agreement and located at a Manufacturing Site or that is otherwise under Patheon's care and control ("**Client Property**"). If Client fails to remove the Client Property within 30 days or within such longer time as the parties may agree following written notice from Patheon describing the nature and location of all Client Property to be removed by Client due to the completion, termination or expiration of a Product Agreement, Client will pay Patheon $300.00 per pallet, per month, one pallet minimum (except that Client will pay $600 per pallet, per month, one pallet minimum, for any of the Client Property that contains controlled substances, requires refrigeration or other special storage requirements) thereafter for storing the Client Property and will assume any reasonable third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.5 of this Agreement.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1. Authority.

Each party hereby represents and warrants to the other party as follows:

(a) The party (i) is duly formed and in good standing under the laws of the jurisdiction of its formation, (ii) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (iii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered by the party and constitutes a legal, valid and binding obligation of the party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered in a proceeding at law or equity.

(b) All necessary consents, approvals and authorizations of all Authorities and other persons required to be obtained by the party in connection with (i) the execution and delivery of this Agreement have been obtained and (ii) the performance of its obligations hereunder have been obtained or will be obtained prior to the time that these consents, approvals and authorizations are required.

(c) The execution and delivery of this Agreement and the performance of the party's obligations hereunder (i) do not and will not conflict with or violate any requirement of Applicable Laws or any provision of the articles of incorporation, bylaws or any other constitutive document of the party and (ii) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which the party is bound.

9.2. Client Representations, Warranties, and Covenants.

Client covenants, represents, and warrants that:

(a) Non-Infringement.

(i) the Specifications for each of the Products do not infringe any Third Party Rights and Client may lawfully disclose the Specifications to Patheon;

(ii) any Client Intellectual Property used by Patheon in performing the Manufacturing Services according to the Specifications may be lawfully used as directed by Client without infringing any Third Party Rights; and

(iii) to Client's knowledge, there are no pending legal proceedings claiming that any of the Specifications, or any of the Active Materials and the Components, or the sale, use, or other disposition of any Product made in accordance with the Specifications infringes any Third Party Rights.

(b) Quality and Compliance.

(i) the Specifications for a Product will be consistent with the specifications set forth in the Product's applicable marketing authorization;

(ii) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws, may be lawfully sold and distributed in every jurisdiction in which Client will sell and distribute the Products; and

(iii) on the date of shipment by or on behalf of Client to Patheon, the Active Materials will conform to the Specifications for the Active Materials that Client has given to Patheon and the Active Materials will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

9.3. Patheon Representations, Warranties, and Covenants.

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services and provide Products to Client in accordance with the Specifications, cGMPs, Applicable Laws and any other warranties or other requirements herein;

(b) At the time of delivery of Product by Patheon:

(i) the Manufacturing Site at which the Product was manufactured, at the time of manufacture, was in compliance with all cGMPs and other Applicable Laws (including applicable inspection requirements of the FDA);

(ii) the Product will have been manufactured in strict compliance with the requirements of cGMPs, this Agreement, the Quality Agreement, the Specifications and all Applicable Laws;

(iii) the Product will be in conformity with the Specifications;

(iv) the Product will have a remaining shelf life of at least 80% of the Product's approved shelf life from the date of manufacture;

(v) title to the Product will pass to Client free and clear of any security interest, lien or other encumbrance;

(vi) the Product will not be adulterated or misbranded under the FFDCA; and

(vii) no act or omission of Patheon would cause or result in the Product being a product that cannot be introduced into interstate commerce under the FFDCA.

(c) any Intellectual Property used by Patheon to perform the Manufacturing Services (other than Intellectual Property provided by Client) may be lawfully used by Patheon without infringing any Third Party Rights.

9.4. Debarred Persons.

Patheon hereby represents, warrants, and covenants to Client that (a) neither Patheon nor any of its Affiliates has been debarred or is subject to debarment under Section 306 of the FFDCA or any similar law in any country in the Territory or listed on either Excluded List, and (b) neither Patheon nor any of its Affiliates will use in any capacity, including as officer, director, managing employee, or any other way, in connection with the services to be performed under this Agreement, any person who has been debarred under Section 306 of the FFDCA or any similar law in any country in the Territory, or who is the subject of a conviction described in that section or listed on either Excluded List. Patheon will inform Client in writing immediately if it or any person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 of the FFDCA or any similar law in any country in the Territory or listed on either Excluded List, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of Patheon's knowledge, is threatened, relating to the debarment or conviction Section 306 of the FFDCA or any similar law in any country in the Territory, or listing on either Excluded List, of Patheon or any person performing services hereunder.

9.5. Permits.

(a) Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the marketing and sale of the Products, including all marketing and post-marketing approvals.

(b) Patheon represents, warrants and covenants to Client that it has obtained, or will obtain prior to the time that Governmental Approval is required, and will maintain in full force and effect and in good standing, any and all Governmental Approvals required by Applicable Laws to be held by Patheon in order to provide the Manufacturing Services for the Products at its Manufacturing Sites and to perform all of its other obligations hereunder in accordance with the terms of this Agreement and the Product Agreements.

9.6. No Warranty.

EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1. Consequential Damages.

Except for breaches of Article 11 and ***Appendix 2,*** neither party will be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for any loss of profits, of production, of anticipated savings, of business, or goodwill or 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. This disclaimer does not extend to damages owed to third parties under Sections 10.3 or 10.4.

