Exhibit 10.7  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
MANUFACTURING AND SUPPLY AGREEMENT  
This MANUFACTURING AND SUPPLY AGREEMENT (this “Agreement”) dated as of September 25, 2018 (the “Effective Date”) is made by and between Zosano Pharma Corporation, a corporation existing under the laws of the State of Delaware, having its principal place of business at 00000 Xxxxxxxxx Xxxxx, Xxxxxxx, Xxxxxxxxxx 00000 (“Client”), and Patheon Manufacturing Services LLC, a limited liability company existing under the laws of the State of Delaware, having a principal place of business at [\*\*\*] (“Patheon”). Client and Patheon are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”  
BACKGROUND  
Client has a commercial interest in the manufacture and commercialization of its proprietary product known as M207 (zolmitriptan microneedle system), a low-bioburden, combination product designed for docking on to an applicator, and application to a subject’s upper arm during a migraine attack.  
Patheon has expertise and experience in manufacturing and packaging pharmaceutical products and is interested in providing manufacturing services to Client for the Product (as defined in the Technology Transfer Agreement, defined beow).  
In anticipation of this Agreement and the services that Patheon will supply hereunder, the Parties are executing a Technology Transfer Agreement under which Patheon will perform certain technology transfer and construction services in order to validate Client’s technology and process for manufacturing M207, and prepare Patheon’s facilities for the manufacture of the Product.  
AGREEMENT  
NOW, THEREFORE, in consideration of the foregoing, the mutual promises and covenants of the Parties contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:  
ARTICLE I. DEFINITIONS  
The following terms will have the meanings set forth below. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular. Any term used but not defined hereunder will have the meaning ascribed to that term in the Technology Transfer Agreement.  
“Additional Services” means any services requested and approved by Client that supplement Patheon’s regular performance of the Manufacturing Services under this Agreement (including without limitation those set forth in Schedule B) or that supplement Patheon’s regular performance of the Transfer Services under the Technology Transfer Agreement, as applicable.  
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“Affiliate” means, for any Person, any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, that Person. For the purposes of this definition only, a Person will be regarded as in control of another Person if the Person owns, or directly or indirectly controls, 50% or more of the voting securities (or comparable equity interests) or other ownership interests of the other Person, or if the Person directly or indirectly possesses the power to direct or cause the direction of the management or policies of the other Person, whether through the ownership of voting securities, by contract, or any other means whatsoever.  
“Agreed Delivery Date” has the meaning set forth in Section 2.3(f).  
“Agreement” has the meaning set forth in the Preamble hereto.  
“API” means the active pharmaceutical ingredient Zolmitriptan USP (CAS Number: 139264-17-8).  
“Applicable Law” means applicable United States and foreign federal, state, and local laws, orders, rules, regulations, guidelines, standards, customs and ordinances, including, without limitation, those (to the extent they are applicable) of the FDA and comparable foreign Regulatory Authorities, including the FDA Act, including without limitation GMP.  
“Applicator” means the device developed by or on behalf of Client for applying a microneedle system to the upper arm of a patient.  
“Base Fee” means the annual fee to be paid by Client in monthly installments, as more specifically set forth in Schedule B. Base Fees do not include Technology Transfer Fees or Capital Expenditures (both as defined in the Technology Transfer Agreement), Product Fees, Material Costs, Maintenance Costs, Disposal Costs or charges for Xxxx Back Items or Additional Services.  
“Basic Engineering Design” means the basic engineering design to be conducted by Patheon as established by the Steering Committee under the Technology Transfer Agreement.  
“Xxxx Back Items” means the items and services set forth in Schedule B or other project-specific items that are used or necessary in connection with the Manufacture of the Products and that are not included as Materials, and that are approved by Client.  
“Certificate of Analysis” means a certificate evidencing the analytical tests conducted on a specific batch of Product or Material and setting forth, inter alia, the items tested, specifications, and test results.  
“Certificate of Compliance” means a certificate stating that a specific batch of Product has been Manufactured in compliance with GMP and the Specifications.  
“Claim” has the meaning set forth in Section 9.3(a).  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
“Client” has the meaning set forth in the Preamble hereto.  
“Client Indemnified Parties” has the meaning set forth in Section 9.2.  
“Client Manufacturing Equipment” means equipment necessary to Manufacture the primary packaged Product that consists of equipment for the bulk Manufacturing of the microneedle system, formulation preparation, drug product coating of the microneedle system, and in-process control testing of the Product and its intermediates or components as more fully set forth in Exhibit F of the Technology Transfer Agreement.  
“Client Manufacturing Process” means the proprietary process developed by or on behalf of Client for Manufacturing the Product as of the Effective Date, as the same will be disclosed by Client to Patheon pursuant to the Technology Transfer Agreement, and each intermediate or component of the Product, including without limitation, as set forth in the investigational new drug application filed with the FDA for the Product, and, when applicable, as set forth in the NDA as may be filed with, and approved by, the FDA for the Product.  
“Client Manufacturing Process Improvements” has the meaning set forth in Section 5.1(e)(i).  
“Client Product Improvements” has the meaning set forth in Section 5.1(e)(i).  
“Client Specification Improvements” has the meaning set forth in Section 5.1(e)(i).  
“Client-Supplied Materials” has the meaning set forth in Section 2.2(a).  
“Commercially Reasonable Efforts” means, with respect to the efforts to be expended by a Party to achieve any objective, the reasonable, diligent efforts to accomplish the objective as a similarly situated party (with respect to size, resources and assets) in the pharmaceutical industry would normally use to accomplish a similar objective in its own interests under similar circumstances for comparable products.  
“Confidentiality Agreement” has the meaning set forth in Section 7.1.  
“Confidential Information” has the meaning set out in the Confidentiality Agreement.  
“Control” or “Controlled” means that a Party owns or has the right to assign or grant a license or sublicense under Intellectual Property rights to the other Party of the scope set forth herein, without breaching or conflicting with any agreement between the granting party and with a Third Party.  
“Deficiency Notice” has the meaning set forth in Section 2.8(b).  
“Discretionary Manufacturing Changes” has the meaning set forth in Section 2.10(b)(ii).  
“Disposal Costs” means the cost charged by a Third Party for disposal of waste from the Manufacture of the Product plus [\*\*\*].  
“Effective Date” has the meaning set forth in the Preamble hereto  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
“EMA” means the European Medicines Agency or its successor.  
“Equipment” means any equipment to be used in the Manufacture of the Product as more fully set forth in Exhibit F of the Technology Transfer Agreement.  
“Existing Client Intellectual Property” has the meaning set forth in Section 5.1(a).  
“Existing Patheon Intellectual Property” has the meaning set forth in Section 5.1(b).  
“Expected Yield” has the meaning set forth in Section 2.9(a).  
“Expert” has the meaning set forth in Section 2.8(d)(vi).  
“Exploit” means to make, have made, import, use, sell, offer for sale, receive or otherwise dispose of a product or process, including the research, development (including the conduct of clinical trials), registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, export, transport, distribution, promotion, or marketing of a product or process.  
“Facility” means Patheon’s facility located at [\*\*\*], or any other facility approved in accordance with Section 3.4(a).  
“FDA” means the United States Food and Drug Administration and any successor organization thereto and all agencies under its direct control.  
“FDA Act” means the US Federal Food, Drug, and Cosmetic Act, as amended.  
“FDA Approval Date” means the date of receipt by Client of Regulatory Approval in the United States for Products Manufactured at the Manufacturing Suite.  
“Filing Party” has the meaning set forth in Section 3.17(d).  
“Final Filing” has the meaning set forth in Section 3.17(g).  
“Forecast” has the meaning set forth in Section 2.3(a).  
“GMP” means the current good manufacturing practices applicable to the Manufacturing of the Product, or any intermediate of the Product, under Applicable Law, including those promulgated under the FDA Act at 21 C.F.R. (Parts 210 and 211 and Part 4 as relevant for combination products), Commission Directive (EU) 2017/1572 (art. 2), together with the latest FDA, EMA and European Commission guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time. Guidance in draft status will be considered as in effect for the purposes of this definition if this guidance has been adopted by Patheon at the Facility in relation to all its other clients and included as part of Patheon’s Standard Operating Procedures or if it is agreed to be adopted by the Commercial Steering Committee.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
“Indemnified Party” has the meaning set forth in Section 9.3(a).  
“Indemnifying Party” has the meaning set forth in Section 9.3(a).  
“Initial Draft” has the meaning set forth in Section 3.17(e).  
“Initial Term” has the meaning set forth in Section 8.1.  
“Intellectual Property” includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, designs, trade secrets, databases and rights in know how (whether or not any of these is registered or capable of registration and including applications for registration of any such thing) and all other similar rights or forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world.  
“Invention” means any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable.  
“Loss” means any claims, lawsuits, subpoenas, losses, damages, liabilities, penalties, costs, and expenses (including reasonable attorneys’ fees and disbursements).  
“Maintenance” means the maintenance of Equipment and the Facility in satisfactory operating condition, including performing systematic inspection and service of Equipment under to the applicable Standard Operating Procedures of Patheon, as reviewed and agreed to by Client (the “Equipment Standard Operating Procedures”), or the manufacturer’s terms of operation and recommended procedures.  
“Maintenance Costs” means the cost charged by a Third Party for (a) [\*\*\*] Maintenance; or (b) [\*\*\*], plus [\*\*\*].  
“Make Good Costs” has the meaning set forth in Section 8.3(d).  
“Manufacture” and “Manufacturing Services” means the manufacture of the Products, including without limitation the planning, purchasing and receipt of Patheon-Supplied Materials, planning (based on the Forecast), receipt of Client-Supplied Materials and the manufacturing, processing, formulating, coating, primary packaging, sterilization, bulk packaging, bulk labelling, storage, handling, quality release of Products (Certificate of Compliance), together with all agreed sample retention, stability testing, quality control and assurance and waste disposal.  
“Manufacturing Services Termination Costs” has the meaning set forth in Section 8.3(e).  
“Manufacturing Suite” means the manufacturing suite at the Facility, whose footprint was determined in accordance with the Technology Transfer Agreement.  
“Marketing Authorization” means an approved New Drug Application as defined in the FDA Act and the regulations promulgated thereunder, or any corresponding foreign application, registration, or certification, necessary or reasonably useful to market any product containing the Product and an Applicator in a country or regulatory jurisdiction other than the United States, including applicable pricing and reimbursement approvals, and all supplements and amendments thereto.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
“Material Costs” has the meaning set forth in Section 2.2(b).  
“Materials” means all API, excipients and processing aids, processing, coating and packaging components listed in Schedule C, as amended by agreement in writing.  
“NDA” means the US new drug application for a product, including a product containing the Product and the Applicator, requesting permission to place a drug on the market in accordance with 21 C.F.R. Part 314, and all supplements (SNDA) filed under the requirements of the FDA, including all documents, data, and other information filed concerning a product that are necessary for FDA approval to market a product in the Territory.  
“Non-Conforming Product” means (a) a batch of Product that is not Manufactured to completion, or is aborted during processing; or (b) a Product Manufactured by Patheon that fails to conform to the warranty set forth in Section 6.3.  
“Non-Filing Party” has the meaning set forth in Section 3.17(d).  
“Party” and “Parties” have the meanings set forth in the Preamble hereto.  
“Patheon” has the meaning set forth in the Preamble hereto.  
“Patheon Indemnified Parties” has the meaning set forth in Section 9.1.  
“Patheon Independent Manufacturing Equipment Improvements” has the meaning set forth in Section 5.1(f)(i).  
“Patheon Manufacturing Equipment” means any equipment, other than the Client Manufacturing Equipment, necessary to Manufacture the Product including as more fully set forth in Exhibit F of the Technology Transfer Agreement, waste handling systems and all building infrastructure and any and all improvements or additions made thereto, as approved in writing by Client.  
“Patheon Nonconformance” has the meaning set forth in Section 2.8(d)(i).  
“Patheon-Supplied Materials” has the meaning set forth in Section 2.2(a).  
“Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, or other similar entity or organization, including a government or political subdivision, department, or agency of a government.  
“Product” has the meaning set forth in the Technology Transfer Agreement.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
“Product Fee” has the meaning set forth in Section 2.4.  
“Project Manager” and “Project Managers” have the meaning set forth in Section 3.5(a).  
“Purchase Order” means a written purchase order that sets forth (a) the quantities of each presentation of Product to be delivered by Patheon to Client, (b) the requested delivery dates therefor, and (c) the bulk packaging to be used for the Product.  
“Quality Agreement” has the meaning set forth in Section 3.1.  
“Regulatory Approval” means all approvals (including pricing and reimbursement approvals), licenses, registrations, or authorizations of any Regulatory Authority necessary to Exploit a product containing the Product and an Applicator in any country in the Territory, including any Marketing Authorization and supplements and amendments thereto.  
“Regulatory Authority” means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils, or other government entities regulating or otherwise exercising authority for the Exploitation of a product containing the Product and an Applicator in the Territory.  
“Regulatory Filings” has the meaning set forth in Section 3.17.  
“Regulatory Obligations” has the meaning set forth in Section 3.17.  
“Remediation Period” has the meaning set forth in Section 8.2(a)(vi).  
“Reports” has the meaning set forth in Section 3.13.  
“Required Manufacturing Changes” has the meaning set forth in Section 2.10(b)(i).  
“Shipment Costs” has the meaning set forth in Section 2.8(d)(ii).  
“Specifications” means the specifications for each presentation of Product (i.e., the dosage forms in Schedule A) given by Client to Patheon relating to: the specifications of the Materials; the Manufacturing specifications, directions and processes; the storage requirements; all environmental, health and safety information for the Product including material safety data sheets and the finished Product specifications, specifications for bulk and primary packaging and shipping requirements for the Product, in each case as amended, modified, or supplemented by the Parties.  
“Standard Operating Procedures” means Patheon’s standard operating procedures used for the Manufacture of the Product.  
“Technology Transfer Agreement” means the agreement executed on the date hereof between Client and Patheon in order for Patheon to establish and qualify the Facility to Manufacture the Products, and the processes for Manufacturing the Product at the Facility, as described in more detail in the Background Section.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
“Term” has the meaning set forth in Section 8.1.  
“Territory” means the United States and other territories agreed by the Parties under Section 2.2(t).  
“Third Party” means a Person who is neither a Party nor an Affiliate of a Party.  
“Third Party Losses” means Losses incurred as a result of claims brought by Third Parties.  
“Third Party Subcontractors” has the meaning set forth in Section 3.16.  
ARTICLE II. MANUFACTURING SERVICES  
2.1 Supply Obligations.  
(a) Subject to the completion of the Transfer Services under the Technology Transfer Agreement to validate Client’s technology package and prepare Patheon’s facilities for the Manufacture of the Product, and the terms and conditions hereof, and in consideration for the payments set forth in Schedule B, Client appoints Patheon as a non-exclusive supplier of the Products and Patheon will perform the Manufacturing Services and will supply the Product to Client.  
(b) Under the Technology Transfer Agreement, Client will transfer to Patheon, and Patheon will confirm, the Client Manufacturing Process. The Client Manufacturing Process is the Confidential Information of Client, is subject to the Confidentiality Agreement, and accordingly Patheon may not allow Third Parties (other than relevant Regulatory Authorities or Third Party Subcontractors) to access the Manufacturing Suite or view documentation describing the Client Manufacturing Process without Client’s prior written consent, [\*\*\*].  
(c) Patheon will Manufacture all Products delivered hereunder:  
(i) in the Facility;  
(ii) in accordance with the Specifications, this Agreement and the Quality Agreement; and  
(iii) in compliance with GMP and other Applicable Law,  
(iv) in conformance with the applicable Specifications.  
(d) Patheon will ensure that sufficient numbers of adequately educated and experienced staff are retained at the Facility to Manufacture the volumes of Product set out in the Forecast. Patheon will perform all activities necessary to maintain a GMP compliant status of the manufacturing lines and areas of the Facility applicable to the Manufacture of the Product.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
2.2 Materials, Xxxx Back Items and Additional Services.  
(a) All Materials necessary for the Manufacture of the Product are set forth in Schedule C. Materials that will be purchased by Client and shipped to Patheon (“Client-Supplied Materials”) are listed in Part A of Schedule C. Materials that will be purchased by Patheon (“Patheon-Supplied Materials”) are listed in Part B of Schedule C.  