10.2. Limitation of Liability.

(a) Active Materials. Except for loss and damage for which provision is made in Section 2.2, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials. Patheon's maximum responsibility for loss or damage to the Active Materials with respect to a Product in a Year will not exceed the Maximum Credit Value set forth in Schedule D of the applicable Product Agreement.

(b) Maximum Liability. Patheon's maximum aggregate liability to Client under this Agreement or any Product Agreement in any Year for any reason whatsoever, including any liability arising from any and all breaches of its representations, warranties, or any other obligations under this Agreement or any Product Agreement, will not exceed, on a per Product basis, (**the "Maximum Amount**") specified in the applicable Product Agreement. Notwithstanding the foregoing, the parties agree that the limitation on liability described in this Section 10.2(b) will not apply to, nor take into account, any Patheon liability arising under Section 10.3 or Article 11 or from Patheon's fraudulent misrepresentation, or Patheon's internal Component and conversion costs to manufacture replacement Product under Article 6.

10.3. Indemnification by Patheon.

Patheon will defend, hold harmless and indemnify Client, its Affiliates and its and their respective directors, officers, employees and agents (the "**Client Indemnitees**"), from all losses, damages, liabilities, penalties, costs and expenses (including reasonable attorneys' fees and disbursements) (collectively, "**Losses**") arising from or occurring as a result of (a) any third party claims, lawsuits, actions, proceedings, subpoenas, ("**Third Party Claims**") against a Client Indemnitee arising from or occurring as a result of (i) the breach by Patheon, of this Agreement; (ii) the negligence or willful misconduct of any Patheon Indemnitee or of any Manufacturing Site in connection with the performance of this Agreement or any Product Agreement; (iii) any claim that the use or practice of Patheon Intellectual Property in connection with the manufacture of any Product violates, breaches, or infringes any Third Party Rights, or (iv) the handling, release, or disposal of any waste by Patheon; (b) any personal injury or death suffered by any Patheon Indemnitee in connection with the manufacturing of Products hereunder or the performance of Patheon's other obligations hereunder; or (c) the enforcement by a Client Indemnitee of its rights under this Section 10.3; except in each case for those Losses for which Client has an obligation to indemnify the Patheon Indemnitees under Section 10.4, as to which Losses each party will indemnify the other party to the extent of its respective liability for the Losses.

10.4. Indemnification by Client.

Client will defend, hold harmless and indemnify Patheon, its Affiliates and its and their respective directors, officers, employees and agents (collectively, the "**Patheon Indemnitees** from all Losses arising from or occurring as a result of (a) any Third Party Claims against a Patheon Indemnitee due to (i) the breach by Client of this Agreement; (ii) the negligence or willful misconduct of any Client Indemnitee in connection with the performance of this Agreement; or (iii) any claim that the use of Active Materials or the use or practice of Client Intellectual Property in connection with the manufacture of any Product in accordance with the terms of this Agreement violates, breaches, or infringes any Third Party Rights; and (b) the enforcement by a Patheon Indemnitee of its rights under this Section 10.4; except in each case for those Losses for which Patheon has an obligation to indemnify the Client Indemnitees under Section 10.3, as to which Losses each party will indemnify the other party to the extent of its respective liability for the Losses.

10.5. Indemnification Procedure.

(a) Notice. The indemnified party (the "**Indemnified Party**") will promptly provide the indemnifying party (the "**Indemnifying Party**") notice ("**Indemnification Claim Notice**") of any Loss or discovery of fact upon which the Indemnified Party intends to base a request for indemnification under Section 10.3 or 10.4, but any delay in providing the notice will qualify the obligations of the Indemnifying Party under Section 10.3 or 10.4, as relevant, only to the extent of actual prejudice to the ability of the Indemnifying Party to defend the claim. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of the Loss (to the extent that the nature and amount of the Loss are known at that time).

(b) Third Party Claims. The obligations of an Indemnifying Party under this Article 10 with respect to Third Party Claims will be governed by and be contingent upon the following:

(i) Defense. At its option, the Indemnifying Party may assume the defense of any Third Party Claim by giving notice to the Indemnified Party within 30 days after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the Indemnifying Party will constitute an acknowledgment that the Indemnifying Party is liable to indemnify hereunder the Indemnified Party for the Third Party Claim. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party which will be reasonably acceptable to the Indemnified Party. If the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party will immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Subject to Section 10.5(b)(ii), if the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim.

(ii) Right to Participate in Defense. Without limiting Section 10.5(b)(i), any Indemnified Party will be entitled to participate in, but not control, the defense of the Third Party Claim and to employ counsel of its choice for this purpose, but this employment will be at the Indemnified Party's own expense unless:

(A) the employment thereof, and the assumption by the Indemnifying Party of the expense, has been specifically authorized by the Indemnifying Party in writing;

(B) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 10.5(b)(i) (in which case the Indemnified Party will control the defense); or

(C) the interests of the Indemnified Party and the Indemnifying Party with respect to the Third Party Claim are sufficiently adverse to make inappropriate or impermissible the representation by the same counsel of both parties under Applicable Laws, ethical rules or equitable principles.

(iii) Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not constitute an admission of liability by the Indemnified Party, result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of the Loss, on the terms that the Indemnifying Party, in its sole discretion, considers appropriate. For all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 10.5(b)(i), the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of the Loss if it obtains the prior written consent of the Indemnified Party (which consent will not be unreasonably withheld, conditioned, or delayed). The Indemnifying Party will not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend any Third Party Claim, no Indemnified Party will admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim for which it intends to seek indemnification under Section 10.3 or 10.4, as applicable, without the prior written consent of the Indemnifying Party (which consent will not be unreasonably withheld, conditioned or delayed).

(iv) Cooperation. If the Indemnifying Party chooses to defend any Third Party Claim, the Indemnified Party will cooperate in the defense thereof and will furnish records, information and testimony, provide witnesses and attend conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. This cooperation will include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to the Third Party Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. The Indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection with the foregoing.

(v) Expenses. Except as set forth above, the reasonable and verifiable out-of-pocket costs and expenses, including documented fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim will be reimbursed on a monthly basis in arrears by the Indemnifying Party.

10.6. Reasonable Allocation of Risk.

The parties acknowledge and agree that this Agreement (including this Article 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Products.

ARTICLE 11

CONFIDENTIALITY

11.1. Confidentiality. By executing this Agreement, the parties are hereby expressly agreeing to abide by, and comply with the Confidentiality Terms set forth in ***Appendix 2*** attached hereto and incorporated into this Agreement by this reference.

11.2. Notification. The Receiving Party will notify the Disclosing Party immediately, and cooperate with the Disclosing Party as the Disclosing Party may reasonably request, upon the Receiving Party's discovery of any loss or compromise of the Disclosing Party's Confidential Information.

ARTICLE 12

DISPUTE RESOLUTION

12.1. Dispute Resolution. Any dispute, controversy or claim arising out of or relating to this Agreement or the breach, termination, or validity thereof (each, a "**Dispute**"), will be referred to a senior executive of each party. The senior executives will meet to attempt to resolve the Dispute by good faith negotiations within 30 days of referral of the Dispute. If the Dispute remains unresolved after this 30-day negotiation period, then, at the election of either party, the Dispute will be decided in accordance with Section 13.20.

ARTICLE 13

MISCELLANEOUS

13.1. Intellectual Property Ownership and Licenses

(a) License Grants to Patheon.

(i) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license, solely for purposes of Patheon's performing the Manufacturing Services, of Client Intellectual Property, and all other Intellectual Property as to which Client may grant a license, that Patheon must use in order to perform the Manufacturing Services.

(ii) Client hereby grants to Patheon a perpetual, non-exclusive, paid-up, royalty-free, transferable license, solely to enable Patheon to manufacture or develop products for any of its third-party clients, of any Intellectual Property included in the Product IP that has general application to manufacturing processes, the formulation or development of drug products, drug product dosage forms or drug delivery systems and is not specific to any Product or Active Materials.

(b) License Grant to Client. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable and sublicensable (with the right to grant sublicenses through multiple tiers) license to use the Patheon Intellectual Property and any Information used by Patheon to perform the Manufacturing Services to enable Client to manufacture, develop, commercialize, market and sell the Products.

(c) Ownership of Intellectual Property.

(i) Client Intellectual Property will be the exclusive property of Client. Patheon will, and will cause the Manufacturing Site at which the Product is being manufactured and its other relevant Affiliates to, promptly disclose in writing to Client the discovery, development, making, conception, or reduction to practice of any Invention included in or giving rise to Client Intellectual Property and, promptly upon Client's request, execute all instruments and other documents that are required to vest ownership in Client.

(ii) Patheon Intellectual Property will be the exclusive property of Patheon.

(iii) Except as otherwise provided in Section 13.1(d)(iii) for Joint Invention Patents, each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications included in or claiming Intellectual Property as to which it is allocated ownership hereunder.

(d) Joint Intellectual Property

(i) The parties will jointly own all right, title, and interest in and to Joint Intellectual Property. Each party will, and will cause its Affiliates to, promptly disclose in writing to the other party the discovery, development, making, conception, or reduction to practice of any Invention included in or giving rise to Joint Intellectual Property.

(ii) Patheon will, and does hereby, grant to Client an irrevocable, perpetual, fully paid-up, royalty-free, non-exclusive license, transferable, sublicensable (with the right to grant sublicenses through multiple tiers), to use for any purpose all of Patheon's right, title and interest in and to all Joint Intellectual Property. Client will, and does hereby, grant to Patheon an irrevocable, perpetual, fully paid-up, royalty-free, non-exclusive license, with the right to grant sublicenses through multiple tiers, to use for any purpose all of Client's right, title and interest in and to all Joint Intellectual Property.

(iii) Client will have the first right, but not the obligation, to prepare, file, prosecute, and maintain any patent applications and patents included in or giving rise to Joint Intellectual Property (the "**Joint Invention Patents**") and, if Client elects to file, prosecute and maintain any patent application, then Client will be responsible for related interference, re-issuance, re-examination and opposition proceedings. But if Client plans to abandon any Joint Invention Patent, then Client will notify Patheon in writing at least 60 days in advance of the due date of any payment or other action that is required to prepare, file, prosecute or maintain the Joint Invention Patent, and Patheon may elect, upon written notice within the 60 day period to Client, to make the payment or take the action, at its own expense.

13.2. No Implied Rights.

Except as provided in Section 13.1, neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party except as specifically authorized herein or in writing by the other party.

13.3. Insurance.

(a) Subject to Section 13.3(b), each party will maintain commercial general 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 annually 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, or material change in, the insurance.