(b) Patheon-Supplied Materials will be invoiced to Client monthly at the time of purchase by Patheon at cost plus [\*\*\*], in accordance with the invoicing procedure set forth in ARTICLE IV (“Material Costs”). Patheon will obtain the prior written approval of Client on the cost of the Patheon-Supplied Materials if the cost of any individual item of Patheon-Supplied Material increases by more than (i) [\*\*\*]%; or (ii) $[\*\*\*], whichever is the lower. Where Client nominates a particular supplier to supply certain Patheon-Supplied Materials, Patheon will purchase those Materials from that supplier subject to Section 2.2(d). All purchases of Patheon-Supplied Materials by Patheon will be made on Patheon’s own behalf and not as an agent for Client.  
(c) Patheon will store, handle, and protect the Materials supplied or purchased for the Manufacturing Services other than in connection with the Transfer Services, with no less than a reasonable level of care, which will include taking all reasonable precautions to ensure that the Materials are not subject to contamination, deterioration, destruction, or theft. Patheon will keep adequate records of its use of the Materials for Manufacturing Services during the Term.  
(d) Client acknowledges that Patheon is required under GMP to follow certain verification and approval processes for all vendors used by Patheon in the procurement of Materials. If Client requests Patheon to procure Materials from a vendor that is not [\*\*\*], Client will [\*\*\*], provided that Patheon must notify Client if the vendor [\*\*\*] and Client will have the right to approve [\*\*\*]. Client will be responsible for validation of suppliers of Client-Supplied Materials unless otherwise agreed. Patheon will be responsible for validation of suppliers of Patheon-Supplied Materials. Any changes to a supplier of Materials proposed by either Party will be subject to the change control procedure set out in Section 2.10(b) and may not be used until, as applicable, a regulatory submission has been filed to necessary health authorities if necessary therefor and appropriate required approvals are obtained.  
(e) Patheon will be responsible for ordering and paying for the relevant quantities of Patheon-Supplied Materials necessary for the Manufacture of Products on the terms and conditions that Patheon agrees to with relevant suppliers.  
(f) The Commercial Steering Committee will discuss and agree the process by which Patheon will order from Client the relevant quantities of Client-Supplied Materials necessary for the Manufacture of Products during the Term. Client will keep Patheon informed of the standard lead time for and cost of Client-Supplied Materials and will supply the Client-Supplied Materials free of charge on a consignment basis in response to orders placed by Patheon under this Agreement.  
(g) Client will at its sole cost and expense, deliver Client-Supplied Materials to the Facility [\*\*\*] (Incoterms 2010) at no cost to Patheon in the quantities and on the dates agreed with Patheon in response to orders placed under the process agreed under Section 2.2(f). If the Client-Supplied Materials are not received on or before the agreed date, Patheon may delay the Manufacture of Product for a period of time [\*\*\*] to the delay.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(h) All shipments of Client-Supplied Materials, if required, will be accompanied by Certificates of Analysis and/or Certificates of Conformance from the Material manufacturer or Client confirming in writing its compliance with the Material’s specifications, together with all required documentation as specified in the Quality Agreement. Client or Client’s designee will be the “Importer of Record” for Client-Supplied Materials imported to the Facility. Client-Supplied Materials will be held by Patheon on behalf of Client as set forth in this Agreement or as otherwise required by Client.  
(i) Title to Client-Supplied Materials will at all times remain the property of Client. Risk in the Client-Supplied Materials will remain with Patheon at all times from the point when the Client-Supplied Materials are delivered to Patheon until delivery of the Products to Client (or return of the Client-Supplied Materials to Client), at which time it will pass to Client (or its relevant Affiliate). The transfer of risk in the Client-Supplied Materials to Patheon will be without prejudice to Section 9.5 ([\*\*\*]) and will be subject to [\*\*\*]. Patheon will not be liable for [\*\*\*]. The transfer of risk will further be subject to [\*\*\*].  
(j) Client-Supplied Materials will only be used by Patheon to perform the Manufacturing Services or associated activities necessary to perform the Manufacturing Services and will be kept in a manner that prevents access thereto by any personnel or Third Parties not performing Transfer or Manufacturing Services under this Agreement.  
(k) Client will supply the Client-Supplied Materials in accordance with the requirements of the Quality Agreement, the Specifications, the Marketing Authorization, and Applicable Law.  
(l) Patheon will notify Client [\*\*\*] in writing if, after having carried out the analysis and testing of Client-Supplied Materials as set out in the Quality Agreement or the Specifications it considers that any delivered Client-Supplied Materials do not comply with Section 2.2(k), and will provide samples of the delivery together with copies of any relevant analysis records. Upon receipt of notification under to this Section 2.2(l) by Client, the Parties will use Commercially Reasonable Efforts to agree (each acting in good faith) whether or not the Client-Supplied Materials in question are compliant with the requirements set out in Section 2.2(k) and:  
(i) Client will be entitled at all reasonable times to inspect and/or analyze the delivery in question;  
(ii) Patheon will not use any of the Client-Supplied Materials in question in the Manufacture of Product until the matter has been resolved in accordance with this Section 2.2(l) and Section 2.2(m) unless agreed otherwise; and  
(iii) at Patheon’s request, Client will deliver to Patheon replacement Client-Supplied Materials as soon as practicable, using Commercially Reasonable Efforts to enable continuity of Patheon’s Manufacture of the relevant Products.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(m) If the Parties do not agree on whether the Client-Supplied Materials in question are compliant with the requirements set out in Section 2.2(k), the matter may be referred to an Expert in accordance with the procedure in Section 2.8(d)(vi).  
(n) If Client-Supplied Materials are not compliant (or are determined to be non-compliant) with the requirements set out in Section 2.2(k) and Patheon does not have sufficient quantity of released Client-Supplied Materials that are compliant, then Patheon will have no liability to Client [\*\*\*] if [\*\*\*]. Client will pay Patheon for the Purchase Order in accordance with Section 2.4 which payment will be credited against the Product Fees that are payable for future Purchase Orders.  
(o) Where Patheon fails to carry out incoming analysis of Client-Supplied Materials in accordance with the Specifications and uses the Client-Supplied Materials in question in the Manufacture of Product and these Client-Supplied Materials thereafter are agreed or determined under Section 2.8(d)(vi) to not comply with the requirements set out in Section 2.2(k), Patheon will:  
(i) provide the remedies set out in Section 2.8(d)(ii) for any Non-Conforming Product that is caused by the failure (and Patheon’s obligation to reimburse Client-Supplied Materials incorporated into Non-Conforming Product caused by the failure will be captured and calculated in the Yield Reimbursement Payment under Section 2.9, which will be subject to the limitation of liability in Section 9.5(a)); and  
(ii) at Client’s option, subject to completion of any quality investigation, any sample retention requirements and the provisions of the Quality Agreement, take all necessary action (at its own expense), to rework or reprocess (both of which will be done promptly) or destroy any Non-Conforming Products caused by the failure.  
(p) [\*\*\*] for all Non-Conforming Product that arises from Client-Supplied Materials that do not comply with the requirements set out in Section 2.2(k) that could not be detected by Patheon carrying out the incoming analysis of Client-Supplied Materials in accordance with this Agreement, the Specifications and the Quality Agreement.  
(q) Patheon will provide free of charge sufficient storage capacity to support storage of the required quantity of Materials for the longer of [\*\*\*] or the amount of time set forth for the applicable Material on Schedule C. Patheon will also provide free of charge sufficient storage capacity to support storage of Product for up to [\*\*\*] after the release of the relevant Product. Any additional storage, or storage of Materials or Product beyond the applicable period stated herein will be subject to the mutual agreement of the Parties, this agreement to include the fees relating thereto. Patheon’s standard storage fees as of the Effective Date are $[\*\*\*] per pallet, per month for storing the Materials or finished Product. Storage fees for Materials or Product that contain controlled substances or require refrigeration are charged at $[\*\*\*] per pallet per month. Storage fees are subject to a one pallet minimum charge per month. Storage fees will not apply to (i) any registration batches for up to [\*\*\*] after the Marketing Authorization for the United States has been granted; and (ii) any stocks of Products Manufactured during the first [\*\*\*] after the Effective Date in anticipation of launch in the US, but where Patheon is unable to accommodate all or some of the launch quantities it may engage a Third Party Subcontractor approved by Client (not to be unreasonably withheld, conditioned or delayed) to do so in accordance with Section 3.16.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(r) Xxxx Back Items will be charged to Client at Patheon’s cost plus [\*\*\*]. Patheon will invoice Client monthly for any Xxxx Back Items used to Manufacture the Products during the preceding month in accordance with ARTICLE IV. Patheon may only invoice Xxxx Back Items that have been quoted to and approved in writing by an authorized person of Client in advance. The cost of any Xxxx Back Items where use is shared between Client and Patheon or other clients of Patheon will be apportioned in good faith in proportion to their use.  
(s) If Client is interested in having Patheon perform Additional Services, Client will provide Patheon with a written request containing sufficient detail to enable Patheon to provide Client with a quote and proposal to provide the Additional Services. Patheon may only invoice for Additional Services that have been quoted to and approved in writing by an authorized person of Client in advance. Where a rate for Additional Services has been specified in Schedule B, the rates are calculated as at the Effective Date. These fees will be adjusted on 1st January of each year (first review [\*\*\*]) to reflect any increase in the Producer Price Index pcu32541235412 for Pharmaceutical Preparation Manufacturing (PPI) published by the United States Department of Labor, Bureau of Labor Statistics during the previous 12 months (based on the average of the monthly changes over the 12-month period). Patheon will invoice Client monthly for any Additional Services performed by Patheon during the preceding month in accordance with ARTICLE IV.  
(t) If Client decides to have Patheon perform Manufacturing Services for the Product for a territory outside the United States, then Client will inform Patheon of the additional requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional costs for the Product destined for each new country. The agreed additional requirements and change to any Product Fees will be set out in a written amendment to this Agreement. The Product Fees for products supplied to [\*\*\*] will be consistent with those for the United States save to the extent Additional Services are required for the Products, e.g., [\*\*\*], which will be subject to Section 2.2(s).  
(u) Patheon-Supplied Materials.  
(i) If the Parties agree that Patheon is to source all or any of the Materials, Client understands and acknowledges that Patheon will rely on Client’s Purchase Orders and Forecasts in ordering the Patheon-Supplied Materials required to meet the Purchase Orders. Accordingly, Client authorizes Patheon to purchase Patheon-Supplied Materials to satisfy the Manufacturing Services requirements for Products for the first [\*\*\*] contemplated in the most recent Forecast. Patheon may make other purchases of Patheon-Supplied Materials to meet Manufacturing Services requirements for longer periods if agreed to in writing by the Parties. Client will give Patheon written authorization to order Patheon-Supplied Materials for any launch quantities of Product requested by Client, which order will expressly state that the authorization is for launch quantities, and will be considered a Purchase Order when accepted by Patheon.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(ii) Client will reimburse Patheon for any destruction costs of any Patheon-Supplied Materials ordered by Patheon under Purchase Orders or under Section 2.2(u)(i) that are not included in finished Products Manufactured for Client within [\*\*\*] after the forecasted month for which the purchases have been made (or for a longer period as the Parties may agree in writing). If any non-expired Patheon-Supplied Materials are used in Products subsequently manufactured for Client, Client will receive credit for any costs of those Patheon-Supplied Materials previously paid to Patheon by Client.  
(v) Waste Disposal. Patheon will dispose of waste arising from the Manufacture of the Product. Disposal Costs will be invoiced to Client monthly in accordance with the invoicing procedure set forth in ARTICLE IV. Patheon may only invoice Disposal Costs that have been quoted to and approved in writing by an authorized person of Client in advance.  
2.3 Forecasting, Order, and Delivery of Products.  
(a) No later than [\*\*\*] prior to the anticipated FDA Approval Date and thereafter at least [\*\*\*] prior to the first day of each calendar month during the Term, Client will deliver to Patheon a written good faith [\*\*\*] forecast, calculated monthly, estimating the quantities of each presentation of Product that Client expects to order from Patheon during the period (each, a “Forecast”).  
(b) If Patheon is unable to accommodate any portion of the Forecast, it will notify Client in writing setting out the reasons and the Parties will [\*\*\*] any revisions to the Forecast. Without prejudice to Client’s other rights and remedies under this Agreement, Patheon will take actions as reasonably requested by Client to minimize the damage to Client (if any) caused by Patheon’s inability to accommodate any portion of the Forecast at its own cost where this inability is a result of a failure by Patheon to comply with its obligations under this Agreement, and otherwise at Client’s cost. Taking these actions will not constitute an admission of liability by Patheon or any acceptance that an inability to accommodate any portion of the Forecast will cause damage to Client.  
(c) Client will update the Forecast within [\*\*\*] of each calendar month on a rolling forward basis. Patheon’s obligations under this Agreement will be determined based on the most recent Forecast submitted by Client. Except as set forth in Section 2.3(e) below, each Forecast will be non-binding and will be used by Patheon for planning purposes only.  
(d) When this Agreement is executed, Client will give Patheon a written non-binding [\*\*\*] forecast for strategic purposes, of the volume of Product Client then anticipates to purchase from Patheon for each year during this period (the “Long Term Forecast”). The Long Term Forecast will thereafter be updated every [\*\*\*] during the Term. If Patheon is unable to accommodate any portion of the Long Term Forecast, it will notify Client and the Parties will [\*\*\*] any revisions to the Long Term Forecast.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(e) The first [\*\*\*] of each Forecast will be considered binding firm orders. Client will issue corresponding Purchase Orders on a monthly basis to purchase and, when accepted by Patheon, for Patheon to Manufacture and deliver the agreed quantity of the Product for each month of the [\*\*\*] period, but the delivery lead time must be at least [\*\*\*] from the date of Patheon’s acceptance (or deemed acceptance) of the Purchase Order under Section 2.3(f) below. With respect to the next month which becomes binding in a subsequent Forecast, Patheon will be obligated to accept Purchase Orders for Product for that month up to [\*\*\*]% of the amount forecasted for the same month in the immediately prior Forecast, and Patheon will use Commercially Reasonable Efforts to fulfill and accept Purchase Orders for any additional amount forecasted, subject to the then-existing Manufacturing Equipment capacity. Expedited Purchase Orders will be subject to additional fees on reasonable terms that are consistent with those generally offered to Patheon’s other customers.  
(f) Patheon will accept Purchase Orders for amounts of Product ordered in the binding portion of a Forecast by sending an acknowledgement to Client within [\*\*\*] days of its receipt of the Purchase Order. The acknowledgement will include confirmation of the quantity of Product ordered as set out in the Purchase Order and the delivery dates for the Product ordered as set out in the Purchase Order (“Agreed Delivery Date”). Upon receipt of the acknowledgement, each Purchase Order will be regarded by the Parties as a binding irrevocable commitment by Client to purchase from Patheon, and for Patheon to Manufacture and supply to Client, the relevant quantity of Product according to the requirements set out in the Purchase Order.  
(g) Patheon will only be required to provide a delivery month for any Purchase Orders or part thereof that do not relate to the first [\*\*\*] of the applicable Forecast. The Agreed Delivery Date may be amended by agreement of the Parties. If Patheon fails to acknowledge receipt of a Purchase Order within the five business day period, the Purchase Order will be considered to have been accepted by Patheon.  
(h) Patheon will deliver Product to Client [\*\*\*] (as defined in Incoterms 2010) by the Agreed Delivery Date and in the quantities specified in the relevant Purchase Order. Client may accept deliveries in advance of the Agreed Delivery Date at its discretion. All Product will be packed for shipping in accordance with the Specifications.  
(i) Title to the Products will vest in Client from the point during the Manufacturing process when the Client-Supplied Materials are first converted into, or used in, the Product. Risk of loss to Product will pass to Client (or a designated Client Affiliate) at the time when Patheon [\*\*\*]. Neither payment for the Products by Client, nor passing of risk in the Products to Client, will be considered acceptance of the Products by Client.  