(b) If a party is unable to maintain the insurance policies required under this Agreement on commercially reasonable terms and at commercially reasonable cost 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 on commercially reasonable terms and at commercially reasonable cost.

13.4. Independent Contractors.

The parties are independent contractors and this Agreement and any Product 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 or any Product Agreement will not be considered a waiver of the provision or any other provision of this Agreement or any Product Agreement, except as expressly set forth in Sections 6.1 and 8.2(a).

13.6. Assignment.

(a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations without the written consent of Client. Patheon will not arrange for any subcontractor to perform testing or other services arising under any Product Agreement without obtaining Client's prior written consent for the use of the approved subcontractor, this consent not to be unreasonably withheld. Patheon may subcontract any part of the Manufacturing Services under a Product Agreement to any of its Affiliates but the subcontract must be in writing and signed by both Patheon and the Affiliate.

(b) Subject to Section 8.2(d), Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon. But Client will give Patheon written notice of any assignment within 30 Business Days after the effective date of the assignment, and any assignee will be required to agree in writing with Patheon to be bound by the terms of this Agreement or the applicable Product Agreement. If there is a partial assignment in which Client assigns one or more (but not all) Product Agreements and this Agreement solely as it relates to the assigned Product Agreement to a third party who is not an Affiliate of Client, then Patheon will have the right to request a re-negotiation of fees paid under the assigned agreements with the assignee and, if good faith discussions do not lead to agreement on amended fees applicable to the assigned agreement within a reasonable time, then on 12 months' prior written notice to Client and the assignee, Patheon will have the right to terminate the assigned Product Agreement.

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

(d) Any purported assignment in breach of the provisions of this Section 13.6 will be void and of no effect.

13.7. Force Majeure.

Neither party will be liable for the failure to perform its obligations under this Agreement or any Product Agreement if the failure is caused by an event beyond that party's reasonable control, including strikes or other labor 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 color 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 and steps to be taken by it to remedy the same. The suspension of performance will be of no greater scope and no longer duration than is reasonably required and the non-performing party will use commercially reasonable efforts to remedy its inability to perform as soon as possible. If the suspension of performance continues for 60 days after the date of the occurrence, and the failure to perform would constitute a material breach of this Agreement in the absence of the Force Majeure Event, the nonaffected party may terminate this Agreement immediately by written notice to the affected party. 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 or any Product Agreement.

13.8. Additional Product.

Additional Products may be added to, or existing Products deleted from, any Product Agreement by amendments to the Product Agreement, in accordance with Section 13.11 below, including Schedules A, B, C, and D as applicable.

13.9. Notices.

(a) Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement will be in writing, will refer specifically to this Agreement, and will be considered given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by nationally recognized overnight delivery service that maintains records of delivery, addressed to the parties at their respective addresses specified in Section 13.9(b) or to another address as the party to whom notice is to be given may have provided to the other party in accordance with this Section 13.9. This notice will be considered to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or on the second Business Day (at the place of delivery) after deposit with a nationally recognized overnight delivery service. Any notice delivered by facsimile will be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 13.9 is not intended to govern the day-to-day business communications necessary between the parties in performing their obligations under the terms of this Agreement.

(b) Address for Notice:

If to Client:

Napo Pharmaceuticals, Inc.
200 Pine Street, Suite 400
San Francisco, CA 94104
Attention: Chief Executive Officer
Email address: **[****]**

with a copy to:

Napo Pharmaceuticals, Inc.
200 Pine Street, Suite 400
San Francisco, CA 94104
Attention: General Counsel
Email address: **[****]**

If to Patheon:

Patheon Pharmaceuticals Inc
2110 East Galbraith Road
Cincinnati, OH 45237-1625
Attention: Director of Legal Services
Telecopier No.: **[****]**
Email address: **[****]**

With a copy to:

Patheon Inc.
4721 Emperor Boulevard
Research Triangle Park,
NC 27703
Attention: General Counsel
Telecopier No.: **[****]**
Email address:

13.10. Severability.

If any provision of this Agreement or any Product 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, because each provision is separate, severable, and distinct.

13.11. Entire Agreement; Amendment; Survival

(a) This Agreement, together with the applicable Product Agreement and Quality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof.

(b) Any modification, amendment, or supplement to this Agreement must be in writing, must specifically reference the Sections of this Agreement to be modified and must be signed by authorized representatives of both parties. Likewise, any modification, amendment, or supplement to a Product Agreement must be in writing, must specifically reference the Sections of the Product Agreement to be modified and must be signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, then the Product Agreement and then the Quality Agreement.

(c) Any termination of this Agreement or a Product Agreement will not affect any outstanding Manufacturing obligations or payments due that have arisen prior to the date of termination, nor will it prejudice any other remedies that the parties may have under this Agreement or a Product Agreement. The provisions of Articles 6, 7, 9, 10, 11, and 12 and Sections 1.3, 1.4, 2.1 (e), 2.2, 4.6, , 5.5, 8.4, 13.1 through 13.3, 13.9, 13.11, 13.13 and 13.17 through 13.20, will survive termination of this Agreement, as well as any other provisions that are by implication or otherwise intended to survive termination.

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 or any Product Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions.

13.13. No Third Party Benefit or Right.

Nothing in this Agreement or any Product 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 or any Product Agreement.

13.14. Execution in Counterparts.

This Agreement and any Product Agreement may be executed in two or more counterparts, by original or facsimile or electronically-transmitted signature, each of which, if the signature is identified, will be considered an original, but all of which together will constitute one and the same instrument.