(j) Each delivery of Product will be accompanied by a Certificate of Analysis and a Certificate of Compliance and any other documents required under the Quality Agreement. All Products will be released for delivery within [\*\*\*]. If the [\*\*\*], the Parties will engage in good faith discussions to agree a remediation plan describing the steps to be taken to improve shelf life performance. Patheon will use Commercially Reasonable Efforts to implement the plan. If Product is released later than [\*\*\*], Client may reject the same [\*\*\*]. Any rejected Product will be regarded as Non-Conforming Product. The costs of all freight, insurance, handling fees, taxes, and other costs associated with the shipment of Product, as well as export licenses, import license, and customs formalities for the import and export of goods will be [\*\*\*]. Client will [\*\*\*] on the date specified in the relevant Purchase Order [\*\*\*].  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(k) If Client cancels any Purchase Order after acceptance by Patheon or considered accepted as described in Section 2.3(f) or (g), Client will pay Patheon [\*\*\*]% of the Product Fee for the Purchase Order which payment will be credited against the Product Fees that are payable for future Purchase Orders.  
(l) Patheon will use Commercially Reasonable Efforts to satisfy, any changes in quantity, delivery phasing or dates requested by Client for Purchase Orders or any additional orders. Any additional fees to reflect additional activities required to be conducted by Patheon as a result of these changes or additional orders will be agreed by the Parties in advance.  
2.4 Product Fees. The purchase price for Products Manufactured hereunder (the “Product Fee”) will be calculated according to the model as set forth in Schedule B. This means that the Product Fee payable per Product varies on an incremental basis as further described in Schedule B. All purchases of Products will be invoiced at the applicable Product Fee based on the volume of Products expected to be supplied in that calendar year (or part thereof) based on most recent Forecast at the start of the calendar year. Patheon will invoice Client for the relevant Product Fee [\*\*\*]. All Product Fees will be due and payable in accordance with the invoicing procedures set forth in ARTICLE IV.  
2.5 Base Fees. Patheon will invoice Client monthly in advance for the Base Fees set forth Schedule B. All Base Fees will be due and payable in accordance with the invoicing procedures set forth in ARTICLE IV.  
2.6 Fee Adjustment.  
(a) The Base Fee and Product Fee stated herein are calculated as at the Effective Date and will be fixed until [\*\*\*]. Thereafter, starting on [\*\*\*] the Base Fee and Product Fee will be adjusted annually to reflect any change in the Producer Price Index pcu32541235412 for Pharmaceutical Preparation Manufacturing (PPI) published by the United States Department of Labor, Bureau of Labor Statistics during the preceding 12 months (based on the average of the monthly changes over the 12-month period).  
(b) Patheon, in collaboration with Client, will use Commercially Reasonable Efforts to identify and target potential areas of cost reduction (e.g., [\*\*\*]) and process improvements (e.g., [\*\*\*]) relating to its performance under this Agreement. The net benefits of cost savings and improved efficiencies achieved as a result of the same will be allocated as follows:  
(i) where benefits of cost reductions and improved efficiencies are only applicable to the Manufacture of the Products, the amount of these benefits will be [\*\*\*]; and  
(ii) where benefits of cost reductions and improved efficiencies are applicable to the general manufacturing and supply chain costs of Patheon, such that Patheon and/or its customers generally benefit, the allocation of the benefits will be discussed in good faith and allocated between the Parties as agreed at the time.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
2.7 Inability to Supply Product.  
(a) Patheon will ensure that Product is Manufactured and delivered to Client on a timely basis consistent with this Agreement (including the Forecast and Purchase Order procedures set forth in Section 2.3). If Patheon, at any time during the Term, is unable or will have reason to believe that it will be unable to supply Client with the full quantity of Product forecasted to be ordered or actually ordered by Client in a timely manner and in conformity with the warranty set forth in Section 6.3 (whether by reason of force majeure or otherwise), Patheon will notify Client thereof in writing within [\*\*\*] days setting out the reasons for the inability to supply. Promptly thereafter, the Parties will meet to discuss how Client will obtain the full quantity of conforming Product and Patheon will take all actions as may be reasonably agreed by the Parties to minimise any delay. Compliance by Patheon with this Section 2.7(a) will not relieve Patheon of any other obligation or liability under this Agreement. If Patheon’s inability to supply is partial, Patheon will fulfill Purchase Orders with quantities of Product as are available and the Client’s payment obligations relating to the Product Fee will be reduced accordingly. If Patheon’s inability to meet Purchase Orders or forecasts is due to a shortage of production capacity in the Manufacturing Suite, Patheon will in addition to the foregoing requirements, promptly notify Client of the shortage of production capacity and the estimated date the shortage of production capacity is to end.  
(b) The Parties acknowledge that following Completion of the Tech Transfer (as defined in the Technology Transfer Agreement), (i) the engineering approach and footprint agreed by the Parties for the Manufacturing Suite and utility requirements is intended to provide capacity for the Manufacture of [\*\*\*] patches of Product per year and (ii) the provision of personnel supporting the Manufacturing Suite is intended to support the Manufacture of the volumes of Product as set out in the relevant Forecast. Patheon undertakes to maintain the capacity and associated support processes for the Term in order to be able to ramp up to manufacture of at least [\*\*\*] patches of Product per year, subject to Client’s provision of Forecasts for these volumes in accordance with Section 2.3(a). Patheon will not without Client’s prior written consent take any step that might reduce this capacity.  
2.8 Non-Conforming Product.  
(a) If Patheon discovers a potential Non-Conforming Product before delivery of the Product to Client, Patheon will suspend any planned release or delivery of the Products in accordance with the Quality Agreement and provide written notice to Client as soon as practicable describing in detail the Non-Conforming Product and the potential cause for the Non-Conforming Product.  
(b) Client (or its designee) will perform a customary inspection of the Products Manufactured by Patheon on receipt. This inspection [\*\*\*] to a visual inspection of the shipment-ready packaged Products (and associated shipping documentation) and Client (or its designee) will not be obligated to perform any testing of the Product. Client will (i) within [\*\*\*] days after receipt by Client (or its designee) of a shipment of Product or (ii) within [\*\*\*] days after Client (or its designee) discovers or is informed of a discovery of nonconformity that could not reasonably have been detected by the customary inspection on delivery (but not after the expiration date of the Product), give Patheon notice of any Non-Conforming Product (including a sample of the Non-Conforming Product, if applicable) (a “Deficiency Notice”). If Client fails to give Patheon the Deficiency Notice within the expiry of the applicable notice period, then the delivery will be considered to have been accepted by Client. Patheon will have no liability whether under this Section 2.8, Section 3.12 or Section 3.14 or otherwise for any Non-Conforming Product for which it has not received a Deficiency Notice within the expiry of the applicable notice period.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(c) Following receipt of a Deficiency Notice Patheon will conduct a root-cause analysis to verify whether a Product constitutes a Non-Conforming Product and, if found, to determine the cause for the Non-Conforming Product (including by undertaking an appropriate evaluation of a Non-Conforming Product sample, as applicable). Client will provide reasonable cooperation to Patheon in connection with the root-cause analysis. The payment obligation in relation to the Product Fee for the Product will be suspended pending resolution of the issue. Patheon will notify Client in writing of its determination regarding whether the Product constitutes a Non-Conforming Product within [\*\*\*] days after either discovery of the Non-Conforming Product or receipt of the Deficiency Notice from Client, as applicable. This notification will include Patheon’s good faith determination of the cause of the Non-Conforming Product if the notification indicates Patheon agrees that the Product constitutes Non-Conforming Product. At Client’s request and following the issue of a Purchase Order from Client, Patheon will [\*\*\*] deliver a replacement delivery of the Product to Client as soon as practicable after receipt of the Deficiency Notice (subject to Client supplying Patheon with Client-Supplied Materials, if required for the replacement delivery) in order to ensure continuity of supply, and Client will pay Patheon for the delivery in accordance with this Agreement.  
(d) Patheon Nonconformance.  
(i) “Patheon Nonconformance” will mean Patheon’s failure to Manufacture the Products or provide the Manufacturing Services in accordance with Section 2.1(c), any failure of Products to conform to the applicable Specifications or the warranty in Section 6.3 and any failure by Patheon to comply with the terms and conditions of this Agreement.  
(ii) If there is Non-Conforming Product caused by a Patheon Nonconformance, Patheon will reimburse Client for:  
 1.  
the Product Fees for the Non-Conforming Products; and  
 2.  
any shipment costs incurred by Client [\*\*\*] (“Shipment Costs”); and  
 3.  
cost of losses of Patheon-Supplied Materials incorporated into Non-Conforming Product,  
in each case, to the extent applicable and/or already paid by Client.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(iii) Patheon’s obligation to reimburse Client for Client-Supplied Materials incorporated into Non-Conforming Product caused by a Patheon Nonconformance will be captured and calculated in the Yield Reimbursement Payment under Section 2.9 which will be subject to the limitation of liability in Section 9.5(a).  
(iv) Section 9.5(a) will not apply in relation to (A) the internal expenses incurred by Patheon to supply conforming Product to Client under Section 2.8(c) if this is to replace Non-Conforming Product caused by a Patheon Nonconformance, or (B) the cost of any Patheon-Supplied Materials or any Shipment Costs or the reimbursement of the Product Fee under Section 2.8(d)(ii). Client will not be liable to pay Product Fees for Non-Conforming Product caused by a Patheon Nonconformance and Patheon will have no obligation to reimburse any unpaid Product Fees for Non-Conforming Product caused by a Patheon Nonconformance.  
(v) If the Non-Conforming Product was caused by any reason other than a Patheon Nonconformance, by agreement of the Parties or as may be determined by an Expert in accordance with Section 2.8(d)(vi), Client will be liable for all expected Product Fees for this Non-Conforming Product (to the extent not already paid).  
(vi) If, following the root-cause analysis described in Section 2.8(c), Patheon notifies Client that it does not believe the Product is a Non-Conforming Product, or if the Parties disagree as to the cause of a Non-Conforming Product, the Parties will first submit the dispute to the Project Managers for prompt resolution. If the Project Managers cannot resolve the dispute within [\*\*\*] days after considering the matter, the Parties will submit the dispute to [\*\*\*] agreed by the Parties (an “Expert”) for evaluation, but both Parties will be entitled to review and obtain copies of all results of the evaluation. The Expert will determine (i) whether the Product is a Non-Conforming Product and (ii) the cause (or likely cause) of the Non-Conforming Product. Both Parties will cooperate with the Expert’s reasonable requests for assistance in connection with its evaluation hereunder. The findings of the Expert will be binding on the Parties, absent fraud or manifest error. The Expert will act as an expert and not as an arbitrator and (unless the Expert otherwise determines) the fees and expenses of the Expert will be borne (1) by Patheon if the testing confirms the Non-Conforming Product and the cause or likely cause is found to be a Patheon Nonconformance; (2) by Client if the testing confirms the Non-Conforming Product and the cause or likely cause is found not to be a Patheon Nonconformance or if the cause or likely cause of the non-conformance is not identifiable; or (3) by the Party stating the Product was Non-Conforming Product if the testing concludes that the Product meets the warranty set forth in Section 6.3. Costs of dealing with Product complaints and inquiries will be dealt with in accordance with Section 3.12. Costs of recalls will be dealt with in accordance with Section 3.14. Patheon will have no liability for any Non-Conforming Product unless the Non-Conforming Product is identified as being due to a Patheon Nonconformance.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
2.9 Yield Reconciliation.  
(a) During its performance of the Manufacturing Services, on an annual basis Patheon is expected to produce a certain yield of Product using Client-Supplied Material (the “Expected Yield”). The initial Expected Yield and the mechanism for calculating the same will be established by the Commercial Steering Committee after the [\*\*\*] of commercial Product have been Manufactured by Patheon. Pending the establishment of the initial Expected Yield, the Expected Yield of Product conforming to the Specifications and the warranty set forth in Section 6.3 that is produced using Client-Supplied Material is eventually expected to be [\*\*\*]% (e.g., [\*\*\*]% of the Client-Supplied Materials entering into the Manufacturing process over a period of time result in a Product conforming to the Specifications and the warranty set forth in Section 6.3 during the period of time), but this percentage will not be contractually binding and the Parties acknowledge that this may not be attainable for early batches of Product produced by Patheon due to the limited experience that Patheon will have in Manufacturing commercial Product. Accordingly the Yield Reimbursement Payment and credit set out in Section 2.9(c) will not apply to the [\*\*\*] of commercial Product Manufactured by Patheon.  
(b) On a monthly basis during the Term, Patheon will provide Client with a report for the previous month and calendar year to date showing:  
(i) the number of units (one drug patch being one unit) of Products released by Patheon to be delivered to Client in accordance with this Agreement in the applicable time periods;  
(ii) Patheon’s inventory of Client-Supplied Materials, quantity of Client-Supplied Materials that complies with Section 2.2(k) received at the Facility, quantity of Client-Supplied Materials dispensed for use in the Manufacture of Product, quantity of Client-Supplied Materials converted into Product, and any additional information as the Parties may agree; and  
(iii) the Achieved Yield in that month and year to date, where “Achieved Yield” will be calculated under an equation to be agreed by the Steering Committee taking into account losses of Client-Supplied Materials due to Client-Supplied Materials that have expired as a result of a Patheon act or omission and any Client-Supplied Materials lost in the warehouse prior to and during Manufacture, but excluding losses or uses of Client-Supplied Materials due to (i) Client-Supplied Materials retained by Patheon as samples; (ii) Client-Supplied Materials used to Manufacture Product retained as samples; (iii) Client-Supplied Materials used in testing (if applicable) of Product; (iv) [\*\*\*] and (v) Client-Supplied Materials received and used by Patheon under the Technical Transfer Agreement.  
(c) If the Achieved Yield in any year commencing upon or after the date of Manufacture of [\*\*\*] batch of commercial Product by Patheon under this Agreement is more than [\*\*\*]% lower than the then-current Expected Yield established by the Commercial Steering Committee or that year, (i) Patheon and Client will engage in good faith discussions to agree a remediation plan describing the steps to be taken to achieve the then-current Expected Yield and (ii) Patheon will reimburse Client for excess Client-Supplied Materials used by Patheon to Manufacture Product needed as a result of Patheon’s failure to meet the Expected Yield in these batches (i.e., reimbursement to Client for the actual costs of any Client-Supplied Materials) subject to the limitation of liability in Section 9.5(a) (the “Yield Reimbursement Payment”). If the Achieved Yield in any year is more than [\*\*\*]% greater than the then-current Expected Yield for that year, Patheon will be entitled to reduce any Yield Reimbursement Payment to be made in the next year by an amount equal to the value of the excess Client-Supplied Materials that would have been used by Patheon if the Achieved Yield for that year had been equal to the then-applicable Expected Yield for those batches of Product.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(d) Patheon will use Commercially Reasonable Efforts to drive year on year improvements in the Achieved Yield and the Expected Yield.  
2.10 Equipment and Amendment of Product Specifications, Manufacturing Process, Equipment and Formulation.  
(a) Equipment.  
(i) Title to all Client Manufacturing Equipment will be held by Client or a Client Affiliate. Title to all Patheon Manufacturing Equipment will be held by Patheon.  
(ii) Patheon is authorized to use the Client Manufacturing Equipment solely to perform the Manufacturing Services for Client. Patheon may not move the Client Manufacturing Equipment from the Facility nor use the Client Manufacturing Equipment to perform manufacturing services for other clients without the Client’s prior written consent.  
(iii) Patheon will not sell or offer to sell, assign, pledge, lease or otherwise transfer or encumber the Client Manufacturing Equipment or any interest therein, without the prior written consent of Client. Patheon will not create any adverse lien, security interest or encumbrance in the Client Manufacturing Equipment.  
(iv) Patheon will use the Client Manufacturing Equipment in accordance with the Equipment Standard Operating Procedures or the relevant manufacturer’s instructions and Client’s instructions.  
(v) During the Term, Patheon will, at its cost, keep the Client Manufacturing Equipment secure and will not allow Third Parties not performing the Manufacturing Services to have access to the Client Manufacturing Equipment.  