13.15. Further Assurances.

Each party will duly execute and deliver, or cause to be duly executed and delivered, any further instruments and will do and cause to be done any further acts and things, including the executing or filing of assignments, agreements, documents and instruments as may be necessary or as the other party may reasonably request, in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto the other party its rights and remedies under this Agreement.

13.16. Export Control.

This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the parties from time to time. Each party agrees that it will not export, directly or indirectly, any technical or confidential information acquired from the other party under this Agreement or any products using the technical or confidential information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Laws.

13.17. Waiver.

Any term or condition of this Agreement may be waived at any time by the party that is entitled to the benefit thereof, but this waiver will not be effective unless set forth in a written instrument duly executed by or on behalf of the party waiving the term or condition. A waiver by either party of any term or condition of this Agreement, in any one or more instances, will not be a waiver of the same or any other term or condition of this Agreement on any future occasion.

13.18. 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.

13.19. Governing Law; Jurisdiction; Venue; Service.

(a) This Agreement and any Product Agreement will be construed and enforced in accordance with the laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

(b) Subject to Section 12.1, each party irrevocably and unconditionally consents to the exclusive jurisdiction of the Court in the State of Delaware and to the United States District Court for the District of Delaware located in Wilmington, Delaware (collectively, the "**Courts**") for any action, suit or proceeding (other than appeals therefrom) concerning any matter arising out of or relating to this Agreement, and agrees not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in those Courts.

(c) Each party hereto further hereby irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the Courts and hereby further irrevocably and unconditionally agrees not to raise any objection at any time to the laying or maintaining of the venue of the action, suit or proceeding in any of the Courts, irrevocably waives any claim that the action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, to the action, suit or other proceeding, that the Court does not have any jurisdiction over the party.

(d) Each party hereto further agrees that, to the maximum extent permitted by Applicable Laws, service of any process, summons, notice or document by United States registered mail to its address and contact person for notices provided for in Section 13.9 will be effective service of process for any action, suit or proceeding brought against it under this Agreement in any of the Courts.

13.20. No Exclusivity; English Language Controls

(a) Nothing in this Agreement, nor unless otherwise agreed in any Product Agreement, will be construed in any way to state or to imply that either party considers this Agreement to be an exclusive arrangement. Client reserves its right to order and purchase Products from other manufacturer-suppliers**;** and, nothing in this Agreement is to be interpreted or construed to prohibit Client from ordering and purchasing Products from any third party manufacturer-supplier.

(b) This Agreement is written and executed in the English language; and, all other communications between the parties in connection with this Agreement will also be in the English language. Any translation into any other language may be for the convenience of a Manufacturing Site, but the English language version will remain the official version hereof. If there is of any conflict in interpretation between the English version and any translation, the English version will control.

[Signature page to follow]

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

PATHEON PHARMACEUTICALS INC.

By: /s/ Peter Ercoli
Name: Peter Ercoli
Title: Vice President / General Manager

NAPO PHARMACEUTICALS, INC.

By: /s/ Lisa Conte
Name: Lisa Conte
Title: President & CEO

FORM OF PRODUCT AGREEMENT

(Includes Schedules A to D)

PRODUCT AGREEMENT

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated June _, 2022 between Patheon Pharmaceuticals Inc., and Napo Pharmaceuticals, Inc., (the "**Master Agreement**"), and is entered into **[insert effective date]** (the "**Product Effective Date**"), between **[**Patheon Pharmaceuticals Inc. **or applicable Patheon Affiliate]**, a corporation existing under the laws of **[**the State of Delaware **or applicable founding jurisdiction for Patheon Affiliate]**, having a principal place of business at **[**2110 East Galbraith Road, Cincinnati, OH 45237-1625 **or Patheon Affiliate address]** ("**Patheon**") and **[**Napo Pharmaceuticals, Inc. **or applicable Napo Affiliate]**, a corporation existing under the laws of the **[**State of Delaware **or applicable founding jurisdiction for Napo Affiliate]**, having a principal place of business at 200 Pine Street, Suite 400, San Francisco, CA 94104 **[or Napo Affiliate address]** ("**Client**").

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references a specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. **Product List and Specifications** (See Schedule A attached hereto)
2. **Batch Order Quantity, Annual Volume Tiers, and Price** (See Schedule B attached hereto)
3. **Annual Stability Testing and Validation Activities (if applicable)** (See Schedule C attached hereto)
4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)
5. **Yearly Forecasted Volume: (insert for sterile Products manufactured at a Manufacturing Site in Italy, if applicable)**
6. **Required Percentage:**
7. **Required Period:**
8. **Territory:** (insert the description of the Territory here)
9. **Manufacturing Site:** (insert address of the Patheon Manufacturing Site where the Manufacturing Services will be performed)
10. **Initial Product Term:** (if applicable under Section 8.1 of the Master Agreement)

11. **Maximum Amount of Liability:** (per Section 10.2 of the Master Agreement)

12. **Notices:** (if applicable under Section 13.9 of the Master Agreement)

13. **Modifications to the Master Agreement**: (if applicable under Section 1.2 of the Master Agreement)

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Product Effective Date set forth above.

PATHEON PHARMACEUTICALS INC. [or applicable Patheon Affiliate]

By: _____
Name: _____
Title: _____

NAPO PHARMACEUTICALS, INC. [or applicable Napo Affiliate]

By: _____
Name: _____
Title: _____

SCHEDULE A TO PRODUCT AGREEMENT

PRODUCT LIST AND SPECIFICATIONS

Product List

[insert product list]

Specifications

Prior to the start of commercial manufacturing of Product under this Product Agreement, Client will give Patheon the originally executed copies of the Specifications as approved by the applicable Regulatory Authority. If the Specifications received are subsequently amended, then Client will give Patheon the originally executed copies of the revised Specifications. Upon acceptance of the revised Specifications, Patheon will give Client a signed and dated receipt indicating Patheon's acceptance of the revised Specifications.

SCHEDULE B TO PRODUCT AGREEMENT

ANNUAL VOLUME TIERS AND PRICE

[Insert Price Table]

Manufacturing Assumptions:

Packaging Assumptions:

Testing Assumptions:

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

- Product manufactured and packaged under this Product Agreement
- Standard certificate of analysis ("COA")
- Standard certificate of compliance ("COC")
- cGMP required retention samples
- Copies of deviation reports
- Batch Production Records ("BPR")/Lot Packaging Records ("LPR") copies for validation batches, first ten (subject to increase by Client in its reasonable discretion based on any failure by Patheon to develop extended compliance history, to provide consistently compliant and high quality documentation, site audit failures, or other matters considered relevant by Client in its reasonable discretion) 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 TO PRODUCT AGREEMENT

ANNUAL STABILITY TESTING (if applicable)]

Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. This Product Agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing.

SCHEDULE D TO PRODUCT AGREEMENT

ACTIVE MATERIALS

Active Materials	Supplier
●	●

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
		Client's actual cost for Active Materials, not to exceed $_____per kilogram, as reasonably documented

MAXIMUM CREDIT VALUE

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

PRODUCT	MAXIMUM CREDIT VALUE
	[_]% of revenues per Year to Patheon under this Product Agreement, up to a maximum of $**[ ]** in the aggregate per Year.

[End of Product Agreement]

APPENDIX 2

NON-DISCLOSURE AND NON-USE TERMS AND CONDITIONS

This **Appendix 2** contains the Confidentiality Terms between Patheon and Client. For purposes of these Confidentiality Terms, the party receiving Confidential Information of the other party is the "**Receiving Party**" and the party disclosing its Confidential Information is the "**Disclosing Party**."

1. Confidential Information Defined. As used in this Appendix 2, and subject to the exclusions listed in Section 2 (Exclusions) below, the term "**Confidential Information**" means all information disclosed by, or on behalf of, the Disclosing Party (including by a third party) to the Receiving Party (captured on any media whatsoever or orally), that concerns the business and affairs of the Disclosing Party or any of its affiliates, including intellectual property and related applications, specifications, research, development, inventions, designs or drawings, data, algorithms, formulae, chemical entities, compounds, mixtures, prospective and current products, product plans, ideas, concepts, financial information, marketing, personnel, customers, suppliers, licensors, prospective licensors, licensees, prospective licensees, strategic partners, and other materials (tangible or intangible, machine or human readable), processes, techniques, know-how, analyses, plans, and procedures contained in or related to any of the foregoing, and any other nonpublic technical or business information of the Disclosing Party that a reasonably prudent business person would consider confidential, proprietary or of value to the Disclosing Party's business, and all summaries, extracts, memos, reports, analyses and other documents containing or based on the Confidential Information prepared by the Disclosing Party, Receiving Party or any other person, whether disclosed orally, by observation or disclosed or accessed in written, electronic or other form or media, and whether or not marked, designated or otherwise identified as "confidential". The Disclosing Party will not have any obligation to specifically identify any information as to which the protection of the Confidentiality Terms extend by any notice or other action.

2. Exclusions. Confidential Information does not include information that: (i) was already lawfully in the Receiving Party's possession at the time of disclosure by the Disclosing Party; (ii) is or becomes publicly available other than by the violation of these Confidentiality Terms or other fault of the Receiving Party or anyone affiliated with, or in privity of contract with, the Receiving Party; (iii) is received by the Receiving Party from a third party which, to the knowledge of the Receiving Party after its reasonable inquiry and investigation, is rightfully in possession of the information free of any obligation to maintain its confidentiality; or (iv) is independently developed by or on behalf of the Receiving Party without reference to, benefit of, or reliance on any Confidential Information of the Disclosing Party.