(vi) Client will be responsible for additions and replacement cost of any (i) Client Manufacturing Equipment and (ii) Patheon Manufacturing Equipment that is used to Manufacture the Product or that is used for Client and other clients of Patheon (the cost of any additions and replacement for Patheon Manufacturing Equipment that is used for Client and other clients of Patheon will be apportioned in good faith in proportion to their use). All replacement parts and repairs to the Client Manufacturing Equipment will become Client’s property. Patheon will not make any material alterations to the Equipment, the Manufacturing Suite or the Client Manufacturing Process used in the Manufacture of the Products without Client’s prior written consent.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(vii) During the Term, Patheon will provide all Maintenance for the Equipment and the Facility. Maintenance Costs will be invoiced to Client monthly in accordance with the invoicing procedure set forth in ARTICLE IV, but Patheon may only invoice Maintenance Costs that have been quoted to and approved in writing by Client’s authorized person in advance. Maintenance Costs relating to Patheon Manufacturing Equipment that is used for Client and other clients of Patheon will be apportioned in good faith in proportion to their use. Notwithstanding the foregoing, for Client Manufacturing Equipment and Patheon Manufacturing Equipment, Maintenance Costs do not include (A) the cost of spare parts (if Patheon keeps an inventory of original manufacturer spare parts as the Parties agree is reasonably necessary to maintain the Client Manufacturing Equipment, to include at a minimum all critical spares recommended by the manufacturer of the Client Manufacturing Equipment), (B) Equipment breakdowns caused by any reason outside of Patheon’s reasonable control (other than breakdowns caused by Patheon’s willful misconduct or failure to maintain the Equipment in accordance with the applicable Equipment Standard Operating Procedures of Patheon or the manufacturer’s terms of operation and recommended procedures), or (C) specialized maintenance services not within Patheon’s technical expertise or that requires specialist equipment where Patheon is required to utilize a Third Party contractor. Patheon’s costs associated with these spare parts, Equipment breakdowns and Third Party contractors will be reimbursed by Client as a Xxxx Back Item. But where these spare parts, Equipment breakdowns and Third Party contractors relate to Patheon Manufacturing Equipment that is used for Client and other clients of Patheon, the costs will be apportioned in good faith in proportion to their use.  
(viii) Patheon will not be liable for ordinary wear and tear of the Client Manufacturing Equipment or Patheon Manufacturing Equipment. Patheon will only be liable for the repair or replacement of any damage caused to Client Manufacturing Equipment or Patheon Manufacturing Equipment where the damage arises due to its negligence, willful misconduct or its failure to maintain Client Manufacturing Equipment or Patheon Manufacturing Equipment under the applicable Equipment Standard Operating Procedures of Patheon or the manufacturer’s terms of operation and recommended procedures. Where this Section refers to costs relating to any Patheon Manufacturing Equipment, if the Patheon Manufacturing Equipment is used for Client and other clients of Patheon, these costs will be apportioned in good faith in proportion to their use.  
(ix) Throughout the Term of this Agreement, Patheon will maintain property insurance on all Equipment in the amount equal to [\*\*\*].  
(x) Client may examine and inspect the Client Manufacturing Equipment at any reasonable time (wherever the Client Manufacturing Equipment is located in the Facility) so that Client can check the Client Manufacturing Equipment’s existence, condition and proper maintenance.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(xi) Patheon will ensure that at all times the Client Manufacturing Equipment is clearly marked to identify that it is owned by Client and that it is to be used only for Client.  
(xii) Patheon will promptly notify Client if any of the Client Manufacturing Equipment is lost, stolen or damaged.  
(b) Change Control.  
(i) For changes to the Specifications, Quality Agreement, the Client Manufacturing Process, the Equipment, the Manufacturing Services to be performed under this Agreement, the Transfer Services to be performed under the Technology Transfer Agreement or the formulation of the Product that are required by Applicable Law (collectively, “Required Manufacturing Changes”), Patheon and Client will cooperate to promptly make the changes within the required timeline and assess filing implications (prior approval, changes being effected, etc.).  
(ii) For changes to the Specifications, Quality Agreement, the Client Manufacturing Process, the Equipment, the Manufacturing Services to be performed under this Agreement, the Transfer Services to be performed under the Technology Transfer Agreement, or the formulation of the Product that are not Required Manufacturing Changes (collectively, “Discretionary Manufacturing Changes”), Patheon will provide Client with an estimate of the timeframe and cost required to implement these changes. Patheon and Client must each agree to any Discretionary Manufacturing Changes and will cooperate in making the changes, and each agrees that it will not unreasonably withhold or delay its consent to the Discretionary Manufacturing Changes. Once Client has approved the estimate in writing, Patheon will implement the change within the agreed timeframe. Together the Parties will assess filing implications, as for example, annual reportable status.  
(iii) Notwithstanding the foregoing, [\*\*\*] costs, including, without limitation, costs of [\*\*\*] will be allocated between the Parties as described below in this subsection (iii). To the extent that the change relates to the Product, the Specifications, the Client Manufacturing Process, the Equipment, the Manufacturing Services or the Manufacturing Suite or the Transfer Services to be performed under the Technology Transfer Agreement, Client will pay the costs and expenses of implementing the change together with the actual cost of write-off (including waste disposal costs) of any inventory of Products or Materials rendered obsolete as a result of the change. But Client will not be liable for the write-off costs of any Materials purchased in excess of those amounts needed to meet Purchase Orders or as otherwise agreed under Section 2.2(u). To the extent that the change results from a change in GMP or Applicable Laws that requires changes to the Facility or Manufacturing process (other than as a direct result of changes to the Product, the Specifications, the Client Manufacturing Process, the Equipment, the Manufacturing Services or the Manufacturing Suite or the Transfer Services to be performed under the Technology Transfer Agreement), the allocation of the benefits will be discussed in good faith and allocated between the Parties as agreed at the time, having regard to any appropriate allocation where other Patheon customers will benefit from the change.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(iv) The cost of implementing Discretionary Manufacturing Changes will be agreed by the Parties.  
(v) If Client changes the Specifications, Quality Agreement, the Client Manufacturing Process, the Equipment, the Manufacturing Services to be performed under this Agreement, the Transfer Services to be performed under the Technology Transfer Agreement or the formulation of the Product, or consents to any change by Patheon, Patheon will provide to Client at Client’s cost as an Additional Service any documentation or other information that relates to the Manufacturing Services as Client may reasonably request in order to obtain or maintain any Regulatory Approval or comply with GMP or other Applicable Law.  
(vi) Patheon will not change the Specifications, the Materials or the Client Manufacturing Process used to Manufacture the Products, or make any other change which may reasonably be expected to have a regulatory impact on the Product, affect the Marketing Authorization or affect the quality or physical characteristics of the Product, without first obtaining written consent from Client.  
ARTICLE III. REGULATORY, ACCESS, AND OTHER MATTERS  
3.1 Quality Agreement. Prior to the expiry of the Technology Transfer Agreement, the Parties will enter into a mutually agreed upon quality agreement (“Quality Agreement”). If there is any inconsistency between this Agreement and the Quality Agreement, the Quality Agreement will control solely for quality issues, and this Agreement will control for all other issues.  
3.2 Quality Assurance.  
(a) Patheon will at all times ensure that agreed quality assurance tests are adopted and that reference and retention samples are taken, analyzed and retained in accordance with the Quality Agreement. These samples will (notwithstanding any termination of this Agreement) be retained by Patheon for the periods set out in the Quality Agreement at no additional cost.  
(b) Unless otherwise specified in the Quality Agreement, Patheon will provide to Client, in a timely manner, sufficient quantities of reference standards for the Products to enable Client to carry out and/or maintain the necessary testing capability to comply with its Regulatory Obligations and the obligations set out in the Quality Agreement throughout the Term.  
(c) Patheon will institute and maintain process controls during the Manufacture of the Products in accordance with GMP and will maintain full records of the process controls which will be made available to Client on request together with retained in-process samples. These records must align with documentation set out in the Specifications and samples will be retained by the Patheon for the period specified in the Quality Agreement or as otherwise required by Applicable Law at no additional cost.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
3.3 Release. All Product will be released in accordance with the Quality Agreement.  
3.4 Maintenance of Facility.  
(a) Patheon will Manufacture the Product exclusively at the Facility, unless Client has granted prior written consent to Manufacture the Product at any other facility, this consent to be granted by Client in its sole discretion.  
(b) Subject to Section 2.10(b), Patheon will at its own cost ensure that any and all necessary licenses, registrations, and (subject to any payments required under Section 3.10(b)) Regulatory Authority approvals have been obtained for the Facility and Equipment used in connection with the Manufacture of the Product by Patheon.  
(c) Subject to Section 2.10, Patheon will maintain the Facility and Equipment in a state of repair and operating efficiency consistent with the requirements of the Specifications, the Regulatory Approvals, the Client Manufacturing Process, GMP, and all other Applicable Law. Before each use of Equipment in Manufacturing the Product, Patheon will ensure that the Equipment is cleaned and consistent with any procedures reasonably established by Client and notified to Patheon, the Specifications, the Regulatory Approvals, the Client Manufacturing Process, GMP, and all other Applicable Law. Without limiting the foregoing, Patheon agrees to implement, for the Manufacture of the Product, quality assurance and quality control procedures, including validation protocols and process change procedures that are reasonably satisfactory to Client.  
(d) Patheon will maintain in the Facility an adequate GMP and temperature controlled area for the Product, all intermediates thereof and Materials used in Manufacturing the Product in accordance with the Specifications, the Regulatory Approvals, the Client Manufacturing Process, any risk mitigation plan, the Quality Agreement, GMP, and all Applicable Law. All Product, intermediates and Materials (as applicable) will be held by Patheon in a GMP and temperature controlled area (on a separate pallet and SAP reference from other products) until delivery to Client. In order for Patheon and Client to identify any potential effects on quality, safety or efficacy of the Products, subject to obligations of confidentiality that Patheon owes to Third Parties, Patheon will disclose to Client (on a no-names basis) information relating to the nature of any other products manufactured by Patheon for itself or Third Parties at the Facility (in particular, any [\*\*\*]). Client agrees that Patheon may, disclose information (on a no-names basis and subject to ARTICLE VII) relating to the nature of Client’s Product to other clients of Patheon at the Facility if requested.  
(e) Patheon will only use qualified disposal services or sites that have appropriate environmental and operating permits and are in compliance with the Quality Agreement and Applicable Law.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(f) Patheon will develop and put in place a disaster recovery and business continuity plan for the Manufacture of Products at the Manufacturing Suite by [\*\*\*], and will give Client a copy of the plan at Client’s request. Client will provide Patheon with details of its requirements for these plans within a reasonable period from the Effective Date.  
3.5 Project Managers; Steering Committee Meetings.  
(a) Patheon and Client will each appoint a project manager (each, a “Project Manager” and, together, the “Project Managers”), who will meet as needed to resolve any issues or problems arising in the performance of this Agreement.  
(b) Following completion of registration batches the Parties will establish a steering committee in respect of commercial supply (the “Commercial Steering Committee”), which will meet at least quarterly in order to manage the long term manufacturing and supply aspects of this Agreement. The responsibilities of the Commercial Steering Committee will include without limitation:  
(i) reviewing any ongoing development activities for the Products that may lead to changes in demand;  
(ii) reviewing and discussing any trends or concerns related to delivery performance, Achieved Yields, usage of Client-Supplied Materials, quality related issues or plans to improve performance under the Agreement;  
(iii) reviewing any potential restrictions on the availability of additional space within the Facility, which will be notified by Patheon sufficiently far in advance of any proposed agreement with a Third Party in order for Client to be able assess its likely future requirements and for the Parties to have the opportunity to negotiate in good faith any reservation of the same; and  
(iv) performing any other responsibilities as the Parties may agree.  
Unless otherwise agreed by the Parties the Commercial Steering Committee will follow the membership and procedural arrangements agreed for the steering committee under Exhibit G of the Technology Transfer Agreement.  
3.6 Notification of Regulatory Inspections. Patheon will notify Client by telephone within one business day, and in writing within two business days, after learning of any proposed or unannounced visit or inspection of any part of the Facility which relates to the Manufacture of the Product by any Regulatory Authority, including the Occupational Safety and Health Administration or any equivalent governmental agencies of the country of Manufacture, and provide all relevant information known to Patheon regarding the investigation. Patheon will permit Client or its agents to be present at the Facility to support Patheon during any visit or inspection if it impacts the Product or affects the Manufacturing Suite. Patheon will be responsible for conducting the inspection. Patheon will provide to Client in so far as it affects the Product or the Manufacturing Suite either a copy of or a summary of any report and other written communications received from the Regulatory Authority in connection with any visit or inspection, including FDA Form 483 observations and responses (or any equivalent observations and responses from any Regulatory Authority under Applicable Law). This copy or summary will be provided to Client within [\*\*\*] days of Patheon’s receipt thereof (and may be redacted as Patheon acting reasonably deems necessary to protect the confidentiality of matters not affecting the Product or the Manufacturing Suite or which are confidential to Patheon or to other clients of Patheon). Client will have the right to review and comment on any communications with the Regulatory Authority about the inspection as set forth in Section 3.17. If Client is subject to an inspection by any Regulatory Authority that relates to the Products or Patheon’s performance of its obligations under this Agreement, Patheon will provide Client and the Regulatory Authority with access to Patheon’s non-financial records, the Products and those portions of the Facility used in the Manufacture of the Products or storage, testing, handling or receiving of the Materials as required by this Agreement or otherwise by Applicable Law[\*\*\*].  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
3.7 Manufacturing Records. Patheon will maintain, or cause to be maintained, (a) all records necessary to comply with GMP and all other Applicable Law relating to the Manufacture of Product, (b) all Manufacturing records, standard operating procedures, equipment log books, batch records, laboratory notebooks, and all raw data relating to the Manufacturing of the Product, and (c) any other records that Client may reasonably require in order to ensure compliance by Patheon with this Agreement. The template, form and style of all records referred to in this Section are the exclusive property of Patheon. Client Confidential Information and all Product-specific related information contained in these records will be considered Confidential Information of Client and be retained for the time required by GMP and all other Applicable Law.  
3.8 Bulk Packaging. Client will specify all bulk packaging to be used for the Product. Patheon agrees to use only the bulk packaging on the Product as set out in the Specifications.  
3.9 Compliance with Applicable Laws. Patheon will comply and will cause each of its Materials and Xxxx Back Items suppliers to comply with the Quality Agreement, GMP and Applicable Law in carrying out the Manufacturing of the Product and its other duties and obligations under this Agreement.  
3.10 Compliance Audits  
(a) With the exception of “for cause” audits (e.g., audits arising from regulatory issues or material Product conformity issues), Client and its designated representatives will have the right to audit [\*\*\*] per year free of charge all applicable non-financial records of Patheon to determine Patheon’s compliance with the obligations set forth in this Agreement, including Sections 2.2(a) and 6.2, and any Purchase Order. This audit right will include the right to inspect: (a) the Materials used in the Manufacture of the Product, (b) the holding facilities for the Materials, (c) the Manufacturing Suite and all Equipment used in the Manufacture of the Product, (d) all non-financial records relating to the Manufacturing Suite and the Manufacturing of the Product (subject to any other restrictions set forth in this Agreement) and (e) all other documentation set forth in the Quality Agreement, in order to carry out a GMP, quality and/or compliance audit of those parts of the Facility involved in, or which could affect, the Manufacture of the Products. Client will give Patheon [\*\*\*] days prior advance notice of its intention to conduct an audit and the Parties will determine a mutually agreeable date for the audit. Client will include no more than [\*\*\*] of Client’s representatives in each audit, with each audit lasting no more than [\*\*\*] days, in each case without Patheon’s prior written consent. Client will also have the right to carry out follow up audits [\*\*\*] if any observations have been noted during any audit carried out under this Section 3.10(a) (excluding any “for cause” audits as described above or any audits where critical or major observations have been noted).  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(b) Client may request additional GMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of a fee of $[\*\*\*] for each additional audit day and $[\*\*\*] per audit day for each additional auditor. Patheon will support the first Product approval, including its inspection if required, of the FDA or equivalent regulatory launch for other jurisdictions (where applicable). Additional support (including, without limitation, subsequent regulatory launches or Product approval inspections/resulting reports for other jurisdictions) will be subject to additional fees.  
(c) Patheon will use Commercially Reasonable Efforts to ensure that any corrective or preventative actions identified in any audit carried out under this Section 3.10 that are agreed by the Parties are carried out in accordance with any agreed timeline and subject to payment by Client of any agreed fees.  
(d) Patheon will be responsible for ensuring the GMP compliance status of any authorized sub-contractors used to perform its obligations under this Agreement as described in Section 2.2(d). Patheon will assess each sub-contractor using Patheon’s standard vendor assurance program and will report its findings to Client within ten business days of Client’s request.  
3.11 Inventory Reviews. Without limiting the foregoing, Client will have the right, with Patheon’s assistance, to conduct [\*\*\*] inventory count of the Materials and of the Products. Following an audit or inventory, Client may discuss its observations and conclusions with Patheon, and Patheon will promptly implement corrective actions after notification thereof by Client. If the Parties are unable to agree upon whether or not corrective actions are necessary, the dispute will be resolved under Section 10.10.  
3.12 Product Inquiries and Complaints.  
(a) For Products Manufactured by Patheon, Patheon will promptly submit to Client any Product safety and efficacy inquiries, Product quality complaints, and adverse drug event reports that it receives, together with all available evidence and other information relating thereto, in accordance with procedures to be agreed upon by the Parties. Patheon will promptly advise Client of any occurrence or information which arises out of the Manufacture of Products which has or could be reasonably expected to have adverse regulatory compliance and/or reporting consequences concerning the Products, and provide relevant information to Client upon request. Except as otherwise required by, or to comply with, Applicable Law or this Agreement, Client, as the Party holding the applicable Marketing Authorization, will be responsible for investigating and responding to these inquiries, complaints, and adverse events regarding the Product, and reporting to the FDA or any other Regulatory Authority.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(b) Under any reported complaint, adverse drug event or other issue which may pertain to the Manufacture of the Products Patheon will promptly conduct an internal investigations as may be reasonably necessary to determine the validity of the complaint, including performing analytical testing of corresponding Products or retention samples, and will provide the results to Client as soon as reasonably practicable, but no later than [\*\*\*] days after Client’s request. This testing will be performed using approved testing procedures as set forth in the applicable Regulatory Approval or the Quality Agreement. If the investigation or analytical testing concludes that the reported complaint or adverse drug event was the result of a Patheon Nonconformance, subject to Client having given Patheon a Deficiency Notice in accordance with Section 2.8(b) including as to timing, Patheon will reimburse Client for all reasonable out-of-pocket expenses associated with the complaint or adverse drug event and incurred by Client for the Non-Conforming Product, including reasonable costs of returns and destruction. Costs of recalls will be dealt with in accordance with Section 3.14. If the investigation or analytical testing concludes that the reported complaint or adverse drug event was not the result of a Patheon Nonconformance, Client will compensate Patheon for all costs associated with the complaint or adverse drug event and incurred by Patheon for the Non-Conforming Product, including costs of recalls, market withdrawals, returns, and destruction.  
(c) If the Parties disagree as to which Party is responsible, Patheon and Client representatives will attempt to resolve the dispute. If the representatives cannot resolve the dispute within 15 days, the retention samples will be submitted by Patheon and Client to an Expert and Section 2.8(d)(vi) will apply.  
3.13 Reports. Prior to the start of Patheon’s commercial Manufacture of the Product (or as reasonably requested by Client prior to that date), Patheon and Client will work together in good faith to develop and agree upon Patheon’s ordinary course reporting obligations. The reports (“Reports”) will include information necessary for Client to (a) manage Product inventory; (b) measure the Achieved Yield and whether all Products on agreed Purchase Orders order are delivered on time and in full; (c) manage its financial close and reporting; (d) monitor on-going Product and process performance for its internal analysis and reporting; and (e) comply with Applicable Law. Patheon will deliver the reports via electronic delivery methods, including by utilizing Patheon’s existing IT systems as practicable.  
3.14 Product Recalls.  
(a) If (i) any Regulatory Authority issues a request, directive, or order that Product be recalled, (ii) a court of competent jurisdiction orders a recall, or (iii) Client as holder of the applicable Marketing Authorization will reasonably determine that Product should be recalled, withdrawn, or a field correction issued, the Parties will take all appropriate corrective actions, and will cooperate in the investigations surrounding the recall. If Client or a Regulatory Authority determines that Product should be recalled, the recall strategy will be developed by Client in consultation with Patheon to the extent possible and followed by Patheon. To the extent any Product recall, withdrawal, or field correction results from a Patheon Nonconformance, Patheon will bear all Client’s reasonable out-of-pocket expenses associated with the recall, withdrawal, or field correction, which will include expenses of notification and destruction or return of the recalled Product and all other documented out-of-pocket costs incurred in the recall, plus reasonable transportation costs incurred by Client for the Product, up to the maximum liability limits set forth in Section 9.5, with Client bearing the remainder of these costs. In all other circumstances that do not result from Patheon Nonconformance, all cost associated with any Product recall, withdrawal or filed correction will be borne by Client.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(b) If there is any dispute concerning which Party’s acts or omissions gave rise to the recall of Product, Patheon and Client representatives will attempt to resolve the dispute. If the representatives cannot resolve the dispute within 15 days, the matter will be submitted by Patheon and Client to an Expert and Section 2.8(d)(vi) will apply.  
3.15 Payment Audits.  
(a) Upon [\*\*\*] days’ prior written notice, Client may audit any Third Party invoices subsequently invoiced to Client pertaining to Patheon’s provision of Equipment, Materials, Xxxx Back Items and Additional Services. But Client will not be entitled to more than [\*\*\*] audit during any 12 month period. These audits will be conducted during normal business hours, without undue disruption to Patheon’s business, and may be conducted by Client, or by an independent public accounting firm designated by Client who is bound by confidentiality obligations at least as stringent as those set forth in the Confidentiality Agreement. Client will bear the full cost of the performance of the audit.  
(b) If, as a result of any audit of the Third Party invoices, it is shown that the payments or credits from one Party to the other under this Agreement for the time audited were less than or more than the amount that should have been paid or credited, then the Parties will reconcile the amounts owed by each Party to the other.  
3.16 Subcontractors. Patheon may arrange for Third Party subcontractors (“Third Party Subcontractors”) to perform specific Manufacturing Services (such as testing or analysis) under this Agreement only with Client’s written consent or at Client’s request. Patheon will be liable for all acts and ommissions of any Third Party Subcontractors that it engages to perform the Manufacturing Services subject to all limitations on Patheon’s liability as set out in this Agreement. Patheon will have no liability arising from the performance of Manufacturing Services by Third Party Subcontractors to the extent that the Third Party Subcontractor is [\*\*\*]. Patheon will not be obliged to use a Third Party Subcontractor requested by Client if it does not comply with Patheon’s supplier qualification requirements.  
3.17 Regulatory Filing Obligations. (a) Except as otherwise set forth in this Agreement or the Technology Transfer Agreement, each Party will be responsible for all routine filings and communications with Regulatory Authorities (“Regulatory Filings”) required for that Party’s Regulatory Obligations hereunder.  
(b) “Regulatory Obligations” will mean:  
(i) for Client, any Regulatory Filings pertaining to Regulatory Approvals; and  
(ii) for Patheon, any Regulatory Filings pertaining to the Manufacture of the Products at the Facility, including a Facility inspection by a Regulatory Authority (e.g., those described in Section 3.6) (“Patheon Regulatory Obligation”).  
(c) Each Party will have the sole responsibility for Regulatory Filings for its Regulatory Obligations and will provide the other with a copy of any Regulatory Approval relevant to this Agreement on request, to the extent reasonably required for its Regulatory Filings or in order to satisfy its obligations under Applicable Laws.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(d) Cooperation. Each Party (“Non-Filing Party”) will provide reasonable assistance and cooperation free of charge to the other Party (“Filing Party”) for the Filing Party’s Regulatory Obligations consistent with this Section 3.17 and the Non-Filing Party’s obligations under this Agreement. The Filing Party will notify the Non-Filing Party in writing of any written communications received by the Filing Party from a Regulatory Authority related to the other Party’s Regulatory Obligations within three business days after receipt thereof. The Filing Party will consult with the Non-Filing Party concerning the response of the Filing Party to each communication, unless the filing is not relevant to the Non-Filing Party’s Regulatory Obligations.  
(e) Verification of Data. Prior to filing any documents or communications with a Regulatory Authority that incorporate or uses data generated by the Non-Filing Party or otherwise relate to the Non-Filing Party’s Regulatory Obligations, the Filing Party will give the Non-Filing Party a draft of the document or communication (“Initial Draft”) to give the Non-Filing Party the opportunity to verify the accuracy and regulatory validity of the Initial Draft. The Non-Filing Party will be given a minimum of [\*\*\*] days to review the Initial Draft, but the Parties may agree to a different time for the review as needed under the circumstances. The Initial Draft may be redacted by the Filing Party as reasonably deems necessary to protect the confidentiality of matters not affecting the Non-Filing Party or which are confidential to the Filing Party or to other clients or customers of the Non-Filing Party. The Parties agree that in reviewing the Initial Draft, the Non-Filing Party’s role will be limited to verifying the accuracy of the description of its Regulatory Obligations or accuracy of its data or information in the Initial Draft.  
(f) Inaccuracies. If the Non-Filing Party determines that any of its data or information in the Initial Draft is inaccurate or any other errors relating to the Non-Filing Party’s Regulatory Obligations, the Non-Filing Party will notify Filing Party in writing of the inaccuracy and provide a recommendation to remediate the Initial Draft. This notice will also include documentation and data sufficient to substantiate the Non-Filing Party’s claim that the Initial Draft is inaccurate to the Filing Party’s reasonable satisfaction. The Non-Filing Party will provide comments to the Initial Draft no later than [\*\*\*] days prior to the required filing date with the applicable Regulatory Authority. If the Non-Filing Party does not provide comments or notify the Filing Party of inaccuracies within this [\*\*\*] day period, the Non-Filing Party will be deemed to have approved any data or language related to its Regulatory Obligations in the Initial Draft. The Filing Party will be required to incorporate the Non-Filing Party’s recommendations to the extent they [\*\*\*]. The Parties will work together in good faith to resolve any inaccuracies contained in the Initial Draft as soon as practicable under the circumstances to prevent a delay or postponement of the filing (or any related inspections by the Regulatory Authority to which the filing relates).  
(g) Responsibilities. The Filing Party will deliver a copy of the final version of the filing (“Final Filing”) to the Non-Filing Party at least three days prior to the required filing date. Subject to the foregoing, the Non-Filing Party will not assume any responsibility for the accuracy of any other materials submitted by the Filing Party to a Regulatory Authority in connection with this Agreement. Except as otherwise set forth in this Agreement or the Technology Transfer Agreement, the Filing Party is solely responsible for the preparation and filing of any materials required by a Regulatory Authority for that Party’s Regulatory Obligations hereunder and any relevant costs will be borne by the Filing Party.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
3.18 Client On Site Represenatitives. Client will be entitled to have a reasonable number of Client On Site Representatives present (and in any event at least [\*\*\*]) at the Facility to oversee Patheon’s performance of the Manufacturing Services.  
ARTICLE IV. FEES AND INVOICING  
4.1 General. Patheon will invoice Client for all applicable fees and charges incurred by Patheon. All invoices will be sent electronically on the date issued to the email address provided by Client to Patheon. Payment will be due [\*\*\*] days after the date of an undisputed invoice. All fees and costs in this Agreement are shown in US Dollars (USD).  
4.2 Late Fees. For all invoices issued by Patheon under this Agreement, if Client fails to make any payment due to Patheon by the due date for payment, then, without limiting Patheon’s remedies under ARTICLE VIII or at law, Patheon may charge interest on past due accounts at [\*\*\*]% per annum. Patheon may, on giving [\*\*\*] days’ notice to Client, suspend all Manufacturing Services, including release and shipment of Product, until all undisputed past due invoices have been paid in full. Patheon will have no liability to Client for losses caused by this suspension, including without limitation, losses due to delayed Product delivery or Product shortages.  
4.3 Disputed Invoices. If Client disputes any portion of an invoice, (a) Client will give Patheon written notice of the disputed portion within ten business days of the date of Patheon’s invoice and its reasons therefor and will not be obliged to pay the disputed portion until the disputed portion is determined to be due and owing, and (b) Patheon will cancel the invoice and issue a new invoice reflecting the undisputed invoiced amount, which will be paid by Client within [\*\*\*] days after the date thereof. The Parties will use Commercially Reasonable Efforts to resolve the dispute regarding the disputed amount promptly and in good faith, and if the Parties agree that a balance is due, Patheon will issue an invoice for the balance, and payment will be due [\*\*\*] days after receipt of this invoice. If there is any inconsistency between an invoice and this Agreement, this Agreement will control.  
4.4 Taxes.  
(a) Duties. Client will pay all duties, levies, tariffs and similar charges (and any related interest and penalties) (together “Duties”) however designated, arising from the performance of the Manufacturing Services or the Transfer Services by Patheon, including (without limitation) those imposed as a result of the shipping of Materials or Product to, from or between Patheon sites. If these Duties are incurred by Patheon, then Patheon will be entitled to invoice Client for these Duties at the time that they are incurred.  
(b) Withholding Tax.  
(i) Where any sum due to be paid to Patheon under this Agreement or the Technology Transfer Agreement is subject to any withholding or similar tax, Client will pay the withholding or similar tax to the appropriate government authority and deduct the amount paid from the amount then due to Patheon, in a timely manner and promptly transmit to Patheon an official tax certificate or other evidence of the withholding sufficient to enable Patheon to claim the payment of taxes. The Parties agree to cooperate with one another and use Commercially Reasonable Efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Client to Patheon under this Agreement or the Technology Transfer Agreement.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(ii) Patheon will provide Client any tax forms that may be reasonably necessary in order for Client not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty.  
(iii) Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, or similar obligations resulting from payments made under this Agreement or the Technology Transfer Agreement, this recovery to be for the benefit of the Party bearing the withholding tax.  
(c) No Offset. Any tax or Duty that Client pays, or is required to pay, but which Client believes should properly be paid by Patheon under this Agreement or the Technology Transfer Agreement may not be offset against sums due by Client to Patheon whether due under this Agreement or the Technology Transfer Agreement or otherwise  
ARTICLE V. INTELLECTUAL PROPERTY  
5.1 Ownership.  
(a) Client will maintain ownership and Control of all of its technology and Intellectual Property rights existing before the Effective Date (“Existing Client Intellectual Property”).  
(b) Patheon will maintain ownership and Control of all of its technology and Intellectual Property rights existing before the Effective Date (“Existing Patheon Intellectual Property”).  
(c) Existing Client Intellectual Property will include and Client will own all right, title, and interest in and to all Intellectual Property rights covering or claiming (i) the Product, (ii) the Specifications, and (iii) the Client Manufacturing Process.  
(d) Existing Patheon Intellectual Property will include and Patheon will own all right, title, and interest in and to the Patheon Manufacturing Equipment as of the Effective Date.  