3. Nonuse and Nondisclosure. The Receiving Party will use the Confidential Information solely for discussions specific to the performance of performing Manufacturing Services for the Disclosing Party and not for any other purpose, including the benefit of the Receiving Party or the benefit of any third party. The Receiving Party will hold the Confidential Information in strict confidence, and will not, without the prior written consent of the Disclosing Party, copy, or provide or disclose to any third party, all or any portion thereof; thus, the Receiving Party will not convey the Disclosing Party's Confidential Information (unless specifically authorized in writing by the Disclosing Party), and will convey only information about the Disclosing Party that has been disclosed in the Disclosing Party's public filings. With respect to Confidential Information, the Receiving Party may make tangible copies of the Confidential Information but these copies will be subject to the provisions of Section 5 (Return of Documents) hereof (these copies will be considered within Receiving Party's control for purposes of these Confidentiality Terms, this Agreement and all Product Agreements). Without limiting the foregoing, the Receiving Party will protect Confidential Information from reproduction, use, propagation or disclosure other than as permitted herein including taking all steps that the Receiving Party takes to protect its own information that it considers confidential, proprietary, or trade secret. The Receiving Party must employ reasonable care to protect the Confidential Information. The Receiving Party may disclose Confidential Information to its employees, officers, directors, and advisors (collectively, "**Representatives**") with a *bona fide* need to know the Confidential Information, but only to the extent necessary for the Receiving Party to expeditiously further its progress on performance of Manufacturing Services; but before any such disclosure to the applicable Representative, the Representative must execute a written agreement with the Receiving Party containing use and disclosure restrictions at least as protective of the Confidential Information as those imposed on the Receiving Party herein, without any right of further disclosure. The Receiving Party will remain liable to the Disclosing Party for the conduct of all of its Representatives in violation of these Confidentiality Terms and financially responsible for any damage caused by the violation. If the Receiving Party becomes obliged to disclose the Confidential Information to any governmental authority, court, or other tribunal or applicable securities exchange or in response to a subpoena, the Receiving Party promptly will notify the Disclosing Party, to the extent reasonably practicable under the circumstances and not otherwise prohibited by applicable law, so that the Disclosing Party may seek an appropriate protective order or other remedy to resist or narrow the scope of the required disclosure. In the absence of a protective order or other remedy, the Receiving Party will limit the disclosure to the portion of the Confidential Information as is required by laws or the rules of any applicable securities exchange to be disclosed and take reasonable steps (at the Disclosing Party's cost) to have the entity requiring the disclosure to protect to the greatest extent possible the confidentiality of the information disclosed. This disclosure by the Receiving Party will not change, alter or diminish the confidential, proprietary, or trade secret status of the Confidential Information, or treatment as such by the Receiving Party, under these Confidentiality Terms. Notwithstanding the foregoing, Client may disclose Confidential Information to the extent that the disclosure is made to Regulatory Authorities as required for with any filing or application but reasonable measures must will be taken to assure confidential treatment of the Confidential information.

4. Equitable Relief. The Receiving Party agrees and acknowledges that (i) any breach or threatened breach of these Confidentiality Terms by the Receiving Party or any of its Representatives may irreparably harm the Disclosing Party and (ii) any remedy at law for the breach or threatened breach may be inadequate to fully and properly compensate and otherwise protect the Disclosing Party. Therefore, the parties agree that the Disclosing Party will be entitled to injunctive relief for the breach or threatened breach without posting any bond, unless such bond is required by statute and the applicable statute does not permit the bond to be waived, and without a showing of actual damages. Equitable relief will be in addition to, not in lieu of, other available remedies.

5. Return of Documents. Upon the Disclosing Party's written request, the Receiving Party will promptly: (i) return or, at the Disclosing Party's option, destroy or permanently delete from the Receiving Party's computer systems, all originals and copies, whether tangible, electronic, or on any other media whatsoever, of all documents, data, materials, and other information thereof in the Receiving Party's possession, custody, or control that constitute Confidential Information of the Disclosing Party; and (ii) provide a written statement executed by a duly authorized officer of the Receiving Party to the Disclosing Party certifying that all documents, data, materials, and other media containing this information have been so delivered, deleted or destroyed. For purposes of this Section 5, "documents, data, materials, and other media containing this information" includes all information fixed in any tangible medium of expression, in whatever form or format. The Receiving Party may keep Confidential Information of the Disclosing Party to the extent (i) required by law, rule or regulation provided no attempt is made to use the Confidential Information except for compliance purposes or (ii) it is held as a backup in electronic form in backup tapes, servers or other sources as a result of Receiving Party's normal back up procedures for electronic data, provided that no attempt is made to recover the Confidential Information from back-up tapes, servers or other sources (except for compliance purposes).

6. No Obligation. Each party hereto acknowledges and agrees that nothing herein is intended to, or will, obligate either party (i) to provide or disclose any Confidential Information to the other party, and these Confidentiality Terms will apply only to the Confidential Information that the party elects, in its sole discretion, to provide or disclose to the other party or (ii) to enter into any other agreement with the other party, for services or otherwise. These agreements may be entered into upon the terms and conditions as the parties may hereafter agree.

7. Disclaimer. ALL CONFIDENTIAL INFORMATION IS PROVIDED BY THE DISCLOSING PARTY "AS IS" AND WITHOUT WARRANTY OF ANY KIND, WHETHER EXPRESS, IMPLIED, OR OTHERWISE, INCLUDING ANY WARRANTIES REGARDING ITS ACCURACY, COMPLETENESS, PERFORMANCE, NON-INFRINGEMENT OF THIRD PARTY RIGHTS, OR ITS MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

8. No License. All Confidential Information of the Disclosing Party is and will remain the exclusive property of the Disclosing Party, and the Receiving Party acknowledges and agrees that nothing contained in these Confidentiality Terms grants, or will be construed as granting, any rights, whether oral or written or express or implied or by license or otherwise, to the Receiving Party or any other party in or to any Confidential Information, except as expressly specified in these Confidentiality Terms.

9. Term. The Receiving Party's obligations herein will survive for five Years after any expiration or termination of this Agreement. Further, Receiving Party's obligations hereunder will survive and continue in effect in perpetuity thereafter with respect to any Confidential Information that is a trade secret of the Disclosing Party under applicable law and any Confidential Information that has been retained by the Receiving Party under Section 5 of these Confidentiality Terms.

10. Material Non-Public Information. Confidential Information disclosed to Receiving Party may include material non-public information about the Disclosing Party or other third parties. Receiving Party, acknowledges and will ensure that its agents and Representatives who receive Confidential Information under this Agreement, are aware that securities laws prohibit any person or entity who has material non-public information about a company from purchasing, selling or otherwise trading in securities of that company or from communicating the information to any other person or entity under circumstances in which it is reasonably foreseeable that that person or entity is likely to purchase, sell or trade in those securities.

11. General. These Confidentiality Terms will be binding upon and will inure to the benefit of the parties and their respective successors and permitted assigns and may be amended only by a written instrument signed by both parties. No provision of these Confidentiality Terms may be waived except by a writing executed by the party against whom the waiver is to be effective. A party's failure to enforce any of these Confidentiality Terms will neither be construed as a waiver of the provision nor prevent the party from enforcing any of the other Confidentiality Terms. Neither party will assign any of its rights or delegate any of its duties or obligations herein without the prior written consent of the other party, except to an affiliated company or any acquirer of all or substantially all of a party's business or assets or of the business division or product line of the party to which the Confidential Information primarily relates.

END OF APPENDIX 2

EXHIBIT A

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

TO: NAPO PHARMACEUTICALS, INC.
FROM: PATHEON PHARMACEUTICALS INC. [or applicable Patheon entity]

RE: Active Materials quarterly inventory report under Section 2.2(a) of the Master Manufacturing Services Agreement dated June __, 2022 (the "**Master Agreement**")

Reporting quarter: _____

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

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

Quantity Received during quarter: _____ kg (C)

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

Quantity Converted during quarter: _____ 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 Master Agreement.

PATHEON PHARMACEUTICALS INC.
[or applicable Patheon entity]

DATE: _____

Per: _____
Name:
Title:

[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 any regulatory, stability, validation, or test batches manufactured during the quarter.

EXHIBIT B

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION

AND CALCULATION OF ACTUAL ANNUAL YIELD

TO: NAPO PHARMACEUTICALS, INC.
FROM: PATHEON PHARMACEUTICALS INC. [or applicable Patheon entity]

RE: Active Materials annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.2(a) of the Master Manufacturing Services Agreement dated June ___, 2022 (the "**Master 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[2] during Year: (A + C – B)	_____	kg	(D)
Quantity Converted during Year: (total Active Materials in Products produced and not rejected, recalled, or returned)	_____	kg	(E)
Active Materials Credit Value:	$ _____	/kg	(F)
Target Yield:	_____	%	(G)
Actual Annual Yield: ((E/D) * 100)	_____	%	(H)
Shortfall:	$ _____		(I)

[2] 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 any regulatory, stability, validation, or test batches manufactured during the Year.

(((G – 5) - H)/100) * F * D (if a negative number, insert zero)

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 Master Agreement.

DATE: _____

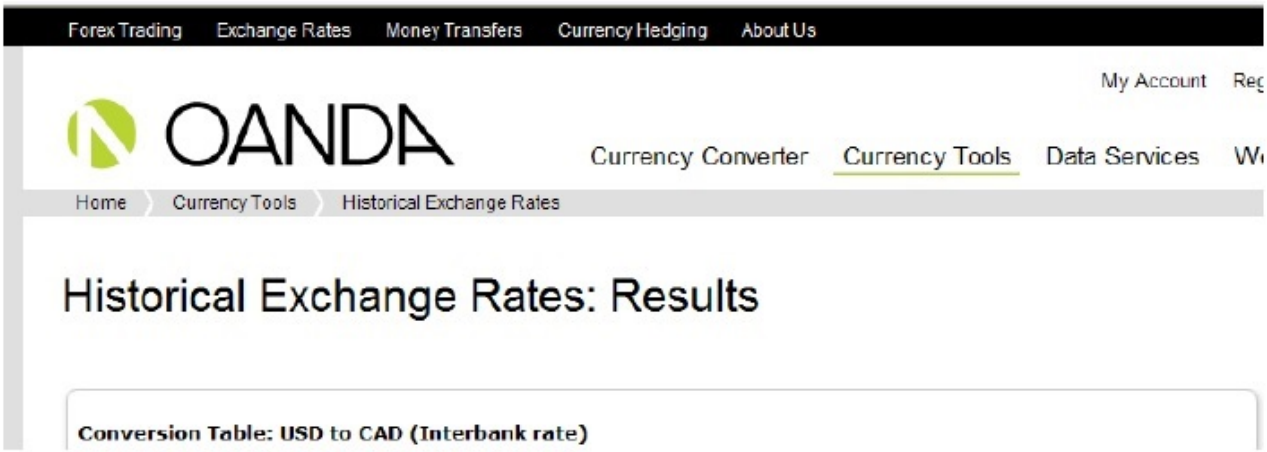
PATHEON PHARMACEUTICALS INC.
[or applicable Patheon entity]

Per: _____
Name:
Title:

EXHIBIT C

EXAMPLE OF PRICE ADJUSTMENT DUE TO CURRENCY FLUCTUATION

Section 4.2(e)



SAMPLE EXCHANGE CALCULATION

Initial Exchange Rate:	1.000	CAD/USD
Set Exchange Rate:	0.998	CAD/USD
Initial Price:	3.59	
Revised Price (FX):	3.70	(Material price and PPI adjustments)

Calculation:

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

= 3.70 X [1.000 / 0.998]

= 3.71