(e) Client will own solely all right, title, and interest in and to, all Intellectual Property and any data, comprising, consisting of or relating to:  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(i) (A) any improvement of, modification of, change of, enhancement of, new indication for, new formula for, new formulation for, new ingredients for, new dosage for, new dosage strength for, new means of delivery for, or new packaging for, the Product (“Client Product Improvements”); (B) any improvement of, modification of, change of, or enhancement of the Specifications (“Client Specification Improvements”); (C) any improvement of, modification of, change of, enhancement of, new process for, new procedure for, new step for the Client Manufacturing Process (the “Client Manufacturing Process Improvements”); and (D) any improvements of, modification of, change of or enhancement of Client Manufacturing Equipment (the “Client Manufacturing Equipment Improvements”) in each of case (A), (B), (C) and (D), (1) that is developed, conceived, or created after the Effective Date specifically as a result of or in connection with this Agreement, including Patheon’s Manufacturing of the Product hereunder, (2) whether or not patentable, (3) whether developed, conceived, or created by employees of, or consultants to, Client or Patheon, alone or jointly with each other or with permitted Third Parties (including permitted sublicensees and subcontractors), and (4) that specifically relates to the Product, Specifications, the Client Manufacturing Process or the Client Manufacturing Equipment, or components of any of the foregoing, as applicable, including without limitation [\*\*\*]; and  
(ii) any Intellectual Property developed, conceived, or created by Client, alone or jointly with Third Parties (other than Patheon or its Affiliates, or their respective employees and consultants), in the course of conducting activities outside the scope of this Agreement and without any use of any Existing Patheon Intellectual Property, Patheon Improvements or Patheon Independent Manufacturing Equipment Improvements (as defined hereunder).  
(f) Patheon will own all right, title, and interest in and to, all Intellectual Property and any data that is not owned by Client pursuant to Section 5.1(e) comprising, consisting of or relating to:  
(i) any improvement of, modification of, change of, enhancement of any Patheon Manufacturing Equipment, (1) that is developed, conceived, or created as a result of or in connection with this Agreement, including Patheon’s Manufacturing of the Product hereunder, (2) whether or not patentable, (3) whether developed, conceived, or created by employees of, or consultants to, Client or Patheon, alone or jointly with each other or with permitted Third Parties (including permitted sublicensees), and (4) that is of general application to the manufacture of products rather than a specific solution that only has applicability to the Product, (“Patheon Independent Manufacturing Equipment Improvements”);  
(ii) any improvement of, modification of, change of, enhancement of manufacturing, processing, formulating, or packaging technology or equipment which is (x) generated or derived by Patheon, alone or jointly, and (y) of general application to the manufacture of products rather than specific to the Product (“Patheon Improvement”); and  
(iii) any Intellectual Property developed, conceived, or created by Patheon, alone or jointly with Third Parties, in the course of conducting activities outside the scope of this Agreement and without any use of any Existing Client Intellectual Property, Client Confidential Information, Client Manufacturing Processes, Client Specifications, Products, Specifications or Client Manufacturing Equipment, or any Client Product Improvements, Client Specification Improvements, Client Manufacturing Process Improvements or Client Manufacturing Equipment Improvements.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(g) Patheon or its Affiliates will, promptly disclose in writing and in reasonable detail to Client any Client Product Improvements, Client Specification Improvements, Client Manufacturing Process Improvements or Client Manufacturing Equipment Improvements developed, conceived, or created by employees, consultants, or subcontractors of Patheon or its Affiliates, alone or jointly with employees, consultants or subcontractors of Client or its Affiliates. This written notice will be treated as the Confidential Information of Client hereunder.  
(h) Client or its Affiliates will promptly disclose in writing and in reasonable detail to Patheon any potential Patheon Independent Manufacturing Equipment Improvements or Patheon Improvement developed, conceived, or created by employees, consultants, or subcontractors of Client or its Affiliates, alone or jointly with employees, consultants, or subcontractors of Patheon or its Affiliates. This written notice will be treated as the Confidential Information of Patheon hereunder.  
(i) The Specifications, the Client Manufacturing Process, Client Manufacturing Equipment and any and all information or material related to the Existing Client Intellectual Property, Products, Client Product Improvements, Client Specification Improvements, Client Manufacturing Process Improvements or Client Manufacturing Equipment Improvements will constitute Confidential Information of Client, which will be deemed the disclosing party for the Confidential Information.  
(j) The Patheon Manufacturing Equipment and any and all information or material related to the Existing Patheon Intellectual Property, the Patheon Independent Manufacturing Equipment Improvements or Patheon Improvements will constitute Confidential Information of Patheon, which will be deemed the Disclosing Party for the Confidential Information.  
5.2 Licenses.  
(a) Client hereby grants, for the purposes of this Agreement only, to Patheon a fully paid-up worldwide, non-exclusive license, under Client’s entire right, title, and interest in and to the Existing Client Intellectual Property for Patheon to Manufacture the Products solely under this Agreement.  
(b) Client hereby grants, for the purposes of this Agreement only, to Patheon a fully paid-up worldwide, non-exclusive license, under Client’s entire right, title, and interest in and to the Client Product Improvements, Client Specification Improvements, Client Manufacturing Process Improvements and Client Manufacturing Equipment Improvements, in each case to make Products solely under this Agreement.  
(c) Patheon hereby grants to Client a fully paid-up perpetual worldwide, non-exclusive license, with the right to sublicense to Affiliates and to Third Parties through multiple tiers, under Patheon’s entire right, title, and interest in and to the Patheon Independent Manufacturing Equipment Improvements, the Existing Patheon Intellectual Property (to the extent incorporated in, or used in the Manufacture of, the Product) and the Patheon Improvements (to the extent incorporated in, or used in the Manufacture of, the Product) to make, use, offer for sale, sell, import, and otherwise dispose of the Product, components thereof and any other product developed by or on behalf of Client or its Affiliates [\*\*\*].  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
ARTICLE VI. REPRESENTATIONS AND WARRANTIES  
6.1 Representations and Warranties of Each Party. 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 on behalf of 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 a proceeding at law or equity.  
(b) From the FDA Approval Date, all necessary consents, approvals, and authorizations of all Regulatory Authorities, other governmental authorities, and other Persons required to be obtained by the Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.  
(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 Law or any provision of the articles of incorporation, bylaws limited partnership agreement, or other constituent 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.  
6.2 Additional Representations, Warranties, and Covenants of Patheon. Patheon warrants, represents, and covenants that:  
(a) it has facilities, personnel, experience, and expertise sufficient in quality and quantity to perform its obligations hereunder;  
(b) it will perform its obligations hereunder in conformity with GMPs where applicable;  
(c) it will comply with the Quality Agreement and comply with all agreed upon quality assurance, quality controls, and review procedures in the performance of its obligations hereunder;  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(d) it has at the Effective Date and will, during the Term of this Agreement and at its cost (subject to Section 2.10(b)), in connection with this Agreement, observe and comply with all Applicable Laws, including federal, state, and local laws, orders, regulations, rules, customs, and ordinances now in force or that may hereafter be in force, pertaining to the Facility and the performance of the Manufacturing Services and including, without limitation, (i) labor laws, orders, regulations, rules, customs, and ordinances of the country of Manufacture and (ii) those of the FDA pertaining to the Manufacturing Services and the Facility (but not those pertaining to non-Manufacturing matters relating to the Product, compliance with which will be the responsibility of Client), and any laws, orders, regulations, rules, or ordinances issued in addition to, as a supplement to or as a replacement of Applicable Laws.  
(e) as at the Effective Date, it has received no warning letter from any Regulatory Authority in relation to the Facility in the [\*\*\*] month period prior to the Effective Date (including in relation to the compliance of that Facility with all applicable requirements of GMP);  
(f) as at the Effective Date, there are no outstanding FDA Form 483 observations (or any equivalent observations from any Regulatory Authority under Applicable Law) for the Facility;  
(g) none of it, its Affiliates, nor any Person under its direction or control (including Third Party Subcontractors), has ever been, nor will it engage suppliers which have to its actual knowledge, after due inquiry, been, (i) debarred or convicted of a crime for which a person can be debarred, under Section 335(a) or 335(b) of the FDA Act, or any equivalent Applicable Law of the country of Manufacture, (ii) threatened to be debarred under the FDA Act or any equivalent Applicable Law of the country of Manufacture or (iii) indicted for a crime or otherwise (to its actual knowledge after due inquiry) engaged in conduct for which a person can be debarred by the FDA or any equivalent Regulatory Authority under Applicable Law of the country of Manufacture, and Patheon agrees that it will promptly notify Client if it receives notification of any debarment, conviction, threat or indictment. If Patheon becomes aware of any suspected non-compliance with the foregoing, Patheon will notify Client in writing of the issue within 48 hours. For the purpose of this Section 6.2, suppliers and subcontractors engaged by Patheon to undertake the Manufacture of the Product will be considered to be under Patheon’s direction or control;  
(h) none of it, its Affiliates, nor any Person under its direction or control is currently excluded from a federal or state health care program under Sections 1128 or 1156 of the Social Security Act, 42 U.S.C. §§ 1320a-7, 1320c-5 or any equivalent Applicable Law of the country of Manufacture, as may be amended or supplemented;  
(i) none of it, its Affiliates, nor any Person under its direction or control is otherwise currently excluded from contracting with the U.S. federal government or the government of the country of Manufacture;  
(j) none of it, its Affiliates, nor any Person under its direction or control is otherwise currently excluded, suspended, or debarred from any U.S. or foreign governmental program;  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(k) to its knowledge, as at the Effective Date, the use of the Patheon-Supplied Materials, the Patheon Manufacturing Equipment and other technology and/or Intellectual Property Controlled by Patheon to perform the Manufacturing Services hereunder, in accordance with the terms and conditions hereof does not infringe or misappropriate any Third Party’s Intellectual Property rights  
(l) it will immediately notify Client if, at any time during the Term, Patheon, its Affiliates, or any Person under its direction or control is convicted of an offense that would subject it or Client to exclusion, suspension, or debarment from any U.S. or foreign governmental program;  
(m) it agrees to keep the Equipment free from all liens and encumbrances; and  
(n) it will not enter into any agreement or arrangement with any other Third Party that would prevent its ability to perform its obligations hereunder  
6.3 Warranty. Patheon warrants that:  
(a) Products will be Manufactured in accordance with Section 2.1(c) of this Agreement, Quality Agreement, GMP, and all other Applicable Law;  
(b) without prejudice to Section 2.8, at the time of delivery the Products will conform with the Specifications in accordance with the testing regime set out therein and will conform with the Certificate of Analysis therefor provided under Section 2.3(j);  
(c) at the time of delivery title to the Product will pass to Client as provided herein free and clear of any security interest, lien, or other encumbrance;  
(d) at the time of delivery the Product will not be adulterated or misbranded within the meaning of the FDA Act as a result of a Patheon Nonconformance; and  
(e) at the time of delivery the Product will not be an article that, under the FDA Act, may not be introduced into interstate commerce as a result of a Patheon Nonconformance.  
6.4 Additional Representations, Warranties, and Covenants of Client. Client warrants, represents, and covenants that:  
(a) Non-Infringement.  
(i) to its knowledge, as at the Effective Date (1) it or its Affiliates Control all right, title, and interest in all Intellectual Property in the Client Manufacturing Process, the Client Manufacturing Equipment, the Product and the Specifications necessary for performance of the Manufacturing Services; and (2) it has the right to authorize Patheon to perform the Manufacturing Services, in each case in accordance with the terms and conditions hereof;  
(ii) to its knowledge, as at the Effective Date, the performance of the Manufacturing Services hereunder, in accordance with the terms and conditions hereof and using the Client Manufacturing Process does not infringe or misappropriate any Third Party’s Intellectual Property rights;  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(iii) Client or its Affiliates Control and have the right to lawfully disclose the Specifications to Patheon and to authorize Patheon to use the Specification to perform the Manufacturing Services;  
(iv) as of the Effective Date, so far as Client is aware there are no actions or other legal proceedings pending concerning the infringement of Third Party Intellectual Property rights related to any of the Specifications, the Client Manufacturing Process or any of the Materials, or the supply, use, or other disposition of any Product made in accordance with the Specifications.  
(b) Quality and Compliance.  
(i) during the Term, the Product, if Manufactured in accordance with the Specifications and in compliance with the Quality Agreement, applicable GMP and Applicable Laws, may be lawfully sold and distributed in every jurisdiction in which Client markets the Product; and  
(ii) during the Term, on the date of shipment, the Client-Supplied Materials will conform to the specifications for the Client-Supplied Materials that Client has given to Patheon and the Client-Supplied Materials will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container, but this will not negate Patheon’s obligations to perform any incoming inspections of Client-Supplied Materials as set out in the Specifications or the Quality Agreement.  
(c) Client agrees that, as a pre-condition to the adding of any country to the Territory under Section 2.2(t), Client will repeat the warranties above as at the date on which the country is added to the Territory.  
6.5 DISCLAIMER. THE FOREGOING EXPRESS WARRANTIES SET FORTH IN THIS ARTICLE VI ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT, AND ALL OTHER WARRANTIES ARE HEREBY DISCLAIMED AND EXCLUDED BY EACH PARTY.  
ARTICLE VII. CONFIDENTIALITY  
7.1 Confidentiality Obligations. The Parties agree that the Confidentiality Agreement dated June 24, 2015, as amended March 7, 2018, between Client and Patheon Inc. (an Affiliate of Patheon), (the “Confidentiality Agreement”), will apply to all Confidential Information disclosed by a Party or its Affiliates to the other Party under this Agreement and is expressly incorporated into this Agreement.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
7.2 Injunctive Relief. Each Party acknowledges that a breach by either Party of the Confidentiality Agreement or of this ARTICLE VII may not reasonably or adequately be compensated in damages in an action at law and that this breach may cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party may be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to apply for preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of the Confidentiality Agreement or this ARTICLE VII. But no specification in this Agreement of a specific legal or equitable remedy will be construed as a waiver or prohibition against pursuing any other legal or equitable remedies if there is a breach. Each Party agrees that the existence of any claim, demand, or cause of action of it against the other Party, whether predicated upon this Agreement, or otherwise, will not constitute a defense to the enforcement by the other Party, or its successors or assigns, of the covenants contained in the Confidentiality Agreement and this ARTICLE VII.  
ARTICLE VIII. TERM AND TERMINATION  
8.1 Term. This Agreement will commence as of the Effective Date and, unless earlier terminated in accordance with the terms hereof, will expire on the seventh anniversary of the FDA Approval Date (the “Initial Term”). Notwithstanding the foregoing, by mutual agreement, the Parties may commence discussions three years prior to the end of the Initial Term with a view to extending the Initial Term for periods of two years each (collectively, the Initial Term and any extensions thereof, the “Term”).  
8.2 Termination. In addition to any other provision of this Agreement expressly providing for termination of this Agreement, this Agreement may be terminated as follows:  
(a) Client may terminate this Agreement by notice in writing to Patheon:  
(i) at any time prior to the grant of the Marketing Authorization for the Product in the United States, by giving Patheon [\*\*\*] prior written notice if: (A) Client’s application for Marketing Authorization in the United States is rejected, or (B) any Regulatory Authority causes the clinical hold or permanent withdrawal of the Product;  
(ii) at any time after the grant of the Marketing Authorization for the Product in the United States, by giving Patheon [\*\*\*] prior written notice if the Product is discontinued or withdrawn from (1) the United States, or (2) any other market in a country or countries of the Territory that represent [\*\*\*]% or more of Client’s overall Product sales, for safety, quality or regulatory reasons;  
(iii) if any Regulatory Approval naming Patheon as the Manufacturer of the Product is withdrawn by the applicable Regulatory Authority for (1) the United States or (2) any other market in a country or countries of the Territory that represent [\*\*\*]% or more of Client’s overall Product sales;  
(iv) if Patheon challenges Client’s ownership of, or right to use, the Existing Client Intellectual Property by submission to a governmental authority responsible for Intellectual Property rights or to a court with jurisdiction over Intellectual Property rights if the performance of manufacturing or development services for other clients will not be regarded as a challenge to Client’s ownership of, or right to use, the Existing Client Intellectual Property;  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(v) [\*\*\*]; or  
(vi) at any time upon written notice if there is any material default by Patheon in the performance of any of its obligations hereunder that has not been cured by Patheon within [\*\*\*] days after receiving written notice thereof (“Remediation Period”). But the Parties will use Commercially Reasonable Efforts to agree a plan to remedy the material default within [\*\*\*] days after written notice is given to Patheon and Patheon will continue performing hereunder under Section 8.4 below. Client’s right to terminate this Agreement for a particular breach under this Section 8.2(a)(vi) may only be exercised for a period of [\*\*\*] days following the expiry of the Remediation Period (where the breach has not been cured) and, if the termination right is not exercised during this period, then Client will be considered to have waived its right to terminate this Agreement for the breach.  
(b) Patheon may terminate this Agreement at any time upon written notice if (i) there is any material default by Client in the performance of any of its obligations hereunder (excluding payment) that has not been cured by Client within [\*\*\*] days after receiving written notice thereof; or (ii) Client’s default of its payment obligations in accordance with ARTICLE IV for undisputed invoices which has not been cured by Client within [\*\*\*] days after receiving written notice thereof.  
(c) This Agreement may be terminated at any time by either Party immediately upon written notice to the other Party (A) under Section 10.2, if there is a force majeure that remains uncured for the period set forth in Section 10.2, or (B) if the other Party files in any court or agency, under any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for arrangement or for the appointment of a receiver or trustee of the other Party or of its assets, or if the other Party proposes a written agreement of composition of its debts, or if the other Party is served with an involuntary petition against it, filed in any insolvency proceeding, and the Party consents to the petition or if the petition is not dismissed within [\*\*\*] days after filing, or if the other Party proposes to be a party to any dissolution or liquidation, or if the other Party makes an assignment for the benefit of its creditors.  
(d) This Agreement will automatically terminate if either Party exercises its right to terminate the Technology Transfer Agreement (but not if the agreement expires as set forth in Section 8.2 thereof) prior to the FDA Approval Date, in which case, any payment to Patheon will be made in accordance with the Technology Transfer Agreement.  
8.3 Effect of Termination.  
(a) The expiration or termination of this Agreement will be without prejudice to any rights or obligations of the Parties that may have accrued prior to the termination, and the provisions of Sections 2.8, 3.7, 3.12, 3.14, 8.3 and 8.4, and ARTICLE I, ARTICLE IV, ARTICLE V, ARTICLE VII, ARTICLE IX and ARTICLE X will survive the expiration or termination of this Agreement. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof will not limit remedies that may otherwise be available in law or equity.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(b) Upon expiration or termination of this Agreement, subject to the Parties’ obligations under Section 8.4 below, each Party, at the request of the other, will return all data, files, records, and other materials in its possession or control containing or comprising the other Party’s Confidential Information.  
(c) Upon expiration or termination of this Agreement for any reason, subject to the Parties’ obligations under Section 8.4 below:  
(i) all submitted but unfilled Purchase Orders for which Patheon has (1) not begun Manufacture of Product will be cancelled, or (2) begun Manufacture of the Product will be completed, unless otherwise agreed;  
(ii) Patheon will dismantle the Client Manufacturing Equipment and prepare and make it available for collection from the Facility according to a procedure reasonably agreed to by the Parties. Client will then remove all Client Manufacturing Equipment, Product and Materials from the Facility within [\*\*\*] days after the completion of the procedure. If Client fails to do so, Client will pay a fee [\*\*\*] for each month or part month the Client Manufacturing Equipment, Product or Materials remains at the Facility after [\*\*\*] days post termination;  
(iii) if Patheon has Manufactured any stocks of finished Product in addition to those ordered under a Purchase Order, or has ordered any Patheon-Supplied Materials in addition to those ordered as set out in Section 2.2(u), Client will at its option place an order with Patheon for any of the finished Products and/or Patheon-Supplied Materials in accordance with this Agreement;  
(iv) Patheon will submit an invoice for any unpaid Material Costs, Maintenance Costs, Disposal Costs or any Xxxx Back Items which were ordered, purchased, produced or maintained by Patheon in contemplation of the Manufacture of the Product before the date of termination in accordance with Section 2.2. But Client will not be liable for the costs of any Materials purchased in excess of those amounts needed to meet Purchase Orders (or for a longer time as agreed to by the Parties);  
(v) Client will pay Patheon any earned but unpaid Product Fees, including those under any outstanding Purchase Order as described in Section 8.3(c)(i);  
(vi) Client will pay for any earned but undisputed and unpaid Base Fees, or fees for Additional Services; and  
(vii) Client will pay all due and outstanding invoices under ARTICLE IV.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(d) Upon expiration or termination of this Agreement for any reason other than by Client under Section 8.2(a)(vi), subject to the Parties’ obligations under Section 8.4 below, Client will pay to Patheon all and any (i) dismantling costs, (ii) removal costs and (iii) Make Good Costs associated with ending the Manufacturing Services or removal of the Client Manufacturing Equipment from the Facility. “Make Good Costs” means the reasonable costs required to clean, decontaminate or repair the Facility and return it to a clean, safe and useable area based on the contamination caused by the Manufacturing Services or repair of damage caused by the installation or removal of Client Manufacturing Equipment.  
(e) Upon expiration or termination of this Agreement for any reason other than by Client under Section 8.2(a)(vi), subject to the Parties’ obligations under Section 8.4 below, Client will pay to Patheon the following costs (“Manufacturing Services Termination Costs”): (i) all actual costs incurred by Patheon to complete activities associated with the completion, expiry or termination including, without limitation, disposal fees that may be payable for any Materials and supplies owned by Client to be disposed of by Patheon; and (ii) [\*\*\*] direct costs and expenses, or wasted costs and expenses, or termination or cancellation fees payable by Patheon arising from the termination of this Agreement, to include but not limited to, [\*\*\*]. Patheon will use Commercially Reasonable Efforts to mitigate the Manufacturing Services Termination Costs. Patheon will provide Client with documentation to substantiate the Manufacturing Services Termination Costs.  
(f) Upon termination (in whole) or expiry of this Agreement for any reason:  
(i) the licenses granted in Sections 5.2(a) and 5.2(b) will terminate and Patheon will not make any use for any purpose whatsoever of any of Client’s Intellectual Property or any of Client’s Confidential Information contained in the Quality Agreement except to the extent necessary to fulfil any Purchase Order or order placed by Client under Section 8.3(c)(iii) or to perform any other obligation under this Agreement;  
(ii) any Yield Reimbursement Payment will be paid which may be pro rata basis for any part year as applicable and which may be offset by any undisputed amounts owing to Patheon under this Agreement.  
(g) Client acknowledges that no Patheon competitor (being a Person that [\*\*\*]) will be permitted access to the Facility.  
(h) For any representatives of Client that are permitted access to the Facility under Sections 3.18, 8.3 or 8.4, Client will ensure that its representatives are appropriately trained by Client (e.g., GMP training) and will observe Patheon’s policies and procedures as they pertain to the Facility, including policies relating to health and safety and compliance with GMP, and comply with all reasonable directions of Patheon. But Client must be given notice of these policies and given a reasonable period of time to review and implement the policies. Patheon may refuse or limit in its sole discretion at any time admission to the Facility by any of Client’s representatives who fail to observe the policies or comply with its reasonable directions.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(i) The Parties agree that if any fees or charges are duplicated under this Agreement and the Technology Transfer Agreement, Client will only be obligated to make the payment once.  
8.4 Transition Assistance. Upon the delivery by either Party of a notice of termination of this Agreement for any reason other than by Patheon under Sections 8.2(b) or (c), upon Client’s request, and subject to this Agreement, Patheon will provide Client with the reasonable assistance of its staff and reasonable access to its other internal resources to provide Client with a reasonable level of technical assistance and consultation to transfer the Manufacture and the regulatory qualification of the Product to a supplier of Client’s election. But Client must reimburse Patheon for its fees and all documented costs and out-of-pocket expenses incurred in connection with this assistance (Patheon would provide a quotation for the services which Client requires under this Section 8.4 as Additional Services and upon acceptance by Client, Patheon will provide the services stated therein), except that Client will not be obligated to reimburse Patheon if this Agreement is terminated by Client pursuant to Section 8.2(a)(vi).  
ARTICLE IX. INDEMNIFICATION  
9.1 Client Indemnification Obligations. Client will indemnify and defend Patheon, its Affiliates, and their respective directors, officers, employees, and agents (the “Patheon Indemnified Parties”), from:  
(a) all Third Party Losses incurred by any of them in connection with, arising from, or occurring as a result of: (i) any negligence or willful misconduct by Client or any of its Affiliates; (ii) any claim made by any Person that the Manufacture and supply of the Product using the Client Manufacturing Process or any of Client’s Intellectual Property, in each case in accordance with the terms hereof, infringes or misappropriates the Intellectual Property rights of the Person (other than to the extent arising as a result of any of Patheon’s Intellectual Property used in accordance this Agreement or the use by Patheon of any Third Party Intellectual Property or by use of the Patheon Supplied Materials or Patheon Manufacturing Equipment); or (iii) any product liability claim made by any Person for any Products which upon delivery conformed to and were Manufactured in accordance with Section 2.1(c); or  
(b) any Loss incurred by any of the Patheon Indemnified Parties in connection with any damage to Patheon’s property or any claims of personal injury to any Patheon employees or Third Party Subcontractors caused as a result of Patheon’s use of the Client Manufacturing Equipment to perform the Manufacturing Services provided that Patheon and its employees and Third Party Subcontractors must have complied with this Agreement, the written instructions of Client, all applicable Equipment Standard Operating Procedures or the manufacturer’s terms of operation and recommended procedures for the Client Manufacturing Equipment, Specifications, and have not otherwise acted in a negligent manner or committed an act of willful misconduct in the use and Maintenance of the Client Manufacturing Equipment;  
(c) Client will not be required to indemnify the Patheon Indemnified Parties for any Loss hereunder to the extent the Loss (i) is caused by any breach of contract, negligent act or omission, or intentional misconduct by any Patheon Indemnified Parties or (ii) is a Loss for which Patheon is obliged to indemnify the Client Indemnified Parties under Section 9.2. Client acknowledges that Patheon has not and will not conduct any freedom to operate searches in relation to the Product or the Client Manufacturing Process or reviewed any Third Party patents in relation thereto and that Patheon’s failure or omission to do so will not be considered negligence for the purposes of excluding or limiting a claim under this indemnity.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
9.2 Patheon Indemnification Obligations. Patheon will indemnify and defend Client, its Affiliates, and their respective directors, officers, employees, and agents (the “Client Indemnified Parties”), from:  
(a) any Third Party Losses incurred by any of them resulting from, or relating to, any claim of personal injury or property damage to the extent that the injury or damage is in connection with, arising from, or occurring as a result of: (i) any failure by Patheon to Manufacture and supply Products in accordance with this Agreement; (ii) any negligence or willful misconduct by Patheon or any of its Affiliates; or (iii) any product liability claim made by any Person for any Product Manufactured by Patheon to the extent the liability is caused by a Patheon Nonconformance; or  
(b) any Third Party Losses incurred by any of them in connection with, arising from, or occurring as a result of a claim that any Patheon-Supplied Materials, Patheon Manufacturing Equipment, Existing Patheon Intellectual Property, Patheon Independent Manufacturing Improvement or Patheon Improvement used by Patheon in the Manufacture of the Product infringes or misappropriates the Intellectual Property rights of the Person;  
(c) Patheon will not be required to indemnify the Client Indemnified Parties for any Loss hereunder to the extent the Loss (i) is caused by any breach of contract, negligent act or omission, or intentional misconduct by any Client Indemnified Parties or (ii) is a Loss for which Client is obliged to indemnify the Patheon Indemnified Parties under Section 9.1.  
9.3 Indemnification Procedure.  
(a) Indemnification Procedure. The indemnified Party (the “Indemnified Party”) will give the indemnifying Party (the “Indemnifying Party”) prompt written notice of any Loss, action, or discovery of facts upon which the Indemnified Party intends to base a request for indemnification under Sections 9.1 or 9.2 (a “Claim”), but the Indemnifying Party will not be liable for any Losses that result from any delay in providing the notice. The Indemnified Party will: (i) use Commercially Reasonable Efforts to mitigate the effects of the Claim; (ii) reasonably cooperate with the Indemnifying Party in the defense of the Claim; and (iii) permit the Indemnifying Party to control the defense and settlement of the Claim, all at the Indemnifying Party’s cost and expense.  
(b) Settlement. For any Losses (i) relating solely to the payment of money damages in connection with a Claim, (ii) that will not result in the Indemnified Party becoming subject to injunctive or other relief or otherwise adversely affect the business or reputation of the Indemnified Party in any manner, and (iii) as to which the Indemnifying Party has 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 such terms as the Indemnifying Party, in its sole discretion, considers appropriate. For all other Losses in connection with Claims, where the Indemnifying Party has assumed the defense of the Claim in accordance with Section 9.3(a), the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement, or otherwise dispose of the Loss but it must obtain the prior written consent of the Indemnified Party, which consent will not be unreasonably withheld or delayed. The Indemnifying Party will not, without the prior written consent of the Indemnified Party, agree to any settlement or acquiesce to any judgment for a Claim that obligates the Indemnified Party to pay any amount subject to indemnification by the Indemnifying Party or causes the Indemnified Party to admit to any civil or criminal liability.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
9.4 Insurance. During the Term and for [\*\*\*] years thereafter, each Party will procure and maintain at its own expense from a qualified and licensed insurer liability insurance or indemnity policies, in an amount not less than $[\*\*\*] in the aggregate, subject to the deductible or self-retention limits as either Party in its business discretion may elect. These policies will insure against liability on the part of each Party and any of its Affiliates, as their interests may appear, due to injury, disability, or death of any person or persons, or injury to property, arising from the distribution of the Products. Upon the execution of this Agreement and thereafter on January 1 of each year during the Term, each Party upon the request of the other Party will provide a certificate of insurance (i) summarizing the insurance coverage and (ii) identifying any exclusions. Each Party will promptly notify the other of any material adverse alterations to this policy or decreases in the amounts for which insurance is provided.  
9.5 Limitation on Damages  
(a) Maximum Liability. Except with respect to a breach by Patheon of its obligations under ARTICLE V or ARTICLE VI, or with respect to costs or damages arising out of the willful misconduct of Patheon, and without limiting Patheon’s obligations under Section 9.2, Patheon’s maximum liability to Client in connection with the performance of the Manufacturing Services under this Agreement for any reason whatsoever, including, without limitation, any liability arising under Sections 2.2(o), 2.9, 3.12, 3.14 or 9.2 hereof or resulting from any breaches of its representations, warranties, or any other obligations under this Agreement in each calendar year will not exceed [\*\*\*]% of the total Product Fees received by or payable to Patheon under this Agreement in the [\*\*\*] month period prior to the month in which the underlying event occurred that gave rise to the liability (e.g., the date of the incident or manufacture). For the first [\*\*\*] month period after the first commercial batch, as Patheon will not have received Product Fees for a full [\*\*\*] month period, the amount of the Product Fees for the purpose of the limitation of liability will be calculated based on the volume of Product set out in the first [\*\*\*] months of the Forecast applicable on the date of Manufacture of the first commercial batch.  
(b) Section 9.5(a) will not apply to any reimbursement of the Product Fee, Shipment Costs or Patheon-Supplied Materials under Section 2.8(d)(ii).  
(c) Subject to Section 9.5(d), except in connection with a Party’s breach of Article V, and without limiting a Party’s obligations under Sections 9.1-9.2, neither Party will be liable to the other in contract, tort, negligence, breach of statutory duty, equity, or otherwise for: (i) any direct or indirect loss of profits, of production, of anticipated savings, of business, or goodwill, or costs of substitute services; (ii) any reliance damages, including but not limited to costs or expenditures incurred to evaluate the viability of entering into this Agreement or to prepare for performance under this Agreement; or (iii) for any other indirect or consequential loss, liability, damage, costs, penalty or expense, in each case, with respect to this Agreement (but excluding the Technology Transfer Agreement, the liabilities of the Parties thereunder being only limited by Section 7.4 therein).  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(d) Nothing in this Agreement will exclude or limit either Party’s liability for (i) personal injury or death caused by the negligence of that Party, or (ii) for fraud or fraudulent misrepresentation.  
(e) The limitations of liability set forth in this Section 9.5 will have no impact on limiting the liabilities of the Parties under the Technology Transfer Agreement, the liabilities of the Parties thereunder being only limited by Sections 7.4 and 7.5 of the Technology Transfer Agreement.  
(f) Sole & Exclusive Remedies. Notwithstanding anything in this ARTICLE IX to the contrary Patheon’s sole liability and Client’s sole and exclusive remedy whether in contract, tort, equity or otherwise for Non-Conforming Product based on or caused by a Patheon Nonconformance will be the rights and remedies set forth in Sections 2.2(o), 2.8, 2.9, 3.12, 3.14, 8.2 and 9.2 of this Agreement.  
9.6 Product Liability Claims. As soon as it becomes aware, each Party will give the other prompt written notice of any defect or alleged defect in a Product, any injury alleged to have occurred as a result of the use or application of the Product, and any circumstances that may give rise to litigation or recall of a Product or regulatory action that may affect the sale or Manufacture of a Product, specifying, to the extent the Party has this information, the time, place, and circumstances thereof and the names and addresses of the persons involved. Each Party will also furnish promptly to the other copies of all papers received for any claim, action, or suit arising out of the alleged defect, injury, or regulatory action.  
9.7 Allocation of Risk. This Agreement (including, without limitation, this ARTICLE IX) is reasonable and creates a reasonable allocation of risk for the relative profits the Parties each expect to derive from the Products.  
ARTICLE X. MISCELLANEOUS  
10.1 Notices. Notwithstanding that advance notification of any notices or other communications may be given by electronic mail transmission, all notices or other communications that will or may be given under this Agreement will be in writing (including by confirmed receipt electronic mail) and will be considered to be effective (a) when delivered if sent by registered or certified mail, return receipt requested, or (b) on the next business day, if sent by overnight courier, (c) when sent if sent by electronic mail if receipt is confirmed, in each case to the Parties at the following addresses (or at such other addresses as will be specified by like notice) with postage or delivery charges prepaid:  
 46  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
If to Client:  
Zosano Pharma Corporation  
00000 Xxxxxxxxx Xxxxx, Xxxxxxx, Xxxxxxxxxx 00000  
Attn: CEO  
With copy to:  
Xxxxxx & Xxxxxxx LLP  
000 Xxxxx Xxxxx, Xxxxx Xxxx, XX, 00000  
Attn: Xxxx Xxxxxxxxx  
If to Patheon:  
Patheon Manufacturing Services LLC  
Executive Director & General Manager  
[\*\*\*]  
with copy to:  
Patheon Pharmaceuticals Inc.  
Director of Legal Services  
0000 Xxxx Xxxxxxxxx Xxxx  
Xxxxxxxxxx, XX 00000-0000  
Email: [\*\*\*]  
10.2 Force Majeure. Neither Party will be liable for delay in delivery, performance or nonperformance, in whole or in part, nor will the other Party have the right to terminate this Agreement except as otherwise specifically provided in this Section 10.2 where the delay in delivery, performance or nonperformance results from acts beyond the reasonable control and without the fault or negligence of the Party including, but not limited to, the following conditions: fires, floods, storms, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, or acts, omissions, or delays in acting by any governmental authority. But the Party affected by this a condition must, within five days of its occurrence, give notice to the other Party stating the nature of the condition, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is reasonably required, and the nonperforming Party will use Commercially Reasonable Efforts to remedy its inability to perform. If the suspension of performance continues for [\*\*\*] 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 non-affected Party may terminate this Agreement immediately by written notice to the affected Party.  
10.3 Independent Contractor. The Parties to this Agreement are independent contractors. Nothing contained in this Agreement will be construed to place the Parties in the relationship of employer and employee, partners, principal, and agent or a joint venture. Neither Party will have the power to bind or obligate the other Party nor will either Party hold itself out as having this authority.  
 47  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
10.4 Waiver. Except where expressly stated to the contrary in this Agreement, including Sections 2.8, 2.9, 3.12, 3.14, 8.2, 8.4 and 9.5, no waiver by either Party of any provision or breach of this Agreement will constitute a waiver by that Party of any other provision or breach, and this waiver will not be effective unless made in writing and signed by an authorized representative of the Party against whom waiver is sought. No course of conduct or dealing between the Parties will act as a modification or waiver of any provision of this Agreement. Either Party’s consent to or approval of any act of the other Party will not be deemed to render unnecessary the obtaining of that Party’s consent to or approval of any subsequent act by the other Party.  
10.5 Entire Agreement. This Agreement (together with all Schedules hereto, which are hereby incorporated by reference), the Quality Agreement, the Confidentiality Agreement, and the Technology Transfer Agreement constitute the final, complete, and exclusive agreement between the Parties relating to the subject matter hereof and supersede all prior conversations, understandings, promises, and agreements relating to the subject matter hereof. The “Background” Section of this document is expressly incorporated into this Agreement. Neither Party has relied upon any communications, representations, terms or promises, verbal or written, not set forth herein. No terms, provisions or conditions of any Purchase Order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the Parties under or otherwise modify this Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement and is signed by both Parties.  
10.6 Assignment; Change of Control. This Agreement may not be assigned by Patheon without the prior written consent of Client. Notwithstanding the foregoing, either Party may assign this Agreement to an Affiliate, or to an acquirer or successor in interest in connection with a Change of Control of the Party, without the prior written consent of the other Party. But the Party must provide the other Party with written notice of this assignment. This Agreement will be binding upon and inure to the benefit of Client and Patheon and their respective successors, heirs, executors, administrators, and permitted assigns. “Change of Control” means the earlier of a public announcement of an agreement in principle or the closing of (a) a merger, consolidation or similar transaction providing for the acquisition of the direct or indirect ownership of more than 50% of a Party’s shares or similar equity interests or voting power of the outstanding voting securities or that represents the power to direct the management and policies of a Party or (b) the sale of all or substantially all of a Party’s assets related to the subject matter of the Agreement.  
10.7 Amendment; Modification. This Agreement may not be amended, modified, altered, or supplemented except by a writing signed by both Parties. No modification of any nature to this Agreement and no representation, agreement, arrangement, or other communication will be binding on the Parties unless it is expressly contained in writing and executed by the Parties as an amendment to this Agreement. This Agreement may not be amended in any respect by any Purchase Order, invoice, acknowledgment, or other similar printed document issued by either Party.  
10.8 Governing Law.  
(a) This Agreement and any matter, claim or dispute arising out of or in connection with it, whether contractual or non-contractual, will be construed under and governed by the laws of the State of Delaware without regard to the application of principles of conflicts of law. Both Parties hereby submit to the exclusive jurisdiction of the courts of the State of Delaware.  
 48  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
(b) The Parties expressly exclude the application of the United Nations Convention on Contracts for the International Sale of Goods, if applicable.  
(c) The Parties agree that nothing in this Agreement will (i) grant Client any property ownership rights in the Manufacturing Suite or the Facility or (ii) constitute a lease to the Manufacturing Suite or the Facility and no relationship of landlord and tenant is created between Patheon and Client under this Agreement. Patheon retains control, possession and management of the Facility and Manufacturing Suite and Client has no right to exclude Patheon from the Facility or Manufacturing Suite.  
10.9 Compliance with Applicable Laws. Each Party and its Affiliates, and their respective representatives, will comply with all Applicable Laws in the performance of their obligations under this Agreement. Without limiting the foregoing, each Party and its Affiliates, and their respective representatives, will comply with export control laws and regulations of the country of Manufacture and of the United States. Neither Party nor its Affiliates (or representatives) will, directly or indirectly, without prior U.S. government authorization, export, re-export, or transfer the Product to any country subject to a U.S. trade embargo, to any resident or national of any country subject to a U.S. trade embargo, or to any person or entity listed on the “Entity List” or “Denied Persons List” maintained by the U.S. Department of Commerce or the list of “Specifically Designated Nationals and Blocked Persons” maintained by the U.S. Department of Treasury. In so far as it applies to a Party or its Affiliates, each Party and its Affiliates and respective representatives will comply with the requirements of the Foreign Corrupt Practices Act of 1977 (15 U.S.C. § 78dd-1, et seq.).  
10.10 Dispute Resolution.  
(a) The Parties recognize that disputes may arise during the Term of this Agreement. It is the objective of the Parties to establish procedures to resolve these disputes in an expedient manner by mutual cooperation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 10.10 if a dispute arises under this Agreement.  
(b) Unless otherwise specifically recited in the Agreement, disputes between the Parties under this Agreement will be first referred to the Project Manager of each Party as soon as reasonably possible after the dispute arises. If the Project Managers are unable to resolve the dispute within [\*\*\*] days of being requested by a Party to resolve the dispute, each Party will have the right, by written notice, to refer the dispute to the Senior Management of each Party for attempted resolution by negotiations within [\*\*\*] days after the written notice is received. If the Senior Management are unable to resolve the dispute within [\*\*\*] days of being requested by a Party to resolve the dispute, each Party will have the right to pursue any remedies available to it at law or in equity.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
10.11 Press Releases; Use of Trademarks. The Parties agree not to disclose in any press release or other public statement any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except as permitted in the Confidentiality Agreement. Neither Party will (a) issue a press release or make any other public statement that references this Agreement or (b) use the other Party’s or the other Party’s Affiliates’ names or trademarks for publicity or advertising purposes, except with the prior written consent of the other Party, except as permitted under the Confidentiality Agreement or Securities and Exchange Commission filings which are required by Applicable Law, in which instance both Parties will work together in good faith to agree the disclosure to be made having due and proper regard to their legal obligations. Each Party agrees that it will cooperate fully and in a timely manner with the other for all disclosures to the Securities and Exchange Commission or any other governmental or regulatory agencies, including requests for confidential treatment of Confidential Information of either Party included in the disclosure.  
10.12 Severability. If any provision of this Agreement is found by a proper authority to be unenforceable, that provision to the extent it is found to be unenforceable or invalid will be severed and the remainder of the provision and this Agreement will continue in full force and effect. The Parties will use their best efforts to agree upon a valid and enforceable provision as a substitute for any invalid or unenforceable provision, taking in to account the Parties’ original intent of this Agreement.  
10.13 Construction. Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms “hereof,” “herein,” “hereby,” and derivative or similar words refer to this entire Agreement; (d) the terms “ARTICLE,” “Section,” “Schedule,” refer to the specified ARTICLE, Section or Schedule of this Agreement; (e) “or” is disjunctive but not necessarily exclusive; and (f) the term “including” or “includes” means “including without limitation” or “includes without limitation.” Whenever this Agreement refers to a number of days, the number will refer to calendar days unless business days are specified. The captions and headings of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement will be deemed to be the language mutually chosen by the Parties, and no rule of strict construction will be applied against either Party hereto.  
10.14 Third Party Beneficiaries. This Agreement is not intended to confer upon any non-party rights or remedies hereunder, except as may be received or created as part of a valid assignment.  
Without prejudice to the previous sentence, any Affiliate of Client may submit Purchase Orders under this Agreement if the quantities of Product ordered are included in the Forecasts given by Client such that Patheon will receive a single consolidated Forecast under Section 2.3(a). Patheon will submit invoices to the Affiliate of Client directly for all applicable fees and charges, which will be payable by the Affiliate of Client directly in accordance with ARTICLE IV. The Parties agree that Client may delegate (in part) the benefits it receives under this Agreement, and its obligations, to any Affiliate in order that it may benefit from this Agreement in connection with Purchase Orders, but Client will remain ultimately liable for any act or omission under this Agreement of its Affiliate. This will not give an Affiliate any right to enforce any term of this Agreement against Patheon.  
 50  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
10.15 The rights of Patheon and Client to terminate, rescind or agree any variation, modification, amendment, waiver or settlement under this Agreement are not subject to the consent of any other person and expressly do not require the consent of any Affiliate.  
10.16 Further Assurances. Each of the Parties agrees to duly execute and deliver, or cause to be duly executed and delivered, any further instruments and do and cause to be done any further acts and things, including the filing of any additional assignments, agreements, documents, and instruments, that may be necessary or as the other Party hereto may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto the other Party its rights and remedies under, this Agreement.  
10.17 Counterparts. This Agreement may be signed in counterparts, each of which will be deemed an original. Electronic signatures will be treated as original signatures.  
[The remainder of this page is left blank intentionally]  
 51  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.  
 PATHEON MANUFACTURING  
SERVICES LLC:  
 ZOSANO PHARMA CORPORATION:  
By: /s/ Xxxxx Xxxxxx  
 By: /s/ Xxxx Xxxxxx  
Name: Xxxxx Xxxxxx  
 Name: Xxxx Xxxxxx  
Title: President DSS & PDS  
 Title: Chariman and CEO  
Date: 27 September 2018  
 Date: 27 September 2018  
[Signature Page of Manufacturing and Supply Agreement]  
Schedule A  
 A-1  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
Product  
 Product  
 Format  
 Dose  
 Packaging Configuration  
Zolmitriptan  
Intracutaneous  
Microneedle Patches  
 Patch  
 [\*\*\*]  
 [\*\*\*]  
 A-2  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
Schedule B  
Fees  
 I.  
Base Fee  
Patheon will charge an annual fee (“Base Fee”) to be paid in equal monthly installments (or pro rata amount for any part of a calendar month), as forth below:  
 Ref   
Base Fee  
 Payment structure  
 Covered Volume/  
Base Fees and  
Product Fees First payment  
due End date  
[\*\*\*]  
 $[\*\*\*]  
 Equal monthly installments [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*]  
[\*\*\*]  
 $[\*\*\*]  
 12 Equal Monthly Installments [\*\*\*] [\*\*\*] [\*\*\*]  
[\*\*\*]  
 $[\*\*\*]  
 12 Equal Monthly Installments [\*\*\*] [\*\*\*] [\*\*\*]  
[\*\*\*]  
 $[\*\*\*]  
 12 Equal Monthly Installments [\*\*\*] [\*\*\*] [\*\*\*]  
[\*\*\*]  
 $[\*\*\*]  
 12 Equal Monthly Installments [\*\*\*] [\*\*\*] [\*\*\*]  
[\*\*\*]  
 $[\*\*\*]  
 12 Equal Monthly Installments [\*\*\*] [\*\*\*] [\*\*\*]  
[\*\*\*]  
 $[\*\*\*]  
 12 Equal Monthly Installments [\*\*\*] [\*\*\*] [\*\*\*]  
The Base Fees will accrue under this Agreement alone. The fees for the Transfer Services are specified in the Technology Transfer Agreement.  
Consequences for the failure to achieve milestones for the Transfer Services or effects of early completion of the Transfer Services are specified in Exhibit H of the Technology Transfer Agreement.  
 II.  
Product Fees  
The Product Fees are to be calculated in accordance with the model as follows:  
Base Fees cover operation and staffing of the Facility including services as noted below. In the years in the table above where a Covered Volume per Base Fee is listed, Client can order and Patheon will Manufacture Product up to an Annual Volume of patches equal to or less than the Covered Volume with no further Product Fees, [\*\*\*].  
 B-1  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
If Client orders Product in excess of the Covered Volume in any year, the incremental Product orders in excess of the Covered Volume would be charged the Product Fee listed in Schedule B I above.  
If Client orders less than the Covered Volume there will be no reimbursement or reduction in the Base Fee. This Base Fee is independent of production up to the Covered Volume.  
Product Fees are invoiced [\*\*\*]. Client should issue purchase orders for this Product including the Product Fees [\*\*\*].  
Base Fees and Product Fees account for Patheon providing the following services set forth below [\*\*\*]:  
 •   
[\*\*\*]  
Base Fee and Product Fees DO NOT Include:  
 •   
Material Costs.  
 •   
[\*\*\*]  
 •   
Disposal Costs.  
 •   
[\*\*\*]  
 •   
Xxxx Back Items costs.  
 •   
Fees for any agreed Additional Services.  
Materials:  
Cost allocation for the procurement of Materials is set forth in Section 2.2. A provisional xxxx of Materials is listed in Schedule C.  
Xxxx Back Items:  
During the performance of the Transfer Services, Patheon and Client will work together to develop a non-exhaustive list of typical Xxxx Back Items. Terms for the procurement of Xxxx Back Items are described in Section 2.2(r).  
Additional Services:  
The following non-exhaustive list will be considered Additional Services and will be invoiced to Client at the price agreed to by the Parties according to Section 2.2(s).  
 •   
[\*\*\*]  
 B-2  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
Schedule C  
Materials  
Part A: Client-Supplied Materials  
[\*\*\*]  
Part B: Patheon-Supplied Materials  
[\*\*\*]  
 E-1  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.